

The Compatibility of the Access to Essential Generic Medicines with Human Rights: An Analysis of the In-Transit Seizure of Essential Generic Medicines from India by the European Union

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Table of Contents

1. Introduction.....	p. 1
1.1. Research Question.....	p. 7
1.2. Methodology.....	p. 9
1.3. Literature Review.....	p. 10
2. A Hindu Nationalist Stance in Indian Foreign Policy.....	p. 17
2.1. Civilisational Clashes.....	p. 73
2.2. “Holy Cow”.....	p. 88
3. The Seizure of Essential Generic Medicines from India by EU Border Agencies	p. 118
3.1. Generic Drugs.....	p. 146
4. Access to Medicine from a Human Rights Perspective.....	p. 158
4.1. The Philosophical Dimension of the Right to Health.....	p. 163
4.2. The Right to Health.....	p. 169
4.3. The Maastricht Principles of Extraterritorial Obligations of States in the Area of the Economic, Social and Cultural Rights.....	p. 194
4.4. Evergreening.....	p. 198
4.5. Initiative for Medicines, Access & Knowledge v. Abbott Laboratories....	p. 203
5. TRIPS.....	p. 211
5.1. Compulsory Licenses.....	p. 220
5.1.1. Natco Pharma Ltd v. Bayer Corporation.....	p. 234
6. Traditional Knowledge.....	p. 238
Exhibit A. Neem.....	p. 243
Exhibit B. Turmeric.....	p. 263
Exhibit C. Basmati.....	p. 267
Exhibit D. <i>Trichopus Zeylanicus</i>	p. 275
Exhibit E. Yoga.....	p. 283
Exhibit F. Property Rights.....	p. 293

7. EU Trade Agreements.....	p. 305
7.1. EU-India FTA.....	p. 322
8. Impact Factors.....	p. 327
8.1. Economic Interests v. Protectionism.....	p. 328
8.2. Brexit.....	p. 345
8.3. Unilateralism v. Multilateralism.....	p. 353
9. Conclusion.....	p. 361
Bibliography.....	p. 372

1. Introduction

"Some 25 to 30 years ago, the world used to think we are a land of snake charmers and black magic. But our youth has surprised the world with its IT skills"¹

Narendra Modi

The Covid-19 pandemic has sensitised the global community on the importance of the access to essential medicines. The nations of the world have engaged in a fierce battle over the lifesaving Covid-19 vaccines, in which developed nations have come out successfully. The access to essential medicines has long been promoted by the United Nations (UN) and other international human rights organisations. In this context, India seems to have done its bit and has emerged as the pharmacy of the developing world and further has been providing the global poor with the advantage of access to essential as well as generic drugs.² Against this background, it would be worth noting that the "Swadeshi" or "Make in India" campaign was launched by the Narendra Modi's government on 25 September 2014 in order to encourage Indian companies to manufacture their products in "Bharat" (India) and provide significant incentives for the same.³ One of the sectors for which "Make in India" is designated are pharmaceuticals.⁴ In this context, it is noteworthy that this research project, *inter alia*, aims to examine the area of the Indian pharmaceutical sector, which seem to have made its mark on the global stage as the world's largest medicine cabinet.

¹ Pandey, Geeta: India: Five unusual messages from Narendra Modi's speech. in: BBC News. Delhi, 2014. - <https://www.bbc.com/news/world-asia-india-28799397>, DOA: 9.6.2020.

² Nonaka, Melissa: Enough is Enough: India's fight against Seizures of Lawful Generic Medicines, in: Journal of Medicine and Law (2011), pp. 37- 57, p. 37.

³ Firstpost: Make In India, Ayushman Bharat, Swachh Bharat: NDA campaign likely to showcase flagship programmes to attract voters. 2019. - <https://www.firstpost.com/india/make-in-india-ayushman-bharat-swachh-bharat-a-look-at-various-schemes-and-polices-of-narendra-modi-government-6237911.html>, DOA: 20.02.2021.

⁴ Make in India, Sector Highlights: Pharmaceuticals, 2020. <https://www.makeinindia.com/sector-highlights-pharmaceuticals>, DOA: 15.05.2021.

The 21st century has widely been proclaimed to be Asia-centric and in light of this global development this research aims to take an Indo-centric focus. In doing so it hopes to provide a narrative that would give weight to, broadly speaking, a non-Western perspective while highlighting Indian specificities and unique concepts in the area of health. In this respect, this work aims to examine the three main components of the Hindutva (Hindu nationalist) doctrine, namely “Hindi, Hindu and Hindustan” (see chapter 2) which form part of the ideological background of Indian foreign policy at the beginning of the 21st century under the Bharatiya Janata Party (BJP). As part of its Hindu nationalist agenda, the BJP government has engaged in the promotion of traditional Indian medicine in an attempt to seriously challenge the dominance of conventional Western (European) medicine. With regard to the BJP’s Hindu nationalist agenda, the second chapter will *inter alia* consider the issue of what the author has termed the “mandarinisation” of India. In other words, the systematic spreading of the linguistic dominance of Hindi, which appears to a long-term objective of the Hindu-nationalists. In this context, International Yoga Day and its symbolics value for the BJP government ambitions to become a yoga guru will be give due consideration. Thus, New Delhi has issued claims about cultural supremacy over the world due to yoga’s Indian heritage. Equally, sub-chapter 2.1 will briefly discuss the aspect of civilisational clashes by drawing on Samuel Huntington’s theory of the “Clash of Civilisations”. This will be followed by sub-chapter 2.2, which will examine the topic of the cow which in Hinduism, and according to Hindu mythology, is sacred and is worshipped by millions. This sub-chapter will pay due regard to the potential medicinal value of Gomutra (cow urine) and other waste products such as cow dung. Gomutra, as per Hinduism, has purifying as well as cleansing characteristics and has been claimed by Hindu nationalist organisations *inter alia* that the Hindu Mahasabha has a viable remedy against the Corona-virus.

This research will also study the case in which a consignment of essential generic medicines from India designated to Brazil was seized, in-transit, by Dutch customs due to a suspected Intellectual Property (IP) infringement (see chapter 3). Following this incident both India and Brazil filed requests with the World Trade Organization's (WTO) Appellate Body to hold consultations with the European Union on the issue of seizure of in transit generic pharmaceuticals by Dutch custom officials. Against this backdrop, this chapter intends to examine whether the seizure of essential generic medicines from India by the EU is compatible with the standards employed by international human rights law. It will also investigate the impact that European Council Regulation 1383/2003 has on in transit medicine which, by default, was never intended to enter the domestic market of the EU in the first place. In this regard, it is worth noting that both Brussels and New Delhi seems to have much in common, including that they happen to be large democracies with India being the largest in the world. Both adhere to the rule of law, the promotion of human rights and have large economies. New Delhi was also among the first to establish bilateral relations with the European Economic Community in 1963. In recent times, both unions have engaged in negotiations over a bilateral Free Trade Agreement (FTA), which has been put on hold (at the time of writing). On the back of this sub-chapter 3.1 will aim to play devil's advocate and investigate whether there had been quality issues with medicines from India. We shall also turn our attention to the problem of antimicrobial resistance hailing from India which has been detected in the EU. This fact begs the question whether the EU was indeed justified to ban around 700 generics from India in 2015.

Chapter four will examine access to medicines from a human rights point of view. This will be followed by an analysis of the philosophical dimension of the right to health (4.1). It will also investigate whether the access to medicine can be classed as a human right from a legal perspective (4.2). Moreover, this sub-chapter will also investigate the supremacy of legal norms. In other words, it will investigate whether

the IP law or international human rights law should prevail in situations where there is a conflict between two competing norms. Sub-chapter 4.3 studies the Maastricht Principles of Extraterritorial Obligations of States in the Area of Economic, Social and Cultural Rights which *inter alia* places particular obligations upon states, when behaving themselves in a way that has real and predictable effects on human rights beyond their national border. In addition, sub-chapter 4.4 will also explore the subject matter of evergreen patents, which consists of minor modifications to already existing patents in order to *de facto* prolong essentially the same patent protection. The issue of evergreening will be illustrated in sub-chapter 4.5 via the example of *Natco Pharma Ltd v. Bayer Corporation* case.

Chapter five will examine the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement and the access to medicines in the context of human rights. Sub-chapter 5.1 discusses compulsory licenses. In this context, it is worth noting that the Doha Declaration both protects public health and also promotes access to medicines for all. This sub-chapter further examines access to medicines to Least Developed Countries (LDC) and developing countries in the context of the Doha Declaration. Likewise, this chapter will discuss the issue of parallel importation when it comes to safeguard the affordability of essential medicines. This will be followed by the landmark case of *Natco Pharma Ltd v. Bayer Corporation* (5.1.1). The dispute between the Indian pharmaceutical company Natco Pharma (an Indian company based in Hyderabad) and Bayer on the subject matter of a compulsory licence shall be discussed.

Chapter six will examine the subject matter of traditional knowledge, an emerging area in the field of Intellectual Property Right (IPR), specifically, the exploitation of India by Western multinational corporations. The reason for choosing the aspect of traditional knowledge, in the Indian context, is twofold. Firstly, traditional knowledge is a rather newly emerging area in the field of IP law and

does indeed create a crossroad between the illegitimate exploitation of traditional knowledge and international human rights law. Secondly, the subjects that have been exploited represent something that is quintessential Indian, and illustrates the detrimental consequences of biopiracy and IP theft by Western multinationals for the original IPRs owners. This chapter will also look into the subject matter of traditional knowledge exploitation. This chapter will examine bioprospecting of the following items: neem, turmeric, basmati, *Trichopus zeylanicus* and Yoga (exhibit A-E). Most of the items discussed in the chapter are plants, except for yoga. The majority of these plants have medicinal value, which have been developed for centuries by utilising Indian traditional medicine. As for yoga, it is both ancient and would technically fall into the category of Indian traditional medicine due to its health benefits. The Basmati exhibit displays the dilemma of misappropriation of traditional agricultural knowledge by an American multinational for the Indian staple Basmati rice. In all this, this chapter aims to investigate the EU's involvement in this area. Finally, exhibit F will consider whether traditional knowledge could be classed as a property right. In doing so, this part will focus on Morris Cohen's work on "Property and Sovereignty".

Chapter seven will consider Brussels' position as a major economic player on the world stage. In particular, this section will examine whether the self-image proclaimed image of the EU as both a norm-based and responsible international actor is indeed able to stand the test of time. In this regard, this chapter endeavours to reflect on the aspect of international trade agreements of the EU. More precisely, it will address the higher IPRs ("TRIPS plus") standards that seem to be part and parcel of both bilateral and multilateral trade agreements of the EU. It shall also consider both FTA's and Economic Partnership Agreements (EPA) of the EU with LDC and developing nations. In addition, it will examine whether the IPRs that are applied by the Brussels could potentially obstruct the full enjoyment of human rights. Sub-chapter 7.1 aims to briefly examine the opportunities for the

signing of a FTA between Brussels and New Delhi against the backdrop of the seizure of essential generics from India.

Chapter eight considers the other relevant impact factors with regard to relations between the EU and India. Sub-chapter 8.1 will investigate the 2015 dispute between India and the EU over ban of 700 generic medicines from India. Moreover, this section will also consider the EU's unwillingness to waive the IPRs protection of the Covid-19 vaccines and India's "vaccine maitri" initiative. Sub-chapter 8.2 aims to examine Brexit and its consequences for the UK's relations with the EU and India. The dispute between the Brussels and London over Covid-19 vaccine distribution shall also be discussed in sub-chapter 8.3, which covers aspects of both unilateralism and multilateralism. It will examine whether the EU and India are taking a unilateral or multilateral approach when engaging in international relations.

To conclude, chapter nine aims to provide an answer to the research question on whether the seizure of essential generic medicines from India by the European Union, designated to developing countries, is compatible with international human rights law. In doing so, the final segment intends to provide tangible recommendations for safeguarding the access to essential generic medicines. Equally, it will provide an outlook with regard to future areas of research in this context.

1.1. Research Question

The Covid-19 pandemic has increasingly highlighted the dependency of the global community on Covid vaccines and other related pharmaceutical drugs. In this context, unlike the rich developed world, vaccines against Covid-19 remains out of reach for most populations living in both the LDC and developing countries. The rich nations in the West, *prima facie*, appear to be protective of IPRs and more precisely when it comes to sharing their IP knowledge to the Covid vaccines with the developing nations and LDC. In particular, the EU bars its pharmaceutical companies from exporting Covid vaccines to nations lacking production capabilities. Brussels' protectionism of its pharmaceutical industry seems to be hardly new. Already as early as in December 2008, EU customs authorities seized hypertension drugs suspected of patent infringement.

To begin with, the EU has implemented Council Regulation 1383/2003 which has placed the supply of essential generic medicine under considerable scrutiny. This has meant that Indian companies have been on the receiving end of the sanction directed at IP violators. Thus, the overarching research question of this PhD project is whether the seizure of essential generic medicines from India by the European Union, designated to developing countries, is compatible with the right to health. More precisely, it will further examine whether the access to essential generic medicines could be classified as falling under the category of the right to health (human right) and consequently whether the seizure and subsequent detention of the in transit cargo of these medicines would qualify as a violation of international human rights law. In this context, it would be relevant to examine whether international human rights law should supersede intellectual property law in cases in which a norm conflict arises. More importantly, this work will assess whether the right to health, in the form of access to medicines, should take precedence over IP law in case of a conflict between both norms.

Another issue that will be investigated is whether Brussels' utilisation of IPRs protection, and the subsequent seizure as well as detention of generic medicines from India, could, potentially, have created a barrier to international trade in the field of generic medicines.

The final aspect that is worth examining is whether the seizure of Indian generics, due to suspected IPRs violations, has been applied in a protectionist fashion to protect the EU's domestic pharmaceutical industry against cheaper competition from India. A reason for this presumption could be drawn from German Chancellor Angela Merkel's statement that the EU had "permitted" India to become a major pharmaceutical producer in the world, while the EU's industry had deteriorated at the same time. On another note, it is worth noting that the term medicines shall be used as a holistic term throughout this work and shall include all pharmaceutical and medical products. Similarly, the subject matter of international human rights law will be analysed from a holistic point of view covering *inter alia* the aspects of politics, law, human rights, medicine, IPRs and trade. Finally, the timeframe for this research will be limited to the beginning of the 21st century.

1.2. Methodology

This dissertation is undertaken in the form of classical desk-based research. Both secondary and primary literature (case law) are discussed as part of this research project. This research utilises the online library catalogue of Philipps-University Marburg. Equally, monographies, anthologies, periodicals, online journals, newspapers article, legal and other databases are consulted. With regard to the legal databases, this work consults Westlaw, Nexis Uni and JSTOR. Equally, extensive case law in the areas of national, region (EU) and international intellectual property law will be considered. Likewise, the websites and databases of different national and European patent offices is given due consideration. Similarly, the website of the WTO also serves as a vital source for this research. More particularly, the TRIPS Agreement is covered in a substantial manner. Multiple international human rights conventions and national as well as regional human right instruments are also covered in detail.

1.3. Literature Review

This chapter will provide an overview of the literature that has been employed as part of this research. To begin with, we shall contemplate on the notion of natural law and human rights. According to Malcolm Shaw, natural law predates the establishment of the nation state, it is recognised by the states rather than being created by them. The subject matter of natural law and, more precisely, natural rights was developed in the wake of the 17th century and is closely linked to John Locke. These natural rights are covered, *inter alia*, the following: the right to life and liberty.⁵ For Gabriele Ali, national and supranational governments on the other hand bestow IPRs. They are subject to rigorous statutory limitations, are alienable and limited in time. They can both be revoked and owned by multinational pharmaceutical and other corporations.⁶ To put it in another terms, IPRs are artificial in nature and not inherent. Human rights lawyers have also argued that IPRs have been a considerable obstacle when it comes to the full realisation of the access to essential medicines globally. In this context, patents have served as a reason for impeding the capillary distribution of affordable drugs.⁷

Today the political universality of human rights can hardly be refuted. The experience of World War II has further strengthened acceptance of the idea of human rights. Most of the international community of states have accepted the universality in one shape or form.⁸ According to Louis Henkin the concept of human right has virtually been incorporated into almost every nation's constitution in the world.⁹ In the religious context all major religious have, *prima facie*, downplayed

⁵ Shaw, Malcolm: International law. 6th ed. Cambridge: Cambridge University Press, 2008, p. 266.

⁶ Alì, Gabriele: Intellectual Property and Human Rights: A Taxonomy of Their Interactions, in: International Review of Intellectual Property and Competition Law (2020), No. 51, p. 411-445, p. 416.

⁷ Ibid.

⁸ Henkin, Louis: The Universality of the Concept of Human Rights, in: The Annals of the American Academy of Political and Social Science (1989), Vol. 506, No. 1, pp.10-16, p.13.

⁹ Ibid.

doctrines that happened to conflict with human rights, for instance, subordination of women or intolerance towards other religions. Human rights are commonly regarded by a multitude of religions as the bare minimum requisite for the good society, particularly, when it comes to the contemporary urbanised societies.¹⁰ Louis Henkin argues that all religions and societies have accepted rights that satisfy basic human requirements.¹¹ Modern technology has allowed the concept of human rights to reach the illiterate rural communities of the world. Henkin also claims that the concept of human rights has been accepted by the community of global leaders, regardless of whether they have been influenced by Western education or not.¹² Yet a particular tension has been created between the universality of human rights and cultural traditions.¹³ As for Donnelly the concept of human rights, and by default international human rights law, are inventions, which hail from the West with the intention to force these concepts on the rest of the world.¹⁴ This has led to rejection and resistance by many cultures.¹⁵ According to Anghie, Western or European standards were proclaimed universally applicable and the failure of non-Western and non-European countries to abide by these principles meant a lack of civilisation that in turn warranted both an intervention as well as the invasion of the natives' lands.¹⁶ Towards the end of the 19th Century, European expansionism meant that European-influenced international law had gained world-wide reach as the one and only system that applied to every society. This was also the method through which European international law became universally applicable.¹⁷ Moreover, a main issue of contention between the West and the emerging new

¹⁰ Ibid, p.14.

¹¹ Ibid.

¹² Ibid.

¹³ Shaw, Malcolm: International law. 6th ed. Cambridge: Cambridge University Press, 2008, p. 269.

¹⁴ Donnelly, Jack: The Relative Universality of Human Rights, in: Human Rights Quarterly (2007), Vol. 29, No. 2, pp. 281-306, p. 286.

¹⁵ Henkin, Louis: The Universality of the Concept of Human Rights, in: The Annals of the American Academy of Political and Social Science (1989), Vol. 506, No. 1, pp.10-16, p.14.

¹⁶ Anghie, Antony: The Evolution of International Law: Colonial and Postcolonial Realities, in: Third World Quarterly (2006), Vol. 27, Is. 5, pp. 739-753, p. 745.

¹⁷ Ibid, p. 746.

nations became international economic law. The newly emerged nations contended that this particular *corpus juris* had been formed by Western nations in an endeavour to advance their own interests. The emerging states themselves had hardly played a role in the creation of this legislation.¹⁸ Various scholars from the West recognised the validity of the allegations made by the newly emerged nations. However, the Western nations contended that the Third World nations were nevertheless legally bound by the older terms of international economic law that were drafted by the West. Likewise, the West made the recognition of these and other legislations of the international system a prerequisite to become an independent sovereign nation.¹⁹ For Huntington the West is endorsing its economic interests together with the intention to inflict upon other states the economic policies it deems fit when it comes to its particular desires.²⁰ The West is also utilising international institutions, economic capital and military supremacy to shift and shake the globe in ways that will guarantee Western dominance, promote the economic as well as political values of the West and protects its interests.²¹

Human rights lawyers and advocates have claimed that there are three generations of human rights. The first generation encompasses civil and political rights. The second generation comprises generally rights covering social and economic and cultural rights, such as the right to health. The third generation includes general notions of collective or group rights, such as the right to health and environmental protection.²² Many policymakers, commentators, and governments themselves have come to the conclusion that all forms of human rights have indeed the same priority and standing. According

¹⁸ Anghie, Antony: The Evolution of International Law: Colonial and Postcolonial Realities, in: Third World Quarterly (2006), Vol. 27, Is. 5, pp. 739-753, p. 748.

¹⁹ Ibid.

²⁰ Huntington, Samuel: Clash of Civilisations and the Remaking of World Order. New York: Simon and Schuster, 1998, p. 184.

²¹ Ibid, p. 186.

²² Dixon, Martin: Textbook on International Law. 7th ed. Oxford: Oxford University Press, 2013, p. 373.

to Peter Yu, many of these protagonists tend to prioritise civil and political rights over economic social and cultural rights or collective rights.²³

In this context, it seems rather apparent that access to medicine can be regarded as forming an integral part of the right to health as evidenced by numerous judgements of courts internationally. For instance, in the case *Minister of Health v. Treatment Action Campaign*, the Constitutional Court of South Africa recognised access to medication as part of the right to health under the Constitution of South Africa. In *Minister of Health v. Treatment Action Campaign*, the court ordered the government of South Africa to make Nevirapine more widely available.²⁴ Nevirapine is a drug that prevents mother-to-child transmission of HIV.²⁵ Yet, in another part of the world, the Supreme Court of Justice in Venezuela (Tribunal Supremo de Justicia de Venezuela) issued a judgement under the same line of argumentation, referring to the Venezuelan Constitution in *Cruz Bermúdez v. Ministerio de Sanidad y Asistencia Social*. In its judgement, the court ordered the government to provide antiretroviral treatment to every AIDS-infected patient in Venezuela.²⁶ Moreover, every year tens of thousands of Brazilians have petitioned the courts to order their government to provide them with one or more particular drugs. They are successful in most cases. From 1999-2014, around 1,3 million right to health cases were litigated in Columbia. Once again, medicines subject to patent protection were broad to the court 80 percent of the time.²⁷

²³ Yu, Peter: EU Economic Partnership Agreements and International Human Rights, in: Drexl, Josef/ Nadde-Phlix, Souheir/ Ruse-Khan, Henning Grosse (eds.): EU Bilateral Trade Agreements and Intellectual Property: For Better or Worse?, Heidelberg: Springer, 2014, pp. 109-131, p. 112.

²⁴ Minister of Health et al. v. Treatment Action Campaign et al. 2002 (5) SA 721 (CC); 2002 (10) BCLR 1033 (CC) (5 July 2002).

²⁵ Hestermeyer, Holger: Access to Medication as a Human Right, in: Max Planck Yearbook of United Nations Law (2004), Vol.8, Is.1, pp. 101-180, p. 128.

²⁶ Tribunal Supremo de Justicia de Venezuela, Cruz Bermúdez v. Ministerio de Sanidad y Asistencia Social, Case No. 15.789, Decision No. 916 (1999).

²⁷ Thambisetty, Sivaramjani: Improving Access to Patented Medicines: Are Human Rights Getting in the Way?, in: Intellectual Property Quarterly (2019), Is. 4, pp. 284-305. p. 286.

Finally, with regard to this research project, it would be worth noting that other scholars have also looked at the subject matter of the seizure of generics from India from multiple angles. It would be advisable at this point to consider the body of work of relevant scholars. Frederick Abbott alleges that the seizures to be an intentional effort to halt the developing countries' reliance on the continuing supply of generics from New Delhi.²⁸ According to Abbott several developing nations fear that *prima facie* the initiative of the EU to combat counterfeit goods does indeed follow a "hidden agenda" with the aim to curtail legitimate trade in generic medicines.²⁹ Drexel, Hilty, Jaeger and Ruse-Khan of the Max Planck Institute for Intellectual Property, Competition and Tax Law, stress that by *inter alia* seizing drugs produced under paragraph 6 of Doha, the EU would directly contradict the efforts undertaken by the WTO and its members to promote access to medicines in these cases. According to Duncan the task of granting access to medicine under TRIPS benefitted from the guilty conscious of the developed nations about the colonial legacy, especially with regard to sub-Saharan Africa.³⁰ Yet, Benvenisti and Downs have observed how international regulatory organisations with overlying jurisdiction and boundaries assisted powerful states and supernational organisations such as the EU to maintain their supremacy in the international domain.³¹ Raustiala has noted that the increasing complexity of IP law could also cause what could be termed as a form of "strategic inconsistency", which assists with the alteration as well as weakening unfavourable legislation in the field of international human rights. According to Huntington, on the macro-level, countries from dissimilar civilisations engage in a competition

²⁸ Abbott, Frederick M.: Seizure of Generic Pharmaceuticals in Transit Based on Allegations of Patent Infringement: A Threat to International Trade, Development and Public Welfare, in: World Intellectual Property Organization Journal (2009), Vol. 1, pp. 43-50, p. 49.

²⁹ Abbott, Frederick M.: Worst fears realized: The Dutch confiscation of medicines bound from India to Brazil, 2009 - www.ictsd.org/bridges-news/bridges/news/worst-fears-realised-the-dutch-confiscation-of-medicines-bound-from-india, DOA: 15.05.2016.

³⁰ Matthews, Duncan: When Framing Meets Law: Using Human Rights as a Practical Instrument to Facilitate Access to Medicines in Developing Countries, in: World Intellectual Property Organization Journal (2011), Vol: 3, Is: 1, pp. 113-128, p. 116.

³¹ Benvenisti Eyal/ Downs George: The Empire's New Clothes: Political Economy and the Fragmentation of International Law, Stanford Law Review (2007), Vol. 60, pp. 595–631, p. 603.

over economic as well as military control. Furthermore, their fight for the control of global institutions as well as over other third parties ended up in advertising their specific religious and political principles.³² Yet, Steffen and Shaver approach the subject matter of the seizure of generic drugs from multiple angles, starting with the right to health, IPRs and international trade.³³ Monoranjan illustrates how these seizures do potentially have a detrimental effect on access to public health in both developing countries and LDC.³⁴ Shashank Kumar analyses the border enforcement of IPRs against in transit generic pharmaceuticals by the EU from the point of view of the TRIPS Agreement.³⁵ Mercurio on the other hand, analyses the seizure and the subsequent dispute between the EU and India from the perspective of a potential dispute settlement procedure before the Appellate Body of the WTO. He has also put forward relevant legal arguments for both conflicting parties.³⁶ Erickson's work investigates whether Brussels had the authority to seize the generics in question under the Trips Agreement.³⁷ Lastly, Brook Baker explores the fictive nature of patent rights that were used by the Union to seize legally manufactured and exported goods. She has also examined the multiple shortcomings and weaknesses of the border enforcement regime of the EU.³⁸

³² Huntington, Samuel P: The Clash of Civilizations? The Next Pattern of Conflict, in: Foreign Affairs (1993), Vol. 72, No. 3, pp. 22-49, p. 29.

³³ Shaver, Lea/ Rosina, Mônica Steffen Guise: Why are Generic Drugs Being Held up in Transit? Intellectual Property Rights, International Trade, and the Right to Health in Brazil and Beyond, in: Journal of Law, Medicine and Ethics (2012), Vol. 40, No: 2, pp. 197-205.

³⁴ Ayilyath, Manoranjan: EU Border Measure Regulation: A Threat to Access to Public Health in Developing Countries and Least Developed Countries, in: European Intellectual Property Review (2013), Vol. 35, No. 4, pp. 212-219.

³⁵ Kumar, Shashank P: Border Enforcement of IP Rights Against in Transit Generic Pharmaceuticals: An Analysis of Character and Consistency, in: European Intellectual Property Review (2010), Vol. 32, Is. 10, pp. 506-519.

³⁶ Mercurio, Bryan: "Seizing" Pharmaceuticals in Transit: Analysing the WTO Dispute that Wasn't, in: International and Comparative Law Quarterly (2012), Vol. 61, Is. 2, pp. 389-426.

³⁷ Erickson, Justin: Call for Reform: Analyzing Trips Through European Seizure of Generic Medication, in: Minnesota Journal of International Law (2012), pp. 382- 413.

³⁸ Baker, Brook K.: Settlement of India/EU WTO Dispute re Seizures of In-Transit Medicines: Why the Proposed EU Border Regulation Isn't Good Enough. in: PIJIP, Research Paper no. 2012-02. Washington D.C.: American University Washington College of Law, 2012.

In sum, as stated in the research question, this research shall examine the seizure of essential generic medicines from India by the EU from a human rights angle. This research therefore approaches the issue of the seizure of generic drugs from a dual angle. The first being the human rights angle and the second being a protectionist angle. This way this research aims to provide a new perspective to the subject matter in question. It also aims to provide a contribution to the existing body of scholarly research in this area.

2. A Hindu Nationalist Stance in Indian Foreign Policy

"You can't go back and change the beginning, but you can start where you are and change the ending."

C. S. Lewis

This section will investigate whether Indian foreign policy has taken a directional shift from secularism towards Hindutva inspired foreign policy. This chapter will, therefore, endeavour to examine whether the three key components of the Hindu nationalist doctrine, namely “Hindi, Hindu and Hindustan” are actually forming part of the ideological background of Indian foreign policy at the beginning of the 21st century. According to the American writer Rita Mac Brown:

*“Language is the road map of a culture. It tells you where its people come from and where they are going.”*³⁹

In this context, it is remarkable to note that the early Rashtriya Swayamsevak Sangh's (RSS) leader and ideologue of Hindutva, Madhav Sadashiv Golwalkar, relied on the quote of the famous writer Anthony Burgess on the subject matter of nation. For Burgess, a Nation is defined by the following:

*“a population having a common language and literature, common customs and common consciousness of rights and wrongs, inhabiting a territory of a geographical unity.”*⁴⁰

Prima facie, when referring to Anthony Burgess' quote, the following key aspects come to mind: “common language and literature and inhabiting a territory of a geographical unity”. While the latter refers to Hindustan, the former arguably indicates Hindi as the common

³⁹ Mac Brown, Rita: Goodreads. 2021. - <https://www.goodreads.com/quotes/1216041-language-is-the-road-map-of-a-culture-it-tells>, DOA: 20.03.2021.

⁴⁰ Golwalkar, Madhav Sadashiv: We or Our Nationhood Defined. Nagpur (India): Bharat Publications, 1939, p. 58.

language. Madhav Golwalkar also refers to the famous German writer on politics Bluntsley when it comes to the defining Nation. Thus, according to him, a nation is defined as follows:

*"It is a union of masses of men of different occupations and social states, in a hereditary society of common spirit; feeling and race bound together especially by a language and customs in a common civilization which gives them a sense of unity and distinction from all foreigners, quite apart from the bond of the state."*⁴¹

Bluntsley himself places a special emphasis on language and customs. Madhav Sadashiv Golwalkar, an early RSS leader, highlights the necessity of language as follows:

*"every race, living in its own country evolves a language of its own, reflecting its culture, its religion, its history and traditions."*⁴²

Moreover, he states that each expression is a display of the life of a nation. For Golwalkar language is the be all and end all for the survival of a nation. In his book, *We or Our Nationhood Defined* he states:

*"take away from a nation its ancient language - its whole-literature goes with it-and the Nation as such ceases-to be".*⁴³

In this context, Golwalkar, being the great freedom fighter and RSS leader that he was, also refers to the fact that the British forced English upon the Irish through military might with the aim of total suppression of the Irish mother tongue.⁴⁴ Like the Irish, the Welsh have also successfully fought, according to Golwalkar, the dominance of the English language. He further mentions:

⁴¹ Golwalkar, Madhav Sadashiv: *We or Our Nationhood Defined*. Nagpur (India): Bharat Publications, 1939, pp. 58-59.

⁴² Ibid, p. 73.

⁴³ Ibid.

⁴⁴ Ibid, pp. 73 -74.

*“for these all know that loss of their ancient language would for ever kill out their dear national sentiment, and with it wipe out any possibility of their building up independent healthy national life.”*⁴⁵

Golwalkar's prominent example for an enslaved nation is rooted in their assimilation with the custom and language of their conquerors. Moreover, he also states:

*“Language, therefore, being inextricably woven in the all-round life of a race is an ingredient of great importance in its nationality. Without it the nation concept is incomplete.”*⁴⁶

Thus, for Golwalkar language, religion and culture form the key component when it comes to the survival of every nation.⁴⁷

Moreover, when it comes to the subject matter of the “Hindi” language, *prima facie*, one could argue that India, when it comes to languages, is taking a page out of the Peoples Republic of China’s book. China has undergone considerable struggles to force the whole country under the umbrella of a single *lingua franca* of Mandarin. For China, as an emerging major economic actor on global stage, having Mandarin as their *lingua franca* has arguable been highly beneficial for their economic success story. Yet, unlike in an autocratic country like China, in which the introduction of a single language for the whole country can be undertaken by means of a “three-line whip” or from top-to-bottom, such an approach is bound to face considerable challenges in a nation, which is considered to be the largest democracy in the world. For the BJP and its supporters the issue of the *langua franca* seem to have been settled by the Constitution. Even though the Indian Union has 22 official languages and hundreds of dialects, Hindi has been awarded the status of official language as per Article 343 (1) of

⁴⁵ Ibid, p. 74.

⁴⁶ Ibid.

⁴⁷ Ibid.

the Indian Constitution.⁴⁸ “Force feeding” Hindi down the throat of the Indian populace has, in the past, backfired rather badly as evidenced by the 1965 language riots in Tamil Nadu.⁴⁹

At this point it would be appropriate to consider the recent conflict between Hindi and the regional south Indian language Tamil which flared up in early September 2020. The slogan “*Hindi Theriyathu Poda*” (“I do not know Hindi go away”) has become a household expression in the South Indian state of Tamil Nadu, with linguistic adaptations in other south Indian states. A t-shirt campaign was started by Tamil music composer Yuvan Shankar Raja, who issued a tweet wearing a designer t-shirt displaying the slogan “we are Tamil-speaking Indians and do not know Hindi”, and thereby setting the Tamil version of Twitter on fire.⁵⁰ Unlike their forefathers, who during the Tamil Nadu anti-Hindi riots took to force in 1965, the *2K kids* (children born after the year 2000) and *netizens* (or *net citizens*, who are individuals actively engaged with the online community) of Tamil Nadu are much more peaceful and have long discovered the advantages of social media, in particular Twitter, both in terms of reach and social distancing.

The t-shirt was released on the heels of a particular incidence at the Chennai International Airport (Tamil Nadu) involving DMK (Dravida Munnetra Kazhagam) Lok Sabha (the lower house of the Indian Parliament) MP Kanimozhi Karunanidhi. Kanimozhi Karunanidhi was stopped at Chennai International Airport by a Central Industrial Security Force (CISF) officer and asked whether she was truly an Indian, given the fact that she was not capable of conversing in

⁴⁸ National Legislative Bodies: The Constitution of India. 1950. - <https://www.refworld.org/docid/3ae6b5e20.html>, DOA: 29.01.2019.

⁴⁹ Roychowdhury, Andrija: Hindi in Tamil Nadu: Stalin warns of ‘1965-like situation’, here is what the DMK chief means. in: The Indian Express. 2018. - <https://indianexpress.com/article/research/what-stalin-meant-by-1965-situation-and-why-centre-must-avoid-another-large-scale-riot/>, DOA: 29.01.2019.

⁵⁰ Sivapriyan, E.T.B: “Hindi Theriyathu Poda” T-shirts set Tamil Twitter on Fire. in: Deccan Herald. 2020. - <https://www.deccanherald.com/national/south/hindi-theriyathu-poda-t-shirts-set-tamil-twitter-on-fire-883268.html>, DOA: 11.10.2020.

Hindi.⁵¹ Equally, yet at another incident displays the push for the linguistic dominance of Hindi in the academic domain. The incidence *prima facie* happened at an online training event in which the AYUSH (Ministry of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy) ministerial secretary requested participants from Tamil Nadu to leave the training session when they requested permission to converse in English instead of in Hindi.⁵² This allegation seems hardly surprising given the AYUSH Ministry's "record of accomplishment", which shall be discussed in more details below. Moreover, an inquiry from Tamil Nadu, under the "Right to Information Act", in English, regarding the Cauvery water rights issue was met with a response by the national government in Hindi.⁵³ It is also worth noting that the BJP government established this Ministry in 2014 after winning the Indian general elections.

The Chennai Airport incident had without a doubt left a mark on the DMK. Udhayanidhi Stalin the DMK youth wing secretary and MP Karunanidhi's nephew has been spotted wearing the same t-shirt as the Tamil music composer Yuvan Shankar Raja during a virtual meeting. Thus, the t-shirt has not only emerged into a fashion statement but also a political one, solemnly questioning and challenging the BJP's pro-Hindi agenda. Indians from Tamil Nadu, other Indian states and from around the world have been spotted posting pictures wearing the previously mentioned t-shirt on social media.⁵⁴ In the American state of Wisconsin, a TikTok user of Indian origin has posted a video in which he questioned the employees of Walmart, whether they knew Hindi. The outcome was unambiguous displaying a broad range of accents uttering the slogan "*Hindi*

⁵¹ Ibid.

⁵² The New Indian Express: Tamil speaking Indian: T-shirt sloganeering adds fresh hues to language activism in TN. 2020. - <https://www.newindianexpress.com/states/tamil-nadu/2020/sep/07/tamil-speaking-indian-t-shirt-sloganeering-adds-fresh-hues-to-language-activism-in-tn-2193415.html>, DOA: 12.10.2020.

⁵³ Ibid.

⁵⁴ Sivapriyan, E.T.B: "Hindi Theriyathu Poda" T-shirts set Tamil Twitter on Fire. in: Deccan Herald. 2020. - <https://www.deccanherald.com/national/south/hindi-theriyathu-poda-t-shirts-set-tamil-twitter-on-fire-883268.html>, DOA: 11.10.2020.

Theriyathu Poda". The famous actor Prakash Raj from the south Indian state of Karnataka was posting a photo on social media wearing a t-shirt with the same slogan in Kannada, which stated "Nange Hindi Baralla, Hogappa".⁵⁵

The anti-Hindi slogans have also opened the eyes and ears of the BJP party, which objected to both the anti-Hindi sentiments on social media and the t-shirts themselves. Equally, the party was accusing the DMK of being behind the anti-Hindi campaign.⁵⁶ BJP's Tamil Nadu spokesperson, Narayanan Thirupathy, was not amused by the anti-Hindi sentiments and instead suggested that the residents of Tamil Nadu should encourage other Indians to learn Tamil. He also added that BJP's New Education Policy both encouraged as well as paved a way for non-Tamil speakers to learn Tamil.⁵⁷

MP Kanimozhi made clear that she was not against any particular language or state and that given the necessity people were willing to learn Hindi, for instance in order to secure a job in the northern Hindi language belt of India. Kanimozhi also resisted the imposition of Hindi. She also stated:

"[w]hat we are against is the notion that you are Indian only if you speak Hindi".⁵⁸

In 2019, a clause in the draft National Educational Policy had to be dropped due to strong backlashes from Tamil Nadu.⁵⁹ The above-

⁵⁵ Ramanujam, Srinivasa: From a T-shirt to a phenomenon: How 'Hindi Theriyathu Poda' clothing went viral. in: The Hindu. 2020. - <https://www.thehindu.com/news/cities/chennai/why-hindi-theriyathu-poda-t-shirts-became-popular/article32642309.ece>, DOA: 10.10.2020.

⁵⁶ Sivapriyan, E.T.B: "Hindi Theriyathu Poda" T-shirts set Tamil Twitter on Fire. in: Deccan Herald. 2020. - <https://www.deccanherald.com/national/south/hindi-theriyathu-poda-t-shirts-set-tamil-twitter-on-fire-883268.html>, DOA: 11.10.2020.

⁵⁷ The New Indian Express: Tamil speaking Indian: T-shirt sloganeering adds fresh hues to language activism in TN. 2020. - <https://www.newindianexpress.com/states/tamil-nadu/2020/sep/07/tamil-speaking-indian-t-shirt-sloganeering-adds-fresh-hues-to-language-activism-in-tn-2193415.html>, DOA: 12.10.2020.

⁵⁸ Ibid.

⁵⁹ Ibid.

mentioned incidences are a mere drop in the ocean. Thus, the BJP should be encouraged to respect the linguistic variety of the Indian nation.

Amidst the national push for Hindi dominance, a young music artist by the name of Hiphop Tamizha from Tamil Nadu has released a patriot Tamil song with the following lyrics:

"All religions are welcome here. The Tami[ll] boon! The Tami[ll] bond! We all are the children of this world. Hail Tamizhi! For it's our way, our life and our bond Long live Tami[ll].

Our mother tongue is what unites us. Our mother tongue is our life. Oh my dear Tami[ll], you are my strength. Tami[ll] is what makes you a Tamizhan. Our mother tongue runs in our blood. Our mother tongue is our love. Oh my dear Tami[ll], you are my strength.

Tami[ll] is what makes you a Tamizhan. Tami[ll] is what makes anyone a Tamizhan. ... [...] Oh my dear Tami[ll], you are my strength. Oh my dear Tami[ll], you are my strength.

All religions are welcome here. The Tami[ll] boon! The Tami[ll] bond! We all are the children of this world. Hail Tamizhi!

All religions are welcome here. The Tami[ll] boon! The Tami[ll] bond! We all are the children of this world. Hail Tamizhi!

You are our heart, mind and soul; Hail Tamizhi! The fire that lights up our creativity; Tamizhi.

End of Tami[ll], will mark an end of [our] race. So learn Tami[ll] and keep passing it like the torch. Why have division among ourselves? Let's unite in the name of Tami[ll].

The history might divide us by religion, caste and race. But Tami[ll] has never paved for any division. If there is humanity in you, then you might be a Tamizhan. But if you are a Tamizhan, my dear friend, then humanity is a part of you.

Classical Tami[ll] has made its way to the digital era. Greetings, to all my hard working Tami[ll] folks world wide. Tami[ll] is what unites us. It

established the love bond between us. The base of many languages out there. Tamil[!] is what defines us, the Tamizhans!

The world is our home and we are its kinds. Discover Tamil[!] and you'll discover yourself. Pass it on to the next generation! Remember Tamil[!] is your identity! Tamil[!] - the classical language originated even before the religions existed. We may die but may you live forever.

Massacre us or destroy us... But we will keep rising, because Tamizhan will live till Tamil[!] is alive. Let's cherish Tamil[!] and let the world know it as a language of love. Even if Tamil[!] history gets buried or even if Tamizhans fade away... Our race will live as long as Tamil[!] survives. Oh dear, Tamil[!]. Oh my dear, Tamil[!].”⁶⁰

Hiphop Tamizha's song displays the significance of the Tamil language for the residency of Tamil Nadu and for the Tamil speaking communities from around the world. This song is a homage to the Tamil language, the only ancient language which is still spoken in India.

Notwithstanding the song's glorification of the Tamil language, it provides useful advice to the central government. The song starts off, declaring that all religions are welcome in Tamil Nadu as compared to the harsh stance of the central government against religious minorities. It further affirms the fact that Tamil being a classical language originated before the very existence of any religion.⁶¹ Moreover, the song states that Tamil is the strength, life and unity against the forceful impregnation of Hindi in the daily life of the people of Tamil Nadu. Moreover, it says that while historically divisions into caste, race and religion have existed in India, such divisions have never been propagated by the Tamil language itself. The importance of the Tamil language and culture for humans has been well showcased through these lines, which state that if humanity exits in a

⁶⁰ Tamizha Hiphop: Official music video of #Tamizhi: A Research documentary series about “Evolution of Tamil Writing Script”.2019. - <https://www.youtube.com/watch?v=V9LChBJ1-B0>, DOA: 15.10.2020.

⁶¹ Ibid.

person than he might be a Tamizhan, however, in order to be the same your humanity needs to be part of yourself.⁶² The song declared Tamil to be the root of many languages and it professes it to be the all-encompassing source of identity of its people. The final verse might as well be one that is directed at the BJP's efforts to challenge anything that is not in line with their one nation based "single language" ambitions. The government and the Hindu nationalists may wish to destroy the linguistic plurality and, in particular, Tamil, the Tamil people will live as long as their language flourishes. Hiphop Tamizha also declares his mother tongue to be a global language of love.⁶³ In any case, the following notion *prime facie* appears to be valid, the more BJP and the national government are pushing for the absolute linguistic dominance of Hindi, the more regional linguistic patriotism and nationalism will emerge.

Alike the Tamil slogan, the t-shirts have gone viral which were initially distributed by the Tamil Nadu MP herself to a small group of friends. Mrs Karunanidhi would not, with any stretch of the imagination, have expected the t-shirts not only to become a global phenomenon but also a commercial success. Unlike rolling stones, which it is well known, do not gather weight, the t-shirts are in heavy demand and, surprisingly enough, promote both the BJP's "Make in India Scheme" and the "Digital India Programme" of the government. The biggest textile hub in the Tiruppur district of Tamil Nadu, which almost went out of business due to the Covid-19 pandemic, has been profiting from the demand for the aforesaid t-shirts. The business did not need any expensive advertisement and has simply been running on word of mouth. A manufacturer from Tiruppur has manufactured 12,000 t-shirts, which he is selling for ₹200 apiece.⁶⁴ Although t-shirts with alternative slogans have entered the market, the t-shirts with the

⁶² Ibid.

⁶³ Ibid.

⁶⁴ The New Indian Express: Tamil speaking Indian: T-shirt sloganeering adds fresh hues to language activism in TN. 2020. - <https://www.newindianexpress.com/states/tamil-nadu/2020/sep/07/tamil-speaking-indian-t-shirt-sloganeering-adds-fresh-hues-to-language-activism-in-tn-2193415.html>, DOA: 12.10.2020.

slogans *Hindi Theriyathu Poda* are highly sought-after and orders have come in all the way from California. In line with the “Digital India Programme” digital payment methods in the form of Google pay are also being offered to customers.⁶⁵ Interestingly enough, Tamil Nadu’s struggle against both the Hindu-nationalists and the BJP government’s agenda of imposing Hindi on the people of Tamil Nadu has benefited from the BJP’s policies twofold. First in the form of the “Make in India Scheme” and, secondly, in the form of “Digital India Programme”. Thus, *prime facie*, combatting the linguistic dominance appears to have its perks.

As for Hindu nationalism itself, it has been at the centre stage of Indian domestic politics ever since the election of the BJP. As the saying goes, all domestic politics is foreign politics, hence a change in domestic policy will have considerable impact for a nation’s foreign policy. Before entering into the discussion of the foreign policy section, it would be advisable to take a closer look at the term “Hindutva” or “Hindu Nationalism”.

To begin with, Hindu Nationalism aims to identify the Indian nation along the lines of Hindu religious affiliations. Unlike other forms of nationalism, which typically rely on the notion of a common race or ethnicity, Hindu nationalism is unable to profit from such common denominators. To overcome the diversity of race, ethnicity, linguistics as well as regionalism, Hindu nationalists have been forced to embrace a shared common culture that would enable them to be regarded as Indians.⁶⁶ Such a shared culture is for the Hindu nationalists the Hindu religion, which serves as a common denominator in their endeavour to overcome these shortcomings. The issue with such a definition is that this would not encompass all Indian nationals, as not every Indian is a follower of the Hindu religion and

⁶⁵ Ibid.

⁶⁶ Swamy, Arun R.: Hindu Nationalisms - What’s Religion Got to Do with It? 2003. - <https://apcss.org/Publications/Ocasional%20Papers/OPHinduNationalism.pdf>, DOA: 19.08.2018.

not every state of the Indian Union has a Hindu majority. The mastermind of the Hindutva movement must have had the humiliating subjugation of India by the British Empire in mind. Partition of British India at the time of independence was not able to prevent the creation of a Muslim-majority province. The best example for this is the former princely state of Jammu and Kashmir.

Hindu nationals have used this obstacle to turn such a shortcoming into an opportunity by identifying minorities, specifically against Muslims and Christians as the others and enemies.⁶⁷ This point would indeed find support from Huntington for whom people determine their identity along religious and ethnic lines and as a result an “us” versus “them” situation prevails between these particular people itself and those of dissimilar religion and ethnic persuasion.⁶⁸ Former RSS chief Golwaker also notes in his book “We or Our Nationhood Defined” that Hindu nationalists should apply Hitler’s methods when it comes to Jews to Indian Muslims and Christians. For Golwaker non-Hindu people in Hindustan had two options either to adopt the culture, language as well as religion and to merge into the Hindu race or to be wiped out from the face of the earth.⁶⁹ These chauvinist and racist remarks were also supported by the BJP and RSS leader Rajeshwar Singh from Uttar Pradesh. He noted that both Muslims and Christians are due to be wiped out in 2021 and openly boosted that the BJP government was intending to ethnically cleanse 200 million Muslims and 28 million Christians from the subcontinent.⁷⁰ These statements have understandably caused an outcry in India and the RSS had to

⁶⁷ Ibid.

⁶⁸ Huntington, Samuel: The Clash of Civilizations? The next pattern of conflict, in: Foreign Affairs (1993), Vol. 72, No. 3, pp. 22-49, p. 30.

⁶⁹ Jha, Krishna: RSS chief Mohan Bhagwat has declared war against Indian ethos: His Dussehra address called for speedy building of the Hindu Rashtra. in: National Herald. 2020. - <https://www.nationalheraldindia.com/opinion/rss-chief-mohan-bhagwat-has-declared-war-against-indian-ethos>, DOA: 22.12.2020.

⁷⁰ Sabrangindia: Muslims and Christians will be wiped out of India by December 31, 2021: BJP leader Rajeshwar Singh. 2014. - <https://sabrangindia.in/article/muslims-and-christians-will-be-wiped-out-india-december-31-2021-bjp-leader-rajeshwar-singh>, DOA: 27.08.2020.

get rid of Singh after Modi's annoyance with his involvement in the "Ghar Wapsi" ("return home") reconversion into Hinduism programme.⁷¹

Yet, in an interesting twist and, possibly, to improve their image RSS went on to open up their membership to India's religious minorities to become part of their organisation. For the Sangh both Muslims and Christians are children of "Mother India".⁷² Their ancestors departed, at some point in history, from the Hindu religion and changed their ways of worship. This in turn would not separate them from the Hindu society at large. In other words, the change in faith does not entail disgracing both culture and ancestry. In sum, both Muslims and Christians share the following: motherland, culture, language and ancestors with their fellow Hindu citizens.⁷³ In many cases, according to the RSS, these minority communities are actively partaking in nation building activities alongside the Sangh. Naturally, in order to join the RSS, they ought to agree with the viewpoint of the RSS. This in turn might turn out to be easier said than done. The RSS persistently pushes the narrative of Hindu, Hindu Rashtra and Hindu Culture. The rather well-known slogan of: "Hindu, Hindi and Hindustan" comes to mind. However, for the RSS Hindu is a term used to describe all the people living in Bharat (India). *Prima facie* the Sangh's website seems to push a narrative that being Hindu is neither a religion nor a sectarian identity but a way of life, as noted by the Indian Supreme Court.⁷⁴ The court stated:

"Hindutva/Hinduism is a way of life of the people in the subcontinent" and is a state of mind" – not a religion – and therefore seeking votes

⁷¹ Venugopal, Vasudha: RSS quietly dumps 'Ghar Wapsi' pointsman Rajeshwar Singh after PM Modi expresses annoyance. in: The Economic Times. 2015. - <https://economictimes.indiatimes.com/news/politics-and-nation/rss-quietly-dumps-ghar-wapsi-pointsman-rajeshwar-singh-after-pm-modi-expresses-annoyance/articleshow/45723956.cms?from=mdr>, DOA: 27.05.2019.

⁷² Rashtriya Swayamsevak Sangh: Basic FAQ on RSS. 2017. - <http://rss.org//Encyc/2017/6/3/basic-faq-on-rss-eng.html>, DOA: 27.01.2019.

⁷³ Ibid.

⁷⁴ Ibid.

was not illegal under the Representation of the People Act, which outlaws poll campaigning on religious grounds.”⁷⁵

The Sangh's belief in “Unity in Diversity” considers the national identity of the people of India as Hindu.⁷⁶ It goes even further by proclaiming that all roads lead to Rome when it comes to religious beliefs. Thus, a regular Hindu believes that while there are multiple expressions, they all lead to the “One Supreme Reality”.⁷⁷ While copying the American slogan of “Unity in Diversity”, the RSS *prime facie* seems to use the term to unite all Hindu first and foremost. As a second notion they might also target those religious minorities that are patriotic Indians. As for the Sangh India's national identity is inherently Hindu, which would in turn transform a patriotic Indian into a Hindu, culturally at the very least. The above-mentioned issues contrast with statements issued by Hindutva supporters such as Koenraad Elst, a Belgian champion of Hindutva, who announced the following:

“[e]very Muslim is a Sita who must be released from Ravana’s prison. We should help Muslims in freeing themselves from Islam...”⁷⁸

Interestingly enough, despite being a nation that consists of a predominantly Hindu majority, the Indian nationalist movement was secular for the most part. The founding father of Indian foreign policy and the first Prime Minister (PM) of India, Jawaharlal Nehru himself was a strong supporter of secular values.⁷⁹ Based on Nehru’s notion, religion in post-independent India did not play a predominant role, at all. In fact, New Delhi’s commitment to a secularism forced it to make

⁷⁵ Sinha Bhadra: Is Hinduism a way of life or just a religion? SC to re-examine today. 2016. - <https://www.hindustantimes.com/india-news/is-hinduism-a-way-of-life-or-just-a-religion-sc-to-re-examine-today/story-ZDU95tarD5kGnWzqfgJELL.html>, DOA: 12.08.2020.

⁷⁶ Rashtriya Swayamsevak Sangh: Basic FAQ on RSS. 2017. - <http://rss.org//Encyc/2017/6/3/basic-faq-on-rss-eng.html>, DOA: 27.01.2019.

⁷⁷ Ibid.

⁷⁸ Nanda, Meera: Hindu Triumphalism and the Clash of Civilisations, in: Economic and Political Weekly (2009), Vol. 44, No. 28, pp. 106-114, p. 106.

⁷⁹ Ganguly, Sumit: Hindu Nationalism and the Foreign Policy of India’s Bharatiya Janata Party. 2015. - <https://docplayer.net/11706791-Hindu-nationalism-and-the-foreign-policy-of-india-s-bharatiya-janata-party-sumit-ganguly-2014-15-paper-series-no-2.html>, DOA: 16.03.2016, p. 1.

some rather difficult foreign- and security-policy choices. This can be seen in the Indian government's willingness to bring Jammu and Kashmir, a predominantly Muslim state, back home into the Union.⁸⁰ By doing so, the founding fathers of Indian policymaking have affronted and tackled Ali Jinnah's "two- nation theory". The founder and first president of the Islamic Republic of Pakistan, Ali Jinnah, developed the theory that British India's Hindu and Muslim population would constitute two distinct and separate nations. Yet, interestingly enough, the Muslims of the British Empire of the time barely constituted what can be considered a coherent unity in India. The Muslim community in those days was fragmented along the lines of region, social, sect, class, language and caste.⁸¹

For Dr. Keshav Baliram Hedgewar, a key ideologist of the Hindu nationalist movement, a qualified medical doctor as well as founded the RSS in 1925, Jammu and Kashmir have been a matter of concern ever since India's independence. The RSS founder was anything but convinced with the aforementioned narrative of integrating Bharat into the Indian state post-independence. The RSS later advanced into the founding organisation of India's ruling party the BJP. Dr Hedgewar believed that without the "premature" ceasefire declaration of the Indian government in Kashmir after independence the Indian Army would have been able to retrieve the whole of Kashmir. Thus, Pakistan-occupied Kashmir (POK) would not have been a thorn in the Indian security landscape.⁸²

Policymakers in India, however, found their long-held scepticism confirmed when the population in East Pakistan, faced with utter discrimination and ruthless repression, gained independence from the rest of Pakistan in 1971. The Indian leadership at the time found itself

⁸⁰ Ibid.

⁸¹ Mushirul, Hasan: Legacy of A Divided Nation: India's Muslims From Independence. London: C. Hurst and Company, 1997.

⁸² Rashtriya Swayamsevak Sangh: RSS: The Mission. 2012. -

<http://rss.org//Encyc/2012/10/22/rss-vision-and-mission.htm>, DOA: 22.01.2019.

in discountenance of the so-called “two nation theory” affirmed. After all, from New Delhi’s point of view, mere religious ties in the form of a common Islamic faith, was insufficient to keep both East and West Pakistan united in as single nation state. With regard to East Pakistan, language has served as an overarching fact for the division of a united Islamic Pakistan. This is where Jinnah’s so-called “two nation theory”, *prima facie*, revealed its biggest shortcoming.⁸³

A remarkable shift has taken place since 1971, as Indian domestic policy has seen a retreat from India’s original pledge to secularism. While these changes in the India’s policies are anything but straightforward, one can, *prima facie*, attribute it to the rise of religious nationalism. Surprisingly enough, a prominent nurturer of communal politics and sectarianism has been the daughter of India’s first PM, who later occupied the same office, Mrs Indira Gandhi. In her endeavour to marginalise the rise of regional political parties in India, which inevitably would have challenged the dominant position of the Indian National Congress Party (INC), Mrs Gandhi did not hesitate to encourage the use of violence. The prominent case of the Indian state of Punjab illustrates the devastating outcome from Gandhi’s change in policy. Faced with the rising popularity of the regional party “Akil Dal”, Gandhi saw herself forced to encourage the increase in violence enacted by the fundamental Sikh preacher Sant Jarnail Singh Bhindranwale.⁸⁴ Gandhi’s strategy did not plan out as expected and had devastating consequences for the Punjab, where ethnic and religious insurgency movements were flourishing. Confronted with such a state of emergency, Indira Gandhi had no option but to avail herself of the support of the Indian Army. The Indian Army did not hesitate to besiege the Golden Temple in Amritsar in their attempt to get rid of the Bhindranwale and his followers. The fundamentalist Sikh preacher had turned the holiest Sikh shrine into a hideout for terrorists.

⁸³ Ganguly, Sumit: Hindu Nationalism and the Foreign Policy of India’s Bharatiya Janata Party. 2015. - <https://docplayer.net/11706791-Hindu-nationalism-and-the-foreign-policy-of-india-s-bharatiya-janata-party-sumit-ganguly-2014-15-paper-series-no-2.html>, DOA: 16.03.2016, p. 2.

⁸⁴ Ibid, p. 3.

The Indian Army's military operations brought a heavy loss of civilian lives with it. As a consequence, PM Indira Gandhi, was assassinated by her two Sikh bodyguards in 1984.⁸⁵

Jawaharlal Nehru's grandson and Indira Gandhi's son, Rajiv Gandhi, became the successor to his mother's office upon her demise. Rajiv Gandhi, in fact, profited from the sympathy wave following his mother's assassination and became India's Prime Minister. Based on the negative experience with the Sikh community, Gandhi was keen to appease the Muslim community which has been a significant and dependable voting bloc for the INC.⁸⁶ Gandhi soon had an opportunity to please the Congress's loyal Muslim voters. In 1985 the Supreme Court of India ruled on the subject matter of alimony for the Muslim women, Shah Bano⁸⁷, thus superseding Muslim Personal Law in place at the time in India. The conservative section of the Islamic community was dissatisfied and protested against the Supreme Court ruling. Faced with protests from the Muslim community Rajiv Gandhi opted to utilise Congress's majority in the Lok Sabha, which in turn exempted the followers of the Muslim faith from the Indian civil code and thereby creating a Muslim Personal Law. In doing so Gandhi himself also broke with the secular nature of the Indian Unions policy initiated by his own grandfather. Gandhi's pandering to the Muslim vote led to his decision being attacked by the Hindu nationalist BJP, who regarded the Congress's approach as "pseudo secularism."⁸⁸

The BJP domestic agenda is aligned with the politics of inclusion and exclusion. For one, the Hindu nationalists believe in creating a narrative of "Us" and "Them", thereby targeting India's Muslim and Christian religious minority communities. In this context, Sita Ram Goel's quotes

⁸⁵ Ibid.

⁸⁶ Ibid, p. 3.

⁸⁷ Mohd. Ahmed Khan vs Shah Bano Begum And Ors, 1985 AIR 945, 1985 SCR (3) 844.

⁸⁸ Ganguly, Sumit: Hindu Nationalism and the Foreign Policy of India's Bharatiya Janata Party. 2015. - <https://docplayer.net/11706791-Hindu-nationalism-and-the-foreign-policy-of-india-s-bharatiya-janata-party-sumit-ganguly-2014-15-paper-series-no-2.html>, DOA: 16.03.2016, p. 4.

comes to mind, the founder of “Voice of India” did not hide his disregard for monotheistic religions. He stated the following:

*“[m]onotheistic creeds are creations of the outer and lower level of the human mind. Is a son regard them as religions in any sense of the word...”*⁸⁹

BJP’s ideological bucket list entails, *inter alia*, the abolition of Article 370 of the Indian Constitution and the implementation of the Uniform Civil Code for the whole of the Indian Union. The former would mean granting a special status in the Muslim majority state of Jammu and Kashmir. The latter would entail the dismantling of Muslim Personal Law. The RSS believed that Kashmir is a problem of India’s own making; they believe that successive Congress governments have been appeasing the Muslim population in Kashmir. They are of the firm view that POK has been illegally occupied. Which in turn, according to the RSS, meant that Islamabad, far too weak to undertake warfare, was waging a cold war against Bharat, and was aiding and abetting the intruders through the supply of arms as well training.⁹⁰

Given the constraints originating from a coalition constellation during BJP’s first term in office, from 1998 to 2004, the aforementioned policy goals which were exclusionary and nationalistic in nature could not be realised. Here the Indian democracy was able to stand firm as not all coalition partners were keen to give way to the Hindu nationalist domestic policy agenda.⁹¹

Lacking necessary support from its coalition partners for BJP’s nationalist agenda, the Hindu nationalists went on to rewrite Indian

⁸⁹ Nanda, Meera: Hindu Triumphalism and the Clash of Civilisations, in: Economic and Political Weekly (2009), Vol. 44, No. 28, pp. 106-114, p. 106.

⁹⁰ Rashtriya Swayamsevak Sangh: RSS: The Mission. 2012. - <http://rss.org/Encyc/2012/10/22/rss-vision-and-mission.htm>, DOA: 22.01.2019.

⁹¹ Ganguly, Sumit: Hindu Nationalism and the Foreign Policy of India’s Bharatiya Janata Party. 2015. - <https://docplayer.net/11706791-Hindu-nationalism-and-the-foreign-policy-of-india-s-bharatiya-janata-party-sumit-ganguly-2014-15-paper-series-no-2.html>, DOA: 16.03.2016, p. 6.

national history by altering the textbooks in schools. They downplayed the relevance as well as the achievements of India's Muslim rulers.⁹² Once in government, Modi appointed Yellapragada Sudarshan Rao, a historian with limited professional accomplishments, as director of the distinguished Indian Council of Historical Research with the capacity to reward fellowships and awards to foreign as well as Indian scholars.⁹³ Thus the Indian Council of Historical Research has the ability to impact the direction and development of historical research as well as scholarship in India.⁹⁴ Rao's limited professional scholarship has led him to proclaim that the two famous Hindu religious epics, Ramayana and Mahabharata, were to be considered as a true account of the Union's historical past.⁹⁵ After having made their mark on the Indian school syllabus, as seen above, the BJP now targeted the university syllabi and pursued their intention to eradicate alternative narratives of the famous Indian epics of Ramayana and Mahabharata.⁹⁶ Sadly enough, the willingness to change does not stop with the Council of Historical Research. During the Science Congress in 2015, some presenters uttered claims that are of a somewhat bizarre nature. Among these claims were those that Indian physicians were pioneers in plastic surgery, which was apparently already in use thousand years back. These extraordinary claims, or to use President Donald Trump's lingo, so-called alternative facts, included the assertion that helicopters have already circulated Indian airspace in ancient times. This assertion was followed by the claim that Indian inventors had piloted a flying machine a decade before the Wright brothers' invention.⁹⁷ Dr.

⁹² Jain, Rupam/ Lasseter, Tom: By Rewriting History, Hindu Nationalists Aim to Assert Their Dominance over India. in: Reuters, 2018. - <https://www.reuters.com/investigates/special-report/india-modi-culture/>, DOA:19.09.2020.

⁹³ Ganguly, Sumit: Hindu Nationalism and the Foreign Policy of India's Bharatiya Janata Party. 2015. - <https://docplayer.net/11706791-Hindu-nationalism-and-the-foreign-policy-of-india-s-bharatiya-janata-party-sumit-ganguly-2014-15-paper-series-no-2.html>, DOA: 16.03.2016, pp. 6-7.

⁹⁴ Ibid, p. 8.

⁹⁵ Ibid, p. 9.

⁹⁶ Ibid.

⁹⁷ Ibid.

Hedgewar, the founder of RSS, was also boasting about Bharat's achievement, *inter alia*, in the areas of science and technology.⁹⁸

While the aforementioned claims seem to be mere figments of imagination and are, at best, assertions leading to *ad absurdum*. The Hindu nationalists together with their Hindu cultural and political dominance have taken a more aggressive stance elsewhere. In 2014, a junior minister in the BJP government, by the name of Sadhvi Niranjan Jyoti, stated that Indians had a choice between a government of those conceived of Ram and those of illegitimate origins.⁹⁹ Faced with heavy criticism, PM Modi estranged himself from his Junior Minister's comments and proceeded to put it down to her hailing from a rural heritage.¹⁰⁰

Once in power Modi has, arguably, loosened his grip on the RSS, which in turn embarked on a mission to jeopardise the already fragile secular order on the Union. The RSS went on to sponsor the "Ghar Wapsi" movement whose declared aim is to convert members of other religious affiliations to Hinduism. The majority of India's religious minority had once been Hindus, at least this is the narrative, and a couple of centuries ago converted to another faith. The strategy of the "Ghar Wapsi" movement was to target minorities from working-class communities and the poor. The movement was able to convert around 8000 persons to Hinduism in the newly establish south Indian state of Telangana and in Andhra Pradesh.¹⁰¹ The so-called "return home" movement's conversion project has been the root course of much agitation amongst the minorities all across the Indian Union. Madhav

⁹⁸ Rashtriya Swayamsevak Sangh: RSS: The Mission. 2012. -

<http://rss.org//Encyc/2012/10/22/rss-vision-and-mission.htm>, DOA: 22.01.2019.

⁹⁹ Sridharan, Eswaran: India's Watershed Vote: Behind Modi's Victory, in: Journal of Democracy. Vol. 25, No. 4, pp. 20-33, p. 26.

¹⁰⁰ Parth, M. N.: India's Narendra Modi Apologizes for Official's Remarks on Non-Hindu. in: The Los Angeles Times. 2014. - <https://www.latimes.com/world/asia/la-fg-india-modi-hindus-20141205-story.html>, DOA: 18.05.20216.

¹⁰¹ Ganguly, Sumit: Hindu Nationalism and the Foreign Policy of India's Bharatiya Janata Party. 2015. - <https://docplayer.net/11706791-Hindu-nationalism-and-the-foreign-policy-of-india-s-bharatiya-janata-party-sumit-ganguly-2014-15-paper-series-no-2.html>, DOA: 16.03.2016, p. 9.

Sadashiv Golwalkar has alluded to the fact that the Hindu nationalist have obtained freedom through defending their religion and culture.

“Many people worked with the inspiration to free the country by throwing the British out. After the formal departure of the British this inspiration slackened. In fact, there was no need to have this much inspiration. We should remember that in our pledge we have talked of the freedom of the country through defending religion and culture. There is no mention of the departure of the British in that.”¹⁰²

Alongside these, acts of forced conversions Christian churches were subject to waves of attacks. Due to heavy protests from the clergy, PM Narendra Modi was forced to renounce the attacks in public. All these conversions and attacks happened despite the fact of Hinduism's disregard for proselytization.¹⁰³

When everything is said and done, the growing level of intolerant rhetoric and actions should not be dismissed, as mere hearsay or actions of the few. There is a clear strategy to fundamentally convert India's domestic politics and constitutional order. As many Hindu nationalist thinkers have stated before, India can only ever archive true success on the world arena if it truly becomes a unitary Hindu nation.¹⁰⁴ India's quest for a homogenous domestic society which ultimately involves favouring and nurturing the Hindu majority seems to be the way forward. Such discriminatory policies might have considerable repercussions for Indian foreign policy. If a situation were to arise in which India's largest religious minority community, Muslims, were to find themselves subjected to severe disadvantages and

¹⁰² Golwalkar, Madhav Sadashiv: in: Quotes & Sayings About British Culture. 2021. - <https://quotessayings.net/topics/british-culture/>, DOA: 17.01.2021.

¹⁰³ Ganguly, Sumit: Modi's Balancing Act India's Conservative Social Agenda Threatens Its Foreign Policy. in: Foreign Affairs. 2015. - <https://www.foreignaffairs.com/articles/india/2015-03-26/modis-balancing-act>, DOA: 18.02.2018.

¹⁰⁴ Ganguly, Sumit: Hindu Nationalism and the Foreign Policy of India's Bharatiya Janata Party. 2015. - <https://docplayer.net/11706791-Hindu-nationalism-and-the-foreign-policy-of-india-s-bharatiya-janata-party-sumit-ganguly-2014-15-paper-series-no-2.html>, DOA: 16.03.2016, pp. 6-7.

systematic discrimination then India would be confronted with radicalisation of its Muslim community at home. This prospect is rather worrisome given the fact that India is expected to have the largest Muslim population in the world by 2050 and thereby surpass Indonesia.

The BJP government and its nationalist agenda like other nationalist agendas appears to consist of symbolism and showmanship. The Modi administration appears to be very much in support of Hedgewar's regarding the subcontinent's scientific and technological achievements. The Modi government, in a manoeuvre to advance Hindustan's accomplishment, added the compound of architectural grandeur to the list. In this regard the construction of a massive statue of Sardar Vallabhai Patel does indeed serve as an excellent example. Modi is a great admirer of the nation's first Minister for Home Affairs and Deputy Prime Minister, Sardar Vallabhai Patel, who himself displayed a firm stance when it came to questions concerning New Delhi's national security.¹⁰⁵ Sardar Vallabhai Patel had been known as an "Iron Man" who was willing to use the threat of force as "means of persuasion" against the feuding states that were not willing to join the then newly emerged Indian Union. Patel had been overshadowed by the Gandhi-Nehru dynasty, given their political domination since independence.¹⁰⁶

For Modi, Patel was a "strategic thinker" and unifier of divisive post-independent India; in a word, a true patriot. India's Iron Man was also among the initial proponents of free enterprise.¹⁰⁷ Thus with the erection of this national monument, the BJP is, arguably, making its

¹⁰⁵ Business Standard: Modi stirs controversy, says Patel should have been India's first PM. 2013. - https://www.business-standard.com/article/news-ani/modi-stirs-controversy-says-patel-should-have-been-india-s-first-pm-113102901041_1.html, DOA: 10.05.2021.

¹⁰⁶ BBC News: Indian Farmers Fume at \$430m Cost of Gujarat Statue. 2018. - <https://www.bbc.com/news/world-asia-india-45978120>, DOA: 19.1.2019.

¹⁰⁷ The Straits Times: India's Statue of Unity Opens to Great Fanfare - and Controversy. 2018. - <https://www.straitstimes.com/asia/south-asia/indias-statue-of-unity-opens-to-great-fanfare-and-controversy>, DOA: 18.01.2019.

mark both on the Gujarati landscape and in the minds of millions of Indians. Equally, the symbolic nature of the “statue of unity” could also be seen as an attempt, by BJP, to put India’s powerful opposition party, the Congress, on notice that a new “Sheriff” is in town. The importance of this symbolic act becomes apparent if one were to look at history. Out of 71 years of post-Independent Indian rule, 49 were under the leadership of the INC Party. Modi, once a “Chaiwala” (tea seller), came to power on a populist ticket and by challenging the corrupt political establishment of the Congress party’s United Progressive Alliance (UPA).

Thus, Modi and the Hindu nationalists have, *prima facie*, by enacting the Patel statue and claiming his legacy for themselves, once again have had the opportunity to fiddle with Indian history and nationalistic narrative. The PM and his supporters are continuing to re-write Indian history along Hindutva lines. They have merely “graduated” from a two-dimensional level (textbooks) to a three-dimensional level (massive statues). The memorial incorporates a museum, a hotel and a research centre which is dedicated to issues close to Patel’s heart such as “agricultural development” as well as “good governance”.¹⁰⁸ The BJP seems to be eager to make their mark, regardless of the estimated costs of 29.9 billion rupees (\$430m) or consequences for people or the environment. The cost was shared between the state government of Gujarat and the central government in New Delhi; the irony in all this lies in the fact that this monument displaying Indian national pride would not have been constructed without the help of both Chinese design and workforce.¹⁰⁹

The “statue of unity”, built in the Indian State of Gujarat, is claimed to be the tallest statue in the world. It has now beaten the 153-meter-tall

¹⁰⁸ BBC News: Indian Farmers Fume at \$430m Cost of Gujarat Statue. 2018. - <https://www.bbc.com/news/world-asia-india-45978120>, DOA: 19.1.2019.

¹⁰⁹ Gamble, Ruth/ E. Davis, Alexander: India Unveils the World’s Tallest Statue, Celebrating Development at the Cost of the Environment. in: The conversation. 2018. - <https://theconversation.com/india-unveils-the-worlds-tallest-statue-celebrating-development-at-the-cost-of-the-environment-105731>, DOA: 19.01.2019.

Chinese “Spring Temple Buddha”, located in the Henan province. For the PM the “statue of unity” symbolises Indian engineering and technical prowess, but the erection of the world’s highest monument did not go very smoothly.¹¹⁰ Critics have drawn attention to the severe environmental damage caused by this colossal building endeavour. Sadly, India’s ambitious building project did not even spare the local indigenous community of the Adivasi. The community’s sacred site had to be given way and their rightful owners were removed by forceful means.¹¹¹ The ruling BJP has displayed its willingness to override both environmental protection and human rights to complete this ambitious project.

Modi’s neoliberal agenda and commitment to rapid economic development has meant that his pro-industrial policy did not forget to take captives. The consequences according to critics were erosion of forests as well as coastal areas, eroded conservation, violation of air pollution protections and the weakening of land rights of minority communities, as seen above. India’s environmental record of accomplishment has been amongst the worst in the world, ranking 177 out of 180 for environmental protection.¹¹² The BJP government’s appalling record of accomplishment when it comes to environmental protection did not prevent the United Nations Environmental Organisation (UNEP) from awarding the Modi administration its highest and most prestigious award. The UNEP has awarded India’s Premier with the “Champion of the Earth” award for endeavours to reduce plastic as well as for his work on solar energy development.¹¹³

¹¹⁰ The Straits Times: India’s Statue of Unity Opens to Great Fanfare - and Controversy. 2018. - <https://www.straitstimes.com/asia/south-asia/indias-statue-of-unity-opens-to-great-fanfare-and-controversy>, DOA: 18.01.2019.

¹¹¹ Gamble, Ruth/ E. Davis, Alexander: India Unveils the World’s Tallest Statue, Celebrating Development at the Cost of the Environment. in: The conversation. 2018. - <https://theconversation.com/india-unveils-the-worlds-tallest-statue-celebrating-development-at-the-cost-of-the-environment-105731>, DOA: 19.01.2019.

¹¹² Ibid.

¹¹³ Jasleen, Dhanota: Celebrating Bold Environmental Leadership and a Plastic-Free Future in India. in: Champions of the Earth. 2018. - <http://web.unep.org/championsofearth/celebrating-bold-environmental-leadership-and-plastic-free-future-india>, DOA: 28.03.2019.

While the critics have indeed valid concerns, from the perspective of a developing country like India, one might wish to point out that developed nations themselves have used the very same method of environmental pollution in order to reach their present level of development, for instance during the course of the industrial revolution or in post-WWII Germany. Yet when developing nations are utilising the same techniques there seems to be an uproar from that part of the industrial world.

A stone's throw away from the "statue of unity", Patel's aspiration for agriculture development seem to have been knocking on closed doors. Farmers in this part of the world are struggling for basic irrigation and are unsurprisingly furious in light of the enormous cost implications for the building of this statue. A considerable number of households in Gujarat's Narmada district continue to live in dire poverty and are malnourished according to state government report published in 2016.¹¹⁴ Consequently, the people in this part of India are anything but amused given the extraordinary cost for the statue. The farming community has been repeatedly disappointed by the government, which has only handed out empty promises to support the farmers. This becomes even more evident if one were to consider the fact that in India's southern state of Tamil Nadu farmer are forced to eat mice and rats due to the droughts and lack of irrigation. In cases where they were no longer able to back their bank loans, suicide remains the last port of call for many.¹¹⁵ Thus, the question that needs to be asked is why a nation with such dire material needs should be embarking on such an extravagant project of nationalistic self-aggrandisement when the money could have been invested in the nation's backbone, the farming community. When all things are said and done, the leading Hindu nationalist leader will hopefully realise that the

¹¹⁴ BBC News: Indian Farmers Fume at \$430m Cost of Gujarat Statue. 2018. - <https://www.bbc.com/news/world-asia-india-45978120>, DOA: 18.3.2019.

¹¹⁵ Soutik, Biswas: Why Are Farmers in India Protesting with Mice and Human Skulls? in: BBC News. 2017. - <https://www.bbc.com/news/world-asia-india-39650496>, DOA: 19.01.2019.

floccinaucinihilipilification of the Indian farmers and ignoring their basic needs will in the future, potentially, lead to discombobulation on the world stage for failing to prevent suicides and overcome poverty.

Based on the Hindu nationalist worldview, it is evident that the Prime Minister would be required to embark on a journey transforming the political arrangements on the home front. This would entail the configuration of a nation state that would consist of a common cultural heritage based on Hinduism.¹¹⁶

Both Jana Sangh and its successor BJP firmly hold the view that Hinduism is closely linked to the territory of the Indian motherland (Bharat).¹¹⁷ The origins of this idea can be traced back to Vinayak Damodar Savarkar a key representative of Hindu nationalism. For Savarkar the idea of Hindutva was rooted on an ethnic community, comprising of equivalent racial as well as cultural traits, while possessing a territory. His definition can be traced back to the mythical construction of the Vedic Golden Age.¹¹⁸ In essence, those who live in the territory of India must be considered as Hindu. The territorial definition commences on the foothills of the Himalayas and stretches all the way to the Indian Ocean.¹¹⁹ For Savarkar, the land of *Bharat Varsha* (Greater India) is the cradle of the Hindu religion, both Holy-Land and Fatherland alike.¹²⁰ In sum, for him Hindu nationalists have collective identities that are religious and national in nature.¹²¹

Yet another fundamental factor that both ideologues, Vinayak Damodar Savarkar and his fellow companion Madhav Golwalkar,

¹¹⁶ Ganguly, Sumit: Hindu Nationalism and the Foreign Policy of India's Bharatiya Janata Party. 2015. - <https://docplayer.net/11706791-Hindu-nationalism-and-the-foreign-policy-of-india-s-bharatiya-janata-party-sumit-ganguly-2014-15-paper-series-no-2.html>, DOA: 16.03.2016, p. 13.

¹¹⁷ Ibid, p. 5.

¹¹⁸ Jaffrelot, Christophe: The Hindu Nationalist Movement in India. London: Hurst, 1993, p. 27.

¹¹⁹ Ganguly, Sumit: Hindu Nationalism and the Foreign Policy of India's Bharatiya Janata Party. 2015. - <https://docplayer.net/11706791-Hindu-nationalism-and-the-foreign-policy-of-india-s-bharatiya-janata-party-sumit-ganguly-2014-15-paper-series-no-2.html>, DOA: 16.03.2016, p. 6.

¹²⁰ Van Der Veer, Peter: Hindus: A superior race. in: Nations and Nationalism (1999), Vol. 5, No.3, pp. 419-30, p. 429.

¹²¹ Ibid.

shared was the fact that they viewed conflict and, for that matter, war as something which one should hardly strive for but yet as something that is unpreventable in a global arena consisting of bigoted societies and egocentric individuals. Both suggested that Bharat should develop the necessary capabilities and readiness to participate in warfare as well as power politics with the aim to defend the motherland against aggressors from outside.¹²² The mere acquisition of military prowess should not be misconstrued with classical realism's acquisition of material capabilities. It is rather a reflection of the exhibition of national strength that supports a nationalism that is exclusive and self-assured.¹²³

Golwalkar and Sarvarkar's Hindu nationalistic plea for the development of military capacity to fend off external aggressors has been utilised by the BJP against the existing diverse cultural and religious minorities on the Indian subcontinent. The Hindu nationalist distrusts minorities, given their potential inability to be loyal to Bharat, and their capability to create social fragmentations has been a long standing concern for the ideological thinker of the nationalist movement. Prime facie, these ideological agendas emanating from the BJP camp are intertwined with the party's approach to domestic policy making.¹²⁴

Hedgewar was also convinced that freedom for the Hindu population of India would only be possible if they themselves were organised as a powerful nation.¹²⁵ He describes the East Indian Company as a handful of traders and shopkeepers who lacked both physical capabilities and intellectual smartness in order to be able to establish

¹²² Sargar, R.: "Jiski Lathi, Uski Bhains": The Hindu Nationalist View of International Politics. in: Bajpai, K./ Basit, S./ Krishnappa V. (eds.): India's Grand Strategy: History, Theory, Cases. London: Routledge, 2014, p. 237.

¹²³ Ibid.

¹²⁴ Ganguly, Sumit: Hindu Nationalism and the Foreign Policy of India's Bharatiya Janata Party. 2015. - <https://docplayer.net/11706791-Hindu-nationalism-and-the-foreign-policy-of-india-s-bharatiya-janata-party-sumit-ganguly-2014-15-paper-series-no-2.html>, DOA: 16.03.2016, p. 6.

¹²⁵ Rashtriya Swayamsevak Sangh: RSS: The Mission. 2012. -

<http://rss.org/Encyc/2012/10/22/rss-vision-and-mission.htm>, DOA: 22.01.2019.

the British Empire on Indian soil. Dr. Hedgewar also blames the chieftains for facilitating the destruction of Bharat by the West.¹²⁶

On another note, Modi appears to be indebted to the foreign policy positions and practices of former Indian PM of the BJP Atal Behari Vajpayee. As with Modi, Vajpayee displayed the ability to direct New Delhi's foreign policy between the notion of *Shakti* (power) and *Shanti* (peace).¹²⁷ While nationalism has a multitude of meanings, depending on the respective recipient, the Hindu nationalists' wish to maintain the sanctuary of Hinduism and are prepared to resort to the use of force as and when needed. The RSS covers this paramilitary arm when defending the religion.¹²⁸ As the Hinduism's place of birth, Bharat is original in terms of its heritage with a significant majority of the population, which are devotees of the Hindu religion. Thus, any given government will be forced to be mindful of this very reality. When it comes to the issue of international relations and Indian foreign policy, Hindu nationalism appears to follow the political science tradition of realism.¹²⁹ The stalwarts of the Hindu nationalist movement Savarkar and Madhav Golwalkar have written extensively about Hindutva (which is roughly similar to the term Hindu nationalism). It is also important to mention the fact that Golwalkar himself was an avid Hitler admirer and was dedicated to the Nazi ideals of a so-called "race spirit".¹³⁰

The term Hindutva was devised by Savarkar himself.¹³¹ Both protagonists of Hindu nationalism developed an understanding for the world from a Hobbesian point of view, namely that in a world in which states are in frequent competition, they are driven by their self-interest and the outcome is zero sum. Thus, in line with Thucydides, the strong

¹²⁶ Ibid.

¹²⁷ Panda, Ankit: Hindu Nationalism and...Foreign Policy? What does Hindu nationalism have to say about international relations? in: The Diplomat. 2014. -

<https://thediplomat.com/2014/04/hindu-nationalism-and-foreign-policy>, DOA: 10.10.2020.

¹²⁸ Ibid.

¹²⁹ Ibid.

¹³⁰ Ibid.

¹³¹ Ibid.

are doing whatever they can and the weak are suffering what they must, and this has been a reality in the realm of foreign policy, both in India and beyond.¹³²

Yet, Hindu nationalists tend to differ from the Western realist thinkers to the likes of Waltz, Morgenthau and Thucydides, in that they insist on the notion that in order for state to be strong it is essential for it to nurture a strong sense of national identity and in the Indian sense a strong national pride.¹³³ Moreover, Savarkar, the “founding father of Hindu nationalism” expressed the same notion in his masterpiece the “Essentials of Hindutva”. He wrote that national identity persists when the following three criteria are given: common culture, common blood, and common law, as well as rites. He also insisted on the fact that more than these three aspects, a common geography ought to demarcate a nation.¹³⁴ If one were to rely on the traditional lines in terms of geography, today’s Pakistan, Bangladesh, Sri Lanka and Bhutan would fall in realm of the Indian nation.

Interestingly, one of the founding fathers of the Hindutva failed to list the aspect of religion in his list of qualifying criteria. The rather simple reason for this is because Savarkar was an atheist himself. In other words, the father of Hindu nationalism is not even a Hindu believer himself. For Savarkar, a Hindu is someone who considers the land of Hindustan from the Ocean to the Sindhu river as his fatherland and holy, and who identifies himself with the culture of this land.¹³⁵ Besides, ever the pragmatist, Savarkar also had the heavy burden of integrating the various religious Indian communities and traditions into the all-encompassing umbrella of Hindutva.¹³⁶ In this context Savarkar remarked:

¹³² Ibid.

¹³³ Ibid.

¹³⁴ Ibid.

¹³⁵ See Savarkar, Vinayak Damodar: *Hindutva*. Delhi: Bharti Sahitya Sadan, 1923, p. 116.

¹³⁶ Panda, Ankit: Hindu Nationalism and...Foreign Policy? What does Hindu nationalism have to say about international relations? in: *The Diplomat*. 2014. -

<https://thediplomat.com/2014/04/hindu-nationalism-and-foreign-policy>, DOA: 10.10.2020.

*"What was the use of a universal faith that instead of soothing the ferociousness and brutal egoism of other nations only excited their lust by leaving India defenceless and unsuspecting? No; the only safeguards in future were valour and strength that could only be born of a national self-consciousness."*¹³⁷

Obviously, Savarkar's classification of national identity has considerable consequences for both Indian defence policy and foreign policy. For Savarkar, a solid national identity, ultimately, meant a considerably strong national military might. Ever the pragmatist, he was absolutely convinced that a firm and all-encompassing national identity was a prerequisite for a national army, as it provides them with a sense of purpose worth fighting for; which, in turn, will be a moral boost for the military forces that will enable them to fight better.¹³⁸ Savarkar also believed that a key aim of Hindutva was constant preparedness when it comes to subject matter of defence. His position of preparedness in terms of defence seems to have been accomplished through the deterrence that was created through the nuclear test in 1998. Apart from a strong defence capacity, the BJP's decision to embark on the nuclear option can arguably been traced back to the Hindu nationalist's ambitions to increase India's stance on the global stage. While such an argument is striking, it fundamentally lacks substance. India's pursuit for both prestige and status on the international stage has been an invariable and arguably an inalienable part of New Delhi's foreign policy agenda ever since gaining independence.¹³⁹

The reason for developing and igniting the so-called Hindu bomb can be seen in the long-term perceived as well as realistic threat originating from India's neighbours in the north, namely China and the

¹³⁷ Ibid.

¹³⁸ Ibid.

¹³⁹ Ganguly, Sumit: Hindu Nationalism and the Foreign Policy of India's Bharatiya Janata Party. 2015. - <https://docplayer.net/11706791-Hindu-nationalism-and-the-foreign-policy-of-india-s-bharatiya-janata-party-sumit-ganguly-2014-15-paper-series-no-2.html>, DOA: 16.03.2016, p. 5.

Islamic Republic of Pakistan. The nuclear option has been a long-established policy commitment by previous Indian governments irrespective of their ideological orientation. When all is said and done, both the extension of the Nuclear Non-proliferation Treaty and the Comprehensive Test Ban Treaty were the relevant factors that ended up becoming “the straw that broke the camel's back”.¹⁴⁰

Both Savarkar and Golwalkar consider conflicts (of any nature) and war as something that is undesirable but, yet, unavoidable so long as the globe is inhabited by selfish communities and, to a wider extent, nations. Consequently, both protagonists of Hindu nationalism pushed for India to embark on the ability as well as willingness to engage in power politics and, if push comes to shove, full-scale war in order to defend the Bharat against aggressions from external powers.¹⁴¹ Savarkar and Golwalkar's understanding of international politics seems to resonate with the international relations theory of realism, thereby giving due regard to the accusation of all capacities possible. However, unlike the realism theorists, both protagonists believe national power to be heavily dependent on the establishment of a self-assured and exclusory nationalism.¹⁴² Both Savarkar and Golwalkar believed religion-based Hindu nationalism was a catalyst, which would eventually provide Bharat with social cohesion and a martial spirit when it comes to defending the Hindu nation against outside hostility.¹⁴³ Arguably, this nationalist sprits should come to play when it comes to external commercial advances that are of a somewhat hostile nature.

Ever the pessimist, Savarkar believed in the “struggle for existence” or, in other words, the Darwinian “survival of the fittest”, which he is

¹⁴⁰ Ibid.

¹⁴¹ Bajpai, Kanti/ Basit, Sarai/ Krishnappa, V. (Eds): India's Grand Strategy: History, Theory, Cases, War and International Politics in South Asia. Routledge: New Delhi, 2014, p. 237.

¹⁴² Ibid.

¹⁴³ Ibid.

convinced is the law of nature.¹⁴⁴ He believes that the rule of law does not accommodate the Gandhian path of non-violence against potential adversaries. Equally, Golwalkar refers to a similar concept of the “law of the jungle” in his work “Bunch of Thoughts”.¹⁴⁵ In the eyes of Golwalkar, the Indian nation would not live up to its calling of being a great nation if it was not being firm and standing up for itself as a confident nation. To repeat it in his own word:

“How can a society given to self-derision, weakened by all-round disruption and dissipation, kicked and humiliated at every point by any and every bully in the world, teach the world? How can one, devoid of the urge or the capacity to enoble one’s own life, show the path of greatness to others.”¹⁴⁶

The contemporary Hindu nationalists from the calibre of RSS and BJP appear to have corrupted the original meaning of the Hindutva (Hindu nationalism) ideology as envisaged by Savarkar. For the next generation of Hindu nationalists, Hindu supremacy is arguably more important than Indian-ness. Interestingly, an ideology which is based on the realism theory has, arguably, been taken over by a religiously-motivated identity politics.¹⁴⁷ When it comes to the political aspect, Savarkar was a true admirer of Chanakya (or Kautilya), the writer of Arthashastra, the treatise on kingship, which could in this context be seen as a forerunner of what could be regarded as contemporary form of “offensive realism”.¹⁴⁸ According to this philosophy, states are caught in a scenario of recurring conflicts and the only option to attain palpable security could be achieved through the creation of an all-

¹⁴⁴ Savarkar, Vinayak Damodar: Hindutva. Delhi: Bharti Sahitya Sadan, 1923, p. 22.

¹⁴⁵ Golwalkar, Madhav Sadashiv: Bunch of thoughts. Bangalore: Jagarana Prakashana, 1980, p. 270.

¹⁴⁶ Golwalkar, Madhav Sadashiv: We or Our Nationhood Defined. Nagpur: Bharat Prakashan, 1939, p. 79.

¹⁴⁷ Panda, Ankit: Hindu Nationalism and...Foreign Policy? What does Hindu nationalism have to say about international relations? in: The Diplomat. 2014. -

<https://thediplomat.com/2014/04/hindu-nationalism-and-foreign-policy>, DOA: 10.10.2020.

¹⁴⁸ Basrur, Rajesh, Gupta Surupa, Hall Ian, et al. (2019). Indian Foreign Policy under Modi: A New Brand or Just Repackaging?, in: International Studies Perspectives, 20, 1-45, p. 7.

encompassing empire. The assumed attainment of a universal empire for the Indian nation, *prima facie*, seems to be a rather far-fetched aspiration. One aspect appears to be certain: the constant conflict scenario or power struggle of the states are in line with the realism theory. Hindutva itself does not focus on global domination in a military-like expansionist sense. For Savarkar and Golwalkar, the expansion of power is of a defensive nature and its use is limited to the preservation of Hindu civilisation from external invasion.¹⁴⁹ Modi himself believes in global independence, and at the same time he is aware that pushing for a one-sided isolation of India would not be practical.¹⁵⁰ For the outside world, at least, Modi foreign policy promotes the concept of Vasudaiva Kutumbakam (the world is one family) and Vishva Bandhuta (world brotherhood).¹⁵¹ Savarkar was also a keen believer in embarking on alliances and taking part in the balance of power politics, which would boost New Delhi's strategic position whatever the threat of the day, may be. When it comes to Golwalkar, the Indian nation should befriend those who tend to serve the nation's interests and remain so-called "friends with benefits" and unfriend them once they do not serve your country's interest.¹⁵² He took this insight from the playbook of the European powers who tend to change their friends and enemies whenever it serves their purpose.¹⁵³

Luckily, from the point of the secular Indian nation, the sixty plus years foreign policy dominance of the INC meant that a secular bureaucracy has remained the last battalion tasked to manoeuvre the shallow waters of Indian foreign policy against the backdrop of the next

¹⁴⁹ Ibid.

¹⁵⁰ Business Standard: Full Text of Narendra Modi's Interview. 2015. - http://www.business-standard.com/article/economy-policy/full-text-of-pm-narendramodi-s-interview-to-pti-115052800367_1.html, DOA: 10.05.2020.

¹⁵¹ Basrur, Rajesh/ Gupta Surupa/ Hall Ian, et al.: Indian Foreign Policy under Modi: A New Brand or Just Repackaging?, in: International Studies Perspectives (2019), Vol. 20, pp. 1-45, p. 8.

¹⁵² Golwalkar, Madhav Sadashiv: Bunch of thoughts. Bangalore: Jagarana Prakashana, 1980, p. 260.

¹⁵³ Ibid.

generation of the Hindu nationalist Indian foreign policy agenda of the BJP government. Moreover, Ankit Panda argues that both the foreign policy intelligentsia and the bureaucracy see very little relevance for the rational of religious Hindu nationalism when it comes to the framework of New Delhi's contemporary foreign policy.¹⁵⁴

Regarding economics, the RSS is convinced that an economic crisis, for instance, could only be overcome by cultural transformation and return to Hindu values, thereby respecting both nature and humanity. At the heart of a Hindu-inspired economy lies a non-acquisitive and non-exploitative life cycle which prioritises reciprocity over individual rights. The RSS's economic policy relies on austerity in the field of consumption as well as on self-sustenance. The Sangh promulgates a value-based system relying on both self-knowledge and self-control.¹⁵⁵ Such a value-based system from the Sangh's point of view guarantees *inter alia*, social harmony, cultural richness, universal peace, individual joy as well as spiritual advancement.¹⁵⁶ *Prime facie*, the Hindu nationalists seem to consider the greed for monetary means as the root cause of economic downfall. RSS tackles the issue of an economic crisis with traditional means of Hindu ascetics, namely a "Swami or Yogi" like abstention when it comes to consumption and acquisition.

The situation on the ground seems to be rather different, as when it comes to economics, Modi has been elected on the ticket to boost rapid economic development as mentioned above. Here Hindu nationalist ideology seems to be in line with the realist notion of emphasising the significance of material power; Hindu nationalism has been a source of attraction for the conservative and economically dynamic Indian middle classes. The PM also enjoys great support

¹⁵⁴ Panda, Ankit: Hindu Nationalism and...Foreign Policy? What does Hindu nationalism have to say about international relations? in: The Diplomat. 2014. -

<https://thediplomat.com/2014/04/hindu-nationalism-and-foreign-policy>, DOA: 10.10.2020.

¹⁵⁵ Rashtriya Swayamsevak Sangh: RSS: The Mission. 2012. -

<http://rss.org//Encyc/2012/10/22/rss-vision-and-mission.htm>, DOA: 22.01.2019.

¹⁵⁶ Ibid.

amongst the economically well-off Indian diaspora in Britain, USA and in other places.¹⁵⁷ Despite criticism, the Modi administration has pressed forward with a number of innovative programs. One such programme being the introduction of a countrywide Goods and Service Tax (GST), followed by the restoration of economic growth above the 5 percent mark and signing an agreement on the contentious issue of food subvention.¹⁵⁸

Modi's pragmatic approach is best displayed when it comes to New Delhi's relationship with Washington. Traditionally, the bilateral relations between these democracies left much to be desired. The BJP Premier himself had previously in March 2005 been denied a US Visa, due to his alleged involvement in the 2002 Gujarat riots. In 2012, the Indian Supreme Court went on to appoint a Special Investigation Team to investigate Narendra Modi's involvement in the Gujarat riots. According to the judgement of April 2012, the Special Investigation Team was not able to establish a link between the Premier and the riots in 2002.¹⁵⁹ A doubt remains whether a thorough investigation has been undertaken considering the wrongdoing of the government of Gujarat's "failure to act" or "being reckless towards" preventing the community riots. When all is said and done, reasonable concern remains whether the state government in Gandhinagar, and ultimately the then Central Minister Narendra Modi, has at the very least failed to take appropriate steps to intervene during the riots. *Prima facie* the state government seem to have played, if not a game of hide and seek, a game of wait and see. Against these odds, once in power, Modi seem to have been committed to make amends with the past

¹⁵⁷ Lieven, Anatol: Hindu Nationalism: A Reality Check for Liberalism and Globalisation. 2017. - <https://valdaclub.com/a/highlights/hindu-nationalism-a-reality-check-for-liberalism/>, DOA: 19.12.2020.

¹⁵⁸ Ganguly, Sumit: Hindu Nationalism and the Foreign Policy of India's Bharatiya Janata Party. 2015. - <https://docplayer.net/11706791-Hindu-nationalism-and-the-foreign-policy-of-india-s-bharatiya-janata-party-sumit-ganguly-2014-15-paper-series-no-2.html>, DOA: 16.03.2016, p. 13.

¹⁵⁹ Ibid, 15.

and he decided to pay Washington a state visit within the first six months of assuming office as Indian Premier.¹⁶⁰

Narendra Modi has also taken similar steps when it comes to the Europe Union. Once again realpolitik's appears to have been on the fore front of the Premier's actions. More precisely, the critical need to tackle the deteriorating equipment of the Indian Air Force during his visit in 2015 to France. During his state visit to Paris and going against traditional acquisition conventions, Modi purchased 36 Rafale fighter jets, and at the same time went on to negotiate a number of other economic conventions.¹⁶¹ Equally, the Prime Minister's state visit to Berlin, a short while after his visit to France, apart from paying due regard to environmental protection, was overshadowed by investment issues and trade promotions.

The Hindu nationalist's ideological ambition of global recognition fits rather nicely with Modi's visit to the capitals of EU Member states and to Washington. Modi's warm welcome during his visit to the U.S. and the EU hardly seems to be a surprise given the Indian Union's emerging economy and strategic importance in South Asia, and its position in multiple multilateral forums. Equally, Modi has been welcomed with a considerable degree of enthusiasm by the large Indian diaspora.¹⁶² Thus Narendra Modi was also elected to improve India's standing on the world stage, while at the same time boosting its existing relationships. Modi's numerous business trips abroad have led to considerable criticism from detractors, who claim that he has become a champion of oversee trips throughout his premiership. According to a Right to Information (RTI) request submitted to the PM Office by the activist Bhimappa Gadad, Modi, throughout his

¹⁶⁰ Ibid, p. 13.

¹⁶¹ Sonwalker, Prasun: Modi in France: India to Buy 36 Rafale Jets in "fly-Away Condition". in: Hindustan Times. 2015. - <https://www.hindustantimes.com/india/modi-in-france-india-to-buy-36-rafaele-jets-in-fly-away-condition/story-w5GOOGrqirOQ8403PKr1L.html>, DOA: 21.01.2019.

¹⁶² Ganguly, Sumit: Hindu Nationalism and the Foreign Policy of India's Bharatiya Janata Party. 2015. - <https://docplayer.net/11706791-Hindu-nationalism-and-the-foreign-policy-of-india-s-bharatiya-janata-party-sumit-ganguly-2014-15-paper-series-no-2.html>, DOA: 16.03.2016, p. 15.

premiership has undertaken 41 trips to 52 countries in the course of four years. The costs for the PM's multiple trips amounted to Rs 355 crore (around 50 Million US Dollars).¹⁶³

The RSS is convinced that the twenty-first century will be a century dominated by Hindutva and its ideology. For them, this has been confirmed by distinguished historians. For the Hindu nationalists, the materialist approach to life and aggressive industrialisation have lost their viability.¹⁶⁴ This issue for them is best visible in the example of the United States. The U.S., with its irresponsible need for consumption and greed to secure global resources, has compelled it to resort to wars. At other end of the spectrum has been Communism, established to counter- balance what was felt to be a reduction of mankind to a tiny molecule by capitalism. After experimenting with socialism for the duration of 50 years, China has made the transition from socialism to capitalism. For RSS neither socialism nor capitalism are viable life-choices. For Hindu nationalists, Hinduism is also the only tangible alternative. Unlike the West, in which man is considered a superior creature separate from nature, in Hinduism man is part and parcel of the whole. This idea has found acceptance beyond the borders India.¹⁶⁵

By comparing itself to capitalism and socialism, Hindutva combines religious beliefs, economic and political system.¹⁶⁶ India's obsession with anything that is Western meant that it has been copying the West blindly, and consequently the country has been digressing. Furthermore, according to RSS, the industrial revolution which had *inter alia* broad prosperity for the Western world, was accomplished,

¹⁶³ Belur, Rashmi: In 41 Trips to 52 Countries in 4 Years, PM Narendra Modi Spent Rs 355 Crore: RTI. in: The New Indian Express. 2018. -

<http://www.newindianexpress.com/nation/2018/jun/28/in-41-trips-to-52-countries-in-4-years-pm-narendra-modi-spent-rs-355-crore-rti-1834783.html>, DOA: 15.09.2019.

¹⁶⁴ Rashtriya Swayamsevak Sangh: RSS: The Mission. 2012. -

<http://rss.org//Encyc/2012/10/22/rss-vision-and-mission.htm>, DOA: 22.01.2019.

¹⁶⁵ Ibid.

¹⁶⁶ Ibid.

according to the Hindu nationalists, by looting from British India. The loss of Bharat's capital to the Brits meant that it could not achieve the same development and financial progress as the West. Consequently, Bharat became a debtor country, subjected to both physical and mental impoverishment. As for mental poverty, the psyche of the Indian, according to RRS, had been indoctrinated through never-ending downgrading by the West. By considering Indian citizens poor, primitive and backward, the West has culturally induced poverty.¹⁶⁷ For Hindu nationalists, the Hindu mind needs to regain self-confidence. This is a considerable effort if one considers the fact that domestic science and technology was, according to the Sangh, purposefully crushed by Western powers, namely the colonial power. Interestingly, the West still intervenes in the form of the IMF, World Bank, GATT and the Nuclear Non-proliferation Treaty.¹⁶⁸

Thus, Hindu nationalism happens to be a popular force which has been instilled through a bottom-up approach. Its roots are based on anti-colonial sentiments against the British Raj's rule. The British colonial rule in this context meant Anglicization of Indian higher education, the Westernisation of Indian culture, and both the perceived as well as real threat of forced conversion by missionaries, Christian and Muslim alike.¹⁶⁹ Equally, the Hindu nationalist movement has been developed as a mass movement by the lower castes against those from the upper castes. While political and nationalist Hinduism can be regarded as a modern phenomenon, it has, however, been developed since the 19th century from the bottom by the masses.¹⁷⁰ It is, however, worth noting that Hindu nationalism, although a mass movement initiated by the lower castes, was traditionally headed by leaders from the higher castes. This dichotomy meant that the movement faced considerable difficulties when it came to the attempt

¹⁶⁷ Ibid.

¹⁶⁸ Ibid.

¹⁶⁹ Lieven, Anatol: Hindu Nationalism: A Reality Check for Liberalism and Globalisation. 2017. - <https://valdaclub.com/a/highlights/hindu-nationalism-a-reality-check-for-liberalism/>, DOA: 19.12.2020.

¹⁷⁰ Ibid.

to eradicate caste distinction within the Hindu religion. Arguably, “caste cacophony”, with its discriminatory sting directed against the lower castes, is in itself a considerable weakness for the nationalists claim that Hindus are the majority of the nation’s populations and thus India ought to be a Hindu country. As the lower castes are discriminated by society in their day-to-day life, they are likely to fall prey to the conversionist efforts by Christians and Muslims alike. This in turn has been the single cause of fear from the Hindu nationalists.¹⁷¹ As a consequence of the political divisions, the emergence of caste-based local parties in north India has led to near paralysis and fragmentation of the Indian political landscape in recent decades. To counterbalance this cacophony within Indian political science, Hindu nationalists have depicted themselves as a source of unity and a modernising force for the nation. Their goal is to archive a universal ethno-religious homogenous nationalist people of sovereign standing.¹⁷²

We shall now turn our attention to potential shifts in Indian foreign policy. Miller and De Estrada have identified a pragmatic shift in the post-Cold War Indian foreign policy. Before embarking on the pragmatic shift of Indian foreign policy, we shall firstly discuss the initial standpoint from which the aforesaid foreign policy shift occurred. New Delhi’s foreign policy in the post-Cold War era was closely aligned, as mentioned above, with faith in Nehruvian idealism, which was based on moral gestures, rather than on the realist notion of material interest and power. Scholars have increasingly criticised New Delhi’s foreign policy of PM Jawaharlal Nehru for its major foreign policy failures due to its moral positng.¹⁷³ Thus, a conventional Indian modern state without the highly principled and, to a fault, perfectionistic notion of being a Vishwa Guru¹⁷⁴ or “universal leader”

¹⁷¹ Ibid.

¹⁷² Ibid.

¹⁷³ Miller, Manjari Chatterjee / Sullivan de Estrada, Kate: Pragmatism in Indian foreign policy: How ideas constrain Modi, in: International Affairs (2017), Vol. 93, Is. 1, pp. 27-49, p. 27.

¹⁷⁴ Basrur, Rajesh/ Gupta Surupa/ Hall Ian, et al.: Indian Foreign Policy under Modi: A New Brand or Just Repackaging?, in: International Studies Perspectives (2019), Vol. 20, pp. 1-45, p. 13.

wanting to transform the world for the better emerged. This statement is in line with former PM Atal Bihari Vajpayee stated the following:

*"We, the Indians, as Guru of all nations. Yes, I believe in that..."*¹⁷⁵

The media was very eager and left no doubt that Indian foreign policy was a significant departure of the pre-Cold War Indian foreign policy. Moreover, Modi's foreign policy has also been driven by domestic sets of ideas. De Estrada and Miller have, in this context, been pushing the concept of procedural pragmatism. They also argue that pragmatism is a process of engaging with any and every idea that is politically motivated and, when it comes to the context, beneficial in achieving a particular policy goal.¹⁷⁶ Miller and De Estrada refer to Modi's foreign policy pragmatism as "bricolage", denoting the selection and fusion of different, and at times, competing ideological commitments and concepts aimed to advance new foreign policy positions. Pragmatism is therefore procedural in nature and concentrated on developing foreign policy novelties, rather than embracing or rejecting particular content. Post-Cold War Indian foreign policy under the Hindu-nationalist BJP has led to a significant shift from the Nehruvian external relations policy.

In the above-mentioned Hindu nationalist slogan: "Hindi, Hind, Hindustan", "Hindustan" (the "land of Indus") is taken from the Persian language and refers broadly to the Indian subcontinent.¹⁷⁷ To quote Bismarck, the BJP seems to be "territorially saturated" and lacks expansionist ambitions in this area. The subcontinent's lack of expansionist ambitions or, in other words, Modi's willingness to settle New Delhi's longstanding territorial dispute with Bangladesh could be attributed to a rather pragmatic approach in its foreign policy. Modi

¹⁷⁵ Nanda, Meera: Hindu Triumphalism and the Clash of Civilisations, in: Economic and Political Weekly (2009), Vol. 44, No. 28, pp. 106-114, p. 106.

¹⁷⁶ Miller, Manjari Chatterjee / Sullivan de Estrada, Kate: Pragmatism in Indian foreign policy: How ideas constrain Modi, in: International Affairs (2017), Vol. 93, Is. 1, pp. 27-49, p. 28.

¹⁷⁷ Britannica: Hindustan: historical area, Indian subcontinent, Asia. -

<https://www.britannica.com/place/Hindustan-historical-area-Asia>, DOA: 21.10.2020.

seems to divert here from the traditional realist's position, which would prevent him from sacrificing Indian territory on the altar of a peaceful settlement of the longstanding territorial dispute with Bangladesh. Border disputes between New Delhi and Dhaka arose over 162 pieces of territory known as administered enclaves. Out of the 162 enclaves, 111 remained part of the India Union and 51 are located in Bangladesh. The population of these enclaves were forced to bear the brunt of this unsettled border row. Despite in theory being citizens of either Bangladesh or the Indian Union, *de facto* they could be considered stateless.¹⁷⁸ In fact they lack any form of contact to their home nation, the host country in which they were residing also failed to provide adequate administrative governance. The lack of adequate governance meant that literally no governmental institutions such as hospitals, public schools, health clinics, police, courts and public works were established in these enclaves. Moreover, the inhabitants of these enclaves had to cross illegally into and out of the host nation in order to go about their daily business of purchasing goods and services. Confusingly, even if they wanted to cross from their enclave through their host nation into their own country, the inhabitants still had to cross the border illegally twice in order to apply for a passport, hoping not to be caught by the border security units, only in order to repeat the whole process again in order to apply for a visa.¹⁷⁹ In other words, to become a law abiding "border crosser", the enclave inhabitants had to illegally cross the Indo-Bangladeshi frontier multiple times.

Due to this devastating situation, Dhaka and New Delhi signed a Land Boundary Agreement in 1974 which provides guidance on the subject matter on how to exchange the enclaves. While Bangladesh ratified the Land Boundary Agreement, the Indian Republic insisted that ratification was subject to the total demarcation of the Indo-

¹⁷⁸ Miller, Manjari Chatterjee/ Sullivan de Estrada, Kate: Pragmatism in Indian foreign policy: How ideas constrain Modi, in: International Affairs (2017), Vol. 93, Is. 1, pp. 27-49, p. 40.

¹⁷⁹ Ibid.

Bangladeshi border.¹⁸⁰ However, on 1 August 2015, just over a year after the commencement of Modi's premiership, both South Asian nations settled one of the most complex frontier disputes on the globe with an arrangement to exchange territorial enclaves.¹⁸¹ The settlement has improved the lives of thousands on both sides of the frontier, erasing the stateless position of the enclave inhabitants.

Despite being a notable and significant accomplishment for the PMs of both nations, the land deal orchestrated by Modi's pragmatic realist manoeuvring is hardly a new concept. The INC under former PM Manmohan Singh also attempted to settle this almost seven-decades-old dispute. Somewhat mesmerising, however, is the fact that PM Modi managed to strike a deal despite the considerable constraints originating from the supporters of the Hindutva fraction and those pertaining from post-imperial ideology.¹⁸²

When it comes to the post-imperial ideology of India's foreign policy, the refusal to accept the bilateral Land Border Agreement meant abiding by New Delhi's rather firm standpoint on the issue of territorial sovereignty. This standpoint originated from the historical legacy of colonialism. Having lost their homeland, first to the East India Company and later to the British Raj, the Indian foreign policy establishment developed a sense of victimhood coupled with a corresponding sense of entitlement when it comes to the maintenance of geographical territory of pre-colonial India. Post-imperial ideology matters to India whenever the Union's sovereignty is endangered and its traditional borders are disputed. The same applies whenever Hindustan's national pride is questioned.¹⁸³

In the circumstances, India finds itself to be a victim and considers those opposing the Union as victimizers, which in turn allows them to

¹⁸⁰ Ibid.

¹⁸¹ Ibid, p. 38.

¹⁸² Ibid, p. 40.

¹⁸³ Ibid, p. 37.

oppress, and at times discriminate, abiding by the nation's absolute conviction that its borders are inviolable. Equally, India's foreign policy establishment remains conscious of losing face.¹⁸⁴ In this context, both the INC as well as the BJP are holding on to pre-colonial rhetoric and to a victim mentality. The BJP has been a strong promotor of maintaining the territorial unity of "*Bharat Mata*" (Mother India). In this context, the Hindu right argues:

*"that the true Hindu homeland of India is the homeland that was described by the early India (anti-colonial) nationalist, which includes all the territory currently controlled by the sovereign states of India, Pakistan and Bangladesh. Consequently, any agreement that includes the transfer of territory, even the small area of the enclaves, is perceived as illegitimate because it would divest more of the Hindu homeland to a Muslim controlled government."*¹⁸⁵

Golwalkar, the second chief of RSS, had an even broader border territorial view of "*Bharat Mata*". For him, the motherland stretched from Singapore in the east to Iran in the west, with Sri Lanka (Ceylon) depicting a lotus petal which is sacrificed at the sanctified feet of "*Bharat Mata*".¹⁸⁶

Moreover, the BJP has expressed strong opposition when it comes to the exchange of territory given the fact that due to colonialism India's borders have been adversely affected. The Union would also highlight weakness when conceding its own territory to a Muslim nation.¹⁸⁷

¹⁸⁴ Miller, Manjari Chatterjee/ Sullivan de Estrada, Kate: Pragmatism in Indian foreign policy: How ideas constrain Modi, in: International Affairs (2017), Vol. 93, Is. 1, pp. 27-49, p. 40.

¹⁸⁵ Ibid.

¹⁸⁶ Golwalkar, Madhav Sadashiv: Bunch of thoughts. Bangalore: Jagarana Prakashana, 1980, p. 111.

¹⁸⁷ Throwback Thursday: The Indo-Bangladesh enclaves. in: Lawfare. 2015. -

<https://www.lawfareblog.com/throwback-thursday-indo-bangladesh-enclaves>, DOA: 24.10.2020.

For all intents and purposes, post-imperial ideology seems to have a considerable impact on the Union's foreign policy. Moreover, New Delhi's contemporary foreign policy has, in line with its post-imperial ideology, developed a sense of victimhood accusing countries, which oppose the previously mentioned foreign policy stance as "victimisers". Equally, the Indian Union is eager to express its aspiration to be acknowledged as and sympathised with as a victim in the international system.¹⁸⁸

Regarding the enclave dispute, Modi might have taken a page from the book of Paul Kennedy, a prominent realist scholar, who points out that:

*"[t]hese were the actions of a country with nothing to gain and much to lose, by being involved in war. Peace, in such circumstances was the greatest of national interests."*¹⁸⁹

When it comes to Modi's foreign policy, like that of many other world leaders, it appears to be subject to more than one constraint. The relevant constraints are institutional ideas and ideologies, which in turn inevitably force the PM to rely on bricolage when it comes to the manoeuvring of New Delhi's foreign policy. Moreover, he also seems to be trapped between his personal as well as domestic belief of Hindutva which is closely enshrined with his leadership.¹⁹⁰ Modi seems to be both confident and competent enough to depart from India's traditionally held Nehruvian foreign policy positions of the past.

Consequently, he is unable to let go of both components of his foreign policy consideration and is forced to work around improving Indian external policy with institutionalised and influential ideals through the

¹⁸⁸ Miller, Manjari Chatterjee/ Sullivan de Estrada, Kate: Pragmatism in Indian foreign policy: How ideas constrain Modi, in: International Affairs (2017), Vol. 93, Is. 1, pp. 27-49, p. 37.

¹⁸⁹ Kennedy, Paul: The Realities Behind Diplomacy: Background Influences on British External Policy, 1865-1980. London: Allen and Unwin, 1981, p. 257.

¹⁹⁰ Miller, Manjari Chatterjee/ Sullivan de Estrada, Kate: Pragmatism in Indian foreign policy: How ideas constrain Modi, in: International Affairs (2017), Vol. 93, Is. 1, pp. 27-49, p. 29.

means of a pragmatic bricolage. In sum, when it comes to Hindutva, the subcontinent's foreign policy is driven by two sets of institutionalised ideational frameworks, namely Indian post-imperial and exceptionalism ideology as mentioned above.¹⁹¹

Modi has managed to keep the Hindutva component intact during the territorial dispute in the Indian foreign policy. Modi's pragmatic approach meant convincing the Indian public that, because of the border settlement, India would be able to strengthen the national border. As Justin Rosenberg puts it:

*"[t]he distinctive character of this realm is given by the condition of anarchy meaning that a competitive pursuit of determinate 'national interests' takes place in the absence of regulation by a superordinate authority."*¹⁹²

Interestingly, in this particular case, the pursuit of national interest, in the realist sense of the word, means sacrificing territory in order to keep up with the BJP's promise to protect the Republic's nation frontiers against illegal (Muslim) immigrants. Surprisingly, in his 2016 election campaign, the then presidential candidate Donald J. Trump *prime facie* took a similar path when he declared Mexican immigrants crossing the border *inter alia* as rapists. More precisely, the former Commander in Chief of the United States stated the following:

*"When Mexico sends its people, they're not sending their best, they're bringing drugs. They're bringing crime. They're rapists. And some, I assume, are good people."*¹⁹³

¹⁹¹ Ibid.

¹⁹² Rosenberg, Justin: What's the matter with realism?, in: Review of International Studies (1990), Vol. 16, No. 4, pp. 285-303, p. 286.

¹⁹³ Gomez, Alan/ Korte, Gregory: Trump ramps up rhetoric on undocumented immigrants: 'These aren't people. These are animals'. in: USA Today. 2018. -

<https://eu.usatoday.com/story/news/politics/2018/05/16/trump-immigrants-animals-mexico-democrats-sanctuary-cities/617252002/>, DOA: 25.10.20.

President Trump's initial rhetoric was followed by deeds. "The president was putting his money where his mouth is" and issued Executive Order 13769, which was titled "Protecting the Nation from Foreign Terrorist Entry into the United States" on 27 January 2017.¹⁹⁴ Executive Order 13769 has also been politically labelled as the "Muslim" ban as it was directed against numerous Muslim countries, a BJP-like approach taken to keep the Muslim invaders out of the country.

Interestingly, the physical loss of Indian land (India conceded more territory than Bangladesh) was going to boost the Indian border security, in particular it would be dealing with illegal immigration from the neighbouring country. Modi also assured the government in Dhaka that the Hindu nationalist rhetoric was merely an election stance and would not manifest itself in bilateral relations.¹⁹⁵

Having looked at the institutionalised ideational framework of the post imperial-ideology, it would now be appropriate to look at the subject matter of Indian exceptionalism, which will be examined here through the case of the International Yoga Day - Indian exceptionalism can be seen to manifest itself during and throughout the International Yoga Day. The United Nations General Assembly (UNGA) approved resolution in December 2014, which established the International Day of Yoga, which was to be held on an annual basis on 21 June.¹⁹⁶ In 2015, the Indian government under Narendra Modi both organised and publicised an event relating to yoga in India. In this context, it is worth

¹⁹⁴ Executive Order 13769 of January 27, 2017, Protecting the Nation From Foreign Terrorist Entry Into the United States, Federal Register. in: The Daily Journal of the United States Government. 2017. -

<https://www.federalregister.gov/documents/2017/02/01/2017-02281/protecting-the-nation-from-foreign-terrorist-entry-into-the-united-states>, DOA: 25.10.2020.

¹⁹⁵ Miller, Manjari Chatterjee/ Sullivan de Estrada, Kate: Pragmatism in Indian foreign policy: How ideas constrain Modi, in: International Affairs (2017), Vol. 93, Is. 1, pp. 27-49, p. 42.

¹⁹⁶ United Nations General Assembly: Resolution A/RES/69/131: International Yoga Day. 2014. - http://www.un.org/en/ga/search/view_doc.asp?symbol=A/RES/69/131, DOA: 25.10.2020.

noting that yoga depicts a Sanskrit word which in turn could be translated as discipline.¹⁹⁷ New Delhi also utilised its overseas missions across the world through which it ran a publicity campaign proclaiming that the cultural origins of yoga are rooted in India.

The International Yoga Day is important for three reasons. Firstly, New Delhi led efforts to rejoice in both the international appeal and the value of yoga which was arguably an early diplomatic success of the Modi administration. In this particular case, Modi's pragmatism is once again visible as he diverts from the otherwise traditional approach of toned-down official yoga promotion campaigns of other administrations. He broke with the traditional approach and seized the chance to declare yoga as a signature cultural export product originating from the subcontinent.¹⁹⁸

As a second point, the PM's advocacy for a Hinduistic understanding of the roots of yoga, at the outset, breaks with the internal stance of Indian exceptionalism, which is based on the prerequisite of India being a pluralistic social order rooted in peaceful co-existence.

Thirdly, the PM's stewardship of International Yoga Day did partly draw on the agenda of Indian exceptionalism through the means of a so-called external stance. When it comes to the external stance, the aim would be to portray the Union as a role model for other nations with the promotion of Indian values and accepting them as a source to resolve international disputes. Initially, Modi had little regard for the ideational framework (internal stance) of Indian exceptionalism, which is based on a pluralistic society and peaceful co-existence. He was more focused on the Hindu roots of yoga based on the Hindutva ideas.

¹⁹⁷ Van Der Veer, Peter: Hindus: A superior race, in: Nations and Nationalism (1999), Vol. 5, No.3, pp. 419-30, p. 428.

¹⁹⁸ Miller, Manjari Chatterjee/ Sullivan de Estrada, Kate: Pragmatism in Indian foreign policy: How ideas constrain Modi, in: International Affairs (2017), Vol. 93, Is. 1, pp. 27-49, p. 43.

However, eventually, he had to give in to the internal stance of yoga in order both please his followers and reassure his critics.¹⁹⁹

The significance of yoga for India is hardly something new, in fact, it formed a significant theme of the “Incredible India” tourist promotions which was launched in 2002 by cross-ministerial efforts. Swami Vivekananda, an Indian monk, philosopher and political thinker, was a keen promotor of Hindu spirituality and in particular supported the concept of the ascetic practice in the ancient system of yoga.²⁰⁰ According to Vivekananda, yoga is a way to systemise Hindu religious belief for the manifestation of spiritual and physical health.²⁰¹ Swami Vivekananda became known beyond the Indian border after his attendance at the World’s Parliament of Religions in Chicago in the year 1893. He attained near celebrity status and was eagerly received in Europe and the United States.²⁰² Moreover, private enterprises, especially, in the United States have taken steps to register intellectual property claims regarding yoga. Such claims over yoga have been a subject matter of much concern for the Indian administrations over the course of a decade.²⁰³

Yoga has indeed also been endorsed by other PMs, such as Nehru and Indira Gandhi. In fact, Mrs Gandhi was travelling in tow with her yoga instructor and had a considerable impact on the introduction of yoga in Indian schools. Unlike the Nehru-Gandhi dynasty, Modi’s push of yoga has acclaimed yet another level. His yoga agenda gained momentum with his maiden speech at the UNGA in 2014, during which he referred to yoga as a precious present from India’s ancient civilisation. Modi’s advertisement for yoga on the global stage was met

¹⁹⁹ Ibid.

²⁰⁰ Van Der Veer, Peter: Hindus: A superior race, in: Nations and Nationalism (1999), Vol. 5, No.3, pp. 419-30, p. 428.

²⁰¹ Ibid.

²⁰² Ibid.

²⁰³ Fish, Allison: The Commodification and Exchange of knowledge in the Case of Transnational Commercial Yoga, in: International Journal of Cultural Property (2006), Vol.13, No. 2, pp. 189–206, p. 198.

with much appreciation by influential Indian yoga gurus to the likes of Baba Ramdev. Ramdev has managed to combine spiritual leadership with a vast business empire. The yogi became famous for his yoga routines, which were televised in India on a daily basis.²⁰⁴ He expressed his appreciation for the Modi administration and their effort to glorify yoga on world stage and to boost both Indianness as well as India itself.²⁰⁵

While admittedly the UN resolution led to the inception of the International Yoga Day, which eventually increased the popularity of yoga all over the world,²⁰⁶ it neither made reference to the origins of yoga nor did it pay tribute to India. The only reference made in the resolution was given to the medical or health related benefits.²⁰⁷ Thus, the very adoption of the International Day of Yoga did not establish a linkage between Indian cultural traditions and yoga. However, *prima facie* such an association might have been established by implication. Moreover, it was obvious that the PM's administration was aiming to establish a connection between yoga and the Indian value system, and to project these beyond the territorial limitations of the Indian Union. New Delhi's permanent representative at the UN made a celebratory remark as to the universal as well as cross-cultural overture of yoga, admits the UN member states.²⁰⁸

On 21 June 2015, the PM went as far as to head a group of 37,000 participants who performed yoga positions at the well-known Delhi avenue of Rajpath. As for the PM's supporters this, *prima facie*, gave

²⁰⁴ Miller, Manjari Chatterjee/ Sullivan de Estrada, Kate: Pragmatism in Indian foreign policy: How ideas constrain Modi, in: International Affairs (2017), Vol. 93, Is. 1, pp. 27-49, p. 44.

²⁰⁵ Laul, Revathi: Godfellas I: A series on gurus and their politics. in: Tehelka. 2011. - <http://old.tehelka.com/godfellas-ii-a-series-on-gurus-and-their-politics/>, DOA: 17.11.2018.

²⁰⁶ Basrur, Rajesh/ Gupta, Surupa/ Hall, Ian/ et al.: Indian Foreign Policy under Modi: A New Brand or Just Repackaging?, in: International Studies Perspectives (2019), Vol. 20, pp. 1-45, p. 13.

²⁰⁷ Miller, Manjari Chatterjee / Sullivan de Estrada, Kate: Pragmatism in Indian Foreign Policy: How ideas constrain Modi, in: International Affairs (2017), Vol. 93, Is. 1, pp. 27-49, p. 44.

²⁰⁸ Ibid.

momentum for the rise of India as a cultural power player.²⁰⁹ In the eyes of the PM, 21 June 2015 was the inauguration of a new age that would be inspirational for the humankind's pursuit of harmony and peace. Modi praised yoga's ability to enhance rapid reduction not only of misunderstandings among families, communities and countries but also to decrease violence, conflict and wars.²¹⁰ His attempt appears to have been to promote Hindu values from the distant past with the aim to promote New Delhi's spiritual superiority and prominent position as the globe's one and only yoga guru.

The PM's message about yoga did not resonate well at home. Indian minorities, in particular, the Muslim community was not particularly amused about Modi's Hindutva style of yoga. They were worried that PM's backing of a Hindutva yogic culture would not have been compatible with the secular fabric of the nation. Moreover, minorities and other critics worried that the BJP government would give preference to Hindu religious practices and tradition while, at the same time, undermining the traditions of the Union's religious minorities. Commentators even went as far to brand the International Day of Yoga as a national project depicting the sheer expression of majoritarianism, whilst questioning the potential gullibility of the UN's effort and support for the establishment of such a day. The critiques made particular reference to the PM's involvement in the violent assaults against the Muslim minority in the West Indian state of Gujarat.²¹¹

The All-Indian Muslim Personal Law Board (AIMPLB), a private body, has viewed the PM's promotion of yoga to force Hindu rituals upon the

²⁰⁹ The Economist: International Yoga Day: The lotus leaders. 2015. - <https://www.economist.com/asia/2015/06/20/the-lotus-leaders>, DOA: 15.11.2020.

²¹⁰ PMINDIA: Text of PM's remarks at International Conference on Yoga for Holistic Health. 2015. - https://www.pmindia.gov.in/en/news_updates/text-of-pms-remarks-at-international-conference-on-yoga-for-holistic-health/, DOA: 15.11.2020.

²¹¹ Asrar, Nadim: By endorsing yoga, has the UN put Indian Muslims on the mat? This sanitised avatar comes with a distinct stamp, and it has saffron written all over. Is Modi even listening? in: Dailyo. 2015. - <https://www.dailyo.in/politics/yoga-day-indian-muslims-united-nations-quinnness-record/story/1/4393.html>, DOA: 15.11.2020.

non-Hindu minorities living within India's borders. Such an approach, they have argued, was a direct violation of the security principle of the Indian Constitution, which prohibits the promotion of religious activities by the central government.²¹²

The issue gained traction due to the administration's plan for International Yoga Day to include the posture of the salutation to the sun (*surya namaskar*) as well as the chant "om", yet another sacrosanct sound in the Hindu religious traditions. Member of Parliament (MP) Asaduddin Owaisi even went as far to reference Muslim scholars who regarded yoga to be against the fundamental values of Islam itself. The rejection of yoga by the Muslim community meant that their patriotism was called into question.²¹³ Some Muslim groups complained against holding International Yoga Day in June 2015 as it was during the Muslim holy month of Ramadan. Equally, a number of Christian organisations were in opposition of celebrating this special day on yoga as it fell on a Sunday. This became an issue after multiple national days were held on a Sunday by the PM.²¹⁴

For some commentators, the actual reasons for choosing June 21 was due to the fact that this was the anniversary of the death of K.B. Hegdewar, the foundering father of the RSS. As for the international reports this Hindu nationalist groups, comprising *inter alia* of RSS and BJP, were trying to reclaim yoga a part of the nation's glory of the long-distance past. This would be an era before Muslin and Christian communities were residing on the Indian continent.²¹⁵ The renowned New York Times even went as far as to compare BJP's rejuvenated

²¹² The Hindu: AIMPLB slams govt over Yoga. 2015. - <https://www.thehindu.com/news/national/all-india-muslim-personal-law-board-slams-modi-government-over-yoga-day/article7346994.ece>, DOA: 25.10.2020.

²¹³ Miller, Manjari Chatterjee / Sullivan de Estrada, Kate: Pragmatism in Indian Foreign Policy: How ideas constrain Modi, in: International Affairs (2017), Vol. 93, Is. 1, pp. 27-49, p. 45.

²¹⁴ Ibid, p. 46.

²¹⁵ Najar, Nida: International Yoga Day Finally Arrives in India, Amid Cheers and Skepticism. in: The New York Times. 2015. - <https://www.nytimes.com/2015/06/22/world/asia/india-narendra-modi-international-yoga-day.html>, DOA: 15.11.2029.

form of yoga with the daily drills of the RSS movements.²¹⁶ Amidst harsh criticism domestically and from abroad against the Hindutva-oriented yoga day and the glorification of the nation's past based on Hindu religious sentiments, the BJP administration was forced to make some concessions towards the Indian Muslim community.²¹⁷ For instance, Shripad Naik, the former First Minister of AYUSH encouraged Muslim participants of the Yoga day celebrations to chant Allah's name instead of the traditional Hindu religious *om* chant. The minister also stated that yoga had nothing to do with a specific religion; rather, it was an encouragement to support the well-being of anyone. He insisted that there was no compulsory obligation on anybody to exercise yoga as it is healthy for both soul and body.²¹⁸ In addition, AYUSH issued a video as well as a booklet outlining the so-called "Common Yoga Protocol". However, it noticeably left the controversial chant *om* as well as the salutation to the sun (*surya namaskar*) out, while adding a prayer in Sanskrit.²¹⁹ Issuing the prayers in Sanskrit are, *prima facie*, in line with Swami Vivekananda's call for reviving of Sanskrit. Vivekananda himself was convinced that the revival of Sanskrit was able to keep the cultural identity of Hinduism intact.²²⁰ The Swami was intending to organise missionaries trained in Hindu religion, Sanskrit, foreign languages as well as in comparative religion with the aim to spread Hinduism among the masses of people through service and the preaching.²²¹ The AYUSH Ministry issued a statement to the press verifying the fact that a delegation of Muslim minority

²¹⁶ Ibid.

²¹⁷ Ibid.

²¹⁸ Business Standards: Minority Leaders support International Day of Yoga. 2015. - https://www.business-standard.com/article/government-press-release/minority-leaders-support-international-day-of-yoga-115061100913_1.html, DOA: 11.11.2020.

²¹⁹ Government of India Ministry of AYUSH: Common Yoga Protocol. 2015. - <https://main.ayush.gov.in/sites/default/files/english%20CYP%20full.pdf>, DOA: 11.11.2020.

²²⁰ Gokhale, B. G.: Swami Vivekananda and Indian Nationalism, in: Journal of Bible and Religion (1964), Vol. 32, No. 1, pp. 35-42. - <https://www.jstor.org/stable/1460427>, DOA: 15.10.2020.

²²¹ Ibid.

leaders had met the Minister expressing their backing for the yoga day.²²²

The efforts by AYUSH to establish a Yoga Day was further supported by the then External Affairs Minister Sushma Swaraj who stated the following:

[...] “*the entire world is one family, and we can unite it with Yoga. At a time when ethnic conflicts and extreme violence are threatening to destabilise societies, Yoga can serve as the perfect antidote to stem such negative tendencies and move us on the path of harmony and peace.*”²²³

She was keen to underline the fact that the world had come to acknowledge New Delhi as a growing soft power.²²⁴

In conclusion, the Hindu nationalist BJP government seems to promote the agenda of the triple “H”, Hindu, Hindi and Hindustan. The BJP has systematically promoted the dominance of Hindi as the lingua franca of the subcontinent. For instance, at the Indian Airport only Security personnel were deployed that could converse in Hindi. The endeavours of the BJP have been met with considerable backlash, *inter alia*, from the state of Tamil Nadu. The “mandarinisation” or the imposition of Hindi by the BJP government has led to backlashes by MP's and other public figures in South Indian in general and Tamil Nadu in particular. The imposition of Hindi might have triggered memories of the 1965 linguistic riots in Tamil Nadu. BJP's desire to

²²² Business Standards: Minority Leaders support International Day of Yoga. 2015. - https://www.business-standard.com/article/government-press-release/minority-leaders-support-international-day-of-yoga-115061100913_1.html, DOA: 11.11.2020.

²²³ The Economic Times: UN's decision to mark Yoga Day shows India's soft power: Sushma Swaraj. 2015. - <https://economictimes.indiatimes.com/news/politics-and-nation/uns-decision-to-mark-yoga-day-shows-indias-soft-power-sushma-swaraj/articleshow/47764925.cms>, DOA: 15.11.2020.

²²⁴ Ibid.

make Hindi a pan-Indian language appears to be a long-term objective of the Hindu Nationalists.

With regard to the term “Hindu” (second “H”), its ordinary meaning would refer to the Hindu religion as the ancient religion of the people of Hindustan. The issue with such a definition is that this would not encompass all Indian nationals, as not every Indian is a follower of the Hindu religion and not every state of the Indian Union has a Hindu majority. This is in sharp contrast to Savarkar’s definition of the term Hindu. For Savarkar, an atheist, a Hindu is someone who considers the land of Hindustan from the Ocean to the Sindhu river as his fatherland and holy, and who identified himself with the culture of this land. Unlike other forms of nationalism, which typically rely on the notion of a common race or ethnicity, Hindu nationalism is unable to profit from such common denominators. To overcome the diversity of race, ethnicity, linguistics as well as regionalism, Hindu nationalists have been forced to embrace a shared common Hindu culture that would enable them to be regarded as culturally Hindus. Such a shared culture is for the BJP the Hindu religion, which serves as a common denominator in their endeavour to overcome these shortcomings. For the BJP administration, Hindu is used as a cultural term going beyond the religious definition. The Indian Supreme Court defined the term as a way of life. Thus, a Hindu would also encompass religious minorities such as Christians and Muslims from the subcontinent, as they had originally been Hindus and have only converted at a later stage. Prima facie, at least at its initial stage the caste system might have arguably been beneficial for the conversion of the lower casts. For the lower casts, a conversation would have been a viable option to forgo the oppression and suppression of the Hindu caste system. The BJP governments claims over cultural Hinduism appears to be a “diplomatic lip-service” at best given the reconversion agenda (“Ghar Wapsi” programme) by its sister organisation RSS to re-convert Indians for religious minorities. However, forced conversions are a direct violation of the freedom of religion as per Article 25 of the Indian

Constitution.²²⁵ BJP's triple "H" agenda has been met with resentments from Indian citizens with regard to Hinduism (the second "H"). The systematic conversion of the minority back to the Hindu religion does seem to be rather worrisome. Thus, the RSS reacted by getting rid of the "Ghar Wapsi" leader Singh and by opening up its membership to non-Hindus. Only time will tell how far the RRS is going to go in their efforts to achieve an absolute Hindu dominance in India, after all for the RSS it is Hinduism that is holding the fragile multi-ethnic construct that is called India together. In other words, it is the glue that holds the nation together.

Finally, Hindustan (third "H") has been the region beyond the Indus River with a vast territorial breadth. Today's BJP government appears to be territorially saturated and only to extend claims on the post independent borders of India. India under the BJP government seem to take a pragmatic stance when it comes to settling the border dispute with Bangladesh. It was willing to surrender land to settle the dispute. However, from a Hindu nationalist point of view, in settling this dispute to Bangladesh, the BJP could save face by arguing that they are merely fulfilling an electoral promise, namely keeping the Muslim immigrations from Bangladesh out of Hindustan. With regard to Jammu and Kashmir, the constitutional amendment further cemented Kashmir's position as an integral part of India.

Regarding the International Yoga Day, the UN resolution seems to have been an energy booster for the Hindu nationalist BJP government. New Delhi has issued claims about cultural supremacy over the world due to yoga's Indian heritage. The BJP administration is utilising yoga and the health benefits that have been attached to it, to claim for itself the status of a yoga guru. PM Modi went as far as to claim that yoga could reduce violence, conflicts and even wars in

²²⁵ Ministry of Law and Justice Legislative Department (Government of India): The Constitution of India, as on 9 December 2020. 2020. - https://legislative.gov.in/sites/default/files/COI_1.pdf, DOA: 20.03.2021.

countries. For External Minister Swaraj the International Yoga Day meant the global recognition of the subcontinent's status as a growing soft power. Moreover, the BJP administrations successful implementation of the International Yoga Day showcased the Hindu nationalist ability to display India's soft power as a responsible power and with the aim to boost India's standing on global stage.

The perception of the Hindu nationalist elite is that they view themselves as Vishwa Guru and are trying to market these ambitions through large sale soft power initiatives rather than utilising its hard power capacities. In this regard, the International Yoga Day is yet another example of India's pursuit of both prestige and status on the international stage. The "vaccine maitri" initiative by New Delhi through which India *inter alia* donates Covid-19 vaccines to developing countries appears to be another move of the BJP government to become a respected major player on global stage.²²⁶ Moreover, the "vaccine maitri" initiative will, from the perspective of the BJP elites, boost India's status as a Vishwa Guru in science and technological as envisaged by the RSS founder Dr. Hedgewar. The BJP government has received considerable appreciation for its vaccine diplomacy from world leaders.²²⁷ It appears that "vaccine maitri" highlights the global success of pharmaceuticals (vaccines) made in India which in turn will both boost India's soft power and enhance New Delhi's global standing. While the West is keeping its best, prohibiting the export of Covid-19 vaccines, India seems be more than willing to share its vaccine with the rest of the world. For the Hindu nationalist elite this is yet another confirmation that India has indeed acquired the status of a truly responsible Vishwa Guru.

²²⁶ Consult chapter 8.1. for more details.

²²⁷ Sibal, Sidhant: World leaders thank PM Narendra Modi as India sends COVID-19 vaccines to 47 countries. in: Zee News. 2021. - <https://zeenews.india.com/india/world-leaders-thank-pm-narendra-modi-as-india-sends-covid-vaccines-to-47-countries-2345750.html>, DOA: 01.05.2021.

Finally, India's post-imperial victimhood approach would view the European border agency's seizure of Indian generic medicines as something that would make the EU victimisers, as they are limiting India from obtaining the status of a Vishwa Guru (world leader) on the global pharmaceutical industry. For the RSS the seizure of generic Indian medicines by an EU border official, due to suspected violations of IPRs, could be interpreted as yet another effort by the West to continue with the never-ending downgrading of India. Similarly, the ban of around 700 Indian generic medicines in 2015 seems to confirm the determination by the EU to curtail India from becoming an economic power from RSS' point of view. Likewise, Brussels is utilising the seizure to culturally induce poverty over New Delhi, or in other words to hinder India's growth as the pharmacy of the world. As per the RSS's ideology, India would need to regain self-confidence. Prima facie, one-way to go about regaining self-confidence could be seen in the BJP government's approach to halt trade negotiations with the EU until an amicable solution has been reached.

2.1. Civilisational Clashes

It would now be suitable to take a brief look at Samuel Huntington's theory of the "Clash of Civilisations" and whether the rise of Hindu nationalism has been beneficial for the aforesaid theory. The Hindu civilisation is, according to Huntington, one of the more successive civilisations. It has existed on the Indian subcontinent since 1500 B.C.²²⁸ He also argues that Hinduism had been key to the culture of the subcontinent. It goes beyond the religion or the social system and emerged as the core of the Indian civilisation. Hinduism has core state for, namely, India.²²⁹

As for Huntington, he does not consider the source of conflicts in the so-called new world to be of a primary ideological nor of an economic kind.²³⁰ Equally, he does not seem to concentrate on conflicts over natural resources. For Huntington, the dividing factor among human beings is culture, hence any conflict will be dealt with among cultural lines.²³¹ While he considers nation states to remain the most powerful actors in global affairs, he is convinced that the principal conflicts of a global stature will take place between nations and groups of different civilisations.²³²

In line with Huntington's dictum, Hindu nationalists have persisted because of the fact that Hindu India does indeed constitute a separate civilisation in all following three aspects: culturally, religiously as well as politically. It is also in potential and actual conflicts with other civilisations.²³³ The former Harvard professor argued that the

²²⁸ Huntington, Samuel: Clash of Civilisations and the Remaking of World Order. New York: Simon and Schuster, 1998, p. 45.

²²⁹ Ibid.

²³⁰ Ibid, pp. 55-59.

²³¹ Ibid, pp. 126-127.

²³² Huntington, Samuel: The Clash of Civilizations? The next pattern of conflict, in: Foreign Affairs (1993), Vol. 72, No. 3, pp. 22-49, p. 22.

²³³ Lieven, Anatol: Hindu Nationalism: A Reality Check for Liberalism and Globalisation, Valdai Discussion Club. 2017. - <https://valdaiclub.com/a/highlights/hindu-nationalism-a-reality-check-for-liberalism/>, DOA: 19.12.2020.

clash of civilisation was going to be the predominant factor in world politics. He was convinced that the fault lines between those civilisations would evolve into battle lines in a futuristic setting. The newest stage in the development of conflicts in the contemporary world is going to be the one between civilisations.²³⁴

Having discussed the term civilisation, it would now be advisable to define the same. For Huntington, “civilisation” is the highest cultural collective of people who culturally identify themselves as part of the same entity.²³⁵ This is the key factor, which distinguishes humans from other species.²³⁶ A civilisation therefore can, according to Huntington’s theory, be defined by both common objectives and subjective elements. The objectives elements include the following: religion, history, language, institutions, and customs. As for the subjective element, it covers the self-identification of people. Huntington is of the opinion that people have various levels of identity. He puts forward the example of a Roman who has a variety of identities. Hence, he would be a Catholic, a Christian, an Italian, a European and a Westerner.²³⁷ In the Indian context, one could put forward the following example a Gujarati would be a Gujarati speaker, a Hindu, a Brahmin (the priest cast), an Indian, and an Asian.

Civilisation is therefore important as it provides for the broad level of identification with which an individual strongly identifies. Because of such self-identification, people are at liberty to redefine or change their identification preferences. Regarding size, a civilisation would numerically be as large as a population like China or very small like that of the English-speaking Caribbean. Unsurprisingly, civilisations can include multiple countries such as the Arab, Western or Latin

²³⁴ Huntington, Samuel: The Clash of Civilizations? The next pattern of conflict, in: Foreign Affairs (1993), Vol. 72, No. 3, pp. 22-49, p. 22.

²³⁵ Huntington, Samuel: Clash of Civilisations and the Remaking of World Order. New York: Simon and Schuster, 1998, p. 40.

²³⁶ Huntington, Samuel: The Clash of Civilizations? The next pattern of conflict, in: Foreign Affairs (1993), Vol. 72, No. 3, pp. 22-49, p. 24.

²³⁷ Ibid.

American civilisation. As for Western Civilisation, it has two key variations, namely Northern American and European.²³⁸ In addition, it is worth noting that civilisations are indeed important entities and while the divisional line tends to be permeable, they do as a matter of fact exist as per Huntington. They are ever evolving and consequently, merge and divide but also rise as well as fall. In the worst case, civilisations, like the ancient Romans and Egyptians disappear or are captured in the passage of time.²³⁹

Identities will steadily increase in significance in the near future, according to Huntington. He further adds that the globe will be shaped through exchanges between seven or eight key civilisations. Future conflicts will transpire along so-called cultural fault lines separating the following civilisations from each other. The relevant civilisations of interest are: Western, Hindu, Confucian, Japanese, Slavic-Orthodox, Latin American, and African.²⁴⁰

Yet the former Harvard professor seemed to assume that Africa ought to be considered as a single civilisation. This is, however, rather inconsiderate of Huntington to group all the African nations as a single unit and thus a civilisation of its own. Admittedly, the ethnically Arab section of North Africa could be considered part of the Arabic civilisation, which in turn would be a contradiction of his theory. Equally, the inhabitants of other parts of Africa can also not be grouped into a single unit as they are divided along religious, cultural, ethnic, historic, linguistic and other lines, so that as such a civilisation has not had the required time to evolve, Huntington argues. *Prima facie*, the same holds true for the so-called Latin American civilisation.

²³⁸ Ibid.

²³⁹ Ibid.

²⁴⁰ Ibid, p.25.

Firstly, the Harvard professor states that dissimilarities among civilisations are both real and rudimentary.²⁴¹ He refers to the fact that protagonists of the different civilisations are poles apart when it comes to the relationship between God and man, groups and individuals, as well as the state and its citizens. For Huntington, the previously mentioned dissimilarities are far more important than those arising from political regimes or political ideologies. He concludes that differences are not necessarily a guarantor, for conflicts and conflicts on their own do not lead to violence. Having said that, Huntington makes it rather clear that interactions between varieties of different people exist and tend to be cause for most longstanding and utmost violent conflicts.²⁴²

Secondly, Huntington, a political science professor, declared that the world is becoming a small place.²⁴³ Moreover, with the advent of modern information technology the earth has indeed turned into what some might refer to as a global village. He also argues that the interaction between people of dissimilar civilizational backgrounds tend to increase, in a globalised world one might add. Such interactions reveal both similarities and differences between various civilisations. Huntington further goes on to bring up the example of how North African immigrants to France have led to increased hostile sentiments among the local Frenchmen. At the same time, immigrants from the, predominantly, Catholic state of Poland are being accepted by the French in an increasing manner.²⁴⁴

Thirdly, Huntington claims that both the social change thought the globe together with the economic modernisation are the reason for separating people from traditional local identities.²⁴⁵ For Huntington,

²⁴¹ Ibid, p. 24.

²⁴² Ibid, p.25.

²⁴³ Ibid.

²⁴⁴ Huntington, Samuel: Clash of Civilisations and the Remaking of World Order. New York: Simon and Schuster, 1998, pp. 67-68.

²⁴⁵ Huntington, Samuel: The Clash of Civilizations? The next pattern of conflict, in: Foreign Affairs (1993), Vol. 72, No. 3, pp. 22-49, p. 26.

these circumstances weaken the nation state as a strong basis of identity. The nation state's loss is religion's gain; in other words, religion in the form of faith-based movements branded as fundamentalist in nature has stepped in to fill the blanks. Regarding Hinduism, RSS and associated Hindu nationalist organisations have arguably been at the helm of such religious movements, ready and willing to fill in the vacant space. The all-encompassing characteristics of the members of these faith-based movements are part of the young, university educated individuals, hailing from the middle-class and are working professionals, technicians and businesspeople alike. Global communities are increasingly turning their backs to secularity, which in turn can be seen as predominant, when it comes to the societal components of life in late twentieth century.²⁴⁶ The second inning of religion on the world stage, as Gilles Kepel puts it, offers a foundation for identity and commitments that surpasses nation state frontiers and amalgamate civilisations.²⁴⁷

Fourthly, civilisation-consciousness has in fact meant that the West has taken a dual position. On the one hand, the Western world is at the pinnacle of its power. On the other hand, one can observe the curiosity of the "back to the roots" phenomenon. In this context people do refer to this as the termination of the Nehruvian legacy and the "Hinduisisation" of the Indian Union or the so-called "Asianisation" of Japan.²⁴⁸

Fifthly, Huntington argues that cultural attributes and dissimilarities are less likely to become subject to alteration. Consequently, such compromises and dispute resolutions are more difficult to resolve than those rooted on economics or politics.²⁴⁹ The political science professor has been putting the example of the former Soviet Union

²⁴⁶ Ibid.

²⁴⁷ Huntington, Samuel: Clash of Civilisations and the Remaking of World Order. New York: Simon and Schuster, 1998, pp. 95-96.

²⁴⁸ Huntington, Samuel: The Clash of Civilizations? The next pattern of conflict, in: Foreign Affairs (1993), Vol. 72, No. 3, pp. 22-49, p. 26.

²⁴⁹ Ibid, p. 27.

into the equation and states that, while Communists, are indeed able to switch their political affiliation and could in fact become democracy. A Russian on the other hand can never forgo his identity and become an Estonian or Armenian for that matter. When it comes to class ideological conflict the all-encompassing question has been on which side an individual has been. Hence people were under the obligation to opt for one side or the other. As for Huntington, the so-called “wrong answer” was both detrimental and fatal alike. While he is referring to the bloody conflicts in Bosnia and Sudan, in which bloodshed has been a consequence of choosing to identify with what some might refer to as the wrong ethic group.

Huntington accommodates the issue in his theory *magnum opus* “Clash of Civilisations”, in which he refers to the historic clash between Hindus and Muslims on the Indian subcontinent.²⁵⁰ Thus, he is going beyond the rivalry between New Delhi and Islamabad and is in fact looking into the religious strife within the Indian nation between the militant Hindu groups representing the majority and the Muslim minority. The destruction of the Babri mosque, for Huntington, meant that the Indian nation has reached a turning point from which a decision had to be made whether it was going to be a democracy based on secularism or a theocratic state.²⁵¹

If one was to apply this section of Huntington’s theory to India, one could see a parallel to the RSS’s involvement in the Babri mosque in Ayodhya incidents and the religious riots in Gujarat. Equally, one could go back even further to the religious civil war scenario during the separation of former British India into a majority Muslim state of Pakistan and a Hindu majority nation of India. On the eve of

²⁵⁰ Ibid, p. 33.

²⁵¹ Ibid, p. 34.

separation of Indian and Pakistan in August 1947, not only was there violence and bloodshed but also mass killings were at the forefront.²⁵²

Huntington is of the opinion that religion, and not ethnicity, is more discriminatory against people, and as such religion seems to be more harshly and exclusively among persons. In this context, he argues that a person can be half-French and half-Arab, and at the same time, can be a dual national.²⁵³ For the sake of this work one could exchange the scenario to a person who is half-Indian and half-British. *Prima facie* it might be somewhat difficult to be half-Hindu and half-Christian.

Last but not least, Huntington is of the opinion that economic regionalism is on the rise. He refers to the fact that the proportion of the sum total of interregional trade in Europe has risen by around 8%, from 50.6 to 58.9 percent in the 1980s.²⁵⁴ In East Asia it went up 4% from 33 to 37 percent.²⁵⁵ Huntington foresees an increase in significance when it comes regional economic blocs in the future. He argues that success itself, when it comes to economic nationalism, will strengthen civilisational-awareness. Economic regionalism in Huntington's eyes would be successful when is based on a shared civilisation. Interestingly, he is referring to the European Community, today's European Union (EU) which he argues is rooted in both Western Christianity and European culture.²⁵⁶ If one was to dwell on Huntington's line of argumentation, Turkey with its contemporary strong emphasis on the Islamic belief-system would thus surely be struggling to integrate itself into the Christianity-based European family.

²⁵² Huntington, Samuel: Clash of Civilisations and the Remaking of World Order. New York: Simon and Schuster, 1998, p. 244.

²⁵³ Huntington, Samuel: The Clash of Civilizations? The next pattern of conflict, in: Foreign Affairs (1993), Vol. 72, No. 3, pp. 22-49, p. 27.

²⁵⁴ Huntington, Samuel: Clash of Civilisations and the Remaking of World Order. New York: Simon and Schuster, 1998, p. 134.

²⁵⁵ Huntington, Samuel: The Clash of Civilizations? The next pattern of conflict, in: Foreign Affairs (1993), Vol. 72, No. 3, pp. 22-49, p. 27.

²⁵⁶ Ibid.

Arguably, his line of argument is not as hard and fast as he makes it out to be. Moreover, Brexit led to a decimation of the idyllic world of the European Union and by deduction implies that the Christian religion might not be enough of a superglue to hold a steadily declining economic union together. Equally, Poland and Hungary have on a somewhat regular basis been in breach with EU legislation. Similarly, strong anti-EU sentiments have surfaced during the Italian Economic crises.

One another note, when it comes to the expansion of economic relations, a common culture does indeed facilitate speedy growth. Huntington put forward the example of China, Hong Kong, Taiwan and Singapore.²⁵⁷ It is worth mentioning that until 1997 Hong Kong had been a British dependent territory. Huntington also is of the opinion that both religion and culture are two main components that form the foundation of the Economic Cooperation Organisation. This institution was established under the leadership of Pakistan, Turkey and Iran in the 1960s. This organisation has brought together the following ten states: Turkey, Iran, Pakistan, Kazakhstan, Kyrgyzstan, Azerbaijan, Afghanistan, Tajikistan, Turkmenistan and Uzbekistan.²⁵⁸

When it comes to the member states of the aforesaid organisation, they share a common Islamic religion and Islamic culture as well as traditions. This organisation might have been a consequence of the fact that numerous leaders from this institution have come to the realisation that they had little or no opportunity to be admitted to the European Community.²⁵⁹ Similarly, for Huntington, the triumph of the North American Free Trade Area (NAFTA) or the present United States-Mexico-Canada-Agreement (USMCA) can also be put down to

²⁵⁷ Huntington, Samuel: The Clash of Civilizations? The next pattern of conflict, in: Foreign Affairs (1993), Vol. 72, No. 3, pp. 22-49, p. 28.

²⁵⁸ Ibid.

²⁵⁹ Ibid.

the underlining cultural commonalities.²⁶⁰ Equally, Mercosur and the Central American Common Market are *prima facie* also based on common cultural and religion foundations. Thus, for Huntington, the EU and Turkey are culturally further apart than the United States and Mexico.²⁶¹ Turkey has in fact issued an application to become a member state of the EU and has been undergoing the applicatory process which has, however, come to a standstill since 2018. Interestingly, the EU has embraced Greece, Bulgaria and Romania, all of whom according to Huntington belong to Orthodox Christianity, while the majority of EU member states happened to be part of Western Christianity.²⁶²

Huntington argues that people determine their identity along religious and ethnic lines, and as a result an “us” versus “them” situation prevails between particular people and those of dissimilar religion and ethnic persuasion. Dissimilarities in both religion and culture have established differences in the subject matter of policy, covering issues from immigration to human rights, trade and commerce, to environmental concerns. In this context, geological proximity increase the conflicts in the form of claims over particular territory, such as Bosnian claims over Mindanao.²⁶³

The West is undertaking considerable efforts to endorse its principles of liberalism and democracy as universally applicable principles. It further aims to maintain its predominant position in military terms as well as to expand economic interests; such an approach leads to considerable opposition from other civilisations. According to Huntington, governments will in fact struggle to rally for backing and to build coalitions along ideological lines, and will as a result increase

²⁶⁰ Huntington, Samuel: Clash of Civilisations and the Remaking of World Order. New York: Simon and Schuster, 1998, p. 150.

²⁶¹ Huntington, Samuel: Clash of Civilisations and the Remaking of World Order. New York: Simon and Schuster, 1998, p. 150.

²⁶² Huntington, Samuel: The Clash of Civilizations? The next pattern of conflict, in: Foreign Affairs (1993), Vol. 72, No. 3, pp. 22-49, p. 30.

²⁶³ Ibid, p. 29.

their support by endeavouring to gather assistance, while appealing to the commonality of religious and civilizational identity.²⁶⁴

Additionally, the clash of civilisation exists on two dimensions. On the micro-level, neighbouring along the fault lines between civilisations undergoing a violent struggle over the control for land and each other. On the macro-level, countries from dissimilar civilisations engage in a competition over economic as well as military control. Furthermore, their fight for the control of global institutions as well as over other third parties, in doing so they end up advertising their specific religious and political principles.

Apart from the notion of “us” versus them, Huntington also believes in the label “West” versus the “Rest”.²⁶⁵ This term was coined by Kishore Mahbubani who foresaw a conflict between “the West and the Rest”.²⁶⁶ According to Huntington, the West faces no real economic adversaries. In fact, decisions taken by the UN, International Monetary Fund and other economic institutions such as WTO or TRIPS are reflecting the economic and other interests of the West.²⁶⁷ He even goes on to state that the West is endorsing its economic interests together with the intention to inflict upon other states the economic policies it deems fit when it comes to its particular desires.²⁶⁸ The West is also utilising international institutions, economic capital and military supremacy to shift and shake the globe in ways that will guarantee Western dominance, promote the economic as well as political values of the West and protects its interests.²⁶⁹ In this context, V. S. Naipaul considers the West as universal in nature which fits all

²⁶⁴ Ibid.

²⁶⁵ Huntington, Samuel: Clash of Civilisations and the Remaking of World Order. New York: Simon and Schuster, 1998, p. 184.

²⁶⁶ Mahbubani, Kishore: "The West and the Rest", in: The National Interest (1992), No. 28, pp. 3-12, pp. 3-4.

²⁶⁷ Huntington, Samuel: Clash of Civilisations and the Remaking of World Order. New York: Simon and Schuster, 1998, p. 184

²⁶⁸ Ibid.

²⁶⁹ Ibid, p. 186.

sizes.²⁷⁰ For Huntington, the universality of culture is diametrically opposed to the human nature. Familiarity when it comes to a particular culture, for him, is a source of discordance rather than being a source of comfort and reverence. He argued that difference has been given more significance than those aspects which have a unifying character.²⁷¹

He also argues that the following Western principles have little resonance with the Hindu civilisation: liberalism, constitutionalism, individualism, human rights, liberty, equality, democracy, rule of law, free market and secularism.²⁷² Moreover, while supporting Non-Western cultures, younger generations in non-Western societies have increased their support for theocratic fundamentalism against “human rights imperialism” and for the reassertion of indigenous principles.²⁷³ The political science professor states that most Asian societies tend to accentuate on what distinguishes one group from another.²⁷⁴

Based on the abovementioned, the Hindu nationalist Indian administration could indeed feel trapped in a situation in which “the West versus the Rest”²⁷⁵ would be on their mind. In other words, the EU could be considered by India as a Western power that controls the WTO and TRIPS, both of which in turn reflect the economic and other interests of the EU as a protagonist of the West.

In this context, it might be worth mentioning that for Swami Vivekananda, the term “West versus the Rest” had unsurprisingly different connotations. Vivekananda is *inter alia* a protagonist of the following two ideas: the first being that Hinduism is the religion of a

²⁷⁰ Ibid, p. 66.

²⁷¹ Nanda, Meera; Hindu Triumphalism and the Clash of Civilisations, in: Economic and Political Weekly, Vol. 44, No 28, pp. 106-114, p. 107.

²⁷² Huntington, Samuel: Clash of Civilisations and the Remaking of World Order. New York: Simon and Schuster, 1998, p. 186.

²⁷³ Ibid, p. 93.

²⁷⁴ Ibid, p. 67.

²⁷⁵ Ibid, p. 183.

supercilious race and the second that Hinduism is a religion which is spiritually superior to other religions.²⁷⁶ Vivekananda's claims goes to the crux of Huntington's theory which flaunts the fact that Western Christianity is superior because of its cultural, religious, economic, political superiority over other civilisations. He has been a tough opponent of Christianity as he saw the Christian religion as promoting bigotry and hypocritical when it comes to demeaning Hinduism, in particular, in the area of missionary endeavours and thereby obstructing his desire to "reawaken" Hindustan.²⁷⁷ Vivekananda has recognised the beneficial accomplishments particularly in the educational sector by European Christianity.²⁷⁸

For the Swami Hinduism, Hindu spirituality, is situated diametrically opposite to Western values which for Vivekananda are rooted on materialism. In this context, Hindu spirituality is superior to Western materialism or, if one is to use a contemporary term, it would be superior to the consumerism of the West,²⁷⁹ which in turn is arguably driven by greed and a "want more" culture.

Enthusiasts of Vivekananda and passionate Hindu nationalists might pass off Huntington's theory through when it comes to cultural essentialism. However, Indians will eventually draw a line when it comes to the issue of whether or not Hindu India is at the helm of the leadership race for civilisational supremacy.²⁸⁰ The protagonist of Hindutva would object to Huntington as he provides little space for Hindu civilisational dominance of the world. Huntington is indeed mindful of the fact that out of all the civilisations he has analysed he

²⁷⁶ Van Der Veer, Peter: Hindus: A superior race, in: Nations and Nationalism (1999), Vol. 5, No. 3, pp. 419-430, p. 421.

²⁷⁷ Beckerlegge, Gwilym: Swami Vivekananda and the sangh parivar: convergent or divergent views on population, religion and national identity?, in: Postcolonial Studies (2006), Vol. 9, No. 2, pp. 121-135, p. 128.

²⁷⁸ Ibid.

²⁷⁹ Van Der Veer, Peter: Hindus: A superior race, in: Nations and Nationalism (1999), Vol. 5, No. 3, pp. 419-430, p. 42.

²⁸⁰ Nanda, Meera: Hindu Triumphalism and the Clash of Civilisations, in: Economic and Political Weekly (2009), Vol. 44, No 28, pp. 106-114, p. 107.

has had little acquaintance with the Hindu civilisation.²⁸¹ Hence he fails to pay tribute to the revival of Hindu civilisation and only makes a remark in passing by mentioning the Hindu revival and resurgence of pride in Hindu culture. While Huntington does not completely wipe out New Delhi's possibility of becoming a serious contender for civilisational dominance, he does, however, envisage India as taking up the position of a small "swing state".²⁸² Such a statement might provide little solace to Hindu nationalists. When it comes to realpolitik, New Delhi has indeed played the role envisioned by Huntington. Following the dictum that the "foe of my foe is my friend", Hindustan (India) has catapulted itself to be a rather strong ally of the US-Israeli "coalition of the willing" against the so-called "axis of evil" countries.²⁸³ Strategically speaking, New Delhi with the support of Washington has managed to situate itself as the so-called beacon of hope on the Asian subcontinent challenging the Sino dominance of continental Asia.²⁸⁴

On another note, Hindu nationalism contradicts Huntington's deeply flawed theory. One cannot separate Hindutva from the greatness of Indian nationalism based on the ideology of great power nationalism.²⁸⁵ Hindu nationalism tends to be supportive of Huntington's concepts of both national power and state-based nationalism. It also seems to be inconsistent with the increasingly fading liberal theory of globalisation with its notion to abolishing state-based nationalism.²⁸⁶ For Hindustan, the junior role assigned by Huntington does not reflect the nation's civilisational supremacy as promoted by Vivekananda and other prominent Hindu nationalists. Hindu nationalists are campaigning for a lessons-learned approach

²⁸¹ Huntington, Samuel: Clash of Civilisations and the Remaking of World Order. New York: Simon and Schuster, 1998, p. 14.

²⁸² Nanda, Meera: Hindu Triumphalism and the Clash of Civilisations, in: Economic and Political Weekly (2009), Vol. 44, No 28, pp. 106-114, p. 107.

²⁸³ Ibid, p. 108.

²⁸⁴ Ibid.

²⁸⁵ Lieven, Anatol: Hindu Nationalism: A Reality Check for Liberalism and Globalisation, Valdai Discussion Club. 2017. - <https://valdaiclub.com/a/highlights/hindu-nationalism-a-reality-check-for-liberalism/>, DOA: 19.12.2020.

²⁸⁶ Ibid.

when it comes to the post-9/11 global community. Vivekananda's political protégés and disciples would be anything but amused by the Harvard professor's instantiations. They in fact are absolutely connived that as a civilisation they are in the position to teach the West a lesson or two when it comes to defeating Islamic invasions.

Yet another fierce proponent of Vivekananda, Swaminathan Gurumurthy claims that the Hindu community might as well be the only one in the world, which was capable to endure and survive the occupation by a theocratic Islamic civilisation.²⁸⁷ Obviously, such statements ought to be taken with a pinch of salt. In other words, life itself and historical events, in general, tend to be neither white nor black. They are increasingly developing into multiple shades of grey or are partly true and half-truth for that matter. The basic thought behind this notion is that the global community must embrace Hindu principles if it is to defeat those civilisations rooted on Islamic theocracy.²⁸⁸ For the Hindu nationalist the ultimate aim, it seems, is to make Hindustan the *jagat guru* (guru of nations), which in turn could be the Hinduism-based interpretation of Huntington's theory. India's civilizational fighters are supportive of Huntington's fundamental notion of religion-based civilisation as at the core of which it is invariable and permanent. Hindu nationalists who support the theory that Greater India extends from South Asia to a large section of South-East Asia as demarcated by Hinduism are similar to claims made by Professor Huntington when it comes to Christianity and the West.²⁸⁹

For Hindu nationalists, it appears obvious that an abstemious attitude when it comes to the clash of civilizations, more precisely, the one between the West and Islam would be rather displaced. Hinduism must compete when it comes to civilizational supremacy and pit

²⁸⁷ Swaminathan, Gurumurthy: Semitic Monotheism: The Root of Intolerance in India, in: New Perspectives Quarterly (1994), pp. 47-53, pp. 47-48.

²⁸⁸ Nanda, Meera: Hindu Triumphalism and the Clash of Civilisations, in: Economic and Political Weekly (2009), Vol. 44, No 28, pp. 106-114, p. 108.

²⁸⁹ Ibid.

Hinduism against Christianity and Islam at the same time.²⁹⁰ From the point of view of the Hindus the actual source of evil and prejudice are not only Islam and Christianity but monotheistic religions as a whole.²⁹¹ Such an interpretation by definition also includes Judaism. Interestingly, however, Judaism forms an exception to the rule, as the God in Judaism is only dedicated for the Jews themselves. In essence, they believe that monotheistic faith-based cultures are those who are inherently intolerant by definition as they only believe in one God and thereby deny plurality and tolerance as a whole.

In sum, Huntington's theory *prima facia* appears to be outdated and needs a considerable overhaul, in particular the us-versus-them concept.²⁹² Religion and culture, while being an important common denominator seems to be rather weak as can be seen in the case of the EU and Brexit. While at the time of writing, a trade deal between both the EU and the United Kingdom has been agreed upon, Brexit once again highlights the shortcomings of Huntington's theory. In this instance, the common culture and religion neither acted as a safety pin nor could they be used as some form of superglue to hold, in global terms, the UK in a brittle alliance with the EU.

²⁹⁰ Ibid.

²⁹¹ Ibid.

²⁹² Barker, Paul J.: The Clash of Civilizations Twenty Years On, in: e-International Relations. 2013. - <https://www.files.ethz.ch/isn/180334/Clash-of-Civilizations-E-IR.pdf>, DOA: 19.06.2016.

2.2. “Holy Cow”

“*Vox Populi, Vox Dei*”²⁹³

This sub-chapter will examine the topic of the cow, which in Hinduism and according to Hindu mythology, is holy and its waste products such as cow urine (Gomutra) have, according to the Hindu religion, purifying qualities. Cows are also being worshipped by many Hindu devotees. Amid the Corona pandemic, the BJP and the Hindu nationalist have sworn by the medical qualities and healing powers of Gomutra.

This sub-chapter will further explore the subject matter of ancient traditional Indian medicine as promoted by the Indian Ministry of AYUSH. This sub-chapter might provide potential reasons as to why the EU might doubt the credibility of Indian generic medicines. A potential reason for this might be rooted in the “superstitious belief” of the Hindu nationalist administration when it comes to, from the Indian point of view, a potentially viable alternative to conventional Western (European) medicine. In this context, it is impertinent to establish that Indian traditional medicine has existed for centuries.²⁹⁴ In this regard, AYUSH’s dubious advice during the initial stages of the Covid-19 pandemic, as well as the propagation of misinformation by the Ministry regarding this crisis, will be outlined in this paper. The BJP’s institutional promotion of traditional Indian medicine might lead to reputation risk of the medical sector in India and by default to the pharmaceutical industry. More precisely, this work shall analyse whether placing traditional medicine with the conventional Western medicine on equal footing will have a detrimental outcome when it comes to the ability of the Indian pharmaceutical industry to comply with the international standards when it comes to the production and

²⁹³ Latin for: “the voice of the people is the voice of God”

²⁹⁴ Kaliyaperumal, Karunamoorthi/ Kaliyaperumal, Jegajeevanram: Traditional Medicinal Plants: A Source of Phytotherapeutic Modality in Resource-Constrained Health Care Settings, in: Journal of Evidence-Based Complementary & Alternative Medicine (2012), pp. 67-74, p. 69.

development of the medication. In this regard, this paper shall examine the usage of cow urine for a pharmaceutical purpose.

The protection of the cow, a sacred animal in the Hindu religion has been close to the heart of Hindu majority in the country. Along the line of *vox populi, vox dei*, the protection of this “sacred animal” has experienced longstanding support of the Indian people and has been fundamental for the creation of Hindu nationalism.²⁹⁵ Gandhi, a Hindu and a true secularist at heart, reasoned with the nationalists in the 1920’s that whilst he agreed with their sentiments, such a ban should not be upheld to the detriment of the Muslim minority. Despite allegations from the Hindu nationalists of sacrificing the majority rights for that of the minority communities, Article 48 of the Indian Constitution²⁹⁶, albeit not justiciable, establishes that the government should take steps to prohibit cattle slaughter. Thus, one could attribute such law making to the prevailing Hindu religious sentiments of the Indian national assembly at the time.²⁹⁷ Unlike Article 48, Article 27²⁹⁸ of the Indian constitution contains a guarantee for personal liberty, which is a fundamental right that allows resort to court if this right is jeopardised or violated. As personal liberty, Indian courts have traditionally inferred it to legally contain the right to privacy, which, in its broader sense would extend to the notion that a person is at liberty to choose according to his liking what he wants to eat.²⁹⁹

²⁹⁵ Corbridge, Stuart/ Craig, Jeffrey/ Harriss, John: Is India Becoming the ‘Hindu Rashtra’ Sought by Hindu Nationalists ?, in: Simons Papers in Security and Development, No. 60/2017, School for International Studies. Vancouver: Simon Fraser University, 2017, p. 23.

²⁹⁶ National Legislative Bodies: The Constitution of India. 1950. -

<https://www.refworld.org/docid/3ae6b5e20.html>, DOA: 29.01.2019.

²⁹⁷ Corbridge, Stuart/ Craig, Jeffrey/ Harriss, John: Is India Becoming the ‘Hindu Rashtra’ Sought by Hindu Nationalists ?, in: Simons Papers in Security and Development, No. 60/2017, School for International Studies. Vancouver: Simon Fraser University, 2017, p. 23.

²⁹⁸ National Legislative Bodies: The Constitution of India. 1950. -

<https://www.refworld.org/docid/3ae6b5e20.html>, DOA: 29.01.2019.

²⁹⁹ Corbridge, Stuart/ Craig, Jeffrey/ Harriss, John: Is India Becoming the ‘Hindu Rashtra’ Sought by Hindu Nationalists ?, in: Simons Papers in Security and Development, No. 60/2017, School for International Studies. Vancouver: Simon Fraser University, 2017, p. 23.

While subject to regulations and against popular belief, the slaughter of cattle has not been prohibited in the past. Yet once the BJP had come to power, state governments in Haryana and Maharashtra passed laws banning cow slaughter. The RSS chief followed suit by calling for a country-wide ban on cow slaughter without admitting the fact that the implementation would be time intensive given the diversity of opinions on this issue.³⁰⁰ The official announcements with regard to cow slaughter encouraged vigilante-sentiments amongst the Hindu nationalist supporter vis-à-vis the Muslim community. Mr Modi's supporters went as far as to murder alleged cow-slaughterers *inter alia* to prove their dedication to the cause of the holy cow.³⁰¹ The Bharateeya Jan Sangh (a Hindu nationalist organisation) for instance had been at the fore-front of a campaign to fighting cow-slaughter as early as 1952.³⁰²

The consumption of the “golden liquid” or Gomutra hardly appears to be a new invention of the Hindu nationalist movement. Some even go as far as to wash themselves in their own “golden liquid” with the intention to improve the quality of their skin. Equally, a number of modern Japanese women are believed to engage in urine bathing. Urine is not quite Hute Cuisine, but it is the elixir of choice for some holy Indian women and men, *prima facie*, urine drinking habit has been practiced for thousands of years. The beverage is also the preferred “tonic” for a growing number of naturopaths and other advocates of “natural remedies.” The main attractions of this ultimate homemade liquor are its cost, availability and portability.³⁰³

³⁰⁰ Ibid.

³⁰¹ Lieven, Anatol: Hindu Nationalism: A Reality Check for Liberalism and Globalisation, Valdai Discussion Club. 2017. - <https://valdaiclub.com/a/highlights/hindu-nationalism-a-reality-check-for-liberalism/>, DOA: 19.12.2020.

³⁰² Rashtriya Swayamsevak Sangh: Basic FAQ on RSS. 2017. -

<http://rss.org//Encyc/2017/6/3/basic-faq-on-rss-eng.html>, DOA: 27.01.2019.

³⁰³ Carroll, Robert Todd: Urine therapy, in the skeptic's dictionary. 2015. -

<http://skepdic.com/urine.html>, DOA: 01.09.2020.

For centuries, cow urine has been used for both internal and external therapeutics in India. Cow urine or Gomutra has been used in the Vedic as well in the pre-Vedic period. Indian cow urine therapy has, *prime facie*, been considered quite efficient when it comes to curing numerous medical disorders and for the maintenance of sound health in general.³⁰⁴

From the perspective of the Hindu nationalists, it appears to be logical for the leaders of the global community to import the liquid from the Indian subcontinent. During the Gomutra party people lined up for their share of cow urine which was poured from kettles into ‘kulhads’ (traditional Indian clay cups), which was organised by Swami Chakrapani, the president of Akhil Bharat Hindu Mahasabha. The aforementioned was hosted at its headquarters in India’s capital, which was attended by 200 people and the organisers hoped to host similar events elsewhere in India.³⁰⁵

The event began with a ‘yagna’ (offering) and prayers to both the cow and the virus itself, asking it, peacefully, for a leave of absence and not take the life’s of even more and more people. The Akhil Bharat Hindu Mahasabha Party even went as far as to depict a large poster in the backdrop with an avatar of the Hindu God Narsinh representing the virus. During this event Chakrapani came up with an outrageous claim alleging COVID-19 to be an “avatar” that has “come to penalise meat lover and non-vegetarians.” Asking for forgiveness from the virus on behalf of meat eaters, he pledged that Indians will never eat meat again.³⁰⁶ He also stated that while vegetarians must not worry as it will

³⁰⁴ Singh, Satyapal: Pharmacotherapeutics of gomutra (Cow urine), in: The Pharma Innovation Journal (2019), Vol. 8, No. 6, pp. 707-712, p. 707.

³⁰⁵ Siddiqui, Danish: Hindu group offers cow urine in a bid to ward off coronavirus. in: Reuters. 2020. - <https://www.reuters.com/article/us-health-coronavirus-india-cow-urine-pa/hindu-group-offers-cow-urine-in-a-bid-to-ward-off-coronavirus-idUSKBN2110D5>, DOA: 19.07.2020.

³⁰⁶ The Hindu: Coronavirus: Group hosts ‘cow urine party’, says COVID-19 due to meat-eaters. New Delhi. 2020. - <https://www.thehindu.com/news/national/coronavirus-group-hosts-cow-urine-party-says-covid-19-due-to-meat-eaters/article31070516.ece>, DOA: 19.07.2020.

not have an impact on them. However, as a precautionary measure, vegetarians may likewise commence consuming Gomutra.³⁰⁷

As from the point of view of the Akhil Bharat Hindu Mahasabha the “Coronavirus has emerged as a consequence of people killing and eating animals. According to Chakrapani the slaughter of an animal creates a sort of an energy that causes destruction in that place. Moreover, as for Mr. Chakrapani the global leaders should endeavour to import cow urine from India as “the almighty creator” only happens to reside in the Indian cow and not in any of the alien breeds.³⁰⁸ His comments came even as the centre had asked people not to pay attention to “false rumours” that the COVID-19 was spreading through non-vegetarian food like eggs, chicken, mutton and seafood. The Corona party was not limited to articles consisting of cow urine products that people will be encouraged to spray onto themselves or consume (drink) in order to keep the coronavirus at bay, and as a substitute for a chocolate cake, they’re going to be serving up cow dung cakes.³⁰⁹ People have been witnessed to consume Gomutra freely from the cow and in considerable quantities rather than a few drops. Chakrapani further stated that, upon using the aforementioned remedies the virus will die instantaneously. He also declared that all cow shelters are going to be involved in the battle against the virus.³¹⁰ The Corona party taking place admits the strict scientifically backed advisories that say people should avoid crowded rooms with chances of person-to-person contact.³¹¹

³⁰⁷ National Herald: Hindu Mahasabha to hold ‘Gaumutra Party’ to ward off coronavirus! 2020. - <https://www.nationalheraldindia.com/india/hindu-mahasabha-to-hold-gaumutra-party-to-ward-off-coronavirus>, DOA: 19.07.2020.

³⁰⁸ The Hindu: Coronavirus: Group hosts ‘cow urine party’, says COVID-19 due to meat-eaters. New Delhi. 2020. - <https://www.thehindu.com/news/national/coronavirus-group-hosts-cow-urine-party-says-covid-19-due-to-meat-eaters/article31070516.ece>, DOA: 19.07.2020.

³⁰⁹ Deutsche Welle: Hindu group hosts cow urine drinking party to ward off coronavirus. 2020. - <https://www.dw.com/en/hindu-group-hosts-cow-urine-drinking-party-to-ward-off-coronavirus/a-52773262>, DOA: 19.01.2021.

³¹⁰ National Herald: Hindu Mahasabha to hold ‘Gaumutra Party’ to ward off coronavirus! 2020. - <https://www.nationalheraldindia.com/india/hindu-mahasabha-to-hold-gaumutra-party-to-ward-off-coronavirus>, DOA: 19.07.2020.

³¹¹ Ibid.

The coronavirus in India has triggered copious debatable health benefit claims, predominantly surrounding traditional medicines, for instance minerals as well as plant extracts and yoga. Yet another interesting example is based on the belief that applying two drops of sesame oil, on a daily basis, into the nostrils is supposed to ward off the Covid-19.³¹² While this appears to be a remedy of an *ad absurdum* nature, this is by no means exceptional. One of India's most renowned yoga teachers and a celebrity in its own right, Baba Ramdev, stated that merely by practicing yoga a person would help increase his or her immunity which in turn could be used to save the life of an infected person.³¹³ Given the fact that low immunity would make it significantly less likely for a person to recover from the virus and its side effects, thus as for Baba Ramdev, yoga, *prima facie*, seems to be the remedy against the Covid-19.

Sadly enough, the deadly coronavirus that has infected more than 170 million people across the world at the time of writing and has countless confirmed cases in India. In midst of this uncertain atmosphere, the country has taken several preventive measures to contain the outbreak, like screening passengers at airports and shutting down schools. It needs to be stated that most of the country is responding to the novel COVID-19 with rationality and medical measures³¹⁴

The Indian Fisheries, Dairying and Animal Husbandry Minister Giriraj Singh told reporters that both the World Organisation for Animal Health and the Indian food safety regulator FSSAI (Food Safety and Standards Authority of India) have stated that relevant scientific evidence to prove transmission of coronavirus from animals to humans

³¹² Deutsche Welle: Hindu group hosts cow urine drinking party to ward off coronavirus. 2020. - <https://www.dw.com/en/hindu-group-hosts-cow-urine-drinking-party-to-ward-off-coronavirus/a-52773262>, DOA. 19.01.2021.

³¹³ Ibid.

³¹⁴ National Herald: Hindu Mahasabha to hold 'Gaumutra Party' to ward off coronavirus! 2020. - <https://www.nationalheraldindia.com/india/hindu-mahasabha-to-hold-gaumutra-party-to-ward-off-coronavirus>, DOA: 19.07.2020.

was indeed lacking. Unfortunately, in this respect, false rumours have made their way and have hit thousands of farmers who were engaged in this business. Consequently, both the livelihood of farmers and those engaged in the entire value chain have suffered. The minister requested people not to become victims of such stories. At the time of writing medical experts around the world have repeatedly stated that there isn't an exact cure for coronavirus. Yet, Mr Chakrapani expressed his belief that cow urine possesses the sole potential to cure COVID-19 and encouraged global leaders to devour this unique elixir in their fight against this highly contagious disease.³¹⁵ Chakrapani alleged that all the Indian leaders were consuming Gomutra in secret and whenever they fell ill. Thus, a daily consumption of Gomutra appears to be a prerequisite in order to keep the sickness away. He also mentioned that leaders were ashamed of this God-given golden liquid presented by the almighty to the Indian nation.³¹⁶

Chakrapani seems to have the "Make in India" slogan in mind when he urges world leaders to import Gomutra only from an Indian breed. His business acumen seems to have no limits, he pleads that all prime ministers and presidents of globe should not hesitate to have a daily intake of cow urine. As the global scientific community lacks the much-needed cure against Covid-19 and, yet, Chakrapani claimed that only India possess the cure against corona.³¹⁷

Now the question arises whether Chakrapani's claim that Gomutra is the only actual solution, and is actually a cure against Covid-19. Former director general of the Directorate General of Health Services, Kriti Bhushan, stated that there was no scientific evidence against the claim that cow urine could possibly cure coronavirus.³¹⁸ He also added that when it comes to the subject matter of medical science, one could

³¹⁵ The Hindu: Coronavirus: Group hosts 'cow urine party', says COVID-19 due to meat-eaters. New Delhi, 2020. - <https://www.thehindu.com/news/national/coronavirus-group-hosts-cow-urine-party-says-covid-19-due-to-meat-eaters/article31070516.ece>, DOA: 19.07.2020.

³¹⁶ Ibid.

³¹⁷ Ibid.

³¹⁸ Ibid.

only consider something as cure against Covid-19 after having tested it on at least 100 or more infected persons. Bhushan also declared that such unilateral claims are baseless. She also explained that there is no cure for the coronavirus and that numerous scientists are continuously working on a solution for this.³¹⁹

A volunteer at the event, Rajesh Sharma, even went as far as to vouch for its phenomenal assets while offering the drink to others around him. He further declared that the sheer intake of a single glass today would make a visible difference tomorrow. Sharma, like many other genuine believers in Gomutra, is convinced that it can cure all diseases. He was even willing to offer a warrantee in writing. Savita, a homemaker from Paschim Vihar (West Delhi), who attended the 'gomutra party' and stated that she and her family were consuming the golden liquid on a daily basis. She even went as far as to assure that nothing is healthier than the golden syrup.³²⁰

In a contradictory action the right-wing organisations, Akhil Bharatiya Hindu Mahasabha³²¹, organised a 'Gomutra party' in Delhi, convinced that they can defeat coronavirus with both waste products of the cow, namely urine and dung. Yet, notwithstanding this move, the RSS annulled a three-day annual meeting of its highest decision-making body scheduled to begin in Bengaluru due to fear of Covid-19, for the statement issues by RSS general secretary Suresh 'Bhaiyyaji' Joshi.³²² The right-wing organisation was expected to discuss a whole host of issues, which included the roadmap for the construction of the Ram temple in Ayodhya. The BJP's national president J.P. Nadda was also scheduled to take part in the meeting, which was cancelled due to

³¹⁹ Ibid.

³²⁰ Ibid.

³²¹ A Hindu nationalist political party in India.

³²² National Herald Web Desk: Hindu Mahasabha says 'gaumutra' can prevent coronavirus, but RSS cancels meet amid fear. 2020. - <https://www.nationalheraldindia.com/india/hindu-mahasabha-says-gaumutra-can-prevent-coronavirus-but-rss-cancels-meet-amid-fear>, DOA: 19.07.2021.

Covid-19. Equally, in midst of the magnitude of the Covid-19 pandemic and in consideration of the instructions and advisories issued by the national as well as by the state governments, the Akhil Bharatiya Pratinidhi Sabha (the highest decision-making body of the RSS) meeting scheduled in Bengaluru has been suspended.³²³ The Hindu Mahasabha had initially issued a statement in which they regard the coronavirus as an angry avatar of a Hindu God who has released its fury to punish non-vegetarians. The party is swearing by the miraculous and magical healing properties of the cow, as the sole remedy against the public health crisis.

In Hindu mythology, the Indian cow is the most valued in all the Veda (ancient Hindu scripture) and mother of them all. According to the vital products provided from the cow included the following substances: Go-ksheer (cow milk), Dadhi (curd), Ghrita (ghee or melted butter), Go-mutra (cow urine) and Gomaya (cow dung).³²⁴ The aforementioned five ingredients are referred to as “Panchagavya”, which, *prima facie*, seemed to be given to mothers of newborns once they had delivered their baby.³²⁵ The holy cow is also revered as a mobile dispensary. It is also referred to as the treasure of medicines. Moreover, according to the ancient Hindu scripture, cow urine has the capability of curing several both curable and incurable diseases. The following Holy Scriptures: Rajni Ghuntu, Atharva Veda, Charak Samhita, Amritasagar, Bhavprakash, Vridhabhagabhatt, Sushrut and Samhita contain descriptions of the same.³²⁶ The cow has also been mentioned in the ancient Tamil Veda ‘Tirukkural’, a particular verse (Kural in Tamil) states the following:

³²³ Ibid.

³²⁴ Singh, Satyapal: Pharmacotherapeutics of gomutra (Cow urine), in: The Pharma Innovation Journal (2019), Vol. 8, No. 6, pp. 707-712, p. 707.

³²⁵ Anusha, P./ Krishnaiah, N./ Ramya, P./ Sahu, R. K.: Cow Urine - Therapeutic Value, in: International Journal of Livestock Research (2016), Vol. 6, No. 11, pp. 93-99, p. 93.

³²⁶ Ibid.

*“As if a steer should graze wrapped round with tiger's skin, Is show of virtuous might when weakness lurks within.”*³²⁷

This would mean in plain English that the mere appearance of physical power by a man, who in reality does not have such power could be compared to a cow that is feeding on grass enclosed with the skin of a tiger.³²⁸ The distinguished Tamil poet and philosopher Thiruvalluvar is the author of this *magnum opus*, which has set the tune for Tamil culture.³²⁹ Tirukkural is a selection couplet of verses covering the following subject matter on ethics, politics and economics and matters of the heart. It has had significant influence on Tamil literature, writings and almost all other aspects of Tamil culture.³³⁰ In the Hindu culture of Tamil Nadu cows are tied to the poles and religious believer feed them with leaves to earn *Punya* (good merits).³³¹ Likewise, the daily prayer Hindu devotees includes the cow, praying the following:

*“Go brahmanebya subamastu nityam lokas samasto sukino bhavantu”.*³³²

The prayer gives importance to cows and Brahmins and encourages all beings to live happily. The reason for this might have been that they are considered indicators for purity and selflessness.³³³

³²⁷ Drew, W. H./ Ellis, F. W./ Lazarus, John/ Pope, G. U.: Tirukkural English Translation and Commentary: The South India Saiva Siddhantha Works Publishing Society. Madras. 1982. - https://www.projectmadurai.org/pm_etexts/pdf/pm0153.pdf, DOA: 17.01.2021, p. 34.

³²⁸ Kural.Pro: Tirukkural: Kural – 273. - <https://kural.pro/english/holy-kural-273-imposture>, DOA: 17.01.2021.

³²⁹ Britannica: Tirukkural work by Tiruvalluvar. - <https://www.britannica.com/topic/Tirukkural>, DOA: 21.01.2021.

³³⁰ Ibid.

³³¹ Swaminathan London: Tamil and Vedas, A blog exploring themes in Tamil and Vedic literature: Sacred Cow in Tamil Veda ‘Tirukkural’. 2017. - <https://tamilandvedas.com/2017/07/06/sacred-cow-in-tamil-veda-tirukkural-post-no-4057/>, DOA: 17.01.2021.

³³² Ibid.

³³³ Ibid.

When it comes to the subject matter of Indian culture it is evident that the cow has been revered and maintains a special place. To put it more precisely, the cow accompanies a sum total number of 33 Hindu Gods. Hindu believers, like the majority of BJP members, are absolutely convinced that the cow takes very little from humans and gives so much more. With the assistance of strict religious devotion and firm dedication, Indians throughout history have displayed that fact that the cow as a devotional animal has taken a prominent position in both life as well as in the economy of the Indian nation. Moreover, for devoted Hindu's wealth, religion, sex as well as salvation are accomplished in line with service to the cow. Thus, for Hindu's the black cow statue, which is tied in a temple devoted to God Shiva, has the effect of overcoming the malefic effects of planets in our natal horoscope. The animals' ankles are believed to protect devotees from evil of sudden death. Circumnavigating the Idol in the form of the cow would equate to visiting all the holy places of the Hindu religions.³³⁴ Thus, they also believe the cow to be the only animal, which emits major amount of oxygen. The devotees believe that a single spoon of pure ghee is poured on burning cow dung cakes which in turn can, as per their belief, produce one-ton oxygen, thus ghee made with cow milk is used in sacrificial fires and havens.³³⁵ In sum, they claim that there is no better way of pollution removal. The devotees are fierce believers of the excretory products being a vibrant remedy against numerous illnesses; it is also known as the water of life and Amrita (immortality liquor of the Gods) given its medicinal value.³³⁶ When it comes to the maintenance of the adequate balance of the internal body covering the Ayurveda areas of Vaata (air & space), Pitta (fire & water) and Kapha (water & earth). Having mentioned all the medicinal qualities of cow urine, it would now be apt to discuss the chemical

³³⁴ Anusha, P./ Krishnaiah, N./ Ramya, P./ Sahu, R. K.: Cow Urine - Therapeutic Value, in: International Journal of Livestock Research (2016), Vol. 6, No. 11, pp. 93-99, p. 93.

³³⁵ Ibid.

³³⁶ Ibid, p. 94.

components of Gomutra, which contains the following: water (95%), urea & Mineral salts (2.5%), Hormones and Enzymes (2.5%).³³⁷

The above-mentioned events have conveyed a confusing message about the spread of the virus. Moreover, significant questions have arisen regarding the panacea nature of Gomutra. Namely, if Gomutra is a remedy against all evil, the question remains why a renowned and biggest right-wing organisation such as the RSS has cancelled its annual meeting.³³⁸ On the other hand, the so-called Gomutra Party was mocked on Twitter with numerous satirical posts. The right-wing organisation has also experienced its fair share of ridicule and mockery.³³⁹

The majority of Hindus regard cows to be sacred animals, with a considerable amount of them attributing numerous and for other hardly believable health benefits to both the urine and faeces of the ruminant. Yet prominent advocates of these claims include members of PM Narendra Modi's Hindu nationalist BJP. Unsurprisingly, such claims have, however, been rejected by medical experts who are absolutely convinced that there is no evidence that waste products of an animal possess medicinal remedies that can cure cancer and a whole host of other serious sicknesses.³⁴⁰ It also lacks relevant evidence that it can prevent the coronavirus itself.³⁴¹

³³⁷ Ibid.

³³⁸ National Herald Web Desk: Hindu Mahasabha says 'gaumutra' can prevent coronavirus, but RSS cancels meet amid fear. 2020. - <https://www.nationalheraldindia.com/india/hindu-mahasabha-says-gaumutra-can-prevent-coronavirus-but-rss-cancels-meet-amid-fear>, DOA: 19.07.20.

³³⁹ Ibid.

³⁴⁰ Getty: Hundreds of devotees gathered to drink cow's urine on Saturday. 2020. - <https://english.alaraby.co.uk/english/news/2020/3/17/cow-urine-drinking-party-held-to-battle-india-coronavirus>, DOA: 19.07.2020.

³⁴¹ Siddiqui, Danish: Hindu group offers cow urine in a bid to ward off coronavirus. in: Reuters. 2020. - <https://www.reuters.com/article/us-health-coronavirus-india-cow-urine-pa/hindu-group-offers-cow-urine-in-a-bid-to-ward-off-coronavirus-idUSKBN2110D5>, DOA: 19.07.2020.

The BJP members further stated that they have been drinking cow urine for the duration of 21 years and have taken part in the ritual bathing in cow dung.³⁴² Equally, a leader from the North Eastern state of Assam told state lawmakers during an assembly session that both cow urine and dung could be used to treat the coronavirus. The Hindu nationalists attending the above-mentioned event argued that they never felt the want to consume English medicine or Western medicine.³⁴³ Chakrapani Maharaj, the chief of the All-India Hindu Union, posed for photographs as he placed a spoon filled with cow urine near the face of a caricature of the coronavirus. As for one cow urine vendor, who was interviewed by India's *Economic Times*, a litre of the "medicinal beverage" can cost up to Rs 500 (\$6.77), while "holy dung" sells at the same rate per kilo.³⁴⁴

India is a country of 1.3 billion and many in the Hindu-majority nation consider cows sacred, and over the course of the last few years have made several proclamations about the medical capacities of cow urine, however, such claims have been rejected by opponents as trickery. Chakrapani Maharaj, the leader of a Hindu-nationalist group stated that they had gathered to make an offering to the coronavirus to calm it. Equally, they even went further and prayed for world peace. Moreover, the group insisted that people should embrace the "well-founded practice" of drinking cow urine to fight off diseases and abstain from the practice of slaughtering and eating animal meat.³⁴⁵ Moreover, he insisted that people should embrace the time-tested practice of Gomutra consumption to ward off diseases, and resist the

³⁴² Deutsch Welle: Hindu group hosts cow urine drinking party to ward off coronavirus. 2020. - <https://www.dw.com/en/hindu-group-hosts-cow-urine-drinking-party-to-ward-off-coronavirus/a-52773262>, DOA: 19.07.2020.

³⁴³ Siddiqui, Danish: Hindu group offers cow urine in a bid to ward off coronavirus. in: Reuters. 2020. - <https://www.reuters.com/article/us-health-coronavirus-india-cow-urine-pa/hindu-group-offers-cow-urine-in-a-bid-to-ward-off-coronavirus-idUSKBN2110D5>, DOA: 19.07.2020.

³⁴⁴ Getty: Hundreds of devotees gathered to drink cow's urine on Saturday. 2020. - <https://english.alaraby.co.uk/english/news/2020/3/17/cow-urine-drinking-party-held-to-battle-india-coronavirus>, DOA: 19.07.2020.

³⁴⁵ AFP: Hindu group touts cow urine elixir for coronavirus. 2020. - <https://www.rfi.fr/en/wires/20200314-hindu-group-touts-cow-urine-elixir-coronavirus>, DOA: 18.08.2020.

urge to kill animals and consume meat. Chakrapani and his followers are of the opinion that cow urine is efficient, and a cure against all forms of bacteria that are harmful towards human beings. Other members of the PM Narendra Modi's, Hindu nationalist party, have also praised Gomutra for its medicinal potentials which in their opinion can even cure fatal deceases such as cancer.³⁴⁶ Yet, a legislator from Modi's party suggested, last week, that both the use of the urine as well as cow dung can cure the coronavirus.³⁴⁷

Another politician and fellow BJP Member of the Legislative Assembly (MLA) from India's North Eastern state of Assam has stated at the assembly that while the world failed to secure a cure for the fatal coronavirus that both Gomutra and Gobar (cow dung) could be the potential cure against this virus. This statement did indeed leave the assembly stunned.³⁴⁸ Assamese legislator and BJP MLA, Suman Haripriya, claimed the above-mentioned cow waste products to be useful in curing deadly diseases such as cancer. Haripriya further claimed that wherever Gomutra is sprayed it fundamentally purifies any area. Equally, she was convinced that something of this nature should be done with Gomutra and Gobar to be used as a cure against this virus. As such, the cow is regarded as a holy animal on the subcontinent and the use of cow urine for therapeutic purposes has had a long-standing tradition in Indian culture.³⁴⁹

It seems that Suman Haripriya and Chakrapani Maharaj were among many Hindu-nationalists who were pushing the "golden liquid" as well as Gobar as magical remedies against the coronavirus. However, these are not the only remedies, which Hindu-nationalists have in

³⁴⁶ Ibid.

³⁴⁷ Ibid.

³⁴⁸ The Economic Times: 'Gaumutra', 'gobar' may cure coronavirus: BJP MLA tells Assam assembly. 2020. - https://economictimes.indiatimes.com/news/politics-and-nation/gaumutra-gobar-may-cure-coronavirus-bjp-mla-tells-assam-assembly/articleshow/74444488.cms?utm_source=contentofinterest&utm_medium=text&utm_campaign=cppst, DOA: 19.07.2020.

³⁴⁹ Ibid.

store for those in need for an urgent and affordable solution. The coronavirus has further triggered and expanded the growth of nationalist pseudoscience under the BJP government. Both the Indian scientific community and sceptics alike have repeatedly expressed their worries for years regarding these nationalist and pseudoscientific sentiments. Ever since the Hindu-nationalist BJP government under PM Narendra Modi came to power in 2014, even the otherwise sceptical scientists have turned a blind eye and, possibly, to please the government were riding on the BJP bandwagon and issuing both untenable and at times outlandish claims. The aforementioned examples included claims about ancient India having had airplanes as well as stem-cell research.³⁵⁰ This was further promoted by public figures together with the Hindu-nationalists camp advertising this traditional tonic and promoting this ancient elixir. Recently, key politicians from various Indian states have, repeatedly, been issuing similar statements. For instance, the Chief Minister (CM) of Tripura, Biplab Kumar Deb, a small state that borders Bangladesh, said in 2018 that the internet as well as a satellite communication system could, in fact, be traced back to the ancient times. According to the CM this dates back to the period when the Sanskrit epos *Mahabharata* was written.³⁵¹ He further added that communication was possible as India's technology was both sophisticated and developed during those times. PM Modi went as far as to proclaim that plastic surgery was the probable reason behind God Ganesh's elephant head on a "mortal body". Even the bible, in the book of Ecclesiastes, states:

"[...] *there is nothing new under the sun*".³⁵²

³⁵⁰ Dore, Bhavya: Hindu Nationalists Are Pushing Magical Remedies for the Coronavirus. 2020. - <https://foreignpolicy.com/2020/03/09/hindu-nationalists-magical-remedies-coronavirus-bjp-india/>, DOA: 19.07.2020.

³⁵¹ Madrigal, Alexis C.: An Indian Politician Claimed Ancient Hindus Invented the Internet... then the Indian internet laughed at him. in: The Atlantic. 2018. - <https://www.theatlantic.com/technology/archive/2018/04/india-ancient-internet/558725/>, DOA: 15.09.2020.

³⁵² Holy Bible: New International Version, Ecclesiastes 1:9. in: Bible Gateway. - <https://www.biblegateway.com/passage/?search=Ecclesiastes%201%3A9&version=NIV>, DOA: 06.12.2020.

While this statement seems to be true in multiple cases, it is rather misplaced or mythical in the case of the “elephant God” Ganesh. Why the PM’s claims, *de facto*, lacks any form of a tangible evidence, pursuing such a case would be of an *ad absurdum* nature. Against such criticism, the populist Hindu nationalist might react by quoting President Donald Trump who amidst of 100 000 Corona death merely stated:

“*It is what it is*”³⁵³

Yet another BJP CM asserting that cows exhaled oxygen, and union ministers who said that both can be used when treating cancer.³⁵⁴ Amidst all these nationalist sentiments there have been intense struggles over endeavours to issue licenses for practitioners working in the field of traditional Indian medicine.³⁵⁵

The Indian government has reorganised a number of prior existing departments in their attempt to construct the Ministry of AYUSH (this acronym represents a combination of several traditional and pseudoscientific schools of medicine), in order to cover such practices.³⁵⁶ Yet, the coronavirus has further worsened the stance of the Ministry of AYUSH which issued a rather a dubious advisory in January 2020, soon after the spread of the coronavirus outside the Republic of China increased significantly. The advisory with the title “Homoeopathy for Prevention of Corona virus Infections: Unani Medicines useful in symptomatic management of Corona Virus infection” was issued with an aim to propose traditional remedies to

³⁵³ Shabad, Rebecca: It is what it is: Trump in interview on COVID-19 death toll in U.S.: The president told Axios in a recent interview that the "horrible plague" is under control. 2020. - <https://www.nbcnews.com/politics/donald-trump/it-what-it-trump-interview-covid-19-death-toll-un1235734>, DOA: 05.12.2020.

³⁵⁴ Dore, Bhavya: Hindu Nationalists Are Pushing Magical Remedies for the Coronavirus. 2020. - <https://foreignpolicy.com/2020/03/09/hindu-nationalists-magical-remedies-coronavirus-bjp-india/>, DOA: 19.07.2020.

³⁵⁵ Ibid.

³⁵⁶ Ibid.

treat the virus.³⁵⁷ This was then followed by a second advisory opinion with regard to homeopathic medicine claiming that the medication “arsenicum album 30” could be used prophylactically as a deterrent.³⁵⁸ Homeopathy is a pseudoscience which is based on a Western-invention that doles out minute dosages of treatments, which in turn has gained immense popularity in India. However, there is no therapeutic use for such a treatment. In a country like India where, *inter alia*, faith in supernatural healing, faith healers (Swami's, Siddhas and Sadhus) prevail, false and misinformation has been prevalent, this situation further worsened since the formation of the Ministry of AYUSH, which has officially been spreading misinformation on the subject matter of health. The statements issued by the Ministry of AYUSH and by the health ministry are not necessarily corresponding. According to, Anant Bhan, a researcher in bioethics and global health, the random claims around treatment or prevention of the coronavirus through cow dung or yoga is unreliable, regardless whether such claims originate from the Indian government or other sources.³⁵⁹ As for the misinformation spread by AYUSH which was, *inter alia*, discovered and published by *Alt News*, a fact-checking site, which has run pieces debunking such claims.³⁶⁰

Both misinformation and disinformation can easily be understood as India, similar to other developing countries has a low literacy rate and high Internet connectivity. The aforementioned mixture of poor information could have fatal consequences, particularly, when it comes to conflict situations or to the Covid-19 pandemic. Thus, any careless or reckless statement could have potential negative consequences including panic spreading and fear mongering. When it comes to the

³⁵⁷ Ibid.

³⁵⁸ Ibid.

³⁵⁹ Deutsche Welle: Hindu group hosts cow urine drinking party to ward off coronavirus. 2020. - <https://www.dw.com/en/hindu-group-hosts-cow-urine-drinking-party-to-ward-off-coronavirus/a-52773262>, DOA. 19.01.2021.

³⁶⁰ Dore, Bhavya: Hindu Nationalists Are Pushing Magical Remedies for the Coronavirus. 2020. - <https://foreignpolicy.com/2020/03/09/hindu-nationalists-magical-remedies-coronavirus-bjp-india/>, DOA: 19.07.2020.

subject matter of Indian pseudoscience, Hindu-nationalists fuel a false sense of national pride, which tends to put traditional Indian medicinal remedies above Western medicine.³⁶¹ Despite all the religiously enshrined national pride, India remains a “secular” country as per its constitution and the nation’s first PM Jawaharlal Nehru, was a visionary when it comes to India’s regard for science and scientific accomplishments, thus he put an emphasis on the nation’s educational and research institutes.³⁶² Following the visionary dream of its founding father with regard to science, New Delhi has realised the first PM’s ambitions that the subcontinent has experienced the realisation of its ambitious space missions and the growth of a globally renown tech industry since the 1990s. The nation’s space missions have further fuelled New Delhi’s ambition to join the ranks of a global superpower.³⁶³ Ever since the BJP and the Hindu-nationalist right have gained strength in number, over decades, religion, pseudoscience and science have merged into the nationalist’s ambition to relive the glories of the past. BJP’s return to power in 2019, led to the government taking ownership over modern innovations and discoveries as essentially Indian and regarding it as the legacy of the Hindus’ valley civilisation.³⁶⁴ BJP’s Hindu nationalist tale appears to be a mixture of science, myth and pseudoscience together with a political message.³⁶⁵ The national party reverts to its roots in the ancient Indian civilisation where philosophy, technology and science were prospering. The nationalists are hoping to restore New Delhi’s greatness by connecting it to the nation’s past accomplishments. Banu Subramaniam calls this notion a “scientized religion” as well as a “religionized science”.³⁶⁶ This particular example, arguably, creates a vision of India as an archaic civilisation on the

³⁶¹ Ibid.

³⁶² Ibid.

³⁶³ Ibid.

³⁶⁴ Ibid.

³⁶⁵ Perur, Srinath: Science and rising nationalism in India: Srinath Perur on a study of how a political movement is co-opting science, myth and pseudoscience. in: Nature (2019), Vol. 571, pp. 476-477, p. 476.

³⁶⁶ Ibid.

verge of entering modernity. While India's approach is hardly unique, as the example right across the border in Pakistan proves where law making is undertaken subject to a specific interpretation of Islamic belief.

The nationalists are absolutely convinced that ancient India had a wealth of scientific advancements. These extend from Mathematics to metallurgy to astronomy. For instance, *Sushruta Samhita* is a Sanskrit text that can be traced back to the first millennium BC, which analyses techniques for nose reconstruction and skin grafts.³⁶⁷ The previously mentioned scientific and other achievements have been side-lined through the rule of the British Empire. The Hindu nationalist administration has engaged in a historical spin or in other words, a deliberate distortion of facts. Yet another proclamation of the Indian PM was that yoga could assist with tackling one of the hot topics of the 21st century, namely climate change.

Moreover, a similar innovation that has been claimed by the nationalist is contemporary revival of the *vaastu shastra* concept (literally translated it means the science of architecture). While *vaastu shastra* is an Indian tradition similar to that of Chinese *feng shui* ("an ancient Chinse belief that way [a] house is built or the way that [one] arranges objects that affect [one's] success, health and happiness")³⁶⁸, its origins date back to the holy Hindu scriptures of the Vedas. In this regard it is imperative to note that the Vedas have surpassed more than three millennia since the conception.³⁶⁹ This faith-based system is convinced that the entrance as well as the sitting rooms ought to be built in a particular way to bequeath well-being and harmony. This firm Hindu belief led to the fact that architects increasingly feel pressured to offer so called *vaastu-compliant* buildings. It has become standard

³⁶⁷ Ibid.

³⁶⁸ Cambridge Dictionary: Meaning of feng shui – Learner's Dictionary. - <https://dictionary.cambridge.org/dictionary/learner-english/feng-shui>, DOA: 29.11.20.

³⁶⁹ Perur, Srinath: Science and rising nationalism in India: Srinath Perur on a study of how a political movement is co-opting science, myth and pseudoscience. in: Nature (2019), Vol. 571, pp. 476-477, p. 476.

practice to modify pre-existing buildings to make them *vaastu-compliant*.³⁷⁰ This trend has existed for quite some time now, particularly in large cosmopolitan cities such as Bengaluru and Mumbai. Numerous elected representatives have been increasingly following this trend. For instance, the Telangana CM Chandrasekhar Rao, who was elected in 2015, went as far as to employ a *vaastu* consultant in the posting of a governmental advisor on architecture.³⁷¹

Yet the combination of science and religion can also lead to a somewhat positive outcome. In 2005, New Delhi launched the Sethusamudram Shipping Canal Project with the goal to dig a passageway through limestone between Sri Lanka and India. Both environmental scientists and politicians alike have been protesting against destruction of this delicate ecosystem and seem to have joined hands with the Hindu nationalist leader. For the Hindu nationalist leader considers this particular site as holy, as this location features in ancient Hindu mythology which generated Ramayana, an epic poem, according to which a bridge was constructed by the Hindu deity Rama with the help of his army of monkeys. The contested canal project eventually went as far as to involve the Indian Parliament, the Archaeological Survey and the Supreme Court and consequently the previously mentioned project was halted in 2009. These are some incidences where scientific studies have been used both in a positive and negative manner.³⁷²

The BJP has been subject to heavy criticism by the Congress Party's MP, former Indian diplomat at the UN and writer, Dr. Shashi Tharoor. Dr. Tharoor condemned New Delhi's fight against common sense and reasoning. He has been worried that the all-encompassing conformism attitude of the BJP government, with its desire to transform the secular

³⁷⁰ Ibid.

³⁷¹ Ibid.

³⁷² Ibid, p. 477.

Indian nation into a “traditional” Hindu state. Arguably, BJP’s trinity agenda (hindu, hindi and hindustan) has gained a fourth component, namely weakening the position of the role of science in India.³⁷³ As science is based on critical thinking and the constant questioning of existing surroundings and circumstances. Such an approach might not necessarily suit the New Delhi agenda of reviving and awakening India’s national pride as well as trusting in its ancient traditional medicine. One could compare BJP’s Hindu-nationalist sceptism towards scientific accomplishment, medical and otherwise, originating from the West and its deliberate attempt to pursue the narrative of the allegedly glorious scientific achievements of ancient India could be compared to penicillin resisting the syphilis of the, more recent, Indian body politics.

The BJP government has, over the years, been accused of working hard to actively eliminate any form of dissent or criticism against the government and its policy as “anti-Indian”, such as if one was to challenge, dissent or criticise traditional Indian medicine promoted by AYUSH. Equally, if one was to challenge the medicinal nature of Gomutra as a scientifically approved medical remedy to cure Covid-19, critics could fall prey to the danger of being branded “anti-Indian”. In other words, BJP seems to have internalised the mantra: “if they are not for us, they inevitably ought to be against us”.

The aforementioned political gains of the religious far-right also meant that *inter alia*, gurus and godmen and religious healers have not only gained fortune but also fame. In the same vein, sound rationalists and genuine left-leaning political activists opposing this right-wing ideology have found themselves under considerable attack. Among the rationalists are the academic and scientific elites of the country who

³⁷³ Dore, Bhavya: Hindu Nationalists Are Pushing Magical Remedies for the Coronavirus. 2020. - <https://foreignpolicy.com/2020/03/09/hindu-nationalists-magical-remedies-coronavirus-bjp-india/>, DOA: 19.07.2020.

have been gradually vocalising their discontent against the Modi government's attack on universities and other research institutions.³⁷⁴ In spite of all these challenges, the above stated outrageous pseudoscientific statements uttered by religious godmen and politicians have not taken hold. The claims issued regarding the coronavirus are putting yet more fuel on the fire in a battle for rationalism. The recent developments are even more worrisome as the already low scientific funds are further dwindling as they are being diverted to the pseudoscientific research on Gomutra and Hindu scriptures.³⁷⁵

Having discussed the subject matter of Gomutra, as a potential global remedy against the Covid-19 pandemic, it would now be advisable to take look at the healing and medicinal properties of the Gomutra. In doing so it is pertinent to establish that for the Hindu-nationalists and the religious-inspired supportive community, Gomutra also has preventive health benefits, for instance, it could also serve as an immunomodulatory. The qualities of Gomutra as an immunomodulatory shall be discussed in the following sub-section. The Indian Sanskrit text of the Sushrita Samhita', which covers the most important ancient practices in the field of medicine and surgery, as well as 'Ashtanga Sangraha', an ancient text written by an Indian physician around 600 A.D, a groundbreaking literal witness of Indian medical tradition.³⁷⁶ Both ancient medical writings were praising cow urine to be the most effective substance of animal origin with immeasurable therapeutic capacities, beneficial for human life. As for In Ayurveda cow urine is highly recommended for generic improvements in human health.³⁷⁷ Having said that, one needs to ensure that in order to utilise the therapeutic values of this cow waste

³⁷⁴ Ibid.

³⁷⁵ Ibid.

³⁷⁶ Ganguly, Subha/ Prasad, Arun: Role of plant extracts and cow urine distillate as immunomodulatory: A review, in: Journal of Medicinal Plants Research (2011), Vol. 5, No. 4, pp. 649-651, p. 650.

³⁷⁷ Ibid.

product, it is of crucial importance that the urine ought to be properly distilled.³⁷⁸ Researchers at the Central Institute of Medicinal and Aromatic Plants in Lucknow, Uttar Pradesh, *prima facie*, seem to have been able to identify a tiny portion of cow urine distillate as an organic or bio-enhancer of ordinarily used antibiotics and anti-cancer drugs. It is however, crucial to note that bio-enhancers as such merely promote bioactivity and lack the ability of drug activity of their own. In other terms, distilled cow urine is used for uptake of drugs in combination therapy.³⁷⁹ Other claims regarding the benefits of the cow urine include the fact that it serves to enhance the antimicrobial effect of an antibiotic. Such an antibiotic would include antifungal agents such as: azoles, clotrimazole, mystatin, or amphotericin.³⁸⁰ There are also other assertions that Gomutra has been used as bio-enhancing antibiotics, aimed at tuberculosis, such as for instance, isoniazid, pyrazinamide as well as ethambutal.³⁸¹ A bioactive fraction of distilled cow urine has also been professed as a bio-enhancer of an anti-infective, anti-cancer agents and nutrients. The bio enhancing qualities of this animal waste product was also known to be a bio-enhancing antibiotic, which target tuberculosis, and claims were even issued to the extent of there being anti-cancer agents from the group consisting of Paclitaxol (Taxol).³⁸² Yet, other sources of redistilled cow urine distillate have been claimed for protecting and/or repairing DNA from oxidative damages. Redistilled cow urine has been proclaimed to have been tested on a few cancer patients.³⁸³

When it comes to anti-cancer therapy, Gomutra or the nectar of the God as referred to in the Vedas, sacred Hindu writing, considered be the one of the oldest books found on the Asian continent. As

³⁷⁸ Ibid.

³⁷⁹ Ibid.

³⁸⁰ Acharya, Balkrishana/ Ananthanarayana, Sharma/ Haridas, Shri/ Kumar, Aman/ Paran, Gowda G.: Can cow urine distillate be used for human health care? If so, what would be the pharmaceutical manufacturing standards?, in: Indian Journal of Ancient Medicine and Yoga (2012), Vol. 5, No. 4, pp. 177- 182, p. 177.

³⁸¹ Ibid.

³⁸² Ibid.

³⁸³ Ibid, p. 178.

mentioned before, cow urine possesses properties which are of an anti-cancerous nature. More precisely, distilled cow urine seems to protect DNA and repairs it swiftly, as observed after damage.³⁸⁴ Allegedly, with regular use of cow urine one can retain the charm of youth, as it prevents free radicals formation. Moreover, cow urine is apparently capable of repairing DNA, which is damaged, thus it can be quite efficient when it comes to cancer prevention and therapy: equally, it is capable of reducing the spread of malignant cancers and is applied to assist with fighting tumours.³⁸⁵ Apart from possessing the capability to reduce the spread of cancer, cow urine also retains antiviral activity; it contains antiviral capacities which have valuable benefits for AIDS patients.³⁸⁶

It would now be a good opportunity to turn our focus onto the use of distilled cow urine, made in India, and consider its effectiveness when it comes to the subject matter of human health care. The American electronic medical research database “MEDLINE” has been looking into the possibilities for the pharmaceutical use of Indian cow urine.³⁸⁷

When it comes to the issue of traditional Indian Ayurveda medicine, raw cow urine is associated with the medical plant named *genus aconitum*, which has also been noted to enhance the effectiveness of cancer therapy: through enhancement of immunocompetence. It has also been known to improve general health, prevent free radical formation, reducing apoptosis in lymphocytes, repairing DNA and acting as an anti-ageing factor.³⁸⁸

³⁸⁴ Anusha, P./ Krishnaiah, N./ Ramya, P./ Sahu, R. K.: Cow Urine - Therapeutic Value, in: International Journal of Livestock Research (2016), Vol. 6, No. 11, pp. 93-99, p. 95.

³⁸⁵ Ibid.

³⁸⁶ Ibid.

³⁸⁷ Acharya, Balkrishna/ Ananthanarayana, Sharma/ Haridas, Shri/ Kumar, Aman/ Paran, Gowda G.: Can cow urine distillate be used for human health care? If so, what would be the pharmaceutical manufacturing standards?, in: Indian Journal of Ancient Medicine and Yoga (2012), Vol. 5, No. 4, pp. 177- 182, pp. 177-178.

³⁸⁸ Ibid, p. 178.

Moreover, a number of Ayurvedic literal classics mentioned the properties and a wide range of therapeutic applications for cow urine. For instance, Charak Samhita, a compendium of Charaka is a Sanskrit text on Ayurveda, which noticed Gomutra to be a somewhat sweet substance, and declared it useful when treating worm infestation (Krim), itching (Kandu), and several types of disorders of the abdomen and for the management of dermatological disorders (Kushtha).³⁸⁹ Equally, the old writing of Bhaisajya Ratnavali, compiling ancient Ayurveda Formulation, also praise the qualities of cow urine to possess medicinal remedies, which were held to medicate various forms of Kushtha.³⁹⁰

Voices in the Hindu-nationalist community have emerged, claiming that Gomutra can serve as a remedy against diabetes. The anti-diabetic effect of Gomutra was established by administration of streptozotocin. *Prime facie*, cow urine in its distilled form, presented a statistically significant reduction of the elevated blood glucose, serum cholesterol and serum triglycerides levels when compared with other forms of diabetic control. The most probable explanation for this is that it increases the glucose transport across cell membrane, which in turn increases the peripheral glucose utilization.³⁹¹ It also enhances the sensitivity of the insulin receptor, decreases insulin resistance, and decreases the insulin absorption from intestine. The innumerable herbal metabolites are present in cow urine, which produces anti hyperglycemic effect.³⁹²

The anti-diabetic effect of “cow urine preparation” has been studied in rats for the duration of twenty-one days; during the aforesaid period treatment was given once a day. Scientists used the urine of a 2-year-old virgin Gujarati Indian cow (“Geer” breed) in a study when analysing

³⁸⁹ Singh, Satyapal: Pharmacotherapeutics of gomutra (Cow urine), in: The Pharma Innovation Journal (2019), Vol.8, No. 6, pp. 707-712, p. 708.

³⁹⁰ Ibid.

³⁹¹ Anusha, P./ Krishnaiah, N./ Ramya, P./ Sahu, R. K.: Cow Urine - Therapeutic Value, in: International Journal of Livestock Research (2016), Vol. 6, No. 11, pp. 93-99, p. 96.

³⁹² Ibid.

the anti-diabetic effect. As part of this study, diabetes was introduced in rats through the injection of 150 mg/kg of alloxan monohydrate intraperitoneally in 0.9% w/v NaCl.³⁹³ The blood sugar level was measured after the period of 72 hours. Compared with standard insulin the cow urine alternative has led to substantial reduction of the rats' blood sugar level.³⁹⁴ Furthermore, in an experiment diabetic animals treated with cow urine also showed a significant increase in High-density lipoprotein (HDL) cholesterol levels and a gain in body weight when compared with other diabetic control agents.³⁹⁵ Given the fact that diabetes is among the number one illnesses in India, the abovementioned study, *prime facie*, plays the gullible and innocent Indian public into the arms of the Hindu nationalist. Apart from the supporters of the Hindu-nationalist, the other targets are, in particular, the poor and, in many cases, illiterate masses of the Indian lower class. Moreover, the Covid-19 related lockdown, which was initially ordered by the Indian government to last for the duration of 21 days, ended up lasting six months. Thus, with literally no social security system, insufficient health care facilities and even lack the basic form of pecuniary assets, the vast majority of the vulnerable 1.3 billion Indians will be tempted to either turn to the above mentioned "quasi-medical remedies" or to the ancient Ayurvedic medical praised and heavily promoted by the Indian government.

When it comes to the issue of purification and detoxification, Gomutra has the qualities if an antitoxin. The waste product itself plays a major role when it comes to the detoxification as well as purification of several pharmaceuticals.³⁹⁶ Moreover, it serves to purify the blood from all kind of impurities and thus increases a person's life span.³⁹⁷

³⁹³ Singh, Satyapal: Pharmacotherapeutics of gomutra (Cow urine), in: The Pharma Innovation Journal (2019), Vol.8, No. 6, pp. 707-712, p. 709.

³⁹⁴ Ibid.

³⁹⁵ Acharya, Balkrishna/ Ananthanarayana, Sharma/ Haridas, Shri/ Kumar, Aman/ Paran, Gowda G.: Can cow urine distillate be used for human health care? If so, what would be the pharmaceutical manufacturing standards?, in: Indian Journal of Ancient Medicine and Yoga (2012), Vol. 5, No. 4, pp. 177- 182, p. 178.

³⁹⁶ Anusha, P./ Krishnaiah, N./ Ramya, P./ Sahu, R. K.: Cow Urine - Therapeutic Value, in:

During the ongoing global pandemic in 2020, disinfectants were rare and heard to come by. Given the ineptitude of the Indian government to provide a vast populous country with adequate disinfectants, a cost-effective alternative in the form of cow urine-based disinfectant could potentially come in handy. Satyapal Singh finds cow urine to be a disinfectant that is more effective and antiseptic with an estimated shelf-life guarantee of five years.³⁹⁸ Cow urine has traditionally been used as a disinfectant and antiseptic in rural India. Equally, it finds good use when it comes to being an efficient antiseptic for wounds as well as skin diseases. Moreover, it is interesting to note that numerous Indian Ayurvedic- and general practitioners are using cow urine to treat their patients on its own or in combination with other medical drugs.³⁹⁹

Having discussed the qualities of cow urine as a bio-enhancer we shall now look at the possibilities of patenting Gomutra and whether the claims of the Hindu-nationalists, the BJP's local as well as national politicians, godmen and gurus have actually stood the test of science. Interestingly enough, distilled Indian cow urine has made the cut and has been patented in the United States under the US Patent No. 6,410,059.⁴⁰⁰ More precisely, the patent was issued for Rifampicin is a front-line anti-tubercular drug subscribed to combat tuberculosis.⁴⁰¹ Scientist likewise found that a distillate segment of cow urine enhanced the effectiveness of 'Taxol' (paclitaxel) against MCF-7 also known as a human breast cancer cell (US Patent No. 6,410,059).⁴⁰²

International Journal of Livestock Research (2016), Vol. 6, No. 11, pp. 93-99, p. 94.

³⁹⁷ Singh, Satyapal: Pharmacotherapeutics of gomutra (Cow urine), in: The Pharma Innovation Journal (2019), Vol.8, No. 6, pp. 707-712, p. 710.

³⁹⁸ Ibid.

³⁹⁹ Ibid, p. 650.

⁴⁰⁰ Ibid, p. 711.

⁴⁰¹ Ganguly, Subha/ Prasad, Arun: Role of plant extracts and cow urine distillate as immunomodulatory: A review, in: Journal of Medicinal Plants Research (2011), Vol. 5, No. 4, pp. 649-651, p. 650.

⁴⁰² Ibid.

Despite obtaining successful patents for the, *inter alia*, above mentioned medicines, utmost care and determination should be taken when it comes to both the patents granted as well as to the published results involving any form of therapy using cow urine distilled or otherwise. One must clearly distinguish the patented medicine from the claims uttered by the traditional or, to use a sturdier term, quack medicine, which is based on Gomutra.⁴⁰³

Having looked at the patentability of cow urine, it would now be advisable to consider what pharmaceutical manufacturing standards are employed. As with all scientific processes religious faith has little to do when it comes to the subject matter of the production of pharmaceuticals. Gomutra has definitely started to make inroads in use as a complementary medicine to mainstream therapies in the field of human health care.⁴⁰⁴

Having mentioned all the *prima facie* health benefits, we shall now consider the potential side effects from the consumption of the waste product of the Indian cow as part of cow urine treatment. Among the many side effects are fever, diarrhea, pain, itching, fatigue, soreness of the shoulder. These side effects may last from 3-7 days but in worst cases, they may last between 1-6 months.⁴⁰⁵ Based on the previously stated adverse effects it seems hardly surprising that some patients tend to abstain from these treatments, yet others seem to disregard such a therapy due to the societal stigma attached to such therapy. As per Sahu *et al.* the persistent patient suffering from chronic illnesses who is willing to adopt cow urine therapy both cheerfully and with a

⁴⁰³ Ibid.

⁴⁰⁴ Acharya, Balkrishna/ Ananthanarayana, Sharma/ Haridas, Shri/ Kumar, Aman/ Paran, Gowda G.: Can cow urine distillate be used for human health care? If so, what would be the pharmaceutical manufacturing standards?, in: Indian Journal of Ancient Medicine and Yoga (2012), Vol. 5, No. 4, pp. 177- 182, p. 178.

⁴⁰⁵ Anusha, P./ Krishnaiah, N./ Ramya, P./ Sahu, R. K.: Cow Urine - Therapeutic Value, in: International Journal of Livestock Research (2016), Vol. 6, No. 11, pp. 93-99, p. 99.

“can do attitude” would allegedly benefit both mentally and physically within 10 to 15 days.⁴⁰⁶

In India, Gomutra seem to have claimed infamous prominence, particularly, among the religious right. It has been praised to be an organic and cost-effective medicine without adverse effects.⁴⁰⁷ Scientists such as Satyapal Singh are promoting the therapeutic use of cow urine and are suggesting clinical practitioners and researchers from around the globe to give cow urine as a potent therapeutic remedy serious consideration.⁴⁰⁸ In other words, he is asking the international scientific community to give “cow urine a chance”. He further urges for the aforementioned subject matter to be promoted at seminars, workshops as well as conferences, by publishing more literature in this area. Equally, social media and online publications should also be utilised when publicising the subject matter. Despite understandable doubts from a common-sense point of view, further research ought to be undertaken in this area. In sum, Gomutra seems to have been used for centuries to cure numerous medical disorders and for the maintenance of sound health.

The Hindu nationalist seems to believe that the consumption of meat has been a root cause for emergence of the Corona virus and consequently they have asked for forgiveness for those in India who have eaten meat. For these Hindu nationals Gomutra is the adequate cure against the Covid-19. Hence, the global community should be encouraged to import cow urine from India as a means for curing the world community. By default, such an approach could potentially be beneficial for the Indian economy. The Corona parties that have been organised by the Hindu right encouraged the consumption of cow urine and cow dung both waste products of the cow. During these Corona parties now social distancing guidelines have not been

⁴⁰⁶ Ibid.

⁴⁰⁷ Singh, Satyapal: Pharmacotherapeutics of gomutra (Cow urine), in: The Pharma Innovation Journal (2019), Vol.8, No. 6, pp. 707-712, p. 711.

⁴⁰⁸ Ibid.

followed. The consumption of Gomutra by the religious right is hardly a remedy that is of *ultima ratione* and as a result, it seems to be a matter of *ad absurdum* to consume fresh cow urine. The scientific evidence that would confirm the curing capacity of Gomutra against Covid-19 are close to zero at the time of writing.

The EU could potentially use the “semi-scientific” approach to medicine by the Hindu nationalist BJP administration to cast doubts as to the quality, as well as the credibility, of the Indian medicine and by inference of its pharmaceutical industry. From both the BJP’s and Hindu nationalist’s standpoint the position of Gomutra seems to follow the rationale to rally the Indian population behind the Hindu nationalist agenda, particularly, when it comes to combatting Covid-19.

3. The Seizure of Essential Generic Medicines from India by EU Border Agencies

This chapter will examine the landmark issue of the seizure of essential generic medicines from India by the EU border agencies. It will consider the impact of European Council Regulation 1383/2003 has on the access to essential generic medicines. It will also examine the concept of manufacturing fiction, which has been applied by the Dutch court. Likewise, it aims to explore the consequences for developing countries with regard to access to essential generic medicines. Finally, it will also consider whether the EU's implementation of Council Regulation 1383/2003 has created a barrier to the trade in generic medicines.

Before commencing the analysis on the seizure of essential generic medicines, it would be vital to define the terms IPRs and patent. IPRs describe the legal rights that originate from intellectual activity in the following sectors: scientific, industrial, artistic and literary fields. Thus, IPRs can be divided into the following branches: Industrial property (patents), industrial designs, trademarks, copyright and geographical indications.⁴⁰⁹ The World Intellectual Property Organization (WIPO) defines patents as:

[...] an exclusive right granted for an invention, which is a product or a process that provides, in general, a new way of doing something, or offers a new technical solution to a problem. To get a patent, technical information about the invention must be disclosed to the public in a patent application.”⁴¹⁰

⁴⁰⁹ FXB Center Harvard University: Health and Human Rights Resource Guide: How is Access to Medicines a Human Rights Issue? 2019. - <https://www.hhrguide.org/2017/06/09/access-to-medicines-and-human-rights/>, DOA: 02.12.2019.

⁴¹⁰ World Intellectual Property Organization: Patents: What is a patent? - <https://www.wipo.int/patents/en/>, DOA: 01.01.2021.

Patents are a form of IPRs awarded to an inventor for the creation of an invention that fulfils the following characteristics: something that can be classed as novelty, non-obvious to a person who is knowledgeable in the field, and useful.⁴¹¹ They permit pharmaceutical companies to control manufacture, distribution and importation. Therefore, the patent owner is in position to set any given price for the product in question. This situation would eventually lead to market monopoly in favour of the patent owner, which in turn results, in the majority of cases, to both excessive prices and impeded access to affordable medications.⁴¹²

Multinational firms from the pharmaceutical industry tend to utilise patents to prevent competition. Through the retention of monopoly pricing on medicines, multinationals make it hard to purchase such medicines for those lacking health insurance, who are thus forced to pay out of pocket for essential medications. Traditionally the purpose of the patent system has been to provide incentives for innovation by giving the patent holder absolute monopoly over the use of the patented technology for a limited period, usually 20 years.⁴¹³ This is their reward for disclosing valuable knowledge to society. Yet the societal gain stemming from this type of protection ought to be balanced against inadequacies resulting from market monopoly and its susceptibility for potential abuse. Thus, it is crucial to strike the optimum balance between a given innovation and access to the same. While this subject matter is complex in nature, it is eventually prejudiced by the socioeconomic development of any given country in

⁴¹¹ FXB Center Harvard University: Health and Human Rights Resource Guide: How is Access to Medicines a Human Rights Issue? 2019. - <https://www.hhrguide.org/2017/06/09/access-to-medicines-and-human-rights/>, DOA: 02.12.2019.

⁴¹² The European Consumer Organisation: Position on Access to Medicines. in: BEUC. Brussels. 2015. - http://www.beuc.eu/publications/beuc-x-2015-104_access_to_medicines.pdf, DOA: 15.05.2018.

⁴¹³ World Health Organisation: Health Topics: Essential Medicines. 2018. - http://www.who.int/topics/essential_medicines/en/, DOA: 27.07.2018.

which patent rights are enjoyed.⁴¹⁴ Vulnerability when it comes to potential abuse of the patent regime, especially with regard to medication for the treatment of serious medical conditions, for the likes of hepatitis C, cancer or HIV could be a matter of life and death.⁴¹⁵

In December 2008, customs authorities from the Netherlands seized 500 kilograms of the generic drug “Losartan Potassium” (from here on referred to as Losartan), a medication used for the treatment of hypertension, suspected of patent infringement.⁴¹⁶ Hypertension is one of the main causes of death in Brazil, around ten million people in this nation are affected by this disease.⁴¹⁷ Due to this particular seizure by the Dutch customs exercising EU jurisdiction, they have conceivably barred 300,000 Brazilians diagnosed with hypertension from receiving essential drugs.⁴¹⁸ The cargo of generic medicines had been transacted between the Indian manufacturer Dr. Reddy's Laboratories Ltd. and the Brazilian Grupo EMS Sigma Pharma. In this context, the WHO defines generic medicines as:

*“a pharmaceutical product, usually intended to be interchangeable with an innovator product, that is manufactured without a licence from the innovator company and marketed after the expiry date of the patent or other exclusive rights”.*⁴¹⁹

⁴¹⁴ The European Consumer Organisation: Position on Access to Medicines. in: BEUC. Brussels. 2015. - http://www.beuc.eu/publications/beuc-x-2015-104_access_to_medicines.pdf, DOA: 15.05.2018.

⁴¹⁵ Ibid.

⁴¹⁶ Regulation 1383/2003 concerning customs action against goods suspected of infringing certain intellectual property rights and the measures to be taken against goods found to have infringed such rights [2003] OJ L196/7, para. 5.

⁴¹⁷ Shaver, Lea/ Rosina, Mônica Steffen Guise: Why are Generic Drugs Being Held up in Transit? Intellectual Property Rights, International Trade, and the Right to Health in Brazil and Beyond, in: Journal of Law, Medicine and Ethics (2012), Vol. 40, No: 2, p. 200.

⁴¹⁸ Ibid.

⁴¹⁹ Ayilyath, Manoranjan: EU Border Measure Regulation: A Threat to Access to Public Health in Developing Countries and Least Developed Countries, in: European Intellectual Property Review (2013), Vol. 35, No. 4, pp. 212-219, p. 218.

The shipment was docked in Rotterdam while in transit from India to Brazil and was held for the duration of 36 days before returning it to India.⁴²⁰ It is worth noting that Losartan has also been listed in the WHO's Model List of Essential Medicines.⁴²¹⁴²² The WHO defines essential medicines as:

[...] *“those satisfy the priority health care needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness. Essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford”.*⁴²³

Losartan had neither been patented in India nor in Brazil, meaning that the medicines are patented neither in the country of export nor in the country of destination (importation).⁴²⁴ Likewise, the drugs were not subject to compulsory licencing. Equally, there had been no indication that the generic medicines at issue were of substandard quality.⁴²⁵ However, in the EU it was patented under the name “Cozaar” with El DuPont Nemours & Co. holding the patent and Merck Sharp & Dohme owning the marketing rights.⁴²⁶ The disputed measures of the Dutch Authorities *prima facie* had been applied due to an administrative

⁴²⁰ Kumar, Shashank P.: Border Enforcement of IP Rights Against in Transit Generic Pharmaceuticals: An Analysis of Character and Consistency, in: European Intellectual Property Review (2010), Vol. 32, Is. 10, pp. 506-519, p. 506.

⁴²¹ The World Health Organization: World Health Organization Model List of Essential Medicines: 21st List. 2019. - <https://apps.who.int/iris/bitstream/handle/10665/325771/WHO-MVP-EMP-IAU-2019.06-eng.pdf>, DOA: 01.01.2021.

⁴²² The subject matter of essential medicines will be discussed in chapter 4 in more detail.

⁴²³ World Health Organisation: Health Topics: Essential Medicines. 2018. - http://www.who.int/topics/essential_medicines/en/, DOA: 27.07.2018.

⁴²⁴ Mercurio, Bryan: "Seizing" pharmaceuticals in transit: Analysing the WTO dispute that wasn't, in: International and Comparative Law Quarterly (2012), Vol. 61, Is. 2, pp. 389-426, p. 390.

⁴²⁵ Ibid.

⁴²⁶ Jishnu, Latha: Choking India's Generic Exports, in: Business Standard. 2009. - <http://www.business-standard.com/india/news/latha-jishnu-choking-indias-genericsexports/01/41/347369/>, DOA: 19.12.2019.

request lodged by the European patentee of “Cozaar”.⁴²⁷ As per the EU the Dutch measure was warranted as a response to the violation of patent rights pursuant to rules set out in the EC Council Regulation 1383/03⁴²⁸, and according to the Dutch Patent Act of 1995.⁴²⁹

Yet in the Losartan incident in 2008 both the Dutch and EU authorities conceded their “error” in applying the border procedures to in transit generic pharmaceuticals and promised to sort out the issue, however, they failed to take the relevant steps in order to solve the issue.⁴³⁰ In this context, it is worth noting that Brasilia had been one of the leaders when it comes to the use of generic medicines to combat health emergencies.⁴³¹ New Delhi in turn is a major global player when it comes to the manufacturing and export of generic drugs.⁴³² Ever since India has emerged as a global leader in the development and export of generic medicines, it has led to considerable competition in the international market in particular for the EU’s pharmaceutical industry.⁴³³ The seizure of goods in transit by the EU were subject to stark criticism on the international stage.⁴³⁴

The detention of the Losartan medication by the border agency of the Netherlands was hardly an isolated incident; similar incidents have

⁴²⁷ International Centre for Trade and Sustainable Development: "Brazil Slams EU for seizure of Generic Drugs", in: Bridges Weekly Trade News Digest (2009), Vol. 13, No. 9. - <https://ictsd.iisd.org/sites/default/files/review/bridgesweekly/bridgesweekly13-9.pdf>, DOA: 18.01.2021.

⁴²⁸ Regulation 1383/2003 concerning customs action against goods suspected of infringing certain intellectual property rights and the measures to be taken against goods found to have infringed such rights [2003] OJ L196/7.

⁴²⁹ Kumar, Shashank P.: Border Enforcement of IP Rights Against in Transit Generic Pharmaceuticals: An Analysis of Character and Consistency, in: European Intellectual Property Review (2010), Vol. 32, Is. 10, pp. 506-519, p. 506.

⁴³⁰ Pandeya, Radhieka: Dutch minister admits to flaw in EC rule. in: Mint. 2009. - <http://www.livemint.com/2009/02/10221134/Dutch-minister-admits-to-flaw.html?d=1>, DOA: 27.08.2013.

⁴³¹ Erickson, Justin: Call for Reform: Analyzing Trips Through European Seizure of Generic Medication. in: Minnesota Journal of International Law (2012), pp. 382- 413, p. 389.

⁴³² Ibid.

⁴³³ Ibid, p. 390.

⁴³⁴ Senftleben, Martin: Seizure of Goods in Transit and International Law. in: M. Vivant (ed.), European Case Law on Infringements of Intellectual Property Rights. Brussels: Larcier/Bruylants, 2016. - <https://ssrn.com/abstract=2915464>, DOA: 29.04.2017, pp. 1-9, p. 2.

frequently taken place in the Union through 2008, as well as in 2009, as per the provisions of the Council Regulation 1383/2003.⁴³⁵ This particular Council Regulation permits customs officials to take relevant actions, *inter alia*, consisting of detention and suspension of goods that have are suspected of IPRs infringement.⁴³⁶ Yet, the medicines at issue and the country of final destination have altered with each destination; New Delhi claimed that Dutch customs officers have seized 19 consignments of generic medicines passing through the territory of the Netherlands in both 2008 as well as 2009⁴³⁷, 16 of which originated from India.⁴³⁸

Initially the generic pharmaceutical titans hailing from developed nations were able to contain the generic medicines industry, which had been threatening their monopoly and coercing them to bring down the costs.⁴³⁹ Later, producers of generic medicines such as Dr. Reddy produced generic versions of the patented drugs and sold them at a much lower cost compared to their patented counterpart. In this way the generic medicines industry went on to create a viable alternative option to guarantee the human right to the access to medicines for the LDC and developing nations.⁴⁴⁰

Unfortunately, one of the consignments originating from India included essential HIV/AIDS medicines⁴⁴¹, which are also listed in the WHO's

⁴³⁵ Mercurio, Bryan: "Seizing" pharmaceuticals in transit: Analysing the WTO dispute that wasn't, in: International and Comparative Law Quarterly (2012), Vol. 61, Is. 2, pp. 389-426, p. 398.

⁴³⁶ Ibid.

⁴³⁷ Datta, Jyothi: Cipla Export Consignment too Seized at Amsterdam. in: Business Line. 2009. - <http://www.thehindubusinessline.com/2009/02/04/stories/2009020451610200.htm>, DOA: 03.05.2019.

⁴³⁸ World Trade Organization: European Union and a Member State – Seizure of Generic, Drugs in Transit, DS408. 2010. - http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds408_e.htm, DOA: 12.12.2015.

⁴³⁹ Ayilyath, Manoranjan: EU Border Measure Regulation: A Threat to Access to Public Health in Developing Countries and Least Developed Countries, in: European Intellectual Property Review (2013), Vol. 35, No. 4, pp. 212-219, p. 215.

⁴⁴⁰ Ibid.

⁴⁴¹ Pandeya, Radhieka: UN agency protests Dutch seizure of Indian HIV drugs. in: Mint. 2009. - <http://www.livemint.com/2009/03/06222950/UN-agency-protests-Dutch-seizure.html>, DOA: 27.08.2013.

Model List of Essential Medicines, as will be discussed in more detail below.⁴⁴² More precisely, a shipment of generic AIDS medicines manufactured on the Indian subcontinent was intercepted on its way to Nigeria. On this occasion, once again the generic pharmaceuticals which were purchased by UNITAID had not been subject to patent protection in India nor in Nigeria.⁴⁴³ While transiting through the Schiphol Airport in Amsterdam in 2009, the shipment was confiscated by Dutch border enforcement due to suspicion of trademark infringement.⁴⁴⁴ Similarly, in May 2009 a shipment of more than 3 million tablets of antibiotic amoxicillin was seized by over-zealous German customs authorities due to trademark violations, as these tablets were sent from India to the Republic of Vanuatu in the Pacific, a least developed country (LDC). The German authorities were informed by GlaxoSmithKline, the former IPRs owner, that the drugs were indeed legally in transit and consequently were released after being detained for a month.⁴⁴⁵ In October 2009, 1.74 million tablets of an anti-platelet drug used to prevent strokes and heart attacks was intercepted at in transit airport in France. The cargo, which originated from India, was on its way to Venezuela. On this occasion, the medicines were released after eight days.⁴⁴⁶ Comparable detentions also transpired in Spain and the UK.⁴⁴⁷

⁴⁴² World Health Organization: World Health Organization Model List of Essential Medicines: 21st List. 2019. - <https://apps.who.int/iris/bitstream/handle/10665/325771/WHO-MVP-EMP-IAU-2019.06-eng.pdf>, DOA: 01.01.2021.

⁴⁴³ Grosse Ruse - Khan, Henning: A Trade Agreement Creating Barriers to International Trade? ACTA Border Measures and Goods in Transit. in: American University International Law Review (2011), Vol. 26, No. 3, pp. 645-726, p. 649.

⁴⁴⁴ Ibid.

⁴⁴⁵ Singh, Khomba: Row over generic drugs intensifies after seizure in Germany. in: The Economic Times. 2009. -

<https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/row-over-generic-drugs-intensifies-after-seizure-in-germany/articleshow/4629426.cms?from=mdr>, DOA: 09.05.2016.

⁴⁴⁶ Nonaka, Melissa: Enough is Enough: India's fight against Seizures of Lawful Generic Medicines, in: Journal of Medicine and Law (2011), pp. 37- 57, p. 51.

⁴⁴⁷ Mercurio, Bryan. (2012). "Seizing" pharmaceuticals in transit: Analysing the WTO dispute that wasn't, in: International and Comparative Law Quarterly, Vol: 61 Issue: 2, pp. 389-426, p. 398.

Moreover, Council Regulation 1383/2003 had recognised the gravity of the subject matter when it comes to cross-border trade of suspected goods and the possibility of goods in transit entering the domestic market of the EU, which are meant to be kept out of the domestic market of the EU.⁴⁴⁸ Moreover, the relevant Regulation extends to both commodities that necessitate customs clearance, as well as to those commodities which do not require the same.⁴⁴⁹

In this regard it would be substantial to consider the doctrine of manufacturing fiction which was developed by Dutch courts. In the *Sisvel* case, the District Court of the Hague upheld the detention of MP4 players which had been in transit from China to Brazil seized by the customs authorities in the Netherlands. In *Sisvel* the court developed the legal concept of “manufacturing fiction” (legal fiction) which it derived from Council Regulation 1383/2003.⁴⁵⁰ Thus, according to the legal fiction developed by the Dutch courts in order to ascertain IPRs infringements, goods in transit can be regarded as goods that have been both produced as well as manufactured in the territory of the Netherlands.⁴⁵¹ In *The Polo Lauren Company v PT Dwidua Langgeng Pratama International Freight Forwarders* case the Austrian court stated:

[a]fter all, the external transit of non-Community goods is not completely devoid of effect on the internal market. It is, in fact, based on a legal fiction. Goods placed under this procedure are subject neither to the corresponding import duties nor to the other measures of commercial policy; it is as if they had not entered Community territory.

⁴⁴⁸ Regulation 1383/2003 concerning customs action against goods suspected of infringing certain intellectual property rights and the measures to be taken against goods found to have infringed such rights [2003] OJ L196/7, para. 2.

⁴⁴⁹ See Mercurio, Bryan: "Seizing" Pharmaceuticals in Transit: Analysing the WTO Dispute that Wasn't, in: International and Comparative Law Quarterly (2012), Vol. 61, Is. 2, pp. 389-426, p. 398.

⁴⁵⁰ *Sisvel SpA v Sosecal* (311378/KG ZA 08-617, July 18 2008).

⁴⁵¹ Kumar, Shashank P.: Border Enforcement of IP Rights Against in Transit Generic Pharmaceuticals: An Analysis of Character and Consistency, in: European Intellectual Property Review (2010), Vol. 32, Is. 10, pp. 506-519, p. 510.

In reality, they are imported from a non-member country and pass through one or more Member States before being exported to another non-member country. This operation is all the more liable to have direct effect on the internal market as there is a risk that counterfeit goods placed under the external transit procedure may be fraudulently brought on to the Community market, as several Governments pointed out in their written observations and at the hearing.”⁴⁵²

The application of legal fiction applied by Dutch courts allows Dutch customs agencies to detain goods which, both in the respective country of origin and in the country of final destination, do not infringe IPRs suspected of being a counterfeit goods.⁴⁵³

Yet, the English High Court held that Council Regulation 1383/2003 would not extend to cover goods (counterfeit) that were only in transit and not earmarked for the UK market. The court went on to reiterate that the goods in question must have been “used in the course of trade” within the territory area of Great Britain for those goods to be seized or detained under Council Regulation 1383/2003.⁴⁵⁴ Evidently, ever since the seized goods are merely being placed in transit, therefore neither production nor manufacturing within the territory of the Netherlands occurs in reality. By doing so the courts in the Netherlands can hold that Dutch law is violated by acts committed outside the territory of the Netherlands. According to Frederick Abbott, Professor of International Law at Florida State University College of Law, who even went to the extent of alleging that the seizures had been an intentional effort to halt the developing countries’ reliance on

⁴⁵² Polo/Lauren Co LP v Dwidua Langgeng Pratama International Freight Forwarders (C-383/98) [2000] E.C.R. I-2519, para. 34.

⁴⁵³ Kumar, Shashank P.: Border Enforcement of IP Rights Against in Transit Generic Pharmaceuticals: An Analysis of Character and Consistency, in: European Intellectual Property Review (2010), Vol. 32, Is. 10, pp. 506-519, p. 510.

⁴⁵⁴ Ibid.

the continuing supply of generics from New Delhi.⁴⁵⁵ Moreover, there exists an inconsistency between the doctrine of “manufacturing fiction” and the independence of patents. For Abbott, it is hardly comprehensible to find a greater deviation from the principle of patent independence than “manufacturing fiction”, more precisely, he finds it difficult to digest that a patent in Netherlands is infringed by an action originated in India. Thus, if a state asserts manufacturing fiction when it comes to assessing the patent or supplementary protection status of a medicine, as the Netherlands and other European countries undoubtedly did, then an in transit generic medicine could still be seized, adjudicated as an infringement, and destroyed. Rather astonishingly, this would even be the case if it would have been produced legally in the state, manufactured and earmarked for legal use in the nation of final importation. Moreover, there is no justification to apply fictive domestic IPRs legislation to goods that are not used within the territorial market of the country in which the transit occurs. The application of these fictive rights turns into an extra-territorial application of entirely domestic IP legislation to goods that have been earmarked for either commercialisation or other usage within a particular territory.⁴⁵⁶ What is worrying is that this fictive territoriality could not be extended with respect to other territorial regimes involving for instances, environmental legislation or labour rights. According to Frederick Abbott, several developing nations fear that the initiative of the EU to combat counterfeit goods potentially follows a “hidden agenda” with the aim to curtail legitimate trade in generic medicines.⁴⁵⁷

⁴⁵⁵ Abbott, Frederick M.: Seizure of Generic Pharmaceuticals in Transit Based on Allegations of Patent Infringement: A Threat to International Trade, Development and Public Welfare, in: World Intellectual Property Organization Journal (2009), Vol. 1, pp. 43-50, p. 49.

⁴⁵⁶ Baker, Brook K.: Settlement of India/EU WTO Dispute re Seizures of In-Transit Medicines: Why the Proposed EU Border Regulation Isn't Good Enough. in: PIJIP, Research Paper no. 2012-02. Washington D.C.: American University Washington College of Law, 2012, p. 13.

⁴⁵⁷ Abbott, Frederick M.: Worst fears realized: The Dutch confiscation of medicines bound from India to Brazil. 2009. - www.ictsd.org/bridges-news/bridges/news/worst-fears-realised-the-dutch-confiscation-of-medicines-bound-from-india, DOI: 15.05.2016.

Equally, there exists no harm neither in nor to the Netherlands.⁴⁵⁸ The doctrine applied by the courts in the Netherlands would go against Article 41 (1) of the TRIPS Agreement which clearly states that the measures applied by Dutch border agencies should not turn into a barrier to legitimate trade.⁴⁵⁹ Equally, the preamble of TRIPS have pledged that both procedures ad measures undertaken to enforce IPRs do not evolve into an obstruction to legitimate trade.⁴⁶⁰

The question which arises, is what exactly constitutes legitimate trade. On the one hand, it seems rather convincing that goods, which are in ordinary transit and are traded between two states may be regarded as comprising of a part of legitimate trade, which could also be termed legitimate traffic in transit. On the other hand, cases that cover the transit of goods that there likely to penetrate into avenues of commerce in the state through which they were intended to transit may not be considered as constituting legitimate trade. Thus, *prima facie*, importation of generic medicines could be construed as to exclude the portion of transit forming part of legitimate trade. Consequently, only in circumstances in which there is a risk of goods in transit, *de facto*, entering into market of the transiting nations should these kinds of instances of transit be regarded as forming part of importation.⁴⁶¹ This notion in turn would also be in line with Article V (1) of GATT Agreement.⁴⁶² Moreover, Article V (2) of GATT mandates

⁴⁵⁸ Abbott, Frederick M.: Seizure of Generic Pharmaceuticals in Transit Based on Allegations of Patent Infringement: A Threat to International Trade, Development and Public Welfare, in: World Intellectual Property Organization Journal (2009), Vol. 1, pp. 43-50, p. 48.

⁴⁵⁹ Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994), Art. 41 (1).

⁴⁶⁰ See preamble Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994).

⁴⁶¹ Kumar, Shashank P.: Border Enforcement of IP Rights Against in Transit Generic Pharmaceuticals: An Analysis of Character and Consistency, in: European Intellectual Property Review (2010), Vol. 32, Is. 10, pp. 506-519, p. 513.

⁴⁶² General Agreement on Tariffs and Trade, 1994, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, 1867 U.N.T.S. 187, 33 I.L.M. 1153 (1994) [hereinafter GATT 1994], Art. V (1).

the freedom of transit through the territory of every member state to the treaty.⁴⁶³

Additionally, both the seizure and detention of essential generics in transit has had considerable consequences not only for free trade and for IPR's holders but also for international human rights, in the form of access to medicines and public health. It is therefore imperative to acknowledge the fact that both the seizure and detention of generics on the territory of the EU could be a major impediment and obstruction to international trade in essential generic medicines. The effects are even serious as many of the generic pharmaceuticals happened to be earmarked for markets of developing states that are heavily dependent on cheaper and more cost-effective generic varieties of the original medicines.⁴⁶⁴ Given the cost-efficient transport route via the EU many exporters from generics have little choice but to transit through the EU. The seizure has already meant that various Indian generic drug manufacturers have had to contemplate utilising alternative, more cost-intensive transport passages.⁴⁶⁵ The previously mentioned concerns appear to be relevant given the fundamental role that is being played by generic medicines in correlation with the reduction of costs for drugs and thereby guaranteeing access to affordable medications. Unfortunately, it is also probable that the detentions of the generics could undermine the capability of lower income WTO member nations to address their public health requirements by utilising compulsory licensing arrangements to support states with inadequate or no manufacturing capabilities to import generic medicines from other WTO members, as authorised by paragraph 6 of the Doha Declaration.⁴⁶⁶ Thus, Doha Declaration notes that the TRIPS Agreement could and ought to be interpreted in a fashion that is

⁴⁶³ Ibid, Article V (2).

⁴⁶⁴ Pandeya, Radhieka: Dr Reddy's consignment of drugs to Brazil seized. in: Live Mint. 2009. - <https://www.livemint.com/Companies/0bALFWn35xriAyHKxX4iaO/Dr-Reddy8217s-consignment-of-drugs-to-Brazil-seized.html>, DOA: 17.09.2018.

⁴⁶⁵ Ibid.

⁴⁶⁶ Doha Declaration: World Trade Organization, Ministerial Declaration of 14 November 2001, WTO Doc. WT/MIN(01)/DEC/1, 41 ILM 746 (2002), para. 4.

supportive of WTO members in the both fields, upholding the right to protect public health as well as promoting access to medications for everyone.⁴⁶⁷ Scholars from the Max Planck Institute also supported the point for Intellectual Property, Competition and Tax Law, and stressed that by *inter alia* seizing drugs produced under the paragraph 6 of Doha, the EU would directly contradict the efforts undertaken by the WTO and its members to promote access to medicines in these cases. Thus, seizures of goods in transit may even essentially annul the supply of drugs, under the paragraph 6 of Doha, to nations, which lack sufficient pharmaceutical production capabilities.⁴⁶⁸ Equally, according to the Max Planck researchers' paragraph 5 (a) of Doha requires the application of the TRIPS Agreement in a way that is conducive to public health procedures without frustrating the same. For these researchers TRIPS should be interpreted in a narrow manner and consequently the "country of importation" would not include transit nations.⁴⁶⁹ The Dutch decision to seize the generics in transit with the aim to uphold EU legislation appears to be in contradiction with the Doha Declaration. The complainant Brazil has clearly issued an unambiguous statement against the detention of generic medicines in transit.⁴⁷⁰ Brasilia asserted that the extraterritorial execution of patent right cannot be in line with the Doha Declaration.⁴⁷¹

⁴⁶⁷ Ibid.

⁴⁶⁸ Drexel, Josef/ Grosse Ruse-Khan, Henning/ Hilty, Reto/ Jaeger, Thomas: Statement of the Max Planck Institute for Intellectual Property, Competition and Tax Law on the Review of EU Legislation on Customs Enforcement of IP Rights, in: International Review of Industrial Property and Copyright Law (2010), Vol. 41, pp. 674-695, p. 687.

⁴⁶⁹ Ibid.

⁴⁷⁰ World Trade Organization: European Union and a Member State - Seizure of generic drugs in transit, Request to Join Consultations, Communication from Brazil, WT/DS408/3. 2010. - https://trade.ec.europa.eu/doclib/docs/2011/january/tradoc_147466.pdf, DOA: 06.04.2018.

⁴⁷¹ United Nations Conference on Trade and Development (UNCTAD) Intellectual Property Unit: European Union and a Member State - Seizure of Generic Drugs in Transit: Request for Consultations by India (DS408/1) and Brazil (DS409/1). Dispute Settlement Body, 2010. - <https://unctad.org/ippcaselaw/sites/default/files/ippcaselaw/2020-12/WTO%20DS408%20DS409%20India%2C%20Brazil%20v%20EU%20on%20seizure%20of%20goods%20in%20transit.pdf>, DOA: 05.05.2019.

Understandably, India was anything but amused about the seizure and detention of the essential generic medicines, which from the point of view of the Indian government violate numerous provisions of the TRIPS and GATT Agreements.⁴⁷² The Indian commerce secretary compared the measures undertaken by the EU as “act of piracy”.⁴⁷³ For the Indian ambassador the actions undertaken by Brussels represent an artful as well as a concerted method of circumventing the TRIPS flexibility.⁴⁷⁴ It had been worried about the public health implications of both the seizure and the lengthy detention of the essential generic medicines. In this context, the seizures go against the essence of the law-based trading systems and symbolise an impediment to free trade. These actions embody a misleading sue of the international intellectual property system and restricts the flexibility of TRIPS. Equally, New Delhi has been concerned about the fact that the repetition of such measures might have a detrimental effect over the choice of the transit routes that are chosen by exporting countries. This in turn would not only have detrimental consequences when it comes to the trade in pharmaceutical products but could also be harmful when it comes to accessing essential generic medicines, as well as to the public health budget of the recipient nations.⁴⁷⁵ For New Delhi, a main concern for the EU was regarding the massive production of generic medicines, and India used the flexibility of the TRIPS to establish a market for generic drugs.⁴⁷⁶ Essentially, India argued that any pharmaceutical drug that originated from New Delhi could not be meddled with if it was manufactured and exported under

⁴⁷² This work will only cover a limited range of provisions of the aforesaid agreements.

⁴⁷³ Pandeya, Radhieka: Dr Reddy's consignment of drugs to Brazil seized. in:

Live Mint. 2009. - <https://www.livemint.com/Companies/0bALFWn35xriAyHKxX4iaO/Dr-Reddy8217s-consignment-of-drugs-to-Brazil-seized.html>, DOA: 17.09.2018.

⁴⁷⁴ Singh, Bhatia Ujal: Ambassador of India to the WTO, Intervention by India. The WTO General Council. 2009. - <http://www.ip-watch.org/files/IndiaStatementtoGeneralCouncilJan2009.doc>, DOA: 31.03.2015.

⁴⁷⁵ Mercurio, Bryan: "Seizing" Pharmaceuticals in Transit: Analysing the WTO Dispute that Wasn't, in: International and Comparative Law Quarterly (2012), Vol. 61, Is. 2, pp. 389-426, p. 400.

⁴⁷⁶ Erickson, Justin: Call for Reform: Analyzing Trips Through European Seizure of Generic Medication, in: Minnesota Journal of International Law (2012), pp. 382- 413, p. 394.

the requirements of the Doha Declaration.⁴⁷⁷ For the subcontinent, the rights bestowed on the proprietor of a patent cannot be utilised in order to intervene with the freedom of transit of generics that have been legally manufactured within, and exported from, the subcontinent. Likewise, as India was attempting to provide medicine to developing countries, it can claim that it was fulfilling the purpose of the Doha Declaration. New Delhi is indeed guaranteeing that developing countries have access to a stream of medicine through generic production.⁴⁷⁸ Most prominent among these is the national emergency exception, which permits a country to produce generic medication in violation of TRIPS if such production is to deal with a public health emergency. Each country is permitted to decide what constitutes such an emergency as per the Doha Declaration there is no international standard.⁴⁷⁹ Yet another supporting argument could be seen in the fact that nations are free to implement their own procedures to gain access to generic medications.⁴⁸⁰ India reinforces this with the General Council decision, declaring that it can use compulsory licensing to produce medications for developing countries that have an inability to produce such medication.⁴⁸¹ From the point of New Delhi, even if Brussels was in a position to justify its seizures, such seizures are nevertheless illegal because Brussels had failed to provide notice of such procedures to India, as required by Article X of the GATT.⁴⁸²

Moreover, the Brazilian government considered the decision by the Dutch border agencies to detain the essential generic medicines represented a significant drawback when it comes to universal access

⁴⁷⁷ Ibid, p. 395.

⁴⁷⁸ Ibid, p. 397.

⁴⁷⁹ Ibid, p. 398.

⁴⁸⁰ Doha Declaration: World Trade Organization, Ministerial Declaration of 14 November 2001, WTO Doc. WT/MIN(01)/DEC/1, 41 ILM 746 (2002), para. 5 (d).

⁴⁸¹ Ibid, para. 5 (b)

⁴⁸² Erickson, Justin: Call for Reform: Analyzing Trips Through European Seizure of Generic Medication, in: Minnesota Journal of International Law (2012), pp. 382- 413, p. 405.

to medicines for developing nations.⁴⁸³ For Brazil the generics are supposed to be subject to the legislation of the nation in which they are meant to be commercialised, here it would be in India or Brazil. Thus, as for Brasilia and New Delhi the law of nation of transit is for the purpose in question irrelevant.⁴⁸⁴ Moreover, mere suspicion of diversion seemed to be rather insufficient, and instead there should be evidence of planned purchase and distribution by clearly detected entry within the local market of the transiting country.⁴⁸⁵

After a year of unsuccessful negotiations, the Indian Union brought a formal complaint against the EU and The Netherlands to the WTO, on 11 May 2010.⁴⁸⁶ As things stand, Brussels has permitted patent right holders to apply for the seizure of goods in transit that are suspected of IPRs infringement, even in cases in which they would be merely in transit EU.⁴⁸⁷ A mere suspicion seems to be sufficient. The EU measure is a dual expansion of Article 51 of TRIPS, as it applied to both patents and goods in transit. Article 51 of TRIPS does not authorise either of these measures.⁴⁸⁸ Thus the fictitious as well as non-territorial application of domestic law to goods in transit is directly in violation of Articles 52 and 51 of the TRIPS, which requires application of "the law of the importing country" when assessing whether an intellectual property right at the border is violated or

⁴⁸³ Mercurio, Bryan: "Seizing" Pharmaceuticals in Transit: Analysing the WTO Dispute that Wasn't, in: International and Comparative Law Quarterly (2012), Vol. 61, Is. 2, pp. 389-426, p. 400.

⁴⁸⁴ Azevedo, Roberto: Ambassador of Brazil to WTO, Intervention by Brazil, (WTO General Council, 3-4 February 2009). 2009. - <http://www.ip-watch.org/files/RemediosIntervencao-do-Brasil-ConselhoGeral-03022008.doc>, DOI: 23.05.2016, para. 2.

⁴⁸⁵ Baker, Brook K.: Settlement of India/EU WTO Dispute re Seizures of In-Transit Medicines: Why the Proposed EU Border Regulation Isn't Good Enough. in: PIJIP, Research Paper no. 2012-02. Washington D.C.: American University Washington College of Law, 2012, p. 14.

⁴⁸⁶ Mercurio, Bryan: "Seizing" Pharmaceuticals in Transit: Analysing the WTO Dispute that Wasn't, in: International and Comparative Law Quarterly (2012), Vol. 61, Is. 2, pp. 389-426, p. 401.

⁴⁸⁷ Regulation 1383/2003 concerning customs action against goods suspected of infringing certain intellectual property rights and the measures to be taken against goods found to have infringed such rights [2003] OJ L196/7, Art 2.1 (c) (i) & Art 10.

⁴⁸⁸ Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994), Art. 51.

whether a good is a trademark counterfeit.⁴⁸⁹ Yet another subsequent question of significance that arises is what qualifies as the “country of importation”. To answer this question, one would need to employ Article 31 of the Vienna Convention of the Law of Treaty (VCLT) which states:

“A treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose.”⁴⁹⁰

Thus, the interpretation of the treaty provisions ought to be derived from the text of the convention, in the present case this would be the TRIPS convention. More precisely, the question is whether the EU or Brazil qualifies as the “country of importation”. In this context, it seems convincing that Brazil as the country of final destination ought to be deemed as the country of importation. If Brazil qualifies as the “country of importation”, this will mean that Brussels’ actions would be inconsistent with Article 52 of TRIPS.⁴⁹¹ As the EU has been utilising its own legislation to discern the basis for the seizures, the complaints will determine Brussels’ measures are inconsistent with Article 51.⁴⁹² Article 51 of TRIPS defines imported goods as those bound for commercial use in the state in which the customs clearance did indeed take place. The relevant provision appears to indicate that a key element of “importation” entails the probability of goods entering the channels of commerce in that state.⁴⁹³ The legitimacy of trade in

⁴⁸⁹ Baker, Brook K.: Settlement of India/EU WTO Dispute re Seizures of In-Transit Medicines: Why the Proposed EU Border Regulation Isn't Good Enough. in: PIJIP, Research Paper no. 2012-02. Washington D.C.: American University Washington College of Law, 2012, p. 13.

⁴⁹⁰ See United Nations, Vienna Convention on the Law of Treaties, 23 May 1969, United Nations, Treaty Series, Vol. 1155, available at: <https://www.refworld.org/docid/3ae6b3a10.html>, DOA: 30.04.2020, Art. 31 (1).

⁴⁹¹ Art. 51 Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994).

⁴⁹² Ibid.

⁴⁹³ Kumar, Shashank P.: Border Enforcement of IP Rights Against in Transit Generic Pharmaceuticals: An Analysis of Character and Consistency, in: European Intellectual Property Review (2010), Vol. 32, Is. 10, pp. 506-519, p. 512.

generic drugs would indicate that the “country of importation” should be interpreted in such a manner as to imply the country of final destination, which in this particular case this is Brazil. Thus, Regulation 1383/2003 evidently obstructs the legitimate trade of essential generic medicines contrary to Article 52 of TRIPS.⁴⁹⁴ New Delhi and Brasilia insisted that there has been a violation of Article V of GATT.⁴⁹⁵ In its statement at the WTO General Council meeting on 3 February 2009 India stated that the WTO rules provide for the freedom of transit utilising the most convenient and economical routes without restrictions and unnecessary delays. Only in exceptional circumstances a derogation would, as per Article V of GATT, be applicable, which according to the Brazilian ambassador was not the case in the present scenario and was setting a dangerous precedent.⁴⁹⁶ According to the Brazilian ambassador the Losartan is hardly an isolated incident but rather a systematic issue if they will not prevent a transit nation from intervening with legitimate trade.⁴⁹⁷ At the same meeting the Indian and Brazilian ambassadors to the WTO reiterated the fact that the EU had no legal basis to block the legitimate shipping of generic drugs on the ground of probable IPRs conflicts in the transiting state. For both ambassadors, the recent cases involving the Netherlands question the WTO legal system. The concerns by both BRICS nations was supported by 17 other development states.⁴⁹⁸

⁴⁹⁴ Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994), Art. 52.

⁴⁹⁵ General Agreement on Tariffs and Trade, 1994, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, 1867 U.N.T.S. 187, 33 I.L.M. 1153 (1994), Article V.

⁴⁹⁶ Azevedo, Roberto: Ambassador of Brazil to WTO, Intervention by Brazil, (WTO General Council, 3-4 February 2009). 2009. - <http://www.ip-watch.org/files/RemediosIntervencao-do-Brasil-ConselhoGeral-03022008.doc>, DOA: 23.05.2016, see para. 2.

⁴⁹⁷ Ibid.

⁴⁹⁸ The following nations supported India and Brazil: Argentina, Bolivia, Burkina Faso, China, Costa Rica, Cuba, Ecuador, Egypt, Indonesia, Israel, Nigeria, Pakistan, Paraguay, Peru, South Africa, Thailand and Venezuela.

Brussels ambassador at the WTO, Eckart Guth, on the other hand defended the action of the Union. For Guth, the action undertaken by the Union were in conformity with both the legislation of the WTO and of the EU, more specifically, Article 51 TRIPS and Article V GATT.⁴⁹⁹ According to the EU ambassador it was anything but the EU's intention to impede any form of legitimate trade in generic medicines or to establish legal obstacles to the transportation of generic pharmaceuticals to developing nations. When clarifying the character of the border actions, he mentioned that these were temporary detentions and different to seizures, destruction and confiscation.⁵⁰⁰ According to ambassador Guth the consignment was tiny in nature and much fuss had been generated over nothing, besides EU legislation permitted the detention of any goods in transit suspected of infringing IPRs. In an attempt to smooth out the situation Guth assured that the goods were soon be released to Dr Reddy's, its rightful owner. He was, however, rather surprised to learn that the goods were returned to India instead of being released in the Netherlands.⁵⁰¹ The approach taken by EU ambassador Eckart Guth with regard to the seizure of essential generic medicines, besides being sesquipedalian, could be compared to the "Four Seasons Total Landscaping saga" of the election stunt of the Trump electoral campaign.⁵⁰² In this context, it

⁴⁹⁹ Guth, Eckart: Ambassador of EU to WTO, EC Intervention. WTO General Council. 2009. - http://www.ip-watch.org/files/WTO_GENERAL_COUNCIL.doc, DOA. 18.04.2016.

⁵⁰⁰ Ibid.

⁵⁰¹ Ibid.

⁵⁰² The background of this new expression is rooted in the fact that US president Donald Trump announced a press conference on 8 November 2020, his election campaign organised a press conference which was going to be held at the Four Seasons. A reasonable person would have expected this to mean that the press brief was going to be held at the posh hotel chain Four Seasons in Philadelphia. This would technically have had adequate facilities to accommodate the needs for a press meeting of such grandeur. The press conference ended up being held outside a somewhat different Four Seasons, the actual venue of choice ended up being a location referred to as "Four Seasons Total Landscaping" in Philadelphia. *Prima facie*, it seems to be worth assuming that a Trump campaign staffer must have gotten both locations mixed up. Instead of changing the venue and admitting his wrongdoing, the Trump campaign tried to conceal the mistake and pretended as if this had been the plan in the first place. To add, yet another layer of insult to injury, Four Seasons Total Landscaping is located between a funeral parlour and an adult shop. The saga ought to be regarded as an allegory of something that was the by-product of good intentions, which, however, went terribly wrong with catastrophic consequences. While Mrs Merriam Webster might not necessarily approve the use of this term, it seems to be somewhat obvious that the saga has made it into the annals of recorded

would be worth mentioning that, according to Dr Reddy, the view of Article 16 of Council Regulation 1383/2003 and the impact of the measure at issue, was a *de facto* seizure, as the terms seizure and suspension were applied in an interchangeable manner.⁵⁰³

The seizure by the Dutch official represents a denial of the rule-based system that the WTO seeks to implement.⁵⁰⁴ Article V of GATT discusses the subject matter of transit and states the following:

*"Goods (including baggage), and also vessels and other means of transport, shall be deemed to be in transit across the territory of a contracting party when the passage across such territory, with or without trans-shipment, warehousing, breaking bulk, or change in the mode of transport, is only a portion of a complete journey beginning and terminating beyond the frontier of the contracting party across whose territory the traffic passes. Traffic of this nature is termed in this article "traffic in transit"."*⁵⁰⁵

*"There shall be freedom of transit through the territory of each contracting party, via the routes most convenient for international transit, for traffic in transit to or from the territory of other contracting parties".*⁵⁰⁶

contemporary history.; Hall, Richard: I saw Donald Trump's presidency come crashing down at Four Seasons Total Landscaping. in: Independent. 2020. -

<https://www.independent.co.uk/news/world/americas/us-election-2020/i-saw-donald-trump-s-presidency-come-crashing-down-at-four-seasons-total-landscaping-b1699962.html>, DOA: 01.01.2021.

⁵⁰³ Kumar, Shashank P.: Border Enforcement of IP Rights Against in Transit Generic Pharmaceuticals: An Analysis of Character and Consistency, in: European Intellectual Property Review (2010), Vol. 32, Is. 10, pp. 506-519, p. 509.

⁵⁰⁴ India, Brazil and the EC made interventions at the WTO General Council Meeting held on 3 February 2009 under agenda item "Other Business". 2009. - <http://indiainthewto.wordpress.com/2009/03/11/text-of-indian-statementon-generics-seizure-beforetrips-council/>, DOA: 15.03.2013.

⁵⁰⁵ General Agreement on Tariffs and Trade, 1994, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, 1867 U.N.T.S. 187, 33 I.L.M. 1153 (1994), Art. V (1).

⁵⁰⁶ Ibid, V (2).

Brazil mentioned that the measure taken by the authorities in the Netherlands has been a violation of the freedom of transit as guaranteed by the GATT agreement.⁵⁰⁷ Moreover, Article V of GATT asserts that contracting parties “shall not be subject to any unnecessary delays or restrictions” and be exempt from customs duties.⁵⁰⁸ A delay in 36 days *prima facie* appears to fall within the category of unnecessary long. In this context, it is worth noting that Article 55 TRIPS Agreement mandates that custom agencies discharge seizure or detained goods within ten working days after the applicant has been served notice of the suspension.⁵⁰⁹ In appropriate circumstances the same provision provides for an additional 10-working-day extension.⁵¹⁰ Similarly, Article 13 of Regulation 1383/2003 provides the IPR’s owner 10 working days to examine the goods and determine whether further action should be initiated.⁵¹¹ The aforesaid initial 10 working day period may yet be extended by an additional 10 working days.⁵¹² While 36 days are hardly within the 20 working days timeframe, this is even more worrying as in some cases the suspension had been more than 80 working days.⁵¹³ Similarly, seized goods may ordinarily be detained until court proceedings have come to an end, which could typically take months or years.⁵¹⁴ Moreover, Article XX of GATT mentions that protection of patents, trademark and

⁵⁰⁷ Thiru: Intervention by Brazil at WTO General Council on seizure of 500 kilos of generic medicines by Dutch customs authorities. 2009. <https://www.keionline.org/20941>, DOA: 29.07.2013.

⁵⁰⁸ General Agreement on Tariffs and Trade, 1994, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, 1867 U.N.T.S. 187, 33 I.L.M. 1153 (1994), Art. V (3).

⁵⁰⁹ Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994), Art. 55.

⁵¹⁰ Ibid.

⁵¹¹ Regulation 1383/2003 concerning customs action against goods suspected of infringing certain intellectual property rights and the measures to be taken against goods found to have infringed such rights [2003] OJ L196/7, Art. 13 (1).

⁵¹² Ibid.

⁵¹³ Mercurio, Bryan: "Seizing" Pharmaceuticals in Transit: Analysing the WTO Dispute that Wasn't, in: International and Comparative Law Quarterly (2012), Vol. 61, Is. 2, pp. 389-426, p. 421.

⁵¹⁴ Baker, Brook K.: Settlement of India/EU WTO Dispute re Seizures of In-Transit Medicines: Why the Proposed EU Border Regulation Isn't Good Enough. in: PIJIP, Research Paper no. 2012-02. Washington D.C.: American University Washington College of Law, 2012, p. 16.

copyrights should not be converted into a concealed restriction on international trade.⁵¹⁵ Thus, if the seizure of essential generic medicines would not qualify as an illegitimate barrier to trade, it could fall under the ambit of disguised restriction to international trade.

In addition, various heated arguments had been exchanged between the EU, Indian and Brazilian diplomats. Impassioned and at times angry statements from non-governmental organizations (NGOs) as well as public health activists followed. After a year of unproductive negotiations both New Delhi and Brasilia issued a complaint at the WTO over this issue. However, India and the EU finally settled the dispute amicably in October 2010.⁵¹⁶ An understanding between the parties was reached and the EU agreed that it would no longer intercept generic medicines that are in transit, the exception would apply to cases which are supported by satisfactory evidence. Similarly, the EU customs agencies are under obligation to provide prove that there would be a considerable probability of diversion of generic medicines into the EU market. Despite the assurances given by Brussels that it would cease the detentions, reports surfaced in early-2012 that the EU had again detained an Indian shipment of generic pharmaceuticals destined for South America.⁵¹⁷ Moreover, recent trends in international IP law seems to suggest a move towards enhanced protection and enforcement in at least the short as well as medium term.⁵¹⁸ The EU agreed to amend the legislation in question accordingly.⁵¹⁹ Consequently, Brussels revised its Customs Regulations in 2013 and adopted guidelines for their adoption.⁵²⁰

⁵¹⁵ General Agreement on Tariffs and Trade, 1994, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, 1867 U.N.T.S. 187, 33 I.L.M. 1153 (1994), Article XX.

⁵¹⁶ Erickson, Justin: Call for Reform: Analyzing Trips Through European Seizure of Generic Medication, in: Minnesota Journal of International Law (2012), pp. 382-413, p. 393.

⁵¹⁷ Mercurio, Bryan: "Seizing" Pharmaceuticals in Transit: Analysing the WTO Dispute that Wasn't, in: International and Comparative Law Quarterly (2012), Vol. 61, Is. 2, pp. 389-426, p. 391.

⁵¹⁸ Ibid, p. 389.

⁵¹⁹ United Nations Conference on Trade and Development (UNCTAD) Intellectual Property Unit: European Union and a Member State - Seizure of Generic Drugs in Transit: Request for Consultations by India (DS408/1) and Brazil (DS409/1). Dispute Settlement Body, 2010. -

On another note, while it would be rather hyperbole to assume that the actions undertaken by the EU and FTA negotiating objectives threaten the very element of trade in generic pharmaceuticals, the measures tend to have a deterrent effect on the trade.⁵²¹ What is more worrying is the fact that Brussels has been strategically exporting Council Regulation 1383/2003 to its trading associates through its FTA negotiations and other international treaties, which would have the detrimental effect of increasing the probability of similar detentions and seizures by other states in the foreseeable future.⁵²² In this respect, Article 1 TRIPS Agreement discourages the implementation of legislation that provided a higher standard of protection than what is provided for by TRIPS.⁵²³

With regard to resolving the litigation between the Indian Union, Brazil and the EU concerning the seizure of essential generic medicines, the EU dedicated to avoiding long standing litigation and endeavoured to settle the dispute. *Prima facie* Brussels eagerness to settle the dispute seemed to have been partially motivated by its ambition to establish a FTA with New Delhi.⁵²⁴

A key judgement with regard to the incident in question was issued by the European Court of Justice on 1 December 2011. This opinion ruling was regarding goods which are subject to customs suspensive

<https://unctad.org/ippcaselaw/sites/default/files/ippcaselaw/2020-12/WTO%20DS408%20DS409%20India%2C%20Brazil%20v%20EU%20on%20seizure%20of%20goods%20in%20transit.pdf>, DOA: 05.05.2019.

⁵²⁰ Regulation (EU) No 608/2013 of the European Parliament and of the Council of 12 June 2013 concerning customs enforcement of intellectual property rights and repealing Council Regulation (EC) No 1383/2003.

⁵²¹ Mercurio, Bryan: "Seizing" Pharmaceuticals in Transit: Analysing the WTO Dispute that Wasn't, in: International and Comparative Law Quarterly (2012), Vol. 61, Is. 2, pp. 389-426, p. 399.

⁵²² Ibid.

⁵²³ See TRIPS Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994), Art. 1 (1).

⁵²⁴ Williams, Matthias: India, EU Heal Drug Seizures Dispute with Interim Settlement, in: Reuters, 2011. - <https://www.reuters.com/article/india-eu-drugs-idUSL3E7IS4WW20110728>, DOA: 14.06.2015.

procedures, in external transit, and are suspected of violating trademark, copyright, and design rights as per the legislation of an EU member nation. According to the judgement, goods may not even be temporarily detained in circumstances in which there is no evidence that the goods in question had been sold, presented for sale or advertised in the EU. The same was also applicable to instances in which there were indications that operators are about to direct the goods towards consumers in the Union or were otherwise disguising their commercial purposes. Consequently, the challenged goods in question could not be regarded as abandoned or be destroyed unless a comprehensive inspection has proven that the challenged goods have been sold, offered for sale or advertised to consumers in the EU or if there is documentation showing that diversion is foreseen.⁵²⁵ In this context, detention which is temporary in nature would require the border agencies to demonstrate, based on the act of the case, a planned or advertised sale or a lack of clarity about the intended destination of the goods the identity of the manufacturer or consignee.⁵²⁶ This would also include a failure to assist the relevant authorities.⁵²⁷ *Prima facie*, the judgment of the European Court of Justice can be regarded as the final blow to the legal concept of production or manufacturing fiction that was employed to warrant both the seizure and diversion of generic medicines in transit.⁵²⁸ Based on the combined judgements of the *Philips* and *Nokia* cases, *prima facie*, it can be concluded that goods in transit would remain untouched by the EU's IP legislation and would enjoy protection in the Union as long as they remain in transit and have not entered the domestic market of the EU.⁵²⁹

⁵²⁵ Joined Cases C-446/09 & C-495/09, Koninklijke Philips Electronics NV v. Lucheng Meijing Indus. Co., Nokia Corp. v. Her Majesty's of Revenue and Customs, 2011 E.C.R, para. 79.

⁵²⁶ Baker, Brook K.: Settlement of India/EU WTO Dispute re Seizures of In-Transit Medicines: Why the Proposed EU Border Regulation Isn't Good Enough. in: PIJIP, Research Paper no. 2012-02. Washington D.C.: American University Washington College of Law, 2012, p. 8.

⁵²⁷ Ibid.

⁵²⁸ Joined Cases C-446/09 & C-495/09, Koninklijke Philips Electronics NV v. Lucheng Meijing Indus. Co., Nokia Corp. v. Her Majesty's of Revenue and Customs, 2011 E.C.R, para. 69.

⁵²⁹ Ibid, para. 63.

Finally, it would be appropriate to apply the legal principle of proportionality. Proportionality is an established method of assessment when considering the legitimacy of the interference by states with fundamental human rights. Equally, it has been utilised by domestic, regional and international courts in the context of IPRs. Despite some variations due to the different judicial systems, proportionality, as a general rule, requires a three-step test through which courts evaluate whether or not an interference with fundamental human rights exists. Thus, the court proves whether the interference serves a pressing social need, whether it is necessary (in other words, there is no other less restrictive measure available) and it does not go beyond whatever is necessary to achieve the aims envisaged by the law.⁵³⁰ We shall now apply the legal principle of proportionality to the seizure of essential generic medicines from India by the EU. In the regard the court would need to establish that the interference (seizure) of essential generic medicines from India by the EU border officials is serving a pressing social need. For instance, prohibiting the influx from substandard generics from India that would be physically flooding the EU's internal market. In the scenario in question, however, the genuine pressing social need only existed on the side of Brazil as 300,000 Brazilians are dependent on the shipment of Losartan. Regarding whether the seizure of generics is necessary, it seems clear that less restrictive measures could have been applied, particularly, due to the fact that seizures only require suspicion. Similarly, seizing the essential medicine for the duration of 36 days and sending its back to India while patients in Brazil are dependent on the shipment seems to be rather excessive. With regard to the last point, these medicines were never earmarked for the EU market. Likewise, they were neither subject to patent protection in the country of origin nor in the country of final destination. Lastly, applying the three-step test with regard to the

⁵³⁰ Ariyaratna, Lasantha/ Kariyawasam, Kanchana: Pharmaceutical Patents and Access to Generic Medicines in Developing Countries, in: European Intellectual Property Review (2020), Vol. 42, Is. 2, pp. 108-118, p. 116.

proportionality principle, the measures applied by the EU appear to be disproportionate. Therefore, one could argue that the seizure of essential generic medicines from India by the EU border officials would qualify as interference with fundamental human rights.

To conclude, the seizure of essential generic Indian medicine from India by the EU border agencies displays the detrimental effects of the Council Resolution 1383/2003 with regard to international trade in generic medicines. The EU Regulations, together with the application of the concept of manufacturing fiction *de jure*, places generic medicines that are in transit and earmarked for destinations outside the EU in the same category as those medicines that would have been designated for the Union. As a result, these generics are subject to the same IPRs standards as those generics and other good which have been designated to the European market in the first place. Both Council Resolution 1383/2003 in accordance with the legal concept of “manufacturing fiction” have enabled the European border agencies to apply the same European IP standards to goods that are not destined to enter the EU. Mere suspicion would be sufficient in order to seize or detain the goods in question. Yet neither under Indian law (exporting state) nor under the law of Brazil (country of destination) have the drugs in question been subject to IPRs protection. Sadly, the seizure of generics from India that was designated to Brazil has hardly been an isolated incident and was followed by multiple seizures or detentions of generic medicines origination from India. In view of the repeated seizures and detentions by EU border authorises it appears to be rather safe to conclude that Brussels might be pursuing targeted and systematic efforts to *de facto* create barriers to trade (on the micro level) through the application of European IP standards to medicines that are in-transit. The European IP standards were applied at a much higher level than is required by the WTO under the TRIPS Agreement. According to Professor Abbott, these seizures have been an intentional effort by the EU to halt the development countries’ reliance

on a continual supply of generic medicines from India. On the macro level, the border enforcement measures that have been applied by the EU, *prime facie*, appear to be concealed actions to curtail the cheaper competition from Indian pharmaceuticals.

On another note, the seizure of essential generic medicine has also had detrimental consequences when it comes to the right to health, more precisely, to access to essential medicines. The Indian pharma industry has played an important role in bringing down the costs for generic medicines and making them affordable to people in the developing world. Consequently, one might argue that Indian generic medicines have substantially contributed to access to medicines for the global poor. Sadly, the seizure of Losartan and other drugs have led to considerable delays of the shipments and cargo to arrive at its ports of destinations. Consequently, in some cases the generic drugs from India have been sent back by the EU authorities to the place of origin, that is the Indian manufacturer. Both the delays and the non-delivery of the shipments and cargos had detrimental consequences for the patients that had been eagerly awaiting these, in some cases, life-saving drugs. For a multitude of developing countries these cost-effective generic medicines happened to be the only viable option.

In this respect it would be worth mentioning that paragraph 4 of the Doha Declaration also underlines the fact that the TRIPS Agreement should be interpreted in manner that is beneficial to access of medicines for all. According to scholars of the Max Plank Institute for Intellectual property, Competition and Tax Law, the seizures by the EU authorities have a detrimental effect on the efforts taken by the WTO to promote the Doha Declaration.

Regarding the question of whether the seizures by the EU border agencies are potentially creating a barrier to trade, it appears that Council Regulation 1383/2003 does indeed violate Article V (2) of the GATT Agreement which mandates the freedom of transit. Similarly,

Council Regulation 1383/2003 also violates Article 52 of TRIPS as, in the instance in question, it has obstructed legitimate trade. The Indian manufacturer had entered into legitimate trade relations, as upon seizure the EU authorities had no reason to challenge this. According to Article 52 TRIPS the law of the country of importation, Brazil, would have been applicable and not that of the EU. According to Brazilian IP law the imported generic medicines were permissible and by default the EU border agency's seizure of generic medicines from India represents a barrier to trade.

In sum, the seizure by the EU of Indian essential generic medicines *prima facie* seems to follow a hidden agenda, namely protecting the EU's internal market from the influx of cheap Indian generics. In any event the doctrine of "manufacturing fiction" has served as a barrier to "traffic in transit" for the legitimate trade in essential generic medicines.⁵³¹ Finally, the seizure of generic drugs from India by the EU appears to be disproportionate.

⁵³¹ Kumar, Shashank P.: Border Enforcement of IP Rights Against in Transit Generic Pharmaceuticals: An Analysis of Character and Consistency, in: European Intellectual Property Review (2010), Vol. 32, Is. 10, pp. 506-519, p. 514.

3.1. Generic Drugs

The seizures of in transit generic medicine of Indian origins by European Union member states exercising EU border regulation have caused much agitation between the EU and India. One such occasion was in December 2008 when Dutch customs authorities seized a shipment containing 570 kilograms of the generic drug Losartan for while in-transit.⁵³² Apart from the EU's IPRs protection regime and its potential protectionist agenda when it comes to competition from cheap generic medicines hailing from India, the question that arises is what other areas could be of concern when it comes to medicines that are produced in India. One such issue of concern could have been the potentially substandard quality of the Indian generic medicine. Regarding the issue in question, we shall consider generic antibiotics. The EU might have considered potential health hazards originating from the pharmaceutical supply chain in India, which might have also been in the minds of the EU regulators when they decided to ban Indian medicines in 2015.

To begin with, we shall look at the issue of antimicrobial resistance (AMR) in India and the various factors emerging as a concern for the global health security. The escalating bacterial resistance to modern antibiotics has been an increasing challenge, for the treatment of infectious illnesses in Indian hospitals.⁵³³ The American Center for Disease Control Prevention estimates that over two million people are suffering from illnesses due to bacterial infections resistant to a single or multiple antibiotics. The death toll in the United States alone amounts to 23,000 people. More than 58,000 babies have passed away in a single year as a direct result of infection with highly resistant bacteria spreading from the mothers.

⁵³² Nonaka, Melissa: Enough is Enough: India's fight against Seizures of Lawful Generic Medicines, in: Journal of Medicine and Law (2011), pp. 37- 57, p.47.

⁵³³ Pandhare, Akash: Bacterial resistance in India: Studying plasma antibiotics levels, in: Indian Journal of Critical Care Medicine (2015), Vol. 19, No.10. -

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4637955/>, DOA: 12.03.2018, pp. 574-575.

Antibiotic-resistant bacteria is a global threat expected to take 10 million lives each year in 2050 and cost \$100 trillion. Health professionals attribute nearly 1 million deaths each year to AMR and the predicted accelerated rise could make most routine procedures or common illnesses a “life-or-death gamble.”⁵³⁴ Although over- and misuse of antibiotics in human medicine and farming are the leading causes of AMR, manufacturing pollution is the third major interlinked cause. *“Changing Markets Foundation published a similar report in September that traced AMR to pollution from factories in India and China, where the vast majority of the world’s antibiotics are manufactured.”*⁵³⁵ 40% of the global antibiotics are produced at the medical production hub of India.⁵³⁶

In its report Changing Markets Foundation, tested for superbugs in water samples from a number of sites, including factories, local bodies of water and a sewage treatment plant. A total number of 34 sites were tested in Hyderabad, New Delhi, and Chennai, out of which investigators were able to find superbugs in 16. Four of the sites hosted bacteria resistant to the three major classes of antibiotics, including those of “last resort” (i.e. prescribed when all other medications fail). Analysis found three factories to be hotbeds of resistance: Aurobindo Pharma, Orchid Chemicals and Asiatic Drugs and Pharmaceuticals. Investigators followed antibiotics from these manufacturers through supply chain data and “Freedom of Information” requests to major distributors in the West, including United Kingdom’s National Health Service (NHS), French hospitals, German insurances and pharma giants Teva, Pfizer and McKesson, whose largest buyer is CVS Health.⁵³⁷ Antibiotics supplied to CVS can be traced directly to Aurobindo Unit 7, where 70% of all bacteria were found to be resistant to the three main classes of antibiotics.

⁵³⁴ Lu, Joanne: Antibiotic factories in India, China are spreading drug-resistant superbugs. in: Global Health. 2016. - <https://www.humanosphere.org/global-health/2016/10/antibiotic-factories-in-india-china-are-spreading-drug-resistant-superbugs/>, DOA: 18.09.2917.

⁵³⁵ Ibid.

⁵³⁶ Ibid.

⁵³⁷ Ibid.

As these factories in India and China are, in many cases, improperly dumping waste into their surroundings, concentrations of antibiotics in rivers in the Hyderabad area, for example, are 1,000 times higher than what is typical in developed countries. The burden of change, therefore, ultimately lies with major buyers, who should commit to supply chain transparency. Major buyers of antibiotics, such as the NHS, should take steps necessary to blacklist suppliers that are contributing to the spread of AMR through industrial pollution and ensure that all drug companies take action to clean up their supply chains, according to the Changing Markets Foundation. Thirteen global pharmaceutical companies pledged at the UN antibiotic resistance summit to review their supply chains for proper disposal of waste.⁵³⁸

Such bacterial resistance evolves as a result of mutations in these organisms as well as selection pressure exerted by unrestrained antibiotic use, which provides a competitive advantage to such mutated strains, thereby decreasing overall effectiveness of antibiotics in treating even common infections. In addition, suboptimal use of antibiotic agents further allows them to foster stepwise selection of resistance.

The resultant resistant clones are amenable to rapid worldwide spread which is facilitated by interspecies gene transmission, poor sanitation and hygiene in communities and hospitals, and the ever-increasing global travel, trade, and disease transmission. One such infamous examples is the “New Delhi matallo-beta-lactamase-1 (NDM-1)” resistance gene.⁵³⁹ It was first discovered in the United Kingdom in patients returning from India, detected in the wastewater of New Delhi, and hence named “NDM-1”.⁵⁴⁰ NDM-1 has been disseminated to 18

⁵³⁸ Ibid

⁵³⁹ Pandhare, Akash: Bacterial resistance in India: Studying plasma antibiotics levels, in: Indian Journal of Critical Care Medicine (2015), Vol. 19, No.10. -

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4637955/>, DOA: 12.03.2018, pp. 574-575.

⁵⁴⁰ Ibid.

countries including the United States and the European countries over the span of one year. Such are the consequences of the resistant gene travel in our modern “close-knit” world.

The following example illustrates how easily antibiotic resistance can spread. Antibiotics are given to poultry to protect them from diseases or to make them gain weight faster, so that more of them can be grown each year for greater profit. One drug typically given this way is colistin (antibiotics). Doctors call it the ‘last hope’ antibiotic because it is used to treat patients critically ill with infections that have become resistant to nearly all other drugs.⁵⁴¹ “*The World Health Organisation (WHO) has called for the use of such antibiotics, which it calls “critically important to human medicines”, to be restricted in animals and banned as growth promoters.*”⁵⁴² Their continued use in farming increases the chance of bacteria developing resistance to them, leaving them useless when treating patients.⁵⁴³

Another matter of concerns are growth promoters in the poultry industry. “*One of these companies, Venky’s, is also a major poultry producer. Apart from selling animal medicines and creating its own chicken meals, it supplies meat directly and indirectly to fast food chains in India such as KFC, McDonald’s, Pizza Hut and Domino’s.*”⁵⁴⁴ Venky’s sells colistin to farmers in India as a growth promoter. It comes in bags with illustrations of happy-looking chickens on the packet. Instructions say the product “improves weight gain” and 50 grams should be added to each ton of chicken feed. Venky’s branded colistin can be bought over the counter from poultry feed and medicines shops without the need for relevant prescription. In India

⁵⁴¹ Madlen, Davies/ Meesaraganda, Rahul: A game of chicken: how India’s poultry farms are spawning global superbugs. 2018. - <https://www.thehindu.com/news/national/a-game-of-chicken-how-indias-poultry-farms-are-spawning-global-superbugs/article22597845.ece>, DOA: 16.03.2018.

⁵⁴² Ibid.

⁵⁴³ Ibid.

⁵⁴⁴ Ibid.

there is no legal requirement for a prescription.⁵⁴⁵ In Europe, colistin is available to farmers only if prescribed by a vet for the treatment of sick animals. Venky's insists that it is not breaking Indian law by selling colistin and by the same token it expressed its willingness to comply with future regulatory changes. The company further insisted that their antibiotic products were designated for therapeutic use; it is acknowledged that some of these antibiotics in mild doses can be used at a preventive level, which may act as growth promoters. Venky's has distanced itself from encouraging an indiscriminative use of the antibiotics. Customs data shows Venky's exported colistin to Nepal and Yemen in 2017. Other poultry companies are selling colistin products or importing it for use on farms. McDonald's, KFC, Pizza Hut and Domino's have clarified that the chicken they sourced from Venky's is not raised on growth-promoting antibiotics and their suppliers follow their policies controlling their use of antibiotics.⁵⁴⁶ McDonald's has taken the initiative to phase out the use of significant antibiotics by 2018 for its major markets including the EU and the US. With regard to colistin McDonald's will take an additional year for phasing out in Europe. KFC has made a similar promise about its US supply chains. They have promised to do the same in India, but without providing a timeframe. Jubilant FoodWorks Limited (which owns Domino's) has set a date, of 2019 to start phasing out the drugs.⁵⁴⁷

In India, the poultry industry is booming. The amount of chicken produced doubled between 2003 and 2013. Chicken is popular because it can be eaten by people of all religions (pork is forbidden to Muslims and beef is generally not eaten by Hindus) and because it is versatile and affordable. Most poultry is now produced by commercial farms, contracted to major companies like Venky's. Researchers who tested meat from supermarkets in the country in 2014 found it

⁵⁴⁵ Ibid.

⁵⁴⁶ Ibid.

⁵⁴⁷ Ibid.

contained residues of six antibiotics, suggesting they were being used rather generously on farms. According to the Union Agriculture Ministry the residues were still within the range allowed by international agencies. Experts anticipate that the rising demand for protein will cause a surge in antibiotic use in livestock. Moreover, India's consumption of antibiotics in chickens is expected to be five times as much by 2030 compared to 2010, which in turn is in line with the global trend, which in animals is expected to rise by 53%. Using antibiotics as growth promoters has been banned in the European Union since 2006.⁵⁴⁸

As for the Director of the Centre for Disease Dynamics, Economics and Policy, Professor Laxminarayan, Indian farmers use antimicrobials as a substitute for good farming practices. According to Laxminarayan an average poultry farm in Punjab is lacking all the basics. Both nutrition and hygiene are particularly poor. So that the use of antibiotics is a substitute to keep the animals alive.⁵⁴⁹ According to Professor Walsh, an adviser to the UN on antimicrobial resistance, colistin is the last line of defence. It is the only drug that is left to treat critically ill patients with a carbapenem-resistant (resistance against so-called last resort drugs) infection. To use these kinds of antibiotics as a feeding supplement, *prima facie*, seems to be highly irresponsible. Colistin-resistant bacteria will spread on the chicken farms, in the air surrounding them, contaminate the meat, disperse to the farm workers and, through their faeces, flies will spread it over considerable distances. Colistin should only be used to treat patients with severe illnesses. Other than that, it should be thought of and treated as an environmental toxin. Moreover, given the inherent dangers, the labelling should clearly indicate the potential dangers of using these antibiotics as a feeding supplement. Hence, it should not be exported all over the world to be used in chicken feed."⁵⁵⁰

⁵⁴⁸ Ibid.

⁵⁴⁹ Ibid.

⁵⁵⁰ Ibid.

England's chief medical officer, Professor Sally Davies, called for a global ban on all antibiotics as growth promoters. "Drug resistance has been called one of the biggest threats to global health, food security and development by the WHO."⁵⁵¹ In situations where antibiotics stop working, doctors will not be in the position to effectively treat deadly infections.⁵⁵² Currently this kind of drug resistance is thought to kill 700,000 people on the globe annually. Consequently, one person dies every minute, these figures have, however, been disputed by some academics. "The death toll is expected to rise to 10 million by 2050 if no action is taken, with 4.7 million of those deaths in Asia".⁵⁵³ "As a result, common procedures like joint replacements, caesarean sections, organ transplants and chemotherapy could potentially become too risky to carry out."⁵⁵⁴

India has been called the epicentre of the global drug resistance crisis.⁵⁵⁵ A combination of factors have come together to accelerate the spread of superbugs. Unregulated sale of the drugs for human or animal use accessed without prescription or diagnosis has led to both unchecked consumption and misuse. Yet another potential factor that promotes the spread of antibiotic resistance in India come down to the fact that it has a large population, some of whom are forced to defecate in the open due to lack of proper sanitation facilities. Waste is often poured untreated into rivers and lakes, creating the perfect surrounding for bugs to share resistance. Despite the lack of exact figures on how many people are dying of resistant infections, a study estimates drug-resistant infections are killing 58,000 new-born children every year in India.⁵⁵⁶ As a consequence of poor sanitation people

⁵⁵¹ Ibid.

⁵⁵² Ibid.

⁵⁵³ Ibid.

⁵⁵⁴ Ibid.

⁵⁵⁵ Pandhare, Akash: Bacterial resistance in India: Studying plasma antibiotics levels, in: Indian Journal of Critical Care Medicine (2015), Vol. 19, No.10. -

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4637955/>, DOA: 12.03.2018, pp. 574-575.

⁵⁵⁶ Ibid.

often catch infections that require treatment with antibiotics. Overuse of the drugs in hospitals has created antibiotic resistant hotspots, and poor infection control means these bugs spread within the hospital and into the community. Some pharmaceutical companies manufacturing antibiotics have also failed to dispose of antibiotic-ridden waste properly, fuelling the spread of resistant bugs in the environment.⁵⁵⁷

All these factors have led to high rates of resistance. In India, 57% of the klebsiella pneumonia bacteria which generally cause urine, lung and bloodstream infections became resistant to last-line antibiotics known as carbapenems. In the UK, by comparison, the figure is below 1%. Doctors in some areas of India see patients with pan-resistant infections (immune to nearly all antibiotics) at least once a month. Another case of an antibiotic resistant superbug was recorded, at the Leicester Royal Infirmary (UK), in August 2018. Patients tested positive for carbapenem resistant organisms. This infection or antibiotics resistance can spread through contact with an infected person. Equally, touching objects or surfaces used by an infected individual will be sufficient for the infection to spread. A true nightmare scenario, which has reached European shores.⁵⁵⁸

Apart from malnutrition, the Indian health system is increasingly facing the challenge of treating patients with multi-drug as well as pan-drug resistance. The medical superintendent at the Amrita Institute of Medical Sciences in Kochi, for instance, has treated patients with multi-drug resistant infections up to three times a week and patients with pan-drug resistant infections up to twice a month.

Clinical practitioners believe that it becomes enormously difficult to treat patients with multi-drug and pan-drug resistant organisms. In most cases, medical personnel are able to diagnose the patient's

⁵⁵⁷ Ibid.

⁵⁵⁸ Orton, Amy: Leicester Royal Infirmary patients tested for antibiotic resistant superbugs after case diagnosed. 2018. - <https://www.leicestermercury.co.uk/news/health/leicester-royal-infirmary-patients-tested-1885609>, DOA: 15.08.2018.

condition but are left with limited options when it comes to relevant treatment. This increases the illness and mortality of patients, and in turn the cost of care has also gone up drastically. Limited options with regard to the relevant treatment is a direct consequence of the rest of the people in the chain, including animal industry, policy makers, waste disposal, not playing their role adequately. Doctors and other medical personnel are left to their own devices and must witness young patients dying in front of their eyes.⁵⁵⁹

The consumption of antibiotics in India has increased sharply while the effectiveness of these drugs to treat bacterial infections has been steadily declining. *"High disease burden, rising income, cheap, unregulated sales of antibiotics and poor public health infrastructure are some of the reasons for the sharp increase in antibiotic use."*⁵⁶⁰ A report (in August 2014) in the journal The Lancet Infectious Diseases, said that in 2010 India consumed 13 billion units of antibiotics, the highest in the world. Between 2005 and 2009, consumption rose by 40%.⁵⁶¹

The consequences of increased prevalence of antimicrobial resistance are best illustrated in the case of neonatal sepsis (a bacterial bloodstream infection by babies). On average 57,000 neonates die each year in India, once again the highest in the world; this is down to a sepsis infection that is resistant to first-line antibiotics. In 2012, India had the highest neonatal deaths (nearly 779,000). The irony of the situation lies in the fact that lack of access or delayed access to effective antibiotics is causing more deaths in India than from drug-resistant bacteria. This is best revealed in the case of pneumonia (lung

⁵⁵⁹ Ibid.

⁵⁶⁰ Prasad, Ravindranath: The antibiotic red line of control. in: The Hindu, 2016. - <https://www.thehindu.com/opinion/op-ed/The-antibiotic-red-line-of-control/article14140186.ece>, DOA: 05.07.2017.

⁵⁶¹ Orton, Amy: Leicester Royal Infirmary patients tested for antibiotic resistant superbugs after case diagnosed. 2018. - <https://www.leicestermercury.co.uk/news/health/leicester-royal-infirmary-patients-tested-1885609>, DOA: 15.08.2018.

infection) in children under five years of age. Most of the 1,70,000 pneumonia deaths that occurred in this age group in India in 2013 could have been averted had these children had access to effective antibiotics. Only 12.5% of affected children received antibiotic treatment for pneumonia.⁵⁶² As a result, like many other developing countries, India must turn the spotlight on to ensuring sustainable access even while maintaining sustainable effectiveness of all antibiotics. The only way to achieve this twin challenge is by ensuring that all stakeholders – the government, patients, veterinarians, doctors, pharmacists, pharmaceutical companies and health-care facilities play their respective roles more responsibly.⁵⁶³ An essential step would be to create awareness that stopping antibiotics midway, missing doses, taking suboptimal dosages, or consuming antibiotics for cold and other viral infections is causing resistance to antibiotics. In such cases where there is subsequent illness, the only recourse will be taking more expensive drugs, or possibly nothing at all. This is best exemplified in the case of multidrug-resistant tuberculosis that requires a longer period of treatment using very toxic drugs that are more expensive.

The Indian government has now woken up to the reality of the superbug pandemonium. A major issue of concern are factories that produce antibiotics in India that are disseminating drug-resistant superbugs; investigations revealed drug-resistant bacteria or superbugs in antibiotic factories in India. These factories are exporting to major distributors in the West, mainly located in the US and EU.

One way to tackle the superbug misery would be for the government in New Delhi to crack down on drug companies manufacturing irrational fixed-dose combination drugs. The issue with these loose antimicrobials is that they do not come with packaging, nor do they

⁵⁶² Prasad, Ravindranath: The antibiotic red line of control. in: The Hindu, 2016. - <https://www.thehindu.com/opinion/op-ed/The-antibiotic-red-line-of-control/article14140186.ece>, DOA: 05.07.2017.

⁵⁶³ Ibid.

state the name of the relevant drug, its manufacturer, the manufacturing date, or the expiry date.⁵⁶⁴ The detrimental consequences of using these drugs are all too imaginable. In this context, it seems almost inevitable that it will be necessary to compel the Indian government to undertake steps to regulate drug companies discharging antimicrobial waste into the “environment, and regulate the use of antibiotics in animal feed to combat antibiotic resistance and obtain healthier animal products. Misuse of antibiotics in food animals is linked to the antibiotic resistance problems we face today.”⁵⁶⁵ Better sanitation and effective infection control measures in health-care settings will also drastically cut the spread of drug-resistant strains.

As a 2013 study in the Indian Journal of Medical Ethics revealed, knowledge of antibiotic resistance was reasonable among doctors, but low in priority.⁵⁶⁶ Inadequate diagnostic facilities, lack of antibiotic guidelines, patients’ demand for quick relief, incentives from drugs companies and chemists to push certain products often determined doctors’ prescription habits.⁵⁶⁷ The collusion of drug companies and chemists is also apparent in the rampant over-the-counter (OTC) sale of antibiotics, particularly carbapenems (among the highest in the world), even for ailments where they are not indicative. The introduction of Schedule H1 category from March 2014 to prevent the sale of 24 third- and fourth-generation antibiotics without prescription is a step in the right direction. Licences of 213 retail pharmacies have been cancelled for non-compliance.⁵⁶⁸ But restricting OTC sales of antibiotics, particularly the commonly used ones, is a double-edged sword. Any intervention to limit access by enforcing prescription-only laws unwittingly cuts off a vast majority of the population, particularly in the rural areas, that lack access to doctors. Consequently, the Indian Ministry of Health & Family Welfare introduced a much-needed public

⁵⁶⁴ Ibid.

⁵⁶⁵ Ibid.

⁵⁶⁶ Ibid.

⁵⁶⁷ Ibid.

⁵⁶⁸ Ibid.

awareness campaign to highlight the dangers of misuse and irrational use of antibiotics, which was referred to as “Medicines with the Red Line”.⁵⁶⁹

In conclusion, the emergence of AMR in India and the spread to the EU might have been a concern for the drug regulators in Brussels. It is important to note that India is producing 40% of the generics in the world. Multiple Indian manufacturers have been tested for superbugs that are resistant to antibiotics in the water of the production sites. The reason for this is *inter alia* due to the fact that factories in India were dumping their wastewaters into the rivers. Generic medicines from these manufacturers have already reached the EU market. Another issue of concern is the spread of AMR in India, which has serious implications for global health security. Unfortunately, this antibiotic resistance spreads globally through multiple avenues, starting from the water and sewage system to agriculture and livestock. Similarly, through poor sanitation and hygiene in communities and hospitals, or through global trade and travel. Antibiotic resistance in the form of “NDM-1” has already been discovered in the EU. Another similar resistance has been recorded in Leicester, which has the capacity to spread through contact with an infected person or through the touching of objects or surfaces used by an infected individual. Given the fact that India has been at the epicentre of the global drug resistance crisis, Brussels’ response could have been triggered by the potential health hazard, originating from New Delhi to ban generic medicines from India out of precaution. In this context, Brussels’ ban of 700 generic drugs originating from India, *prima facie*, appears to be hardly surprising.⁵⁷⁰

⁵⁶⁹ Ibid.

⁵⁷⁰ The Hindu : EU bans 700 generic drugs for manipulation of trials by GVK Biosciences. 2018. - <https://www.thehindubusinessline.com/companies/eu-bans-700-generic-drugs-for-manipulation-of-trials-by-gvk/article7464217.ece>, DOA: 20.03.2018.

4. Access to Medicine from a Human Rights Perspective

*"While intellectual property rights have the important function of providing incentives for innovation, they can, in some cases, obstruct access by pushing up the price of medicines. The right to health requires a company that holds a patent on a lifesaving medicine to make use of all the arrangements at its disposal to render the medicine accessible to all."*⁵⁷¹

UN Expert Consultant

Good health is fundamental to the full enjoyment of life. If one were to fall ill, access to medicines and medical treatment may decide life and death, which by default has an impact on the right to life. In this context it is particularly worrisome that two billion people around the world are facing enormous obstacles with regard to access to medicines. A significant reason for the lack of access to medicines comes down to affordability, and the high prices for medicines that have been charged by the global pharmaceutical industry also referred to as Big Pharma. The pharmaceutical industry for their part tends to cite the enormous costs for the research and development (R&D) of new drugs as the reason for both the high prices for medicines and patent protection. Thus, this work will briefly cover this aspect of R&D. Additionally, in order to emphasise the holistic nature of human rights, the first sub-chapter will consider the philosophical dimension of the concept of human rights, in general, and the right to health, in particular. The second sub-chapter will examine the concept of human rights and investigate whether the access to medicine can be classed as a human right. Similarly, this section also aims to examine relevant human rights treaties, as well as domestic, regional, and international

⁵⁷¹ United Nations General Assembly: Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health. Expert Consultation on Access to Medicines as a Fundamental Component of the Right to Health. in: UN Doc. A/HRC 17/43. 2011. - <https://digitallibrary.un.org/record/706244>, DOA: 21.09.2017.

legislation including case law. This chapter will also investigate the supremacy of conflicting legal norms. In other words, it will investigate whether the IP law or international human rights law should prevail in situations when there is a conflict between two competing norms. More precisely this work will examine whether the right to health, in the form of access to medicines, should take precedence over IP law in the case of a conflict between both norms. This will be followed by the third sub-chapter which intends to study the Maastricht Principles of Extraterritorial Obligations of States in the Area of Economic, Social and Cultural Rights; which *inter alia* places particular obligations upon states, when behaving in a manner that has a real and predictable impact on human rights beyond their national border. In addition, the fourth sub-chapter will also explore the subject matter of evergreen, which consists of minor modifications to already existing patents in order to *de facto* prolong essentially the same patent protection. Finally, the fifth and last sub-chapter examines the landmark case of the Initiative for Medicines, Access & Knowledge (I-MAK) v. Abbott Laboratories⁵⁷² and illustrates how Abbott Laboratory employed evergreen to reap maximum profit with very little effort.

Typically, the proponents of access to affordable medicine have argued that pharmaceutical patents have resulted in higher prices for medicines, and thus have a detrimental effect when it comes to the access to medicines. This is in line with economic theory and empirical studies that both predict that patent protection in the majority of cases leads to a position of monopoly, and goes hand in hand with greater costs for medicines.⁵⁷³ For the pharmaceutical industry, these high costs for medicines are justified as they had to recoup their initial investments for the R&D expenditures that were borne by them.

⁵⁷² From here on referred to as I-MAK case.

⁵⁷³ Watal, Jayashree/ Scherer, FM: Post-TRIPS options for access to patented medicines in developing countries. Commission on macroeconomics and health working paper series. Paper no. WG 4:1. World Health Organization: Geneva, 2001. - <http://www.icrier.org/pdf/jayawatal%20.pdf>, DOA: 03.03.2018.

Patent protection essentially serves as an incentive to invest in scientific inventions.⁵⁷⁴

While R&D is an essential component when it comes to the development of new medication, it needs to be highlighted that a considerable portion of this critical research is undertaken with the help of public funding. For instance, campaigners have pointed out that many antiretrovirals (anti-HIV drugs) were developed in public-funded laboratories. Furthermore, Sofosbuvir, a highly priced and very effective medication for the treatment of Hepatitis C, was also invented with the support of public funds.⁵⁷⁵

Contrary to both the notion of the universality of the right to health, and the aforementioned written statement issued by the UN expert consultant, the Chef Executive Officer (CEO), Marijn Dekkers, of pharmaceutical multinational Bayer has criticised India's compulsory license policy for the cancer drug Sorafenib (Nexavar). In this context, Mr Dekkers issued the following statement:

*"We did not develop this medicine for Indians. We developed it for Western patients who can afford it."*⁵⁷⁶

The statement from the Bayer CEO highlighted, rather nicely, the discriminatory approach by European companies, when they could make essential generic medicines available for the poor population in India, which has been in dire need of access to Nexavar, to provide therapeutic treatments for those who could otherwise not afford Western or European prices for the treatment of cancer. The Nexavar

⁵⁷⁴ CIPR: Integrating intellectual property rights and development policy. Report of the Commission on Intellectual Property Rights. UK Commission on Intellectual Property Rights, London. 2002. - http://www.iprcommission.org/papers/pdfs/final_report/CIPRfullfinal.pdf, DOA: 05.05.2018, pp. 29-30.

⁵⁷⁵ Farmer, Paul: Pathologies of Power: Health, Human Rights, and the New War on the Poor. Berkeley and Los Angeles: University of California Press, 2013, p. 317.

⁵⁷⁶ Knowledge Ecology International: Transcript of Bayer CEO Marjin Dekkers, quote at the FT Event, regarding India compulsory license of Nexavar. 2013. - <https://www.keionline.org/22414>, DOA: 27.02.2016.

example, *prima facie*, seems to be in violation of international human rights law, or precisely, with the spirit of the International Covenant on Economic, Social, and Cultural Rights (ICESCR). Under the ICESCR, access to medicines should be realised without distinction on grounds of race, colour, sex, language, religion, political or other opinion, national or social origin, property, disability, birth or other status.⁵⁷⁷

Moreover, a human rights approach must also be supported by both robust international assistance and cooperation. This is more so the case whenever public health objectives are in danger of not being fulfilled with an immediate effect by any country.⁵⁷⁸ As part of the tripartite classification⁵⁷⁹ when it comes to obligations for all human rights, experts increasingly insist that the duty to fulfil rights suggests that developed countries have positive duties that go beyond the limitation of their borders.⁵⁸⁰ According to the CESCR, developed countries have a responsibility to assist states in need, to the maximum of their capacities, in situations of emergency.⁵⁸¹ Furthermore, while states hold the core responsibility for essential medicines provision, these responsibilities are indeed extended to other non-state actors. This multi-level approach would involve participation and coordination between governments, philanthropic organizations, international entities, civil society groups, and last but not least the private sector.⁵⁸² More precisely, pharmaceutical

⁵⁷⁷ Office of the High Commissioner for Human Rights and World Health Organization: The Right to Health, Fact Sheet No. 31. -

<http://www.ohchr.org/Documents/Publications/Factsheet31.pdf>, DOA: 26.06.2020.

⁵⁷⁸ UN Committee on Economic, Social and Cultural Rights (CESCR), CESCR General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12), 2000. - <https://www.refworld.org/pdfid/4538838d0.pdf>, DOA: 11.01.2021, para. 40.

⁵⁷⁹ The tripartite classification involves the following obligations: respect, protect and fulfil.

⁵⁸⁰ Vandenhole, W.: Is There a Legal Obligation to Cooperate Internationally for Development? Convention of the Rights of the Child (CRC). in: Report to General Day of Discussion. 2007. - <http://www.crin.org/docs/Vandenhole%20International%20Cooperation.pdf>, DOA: 11.01.2021, p. 1.

⁵⁸¹ UN Committee on Economic, Social and Cultural Rights (CESCR), CESCR General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12). 2000. - <https://www.refworld.org/pdfid/4538838d0.pdf>, DOA: 11.01.2021, para. 40.

⁵⁸² FXB Center Harvard University: Health and Human Rights Resource Guide: How is Access to Medicines a Human Rights Issue? 2019. - <https://www.hhrguide.org/2017/06/09/access-to-medicines-and-human-rights/>, DOA: 02.12.2019.

corporations also have human rights responsibilities as per the former UN Special Rapporteur on the Right to Health, this would include the duty to take all reasonable actions to make new medicines “as available as possible” for those in need.⁵⁸³ Equally, the international community itself also has human rights obligations to assist governments lacking resources to achieve their minimum core duties through international cooperation and assistance. In the face of disaster, the international community holds the responsibility to contribute to relief and humanitarian assistance by providing medical supplies as a matter of priority.⁵⁸⁴

⁵⁸³ United Nations General Assembly, The Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health: Report of the Special Rapporteur, Paul Hunt, U.N. General Assembly, 63rd Session, Agenda Item 67(b), U.N. Doc, A/63/263. 2008. - https://www.who.int/medicines/areas/human_rights/A63_263.pdf, DOA: 10.01.2020.

⁵⁸⁴ United Nations General Assembly, International Covenant on Economic, Social and Cultural Rights, International Covenant on Civil and Political Rights and Optional Protocol to the International Covenant on Civil and Political Rights, 16 December 1966, A/RES/2200. - <https://www.refworld.org/docid/3b00f47924.html>, DOA: 11.03.2021, Art. 2(1).

4.1. The Philosophical Dimension of the Right to Health

The right to health prima, *facie forms*, an indispensable component of international human rights law. This section highlights the ethical justiciability of the right to health. Arguments for the supremacy of human rights over IPRs are based on philosophical and legal considerations; the notion of human rights is tightly linked with the ethics and morals, as the *raison d'être* of human rights are found in the inherent dignity of human beings. It has been argued that human rights are universal, irrevocable and inalienable as they find their foundation in natural law. Britannica defends natural law as following:

*[...] in philosophy, a system of right or justice held to be common to all humans and derived from nature rather than from the rules of society, or positive law.*⁵⁸⁵

Moreover, the Office of the High Commissioner for Human Rights defines human rights as:

*...[the] rights we have simply because we exist as human beings, they are not granted by any state. These universal rights are inherent to us all, regardless of nationality, sex, national or ethnic origin, colour, religion, language, or any other status. They range from the most fundamental - the right to life - to those that make life worth living, such as the rights to food, education, work, health, and liberty.*⁵⁸⁶

As natural law predates the establishment of the nation state, it is recognised by states rather than being created by them. The subject matter of natural law and, more precisely, natural rights was developed in the wake of the 17th century and is closely linked to John Locke. These natural rights covered, *inter alia*, the right to life and

⁵⁸⁵ Britannica: Natural law. - <https://www.britannica.com/topic/natural-law>, DOA: 13.03.2021.

⁵⁸⁶ United Nations Office of the High Commissioner for Human Rights: What are human rights? - <https://www.ohchr.org/en/issues/pages/whatarehumanrights.aspx>, DOA: 15.03.2021.

liberty.⁵⁸⁷ IPRs on the other hand are bestowed by national and supranational governments; they are subject to rigorous statutory limitations, are alienable and limited in time. They can both be revoked and owned by multinational pharmaceutical and other corporations.⁵⁸⁸ To put it in other terms, IPRs are artificial in nature and not inherent. Human rights lawyers have argued that IPRs have been a considerable obstacle when it comes to the full realisation of access to essential medicines globally; in this context, patents have served as a reason for impeding the capillary distribution of affordable drugs.⁵⁸⁹ If one was to apply Aristotle's principle of proportional justice to the right to health, it would mean to aid the allocation of resources to those who have the greatest need, in order to take them as close to a particular level of functioning as circumstances permit.⁵⁹⁰

In 1990 NGOs and international organisations alike condemned TRIPS and strict IP regulations, in the context of bilateral treaties, for the reprehensible outcomes of health policies employed by developing countries.⁵⁹¹ In order to rectify this unsatisfactory situation, several legal instruments recommended embracing a more ethical framework. This ethical framework would limit the scope of IPRs with a view to accommodate human rights issues.⁵⁹² These situations were later reaffirmed by intellectual property academics, who only entered the academic landscape just before the end of the 1990s.⁵⁹³

⁵⁸⁷ Shaw, Malcolm: International law. 6th ed. Cambridge: Cambridge University Press, 2008, p. 266.

⁵⁸⁸ Ali, Gabriele: Intellectual Property and Human Rights: A Taxonomy of Their Interactions, in: International Review of Intellectual Property and Competition Law (2020), No. 51, p. 411-445, p. 416.

⁵⁸⁹ Ibid.

⁵⁹⁰ Ruger, Jennifer Prah: Toward a Theory of a Right to Health: Capability and Incompletely Theorized Agreements, in: Yale Journal of Law & The Humanities (2006), Vol.18, Is. 2, pp. 273-326, p. 292.

⁵⁹¹ Papadopoulou, F.: TRIPS and Human Rights. in: Kur, A/ Levin, M (eds.). Intellectual Property Rights in a Fair World trade System. Cheltenham: Edward Elgar Publishing, 2011, p. 262.

⁵⁹² Graeme, Austin/ Helfer, Laurence: Human Rights and Intellectual Property: Mapping the Global Interface. Cambridge: Cambridge University Press, 2011, pp. 53-56.

⁵⁹³ Ibid, pp. 34-65.

It would now be appropriate to discuss the universality of human rights. Political universality of human rights can today hardly be refuted. The experience of World War II and atrocities committed by the Nazi regime has further strengthened acceptance of the idea of human rights; most of the international community of states have accepted the universality in one shape or form.⁵⁹⁴ The concept of human rights has virtually been incorporated into almost every nation's constitution in the world.⁵⁹⁵ However, as the saying goes, talk is cheap and paper is patient, the mere political and legal acceptance of human rights does not guarantee universal respect and adherence of the same. The constitutional and international popularity of human rights seems to have finally arrived in the contemporary world. Thanks to these political developments, religious and philosophical opposition to human rights has largely come to an end.⁵⁹⁶

In the religious context all major religions have, *prima facie*, down played doctrines that were in conflict with human rights, for instance, subordination of women or intolerance towards other religions. There are, however, expectations to the general rule in the form of religious fundamentalists. Human rights are commonly regarded by a multitude of religions as the bare minimum requisite for the good society, particularly, when it comes to contemporary urbanised societies.⁵⁹⁷ Louis Henkin argued that all religions and societies have accepted one or other of rights that satisfy basic human requirements.⁵⁹⁸ Modern technology has allowed for the concept of human rights to have reached illiterate rural communities around the world. Regardless of whatever part of the world one was to look at, *prima facie*, it is gradually being recognised that villages would indeed need human rights, laws, education, institutions, and last but not least, organisation

⁵⁹⁴ Henkin, Louis: The Universality of the Concept of Human Rights, in: The Annals of the American Academy of Political and Social Science (1989), Vol. 506, No. 1, pp.10-16, p.13.

⁵⁹⁵ Ibid.

⁵⁹⁶ Ibid.

⁵⁹⁷ Ibid, p.14.

⁵⁹⁸ Ibid.

in order become part of the modern community of nations.⁵⁹⁹ The concept of human rights has been accepted by the community of global leaders, regardless of whether they have been Western educated or not.⁶⁰⁰

Yet particular tension has been created between the universality of human rights and cultural traditions.⁶⁰¹ Critics have claimed the concept of human rights to be an invention hailing from the West with the intention to force their concept into the rest of the globe.⁶⁰² This has led to rejection and resistance by many cultures.⁶⁰³ For Henkin, much of this resistance to human rights is not going against the concept itself, but are in tension with the politics of the UN and their imposed sanctions for human rights infringements. The global community of states do not, according to Henkin, reject the concept of human rights itself. He also contends that while no one argues that human rights are not a Western concept, by the same token people do not contend that they are culturally estranged and not acceptable.⁶⁰⁴ The danger of the fundamentally pro cultural or religious standpoint would not only challenge the universality of human rights but would, according to Malcolm Shaw, open not only doors but also gates to plead the defence of cultural difference when violating basic human rights covering, for instance, the right to health.⁶⁰⁵

Moreover, the modern rights theories contain a wide array of approaches, including the acknowledgment of the preconditions of an embryonic legal system.⁶⁰⁶ More importantly, the work of the policy-

⁵⁹⁹ Ibid.

⁶⁰⁰ Ibid.

⁶⁰¹ Shaw, Malcolm: International law. 6th ed. Cambridge: Cambridge University Press, 2008, p. 269.

⁶⁰² Donnelly, Jack: The Relative Universality of Human Rights, in: Human Rights Quarterly (2007), Vol. 29, No.2, pp. 281-306, p. 286.

⁶⁰³ Henkin, Louis: The Universality of the Concept of Human Rights, in: The Annals of the American Academy of Political and Social Science (1989), Vol. 506, No. 1, pp.10-16, p.14.

⁶⁰⁴ Ibid.

⁶⁰⁵ Shaw, Malcolm: International law. 6th ed. Cambridge: Cambridge University Press, 2008, p. 270.

⁶⁰⁶ Ibid, p. 267.

oriented movement was seeking to identify a wide range of important components in the process of both human rights creation, as well as equipment. In this context there are eight independent values earmarked. The relevant values are well-being, health, respect, power, enlightenment, skill, affection and rectitude. In addition, human dignity has been regarded as a concept in which the allocation of values is pursued in a democratic manner by the global community.⁶⁰⁷

Furthermore, the Vienna Declaration and Programme of Action mentions that:

*[a]ll human rights are universal, indivisible and interdependent and interrelated. The international community must treat human rights globally in a fair and equal manner, on the same footing, and with the same emphasis.*⁶⁰⁸

Human rights lawyers and advocates have claimed that there are three generations of human rights. The first generation encompasses civil and political rights. The second generation comprises generally rights covering social, economic, and cultural rights, such as the right to health. The third generation includes general notions of collective or group rights, such as self-determination, right to development, right to health and environmental protection.⁶⁰⁹ Unfortunately, many policymakers, commentators, and governments still have to come to the conclusion that all forms of human rights have indeed the same priority and standing. Many of these protagonists tend to prioritise civil and political rights over economic, social and cultural rights or collective rights.⁶¹⁰ In order to complicate matters even more,

⁶⁰⁷ Ibid.

⁶⁰⁸ United Nations General Assembly, Vienna Declaration and Programme of Action. A/CONF.157/23. 12 July 1993. - <https://www.refworld.org/docid/3ae6b39ec.html>, DOA: 28.06.2020.

⁶⁰⁹ Dixon, Martin: Textbook on International Law. 7th ed. Oxford: Oxford University Press, 2013, p. 373.

⁶¹⁰ Yu, Peter: EU Economic Partnership Agreements and International Human Rights, in: Drexel, Josef/ Grosse Ruse-Khan, Henning/ Nadde-Phlix, Souheir (eds.): EU Bilateral Trade

commentators and policymakers have advocated dissimilar concepts of human rights. Some have subscribed to the philosophical approach that relies heavily on natural law, others have taken a stand for a rather positivist approach. The positivist approach tends to concentrate on establishing a compromise between the existing regional and international human rights instruments. In this context Richard Falk observed the following:

[t]he positivists consider the content of human rights to be determined by the text agreed upon by states and embodied in valid treaties or determined by obligatory state practice attaining the status of binding international custom. The naturalists, on the other hand, regard the content of human rights as principally based upon immutable values that endow standards and norms with a universal validity.”

Yet some observers have also questioned whether the rather trivial norms of IPRs could have the same footing as the fundamental human rights such as the right to life, the right health or even the prohibition of slavery or genocide.⁶¹¹ When it comes to access to medicine as a human right both approaches do have their validity, can exist side by side, and could also complement each other in order to put forward the argument that the access to medicine is indeed a human right.

Agreements and Intellectual Property: For Better or Worse? Heidelberg: Springer, 2014, pp. 109-131, p. 112.

⁶¹¹ Yu, Peter: TRIPS and its Achilles' heel, in: Journal of Intellectual Property Law (2011), Vol.18, pp.479–531, p. 713.

4.2. The Right to Health

A billion humans around the world lack access to essential medicines; thus, improving access to existing drugs could save the lives of ten million human beings, out of which four million are living in South- East Asia and Africa.⁶¹² High income countries spend around 100 times the revenue, compared to their counterparts in low-income nations.⁶¹³ Estimations of the WHO further highlight global injustice when it comes to access to medicines, stating that 15 per cent of the global populace consume more than 90 per cent of worldwide medications.⁶¹⁴ There seem to be a multitude of sources that safeguard access to essential medicines, an obvious notion being the right to health. Access to essential medicines, rooted in the right to the highest attainable standard of health, has been established in international law. The 1946 Constitution of the WHO and the 1948 Universal Declaration of Human Rights (UDHR) both expressly recognise the right to health.⁶¹⁵ The 1946 WHO preamble states the following:

*"[t]he enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition."*⁶¹⁶

⁶¹² World Health Organization: Medicines strategy: countries at the core, 2004-2007. Geneva. 2004. -

https://apps.who.int/iris/bitstream/handle/10665/68514/WHO_EDM_2004.2.pdf?sequence=1&isAllowed=y, DOA: 12.02.2021.

⁶¹³ Hunt, Paul/ Khosla, Rajat: The Human Right to Medicines, in: Sur - Revista Internacional de Direitos Humanos (2008), Vol. 5, No.8. -

https://www.scielo.br/scielo.php?script=sci_arttext&pid=S1806-

[64452008000100006&lng=en&nrm=iso&tlng=en#2](#), DOA: 12.04.2016.

⁶¹⁴ World Health Organization: Medicines strategy: countries at the core, 2004-2007. Geneva. 2004. -

https://apps.who.int/iris/bitstream/handle/10665/68514/WHO_EDM_2004.2.pdf?sequence=1&isAllowed=y, DOA: 12.02.2021.

⁶¹⁵ See preamble, United Nations General Assembly, Entry into force of the constitution of the World Health Organization, 17.11.1947, A/RES/131. -

https://apps.who.int/gb/bd/pdf_files/BD_49th-en.pdf, DOA: 13.01.2021.

⁶¹⁶ Ibid.

The same constitution highlights the danger when it comes to different levels of development amongst the international community, and thus states:

*[u]n[equal] development in different countries in the promotion of health and control of disease, especially communicable disease, is a common danger.*⁶¹⁷

Moreover, it also emphasises the essential nature of extending medical knowledge to every people and notes the following:

*[t]he extension to all peoples of the benefits of medical, psychological and related knowledge is essential to the fullest attainment of health.*⁶¹⁸

The WHO, resolutions of the Human Rights Council, several national court cases, and the Doha Declaration on TRIPS and Public Health, reaffirm access to essential medicines as a human right that must be open for everyone.⁶¹⁹ The subject of access to medicines lies at the crossroads between trade law, intellectual property law and international human rights law.

During past decades there have been considerable developments in the field of medical science and technology which have prompted the call for new forms of legal protection for intellectual property; the IP system has also experienced considerable growth over past decades. The right to health, as such, has been codified in numerous legal mechanisms. Article 25 of the UDHR states the following:

⁶¹⁷ Ibid.

⁶¹⁸ Ibid.

⁶¹⁹ FXB Center Harvard University: Health and Human Rights Resource Guide: How is Access to Medicines a Human Rights Issue? 2019. - <https://www.hhrguide.org/2017/06/09/access-to-medicines-and-human-rights/>, DOA: 02.12.2019.

[e]veryone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control.”⁶²⁰

Many of UDHR provisions have widely been recognised, are adhered to, and have evolved into customary international law, thereby become binding upon every state in the world.⁶²¹ Martin Dixon concurs with this position and notes that states are, consequently, bound to give due regard to human rights within their jurisdiction.⁶²² The International Committee of the Red Cross defines customary international law as follows:

[...] rules that come from a general practice accepted as law and exist independent of treaty law.”⁶²³

Prima facie, based on the above-mentioned Article 25 of the UDHR, it would indeed extend to the right to health, and by inference it would also stretch as far as to access to essential medicine, given the fact that it is, arguably, a key component of the right to health and well-being. Moreover, multiple other UN human rights conventions have also incorporated the right to health or other individual aspects of the right, covering specific areas or problems. For instance, Article 5 of the International Convention on the Elimination of All Forms of Racial Discrimination (ICERD) highlights the non-discriminatory notion of the

⁶²⁰ See United Nations General Assembly: Universal Declaration of Human Rights, 10 December 1948, 217 A (III). - <https://www.refworld.org/docid/3ae6b3712c.html>, DOA: 16.2.2021.

⁶²¹ Henkin, Louis: The Universality of the Concept of Human Rights, in: The Annals of the American Academy of Political and Social Science (1989), Vol. 506, No. 1, pp.10-16, p.13.

⁶²² Dixon, Martin: Textbook on International Law. 7th ed. Oxford: Oxford University Press, 2013, p. 359.

⁶²³ See International Committee of the Red Cross: Customary International Law. - <https://www.icrc.org/en/war-and-law/treaties-customary-law/customary-law>, DOA: 15.01.2021.

right to public health, medical care, social security, and services.⁶²⁴ Furthermore, Article 12 (1) of the UN Convention on the Elimination of All Forms of Discrimination against Women (CEDAW) notes the following regarding the subject matter of health care:

*[s]tates Parties shall take all appropriate measures to eliminate discrimination against women in the field of health care in order to ensure, on a basis of equality of men and women, access to health care services, including those related to family planning.*⁶²⁵

CEDAW also covers other aspects of the right to health starting with access to specific health-related information and family planning.⁶²⁶ It also refers to the right to the protection of health and safe working conditions.⁶²⁷ Equally, Article 2 (b) covers aspects of access to adequate health care facilities in the context of family planning.⁶²⁸

In addition, Article 24 (1) of the UN Convention on the Rights of the Child (CRC) states the following in the context of the right to health:

*[s]tates Parties recognize the right of the child to the enjoyment of the highest attainable standard of health and to facilities for the treatment of illness and rehabilitation of health. States Parties shall strive to ensure that no child is deprived of his or her right of access to such health care services.*⁶²⁹

⁶²⁴ See United Nations General Assembly, International Convention on the Elimination of All Forms of Racial Discrimination, 21 December 1965, United Nations, Treaty Series, Vol. 660. - <https://www.refworld.org/docid/3ae6b3940.html>, DOA:18.03.2021, Art. 5 (e) (iv).

⁶²⁵ See United Nations General Assembly, Convention on the Elimination of All Forms of Discrimination Against Women, 18 December 1979, United Nations, Treaty Series, Vol. 1249. - <https://www.refworld.org/docid/3ae6b3970.html>, DOA: 18.03.2021.

⁶²⁶ Ibid, Art. 10 (h).

⁶²⁷ Ibid., Art. 11 (1) (f)

⁶²⁸ United Nations General Assembly, Convention on the Elimination of All Forms of Discrimination Against Women, 18 December 1979, United Nations, Treaty Series, Vol. 1249. - <https://www.refworld.org/docid/3ae6b3970.html>, DOA: 18.03.2021.

⁶²⁹ United Nations General Assembly, Convention on the Rights of the Child, 20 November 1989, United Nations, Treaty Series, Vol. 1577. - <https://www.refworld.org/docid/3ae6b38f0.html>, DOA: 18.03.2021.

Similarly, Article 24 (b) highlights the necessity to provide medical assistance and health care to all children.⁶³⁰ Article 33 CRC talks about the use of illicit and addictive drug use by children.⁶³¹

Unsurprisingly, the right to health also plays a key component when it comes to individuals with disability. Article 25 of the UN Convention on the Rights of Persons with Disabilities (CRPD) states the following with regard to the right to health:

“States Parties recognize that persons with disabilities have the right to the enjoyment of the highest attainable standard of health without discrimination on the basis of disability. States Parties shall take all appropriate measures to ensure access for persons with disabilities to health services that are gender-sensitive, including health-related rehabilitation.”⁶³²

In the context of civil wars, droughts, famine, and environmental degradation, people are increasingly forced to leave their home countries in the pursuit of saving life and limb; in other cases, also in order earn a living. The International Convention on the Protection of the Rights of All Migrant Workers and Members of their Families (ICRMW) of the UN has been implemented to deal with the rights of this community. Article 28 of the ICRMW has covert the right of human rights as following:

“Migrant workers and members of their families shall have the right to receive any medical care that is urgently required for the preservation of their life or the avoidance of irreparable harm to their health on the basis of equality of treatment with nationals of the State concerned.

⁶³⁰ Ibid.

⁶³¹ Ibid.

⁶³² United Nations General Assembly, Convention on the Rights of Persons with Disabilities: Resolution / adopted by the General Assembly, 24 January 2007, A/RES/61/106. - <https://www.refworld.org/docid/45f973632.html>, DOA: 18.03.2021.

Such emergency medical care shall not be refused to them by reason of any irregularity with regard to stay or employment."⁶³³

Besides, the right to the enjoyment of *the highest attainable standard of health* is, however, qualified in Article 43 (e) ICRMW notes the following:

*"[a]ccess to social and health services, provided that the requirements for participation in the respective schemes are met."*⁶³⁴

Thus, the ICRMW, *prima facie*, appears to be an ambivalent legal instrument. On the one hand, it stresses significance of the right to medical care for migrant workers. Yet, on the other hand, it adds a qualifying component which makes the comprehensive medical treatment subject to legal residency status.⁶³⁵

On regional level the Council of Europe, specifically, Article 11 of the European Social Charter, which covers the aspect of the right to the protection of health.⁶³⁶ Likewise, Article 10 of the Protocol of San Salvador, a supplementary treaty to the American Human Rights Convention, mentions the issue of right to health. Article 10 (1) of the Protocol of San Salvador notes the following:

*"[e]veryone shall have the right to health, understood to mean the enjoyment of the highest level of physical, mental and social well-being."*⁶³⁷

⁶³³ See United Nations General Assembly, International Convention on the Protection of the Rights of All Migrant Workers and Members of their Families, 18 December 1990, A/RES/45/158. - <https://www.refworld.org/docid/3ae6b3980.html>, DOA: 18.03.2021.

⁶³⁴ Ibid.

⁶³⁵ Krennerich, Michael: The Human Right to Health, in: Bielefeldt, Heiner/ Frewer, Andreas/ Klotz, Sabine/ Schmidhuber, Martina (eds.): Healthcare as a Human Rights Issue. Bielefeld: Transcript-Verlag, 2018, pp. 23-54, p. 29.

⁶³⁶ See Council of Europe, European Social Charter (Revised), 3 May 1996, ETS 163. - <https://www.refworld.org/docid/3ae6b3678.html>, DOA: 18.03.2021.

⁶³⁷ Organization of American States (OAS), Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights ("Protocol of San Salvador"),

Similarly, on the African continent, Article 16 of the African Charter on Human and Peoples' Rights, also known as the Banjul Charter, states in this context the following:

*"[e]very individual shall have the right to enjoy the best attainable state of physical and mental health. States parties to the present Charter shall take the necessary measures to protect the health of their people and to ensure that they receive medical attention when they are sick."*⁶³⁸

Correspondingly, Article 14 (1) of the African Charter on the Rights and Welfare of the Child mentions the following:

*"[e]very child shall have the right to enjoy the best attainable state of physical, mental and spiritual health."*⁶³⁹

We shall now discuss the international convention and General Comment specifically dedicated to the right to health. To begin with, the ICESCR was established in 1966 and has been ratified by 164 states parties. This convention elaborates that the right to health includes the following:

*"access to health facilities, goods, and services."*⁶⁴⁰

The ICESCR has established the Committee on Economic, Social and Cultural Rights (CESCR), a monitoring body, tasked to monitor the

⁶³⁸ 16 November 1999, A-52. - <https://www.refworld.org/docid/3ae6b3b90.html>, DOA: 13.03.2021, Art. 10.

⁶³⁹ See Organization of African Unity (OAU), African Charter on Human and Peoples' Rights ("Banjul Charter"), 27 June 1981, CAB/LEG/67/3 rev. 5, 21 I.L.M. 58 (1982). - <https://www.refworld.org/docid/3ae6b3630.html>, 14.03.2021, Art. 16 (1) & (2).

⁶⁴⁰ See Organization of African Unity (OAU), African Charter on the Rights and Welfare of the Child, 11 July 1990, CAB/LEG/24.9/49 (1990). - <https://www.refworld.org/docid/3ae6b38c18.html>, DOA: 19.03.2021.

⁶⁴¹ See FXB Center Harvard University: Health and Human Rights Resource Guide: How is Access to Medicines a Human Rights Issue? 2019. - <https://www.hhrguide.org/2017/06/09/access-to-medicines-and-human-rights/>, DOA: 02.12.2019.

implementation of the convention.⁶⁴¹ It was staffed by 18 independent experts. The CESCR produced General Comment No. 14⁶⁴² interpreting and providing guidance on the right to the highest attainable standard of health.⁶⁴³ Although the ICESCR only requires the progressive realisation of the right to health in circumstances in which only limited resources are available, there exist an underlying set of minimum obligations which are not dependent on progressive realisation, this includes access to essential medicines.⁶⁴⁴

Moreover, Article 12 ICESCR takes a rather prominent position in defence of the right to health. Article 12 recognises:

*“the right of everyone to the enjoyment of the highest attainable standard of physical and mental health”.*⁶⁴⁵

Moreover, paragraph 2 of the same Article provides for a non-exhaustive list of entitlements when it comes to the right to health. It encompasses:

“the prevention treatment and control of epidemic, endemic, occupational and other diseases” as well as *“the creation of conditions*

⁶⁴¹ United Nations Office of the High Commissioner for Human Rights: The Committee on Economic, Social and Cultural Rights (CESCR), Monitoring the economic, social and cultural rights. - <https://www.ohchr.org/EN/HRBodies/CESCR/Pages/CESCRIntro.aspx>, DOA: 02.08.2017.

⁶⁴² United Nations Committee on Economic, Social and Cultural Rights (CESCR), General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12), 2000. - <https://www.refworld.org/pdfid/4538838d0.pdf>, DOA: 11.01.2021.

⁶⁴³ Ibid.

⁶⁴⁴ United Nations General Assembly, The Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health: Report of the Special Rapporteur, Paul Hunt, U.N. General Assembly, 63rd Session, Agenda Item 67(b), U.N. Doc, A/63/263, 11.08.2008. - https://www.who.int/medicines/areas/human_rights/A63_263.pdf, DOA: 10.01.2020.

⁶⁴⁵ United Nations Office of the High Commissioner for Human Rights: International Covenant on Economic, Social and Cultural Rights. Adopted and opened for signature, ratification and accession by General Assembly resolution 2200A (XXI) of 16 December 1966 entry into force 3 January 1976. - <https://www.ohchr.org/EN/ProfessionalInterest/Pages/CESCR.aspx>, DOA: 03.03.2021.

which would assure to all medical service and medical attention in the event of sickness".⁶⁴⁶

The use of medicines has evolved into both an indispensable as well as essential component when it comes to the treatment of illnesses. Thus, access to medication is a crucial element in the endeavour for the individual attainment of the highest standard of health. In this regard, Article 2.1 ICESCR outlines the principles obligation placed on state parties to progressively realise those rights captured in this treaty.⁶⁴⁷ In doing so they state a certain margin of appreciation (an umbrella of discretion) to balance an individual right with the national interest of a member state. However, *prima facie*, failure to take relevant measures and to provide access to essential drugs could be considered as a violation by omission of the human right to health.⁶⁴⁸ This is the case, if they take all appropriate means, while utilising the maximum of their existing resources. Article 2.1 also set out obligations to take steps towards the full realisation of the rights enshrined in the convention, and to undertake this in line with the principle of non-discrimination (see Articles 2.2 and 3 ICESCR).⁶⁴⁹ Scott Sheeran advises that the *corpus juris* of human rights features a dynamic method of treaty interpretation, known as a "living instrument"⁶⁵⁰, rather than an interpretation based on the original intention of members to the convention in question.⁶⁵¹ The "living

⁶⁴⁶ Ibid.

⁶⁴⁷ Ibid.

⁶⁴⁸ Hayden, Patrick: The Human Right to Health and the Struggle for Recognition, in: Review of International Studies (2012), Vol. 38, No. 3, 569-588, p. 573.

⁶⁴⁹ United Nations Office of the High Commissioner for Human Rights: International Covenant on Economic, Social and Cultural Rights. Adopted and opened for signature, ratification and accession by General Assembly resolution 2200A (XXI) of 16 December 1966 entry into force 3 January 1976. - <https://www.ohchr.org/EN/ProfessionalInterest/Pages/CESCR.aspx>, DOA: 03.03.2021.

⁶⁵⁰ Sheeran, Scott: The relationship of international human rights law and general international law: a hermeneutic constraint, or pushing the boundaries?, in: Sheeran, Scott/ Rodley, Nigel (eds.): Routledge Handbook on International Human Rights Law. London: Routledge, 2013. p. 102.

⁶⁵¹ Hunt, Paul: Interpreting the International Right to Health in a Human Rights-Based Approach to Health, in: Health Human Rights (2016), Vol. 18, No. 2, pp.109-130. - <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5394996/>, DOA: 18.04.2018.

instrument” principle in the context of human rights was developed by the ECtHR in *Tyrer v. The United Kingdom*.⁶⁵²

Although not legally binding, it has developed into an authority when it comes to the obligation of states parties under Article 12 ICESCR.⁶⁵³ As for the Committee, the right to health consists of four interrelated and, indeed, essential elements: *availability*, *accessibility* (both physical and in economic terms), *acceptability* and finally *quality*. These components have jointly been referred as the AAAQ framework.⁶⁵⁴ When it comes to the subject matter of *availability*, General Comment No. 14, *inter alia*, places the following *availability* requirement on state parties:

*“[f]unctioning public health and health-care facilities, goods and services, as well as programmes, have to be available in sufficient quantity within the State party.”*⁶⁵⁵

Regarding *accessibility*, *inter alia*, the following requirements need to be adhered to:

*“[h]ealth facilities, goods and services have to be accessible to everyone without discrimination, within the jurisdiction of the State party.”*⁶⁵⁶

⁶⁵² See also *Tyrer v. The United Kingdom*, 5856/72, Council of Europe: European Court of Human Rights, 15 March 1978. - <https://www.refworld.org/cases/ECHR,402a2cae4.html>, DOA: 25.05.2019, para. 31.

⁶⁵³ Baker, BK/ Vawda, YA: Achieving Social Justice in the Human Rights/ Intellectual Property Debate: Realising the Goal of Access to Medicines, in: African Human Rights Law Journal (2013), Vol. 13, pp. 55–81, pp. 60-61.

⁶⁵⁴ FXB Center Harvard University: Health and Human Rights Resource Guide: How is Access to Medicines a Human Rights Issue? 2019. - <https://www.hhrguide.org/2017/06/09/access-to-medicines-and-human-rights/>, DOA: 02.12.2019.

⁶⁵⁵ United Nations Committee on Economic, Social and Cultural Rights (CESCR), CESCR General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12), 2000. - <https://www.refworld.org/pdfid/4538838d0.pdf>, DOA: 11.01.2021, para. 12(a).

⁶⁵⁶ Ibid, para. 12(b).

Furthermore, non-discrimination ought to be applied to the following:

*"Health facilities, goods and services must be accessible to all, especially the most vulnerable or marginalized sections of the population, in law and in fact, without discrimination on any of the prohibited grounds."*⁶⁵⁷

Equally, economic affordability applies to goods, services, and health facilities alike.⁶⁵⁸ Moreover, acceptability conveys the following obligations on countries which are party to ICESCR:

*"[a]ll health facilities, goods and services must be respectful of medical ethics and culturally appropriate, i.e. respectful of the culture of individuals, minorities, peoples and communities, sensitive to gender and life-cycle requirements, as well as being designed to respect confidentiality and improve the health status of those concerned."*⁶⁵⁹

Finally, the CESCR places the following obligations on the members states when it comes to quality:

*"As well as being culturally acceptable, health facilities, goods and services must also be scientifically and medically appropriate and of good quality. This requires, inter alia, skilled medical personnel, scientifically approved and unexpired drugs and hospital equipment, safe and potable water, and adequate sanitation."*⁶⁶⁰

Likewise, The Committee has used the tripartite typology of state obligations: respect, protect and fulfil.⁶⁶¹ When it comes to the subject matter of respect, General Comment No. 14, places states under obligation to respect the right to health by, among other things, to

⁶⁵⁷ Ibid.

⁶⁵⁸ Ibid.

⁶⁵⁹ Ibid, para. 12(c).

⁶⁶⁰ Ibid, para. 12(d).

⁶⁶¹ Ibid, paras. 34-37.

refrain from negating or potentially limiting equal access for every individual.⁶⁶² The duty to protect incorporates, *inter alia*, the following duties on states:

- “*to adopt legislation or to take other measures ensuring equal access to health care and health-related services provided by third parties*”;
- “*to ensure that privatization of the health sector does not constitute a threat to the availability, accessibility, acceptability and quality of health facilities, goods and services; to control the marketing of medical equipment and medicines by third parties [...]*”.⁶⁶³

Moreover, the obligation to *fulfil* places contracting parties, among other things, under the following duties:

*“to give sufficient recognition to the right to health in the national political and legal systems, preferably by way of legislative implementation, and to adopt a national health policy with a detailed plan for realizing the right to health.”*⁶⁶⁴

Equally, the obligation to *fulfil*, when it comes to the duty to facilitate, necessitates state parties to do the following:

*“[...] to take positive measures that enable and assist individuals and communities to enjoy the right to health.”*⁶⁶⁵

Furthermore, the member states to the ICESCR also have the following obligation:

*“[t]o provide essential drugs, as from time to time defined under the WHO Action Programme on Essential Drugs.”*⁶⁶⁶

⁶⁶² Ibid, para. 34.

⁶⁶³ Ibid, para. 35.

⁶⁶⁴ Ibid, para. 36.

⁶⁶⁵ Ibid, para. 37.

This obligation for a state to use every available resource that are at its disposal to satisfy its obligations with respect to health, will frequently necessitate a state to make full use of the public health elasticity under international law.⁶⁶⁷ A human rights-based approach to access to medicines draws special attention to marginalised, disadvantaged, and excluded populations, and endows all populations with the ability to achieve outcomes through an inclusive, transparent, and responsive process.⁶⁶⁸ Furthermore, nation states are indeed dutybound as a matter of international human rights law to respect, protect, and fulfil the right to health, which comprises an obligation to adopt legislative, administrative, and financial measures to facilitate access to medicines that are inexpensive, accessible, culturally acceptable, and of good quality.

On another note, the Committee regards the provision of essential medicines as classified by the WHO Action Programme on Essential Drugs, to be a component of the minimum core component of the right to health. If it was not for these components, the right itself would be emptied from any meaningful relevance. Thus, the Committee arrives at the opinion that a contracting party could under no circumstances be allowed to justify its non-compliance with the core-obligations, which in turn are non-derogable.⁶⁶⁹ The CESCR further recognises this argument to be in line with the spirit of Articles 55 and 56 of the Charter.⁶⁷⁰ Article 55 of the UN Charter notes that the UN shall promote universal respect for and observance of human rights.⁶⁷¹ Likewise, Article 56 UN Charter mentions:

⁶⁶⁶ Ibid, para. 43 (d).

⁶⁶⁷ Ibid.

⁶⁶⁸ Ibid.

⁶⁶⁹ Ibid, para. 47.

⁶⁷⁰ United Nations, Charter of the United Nations, 24 October 1945, 1 UNTS XVI. - <https://www.refworld.org/docid/3ae6b3930.html>, DOA:12.03.2021.

⁶⁷¹ Ibid, Art. 55

*[a]ll Members pledge themselves to take joint and separate action in co-operation with the Organization for the achievement of the purposes set forth in Article 55.*⁶⁷²

Unlike the case of individuals, nation states as primary subjects of public international law are obliged to protect and guarantee human rights within the context of international law.⁶⁷³

All UN states are duty-bound to uphold the law beyond their national borders.⁶⁷⁴ The member states of the UN (by default, the EU is also a member of the UN, as all its member states are part of the UN) are obliged to ensure that adequate significance is placed on the right to health when drafting international agreements. The same would also be applicable when they act as members of international organisations.⁶⁷⁵ State practice has also evolved over time when it comes to accessing drugs those targeting HIV/AIDS, malaria and tuberculosis. The General Assembly of the UN has indeed stressed the need to make anti-retroviral (ARV) drugs both available and affordable.⁶⁷⁶ The UN's Sustainable Development Goals also expanded its commitment to ensure, *inter alia*, the access to effective, qualitative, and affordable essential medicines for everyone.⁶⁷⁷

⁶⁷² Ibid, Art. 56.

⁶⁷³ Dixon, Martin: Textbook on International Law. 7th ed. Oxford: Oxford University Press, 2013, p. 3.

⁶⁷⁴ Hestermeyer, Holger: Human Rights and the WTO: The Case of Patents and Access to medicines. Oxford: Oxford University Press, 2007, p. 108.

⁶⁷⁵ See Maastricht Principles on Extraterritorial Obligations of States in the Area of Economic, Social and Cultural Rights. 2013. -

https://www.etoconsortium.org/nc/en/main-navigation/library/maastricht-principles/?tx_drblob_pi1%5BdownloadUid%5D=23, DOA: 11.01.2021, paras. 15, & 17; United Nations Committee on Economic, Social and Cultural Rights (CESCR), CESCR General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12), 2000. - <https://www.refworld.org/pdfid/4538838d0.pdf>, DOA: 11.01.2021, para. 47.

⁶⁷⁶ Resolution 65/277. Political Declaration on HIV/AIDS: Intensifying Our Efforts to Eliminate HIV/AIDS', UN Doc. A/RES/65/277. 2011. - <http://undocs.org/A/RES/65/277>, DOA: 21.06.2016.

⁶⁷⁷ United Nations: Transforming our World the 2030 Agenda for Sustainable Development. - <https://sustainabledevelopment.un.org/content/documents/21252030%20Agenda%20for%20Sustainable%20Development%20web.pdf>, DOA: 27.07.2017.

We shall now elaborate the situations in which the right to health, in the form of the access to medicines, stands in conflict with patent rights. Public health and lack of access to affordable medicines has long taken its place among pressing concerns in the world community. Globally, the poor population face difficulties in their endeavour to acquire essential medicines. As per the World Health Organisation, a minimum of one-third of the global populace lacks regular access to medicines.⁶⁷⁸ Moreover, the Millennium Development Goals (MDG) Gap Task Force of the UN has noted that the cost of many essential medicines, particularly for chronic illnesses, remains exorbitant in many developing nations.⁶⁷⁹ There are a multitude of aspects contributing to the problem leading to lack of access to medicines that is within reach of their financial means, starting from scarce resource, inadequate healthcare systems to corruption.⁶⁸⁰

The UN Sub-Commission on the Promotion and Protection of Human Rights announced that there are obvious conflicts between the intellectual property rights regime personified by the TRIPS Agreement and international human rights law.⁶⁸¹ With regard to access to medicines, patent protection of pharmaceuticals has been regarded to undermine both the right to health and the right to life. Likewise, the UN Secretary-General's High-Level Panel on Intellectual Property and Access to Medicines noted that:

"[p]olicies and agreements related to human right, trade, [IP] rights and public health were developed with different objectives at different times. State obligations include duties not only to respect, but to

⁶⁷⁸ World Health Organisation: The World Medicines Situation: Access to Essential Medicines as part of the Right to Health. 2011. -

https://www.who.int/medicines/areas/policy/world_medicines_situation/WMS_ch14_wRational.pdf, DOA: 03.03.2021.

⁶⁷⁹ Sellin, Jennifer Anna: Does One Size Fit All? Patents, the Right to Health and Access to Medicines, in: Netherlands International Law Review (2015), Vol. 62, pp. 445-473, p. 446.

⁶⁸⁰ Ibid.

⁶⁸¹ United Nations Sub-Commission on the Promotion and Protection of Human Rights, 'Resolution 2000/7. Intellectual Property Rights and Human Rights', UN Doc.

E/CN.4/SUB.2/RES/2000/7. - <https://digitallibrary.un.org/record/420915>, DOA: 20.03.2020, para. 2.

*protect and fulfil the right to health. This requires taking proactive measures to promote public health. As reaffirmed by a recent Human Rights Council resolution, ensuring access to medicines, and particularly to essential medicines, is a fundamental element of these obligations. Trade rules and intellectual property laws were developed to promote economic growth and incentivize innovation. On the one hand, governments seek the economic benefits of increased trade. On the other, the imperative to respect patents on health technologies could, in certain instances, create obstacles to public health objectives of [WTO] members”.*⁶⁸²

Furthermore, the Office of the UN High Commissioner for Human Rights has stressed that access to medicines does indeed form a fundamental element of the right to health.⁶⁸³⁶⁸⁴ In this context, human rights advocates have proposed that in order to resolve this conflict situation, international human rights law should take primacy over IP law, which in turn ought to be accepted where treaty obligations are in conflict.⁶⁸⁵ Policymakers contended that in the national as well as international fora, the human right to health takes both moral and legal precedence over IPRs.⁶⁸⁶ This point was further emphasised by the UN Special Rapporteur in the field of cultural rights, Farida Shaheed, who stated the following:

⁶⁸² See The United Nations Secretary General’s High-Level Panel on Access to Medicines Report: Promoting Innovation and Access to Health Technologies. 2016. - <https://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/t/57d9c6ebf5e231b2f02cd3d4/1473890031320/UNSG+HLP+Report+FINAL+12+Sept+2016.pdf>, DOA: 30.03.2021, p. 7.

⁶⁸³ Office of the High Commissioner for Human Rights: Access to Medicines - a Fundamental Element of the Right to Health. - <https://www.ohchr.org/en/issues/development/pages/accesstomedicines.aspx>, DOA: 27.09.2020.

⁶⁸⁴ Human Rights Council: Resolution adopted by the Human Rights Council: Access to medicine in the context of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, A/HRC/RES/12/24 12 October 2009. - <https://documents-dds-ny.un.org/doc/RESOLUTION/GEN/G09/167/45/PDF/G0916745.pdf?OpenElement>, DOA: 30.01.2020, paras. 4 & 7.

⁶⁸⁵ Cullet, P: Patents and Medicines: The Relationship Between TRIPS and the human Right to Health, in: International Affairs (2003), Vol. 79, Is. 1, pp.139–160, pp. 157-159.

⁶⁸⁶ Austin, Graeme/Helfer, Laurence: Human Rights and Intellectual Property: Mapping the Global Interface. Cambridge, Cambridge University Press, 2011, pp. 53-56.

*[t]he human rights perspective demands that patents do not extend so far as to interfere with the dignity and well-being of individuals. Hence, where patent rights and human rights are in conflict, human rights must prevail.*⁶⁸⁷

This objective of human rights advocates hardly comes as a surprise, as the position that human rights supersede IPRs has already been expanded to the rules of global trade.⁶⁸⁸ The UN Sub-Commission for the Promotion and Protection of Human Rights has reinforced the fact that human rights should take a primary position over patents. In this regard, one could, *prime facie*, argue that Articles 55 and 56 of the UN Charter would prevail over the obligations of the WTO including those under the TRIPS agreement. Article 55(b) stresses the health angle.

Unsurprisingly, the WTO disagrees with the position held by the Sub-Commission and emphasised the complementary nature of Intellectual property rights and that of human rights.⁶⁸⁹ There has indeed been growing acknowledgment for a human rights perspective of the impact of the WTO regime on topics that go beyond the realm of trade, such as social and environmental issues. Despite the fact that the aforementioned issues are part of a contemporary phenomenon, human rights concerns are hardly at the forefront of the WTO agenda for the most part.⁶⁹⁰

Before discussing the subject matter of superiority of international human rights law over patent law we shall consider whether the right

⁶⁸⁷ United Nations: Statement by Ms. Farida Shaheed, Special Rapporteur in the Field of Cultural Rights at the 70th session of the General Assembly Third Committee Item 69 (b and c). New York. 26 October 2015. -

<https://www.ohchr.org/EN/NewsEvents/Pages/DisplayNews.aspx?NewsID=16918&%3BLangID=E>, DOA: 13.02.2021.

⁶⁸⁸ Yigzaw, Destaw: Hierarchy of Norms: The Case for the Primacy of Human Rights over WTO Law, in: International Journal of Innovation and Learning (2015), Vol. 1, Is. 1, pp. 1–41, p. 4.

⁶⁸⁹ Sellin, Jennifer Anna: Does One Size Fit All? Patents, the Right to Health and Access to Medicines, in: Netherlands International Law Review (2015), Vol. 62, pp. 445-473, p. 445.

⁶⁹⁰ Harrison, James: The Human Rights Impact of the World Trade Organisation. Oxford: Hart Publishing, 2007, p. 36.

to health has in fact evolved into a *jus cogens* under international law. International law pays due regard that some norms are inferior to others. *Jus cogens*, which are also known as peremptory norms, are a set of legal norms that are both accepted as well as recognised internationally, which in fact prohibits any form of derogation.⁶⁹¹ Well known examples of *jus cogens* norms are, *inter alia*, genocide, torture, slavery and crimes against humanity.⁶⁹² Applicability of *lex specialis* rule⁶⁹³ is only relevant when it comes to situations of conflict between general and special international law.⁶⁹⁴ However, as a matter of fact, both WTO and human rights law are merely subsystems of public international law.⁶⁹⁵ As a result, any conflict between the right to health and patents cannot be settled by alluding to the *lex specialis* rule and should subsequently be settled through interpretation of the relevant treaty. For CESCR, access to essential medicines happens to be part and parcel of the core components of the right to health, which in turn are non-derogable.⁶⁹⁶ Despite CESCR's rather strong position, international practice does not leave much room to expand the right to health to the "family of *jus cogens* norms" in the field of public international law.⁶⁹⁷ In fact, there seems to be little consensus when it comes to expanding the existing body of

⁶⁹¹ See United Nations, Vienna Convention on the Law of Treaties, 23 May 1969, United Nations, Treaty Series, Vol. 1155. - <https://www.refworld.org/docid/3ae6b3a10.html>, DOA: 12.03.2021, Art. 53.

⁶⁹² International Law Commission: Fragmentation of international law: difficulties arising from the diversification and expansion of international law. Report of the Study Group of the International Law Commission. Finalised by Martti Koskenniemi. UN Doc A/CN.4/L.682. 2006. -

https://legal.un.org/ilc/documentation/english/a_cn4_l682.pdf, DOA: 12.03.2021, paras. 374-376.

⁶⁹³ According to this legal maxim, the more specific rule will prevail over the general rule if there exists a conflict between the two.

⁶⁹⁴ Casebook: *Lex specialis*, How does law protect in war? -

<https://casebook.icrc.org/glossary/lex-specialis>, DOA: 13.03.2021.

⁶⁹⁵ Sellin, Jennifer Anna: Does One Size Fit All? Patents, the Right to Health and Access to Medicines, in: Netherlands International Law Review (2015), Vol. 62, pp. 445-473, p. 457.

⁶⁹⁶ United Nations Committee on Economic, Social and Cultural Rights (CESCR), CESCR General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12), 2000. - <https://www.refworld.org/pdfid/4538838d0.pdf>, DOA: 11.01.2021, para. 43.

⁶⁹⁷ Vidmar, J: Rethinking *Jus Cogens* after *Germany v. Italy*: Back to Article 53?, in: Netherlands International Law Review (2013), Vol. 60, pp. 1-25, p. 22.

law of *jus cogens* norms. For a norm to attain *jus cogens* status it must be acknowledged by a significant number of the international community of states. Unfortunately, there is little evidence that this is the case, when it comes to the right to health in general, and access to essential medicine, in particular.⁶⁹⁸

The emphasis by the CESCR that the core content of the rights entailed are non-derogable would automatically award itself a priority status under international law. *Prima facie*, the priority status in international law of the General Comment No. 14 itself, despite being a non-legally binding instrument, has emerged as an authoritative source when interpreting the right to health from an international human rights law angle. There is relevant regional and local case law that supports this argument. We shall now consider a few of these examples below.

For instance, in the case *Minister of Health v. Treatment Action Campaign*, the Constitutional Court of South Africa recognised access to medication as part of the right to health under the Constitution of South Africa. In *Minister of Health v. Treatment Action Campaign*, the court ordered the government of South Africa take make nevirapine more widely available.⁶⁹⁹ Nevirapine is a drug that prevents mother-to-child transmission of HIV.⁷⁰⁰ Yet, in another part of the world, the Supreme Court of Justice in Venezuela (Tribunal Supremo de Justicia de Venezuela) issued a judgement under the same line of argumentation, referring to the Venezuelan Constitution in *Cruz Bermúdez v. Ministerio de Sanidad y Asistencia Social*. In its judgment the court ordered the government to provide antiretroviral treatment to

⁶⁹⁸ Sellin, Jennifer Anna: Does One Size Fit All? Patents, the Right to Health and Access to Medicines, in: Netherlands International Law Review (2015), Vol. 62, pp. 445-473, p. 460.

⁶⁹⁹ Minister of Health et al. v. Treatment Action Campaign et al. 2002 (5) SA 721 (CC); 2002 (10) BCLR 1033 (CC) (5 July 2002).

⁷⁰⁰ Hestermeyer, Holger: Access to Medication as a Human Right, in: Max Planck Yearbook of United Nations Law (2004), Vol. 8 Is. 1, pp. 101-180, p. 128.

every AIDS-infected patient in Venezuela.⁷⁰¹ Moreover, every year tens of thousands of Brazilians have petitioned the courts to order their government to provide them with one or more particular drugs. They are successful in most cases. From 1999-2014, around 1.3 million right to health cases were litigated in Columbia. Once again, medicines subject to patent protection were brought to the court 80 percent of the time.⁷⁰²

In the same region, the Inter-American Commission on Human Rights decided to tackle access to medication in *Jorge Odir Miranda Cortez v. El Salvador*. In *Jorge Odir Miranda Cortez v. El Salvador* the petitioners, who were HIV-positive, alleged a violation of the right to health, as the government had not provided them with the necessary triple therapy.⁷⁰³ Although the Inter-American Commission found itself not competent *ratione materiae*⁷⁰⁴ to examine a violation of the right to health, which is contained in article 10 of the Protocol of San Salvador⁷⁰⁵, it ruled that it could consider the Protocol in the interpretation of the provisions of the American Convention on Human Rights and declared the case in question admissible for alleged violations of, *inter alia*, the social and cultural rights under Article 26 of the American Convention on Human Rights.⁷⁰⁶

The European Court of Human Rights (ECtHR) has also been contemplating the subject matter of the right to health as a human right. In *N v. The United Kingdom*, ECtHR was considering whether

⁷⁰¹ Tribunal Supremo de Justicia de Venezuela, Cruz Bermúdez v. Ministerio de Sanidad y Asistencia Social, Case No. 15.789, Decision No. 916 (1999).

⁷⁰² Thambisetty, Sivaramjani: Improving Access to Patented Medicines: Are Human Rights Getting in the Way?, in: Intellectual Property Quarterly (2019), Is. 4, pp. 284-305. p. 286.

⁷⁰³ Jorge Odir Miranda Cortez et al. v. El Salvador, Inter-American Commission on Human Rights Report No. 29/01. Case 12.249, (7 March 2001).

⁷⁰⁴ The Tribunal lacked jurisdiction over the nature of the case and the type of relief sought.

⁷⁰⁵ See Organization of American States (OAS), Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights ("Protocol of San Salvador"), 16 November 1999, A-52. - <https://www.refworld.org/docid/3ae6b3b90.html>, DOA: 13.03.2021, Art. 10.

⁷⁰⁶ See Organization of American States (OAS), American Convention on Human Rights, "Pact of San Jose", Costa Rica, 22 November 1969. -

<https://www.refworld.org/docid/3ae6b36510.html>, DOA: 13.03.2021, Art. 26.

the applicant, an asylum seeker in the United Kingdom (UK), was permitted to remain in the country to receive essential antiretroviral treatment and support for AIDS-related diseases. In this context, the court contemplated whether Article 3 of the European Convention of Human Rights (ECHR)⁷⁰⁷, prohibiting “torture and inhuman and degrading treatment” was applicable in the case in question. The claimant, a Ugandan national, entered the UK in 1998. Upon entering the country, she was seriously ill and was diagnosed as HIV positive. In her asylum status application, she claimed that she had been subjected to rape by the National Resistance Movement in Uganda as reprisal for her association with the Lord’s Resistance Army in the same country in question. In March 2001, a physician issued an expert report which stated that without routine antiretroviral treatment and monitoring, the claimant’s life expectancy would be less than one year. Although the medication she needed would be available in Uganda, it would be substantially expensive and in limited supply in the claimant’s hometown.⁷⁰⁸ The Office of Secretary of State of the UK rejected the asylum claim, refusing, among other reasons, her argument that there had been a violation of Article 3, as treatment of AIDS in Uganda was comparable to any other country on the African continent.⁷⁰⁹ The ECtHR found that for ill-treatment to fall within the scope of Article 3, it must attain a minimum level of seriousness that is relative and conditional on all the circumstances of the case, including the duration of treatment, its physical and mental impacts. Equally, ECtHR maintained that the state may apply Article 3 in cases where harm derives from a naturally occurring illness and the lack of sufficient resources to deal with it in the receiving country in the case of a deportation.⁷¹⁰ Unfortunately, the court had found in favour of the

⁷⁰⁷ Council of Europe, European Convention for the Protection of Human Rights and Fundamental Freedoms, as amended by Protocols Nos. 11 and 14, 4 November 1950, ETS 5. - <https://www.refworld.org/docid/3ae6b3b04.html>, DOA: 16.03. 2021.

⁷⁰⁸ N. v. The United Kingdom, Appl. No. 26565/05, Council of Europe: European Court of Human Rights, 27 May 2008. - <https://www.refworld.org/cases/ECHR,483d0d542.html>, DOA: 16.02.2021, p. 3.

⁷⁰⁹ Ibid.

⁷¹⁰ Ibid, pp. 16-17.

UK but, *prima facie*, leaving enough room by referring to the lack of sufficient resources in the receiving country. Yet the dissenting opinion in the case in question, however, reasoned that the case did indeed meet the “very exceptional circumstances” test laid down in *D. v. United Kingdom*.⁷¹¹ As such, the Court should have found a potential Article 3 violation, because there are substantial grounds to believe that the applicant faces a real risk of prohibited treatment in the country removal.⁷¹²

In *D. v the United Kingdom*, the applicant from St. Kitts was held in the UK pending his deportation to his home country. The applicant arrived the UK in 1993 and in 1994 he was diagnosed as HIV and as suffering from AIDS.⁷¹³ The infection appears to have occurred sometime before his arrival in the UK.⁷¹⁴ In March 1995, the applicant was granted a period of compassionate leave to be with his mother whose air fare to the United Kingdom to visit him had been covered by charitable donations.⁷¹⁵ He claims that the proposed deportation to St. Kitts from the UK would place him at risk of reduced life expectancy, of inhuman and degrading treatment and an invasion of his physical integrity since he is suffering from AIDS.⁷¹⁶ Moreover, he will be exposed to a lack of adequate medical treatment and living conditions.⁷¹⁷ The application, *inter alia*, raised issues under Articles 3 of the ECHR. The ECtHR only found a violation of Article 3 ECHR and held that the implementation of the decision to remove the applicant to St Kitts would violate Article 3 of the Convention.⁷¹⁸

⁷¹¹ Ibid, p. 20.

⁷¹² Ibid, p. 24.

⁷¹³ *D. v. United Kingdom*, 146/1996/767/964, Council of Europe: European Court of Human Rights, 2 May 1997, available at: <https://www.refworld.org/cases/ECHR,46deb3452.html>, DOA: 16.03.2021, para. 7.

⁷¹⁴ Ibid, para. 8.

⁷¹⁵ Ibid, para. 9.

⁷¹⁶ Ibid, para. 56.

⁷¹⁷ Ibid, para. 57.

⁷¹⁸ Ibid, paras. 79 & ff.

On a separate note, Article 15 of the ICESCR notes the following when it comes to the protection of IPRs:

*[t]he States Parties to the present Covenant recognize the right of everyone: [...] to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.*⁷¹⁹

In this context, General Comment No. 17, which is widely regarded as the authoritative source for interpreting Art. 15 (1), provides significant limitations when it comes to IPRs:

*[t]he right to the protection of the moral and material interests resulting from one's scientific, literary and artistic productions is subject to limitations and must be balanced with the other rights recognized in the Covenant. However, limitations on the rights protected under article 15, paragraph 1, must be determined by law in a manner compatible with the nature of these rights, must pursue a legitimate aim, and must be strictly necessary for the promotion of the general welfare in a democratic society, in accordance with article 4 of the Covenant.*⁷²⁰

The application of such limitation may indeed involve sufficient compensation as indicated in the same document:

[t]he imposition of limitations may, under certain circumstances, require compensatory measures, such as payment of adequate

⁷¹⁹ United Nations General Assembly, International Covenant on Economic, Social and Cultural Rights, International Covenant on Civil and Political Rights and Optional Protocol to the International Covenant on Civil and Political Rights, 16 December 1966, A/RES/2200. - <https://www.refworld.org/docid/3b00f47924.html>, DOA: 11.03.2021, Art. 15 (1) (c).

⁷²⁰ See United Nations Committee on Economic, Social and Cultural Rights (CESCR), General Comment No. 17: The Right of Everyone to Benefit from the Protection of the Moral and Material Interests Resulting from any Scientific, Literary or Artistic Production of Which He or She is the Author (Art. 15, Para. 1 (c) of the Covenant), 12 January 2006, E/C.12/GC/17. - <https://www.refworld.org/docid/441543594.html>, DOA: 29.03.2021, para. 22.

compensation for the use of scientific, literary or artistic productions in the public interest.”⁷²¹

The General Comment No. 17, *prima facie*, appears to subordinate the access IPRs to human rights, while providing adequate compensation for potential losses that might happen during the realisation as well as implementation of the relevant processes. This point is evidenced in Paragraph 1 of the same document which notes:

“...[h]uman rights are fundamental, inalienable and universal entitlements belonging to individuals and, under certain circumstances, groups of individuals and communities. Human rights are fundamental as they are inherent to the human person as such, whereas intellectual property rights are first and foremost means by which States seek to provide incentives for inventiveness and creativity, encourage the dissemination of creative and innovative productions, as well as the development of cultural identities, and preserve the integrity of scientific, literary and artistic productions for the benefit of society as a whole.”⁷²²

On top of this, human rights advocates have put forward arguments to extend the scope of human rights to a primary status in line with Article 103 of the UN Charter.⁷²³ Article 103 highlights the fact that in the event of conflict between the UN Charter and any other treaty, the Charter takes priority.⁷²⁴ The question which arises in this particular case is whether the duties that derive from human rights treaties, as in the present case the ICESCR, adopted with framework of the UN could then be regarded as obligations under the UN Charter itself. *Prima facie*, Article 103 of the UN Charter does indeed give priority to those obligations explicitly expressed in the UN Charter which stem

⁷²¹ Ibid, para. 24

⁷²² Ibid, para. 1.

⁷²³ Yigzaw, DA: Hierarchy of Norms: The Case for Primacy of Human Rights over WTO Law, in: Suffolk Transnational Law Review (2015), Vol.38, No.1, pp. 33–68, pp. 62-63.

⁷²⁴ See United Nations, Charter of the United Nations, 24 October 1945, 1 UNTS XVI. - <https://www.refworld.org/docid/3ae6b3930.html>, DOA:12.03.2021, Art. 103.

from the binding decisions of the UN bodies, more precisely, the chapter VII resolutions of the UN Security Council.⁷²⁵ This is where one comes across a caveat, as General Comment No. 14 and ICESCR fall in the category of human rights treaty obligations and resolutions adopted by UN human rights bodies that are of a non-legally binding nature.⁷²⁶

Finally, access to medicines does indeed represent a right under international human rights law. Therefore, states party to the ICESCR are dutybound to progressive realisation of these rights.⁷²⁷ Yet they do have a more immediate core obligation to provide essential medicine.⁷²⁸ Thus, members of nations of the above-mentioned treaty are under the duty to give due regard to the right to health, both when interpreting as well as implementation of international treaties. The same must be applicable when they are acting as members of an international organisation.⁷²⁹ Thus the member states of the WTO should be obliged to interpret and apply the TRIPS treaty in a manner that is in line with those commitments arising out of the right to health.⁷³⁰ A solution could be the production of generic medicines while fully utilising compulsory licences provided by the flexibility of the TRIPS agreement. We shall consider this issue in the next chapter.

⁷²⁵ Ibid, Chapter VII.

⁷²⁶ International Law Commission: Fragmentation of international law: difficulties arising from the diversification and expansion of international law. Report of the Study Group of the International Law Commission. Finalised by Martti Koskenniemi. UN Doc A/CN.4/L.682. 2006. - https://legal.un.org/ilc/documentation/english/a_cn4_l682.pdf, DOA: 12.03.2021, para. 331.

⁷²⁷ United Nations Committee on Economic, Social and Cultural Rights (CESCR), CESCR General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12), 2000. - <https://www.refworld.org/pdfid/4538838d0.pdf>, DOA: 11.01.2021, para. 30.

⁷²⁸ Ibid, para. 43 (d).

⁷²⁹ Ibid, para. 39.

⁷³⁰ Hunt, Paul/ Leader, Sheldon: Developing and applying the Right to the Highest Attainable Standard of Health. The Role of the UN Special Rapporteur (2002–2008), in: Stuttaford, M/ Harrington, J (eds.): Global Health and Human Rights: Legal and Philosophical Perspectives. Abingdon: Routledge, 2010, pp 28–61, p. 37.

4.3. The Maastricht Principles of Extraterritorial Obligations of States in the Area of the Economic, Social and Cultural Rights

The Maastricht Principles of Extraterritorial Obligations of States in the Area of the Economic, Social and Cultural Rights were adopted on 28 September 2011; they were drafted by leading experts in the fields of human rights and international law. The question which arises in this context is what, if any, obligations are placed upon states when it comes to the realisation of human rights globally and, particularly, in the area of health care. The Maastricht Principles were developed during a two-year period, between 2009 – 2011, and were finally adopted in a meeting arranged between the Maastricht University and the International Commission of Jurists. Among the signatories were the UN human rights treaty bodies, the Special Rapporteur of the UN Human Rights Council, alongside legal advisors and scholars from leading NGOs.⁷³¹ These principles are the result of longstanding endeavours of the legal community, NGO's and academicians to form an orderly structure to the current state of international law, thereby creating guiding principles when it comes to the extraterritorial human rights obligations in the area of economic, social and cultural rights.⁷³² The Maastricht principles are rooted on two main concepts, the first being that international human rights law places particular obligations upon states, when acting in a way that has real and predictable effects on human rights beyond their national border. In these situations states must ensure that they “respect”, “protect” and in some situations, “fulfil” those rights.⁷³³ The second aspect being international law, most specifically in the field of economic, social and cultural rights, demands dogmatically that nations act in such a way as to

⁷³¹ Salomon, Margot/ Seiderman, Ian: Human Rights Norms for a Globalized World: The Maastricht Principles on Extraterritorial Obligations of States in the area of Economic, Social and Cultural Rights, in: Global Policy (2012), Vol. 3, Is. 4, pp. 458-462, p. 458.

⁷³² Ibid.

⁷³³ Ibid, pp. 458-459.

realise rights in an extraterritorial manner through the means of international assistance and cooperation.⁷³⁴ While the Maastricht Principles are not the creation of an intergovernmental law-making body, their predicted normative authority and influence should by no means be dismissed.⁷³⁵ This is due to the fact that similar expert human rights instruments have been shown to possess significant normative force; this would apply for the Limburg Principles⁷³⁶ and Maastricht Guidelines⁷³⁷ and the international principles on sexual orientation and gender identity.⁷³⁸

A critical area of extraterritorial international human rights law that has on the one hand prompted significant legal development and, yet, on the other hand has led to the disclosure of unsettled legal issues. The areas of concern are the positive extraterritorial obligations of states to “fulfil” economic, social and cultural rights. The question that arises in this context is whether the extraterritorial jurisdiction extends to instances outside of the state’s own territory and consequently also affords those people its protection. As a general rule, international human rights law goes beyond the traditional scope of public international law and thereby creates numerous exceptions. One such extraterritorial action would be the case when a *jus cogens* or peremptory norm in the area of international human rights law has been violated. This would be the case if, for instance, genocide has been committed by the security forces of a particular state A, then the perpetrator would be legally trialled in a court of law for the crime of

⁷³⁴ Ibid, p. 459.

⁷³⁵ Ibid.

⁷³⁶ ESCR-Net-International Network for Economic, Social & Cultural Rights: Limburg Principles on the Implementation of the International Covenant on Economic, Social and Cultural Rights. 1986. - <https://www.escr-net.org/resources/limburg-principles-implementation-international-covenant-economic-social-and-cultural>, DOA: 03.03.2021.

⁷³⁷ University of Minnesota Human Rights Library: Maastricht Guidelines on Violations of Economic, Social and Cultural Rights, Maastricht, 22.-26. January 1997. - <http://hrlibrary.umn.edu/instre/Maastrichtguidelines.html>, DOA: 03.03.2021.

⁷³⁸ The Yogyakarta Principles: Principles on the Application of International Human Rights Law in Relation to Sexual Orientation and Gender Identity. 2007. - <https://www.refworld.org/pdfid/48244e602.pdf>, DOA: 03.03.2021.

genocide by any state, although the crime committed did not take place in the territory in question. *Jus cogens* or peremptory norm are the highest legal norms from which no derogation is permissible, and as a consequence those violating it can and should be brought to justice by any state for extraterritorial human rights violations.

Yet other human rights obligations, while not being a violation of a peremptory norm, require extraterritorial action, and these happen to be rather expansive in nature when it comes to economic, social, and cultural rights. The Maastricht Principles are clear in this case, and require that necessary jurisdiction will also apply in such cases where a country is either under a particular international treaty obligation, or otherwise in a position to take action in an active manner to assist with the fulfilment of the relevant economic, social and cultural rights of those people residing outside its territorial scope.⁷³⁹ Such extraterritorial obligations could have both elements, it could be direct or in the form of indirect interference; while the subject matter of direct interference is rather obvious, indirect interference would require more contemplation.⁷⁴⁰ Indirect interference is when a state curtails the ability of international organisations or that of other states to comply with their own human rights obligations. The same would also apply to cases where it compels or is complicit with another country or international organisation in violating international human rights law. An area of concern in this context are sanctions and equivalent measures, this would arguably also include seizures, that might result in considerable serious human rights consequences. When it comes to the distribution of essential pharmaceuticals, food and sanitary supplies, just to name a few.⁷⁴¹ The Maastricht Principles on Extraterritorial Obligations of States in the area of Economic, Social and Cultural Rights states have an obligation to take action either

⁷³⁹ The Secretariat to the ETO Consortium: Maastricht Principles on Extraterritorial Obligations of States in the Area of Economic, Social and Cultural Rights. 2013. - https://www.etoconsortium.org/nc/en/main-navigation/library/maastricht-principles/?tx_drblob_pi1%5BdownloadUid%5D=23, DOA: 03.03.2021, principle 9 (c).

⁷⁴⁰ Ibid, principles 20 & 21.

⁷⁴¹ Ibid, principle 22.

separately or jointly, through the means of international cooperation and assistance, to fulfil the economic, social and cultural rights of those people living outside their country. Additionally, a state may also be held responsible for violating one or more of the principles, and thus would be required to make reparations for the failure to comply with its extraterritorial obligations in the field of economic, social and cultural rights.⁷⁴² Although the Maastricht Principles on Extraterritorial Obligations of States in the area of Economic, Social and Cultural Rights are not legally binding, they can be used as soft law, and if sufficient states believe that they are obliged to comply with them, could one day become part and parcel of international human rights law.

⁷⁴² Ibid, principle 38.

4.4. Evergreening

We shall now turn our attention to the matter of evergreening. Evergreening describes the multiple ways through which patent owners' attempts exploit ambiguities in patent laws and their regulatory processes, with the aim to maximise their monopoly over their bestselling drugs by filing concealed or artful patents on a previously patented invention. This is usually done before the parent patent protection comes to an end. Some ways to implement additional patents would entail the protection of some of the following characteristics: combinations of two or more drugs, dosing range and dosing route; packaging, different methods of treatment, screening methods and dosing regimen.⁷⁴³

Yet, it represents a particular strategy obtained by the innovator companies to recover the high costs incurred by them in the area of R&D. Ever-greening is also used to legally protect any minor modifications that are done in an intentional manner to the parent patent, to obtain several patents on what is, for the most part, the same drug. After having undertaken relevant tweaks to the medicine created under parent patent, the inventors extend the overall term of the patent to enjoy monopoly for extended periods of time.⁷⁴⁴ To put it simply, let's imagine that a pharmaceutical firm was to launch a drug and as a consequence has managed to obtain patent protection for this particular invention, and just before the end of the term of that patent, the same company would file a new patent for a minor modification in the original molecule that extends the overall term of patent protection. This essentially expands the firm's monopoly status. The reason for this strategy is that extending the patent protection period could either delay or prevent the entry of generic versions of the

⁷⁴³ Kumar, Arun/ Nanda, Arun: Ever-greening in Pharmaceuticals: Strategies, Consequences and Provisions for Prevention in USA, EU, India and Other Countries, in: Pharmaceutical Regulatory Affairs (2017), Vol. 6, Is. 1, pp. 1-6, p.1.

⁷⁴⁴ Ibid.

drug. Such a situation might have a detrimental effect for budgets for public health, in general, and for the individual patient, in particular.⁷⁴⁵

In this context, it is worth referring to the observation of the Indian Madras High Court as quoted by the Indian Supreme Court in the case *AG Novartis v Union of India*:

*"We have borne in mind the object which the amending Act wanted to achieve namely, to prevent evergreening; to provide easy access to the citizens of the country to life saving drugs and to discharge their constitutional obligation of providing good health care to its citizens."*⁷⁴⁶

In this context it is worth mentioning that Article 27 of the TRIPS Agreement provides member states with opportunities to curtail evergreening. More precisely Article 27 (1) of TRIPS, *inter alia*, notes:

*"[...] patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application."*⁷⁴⁷

Hence, as mentioned above, evergreening in most cases neither involves an innovative, nor is it a new invention.

We shall now turn our attention to the issue of access to medicine from a human rights perspective. As early as in 2015, the international community adopted a set of 17 goals, under the name of Sustainable Development Goals (SDGs) of the UN, which are expected to be achieved by 2030. In this context, Goal 3 refers to the commitment to:

⁷⁴⁵ Ibid.

⁷⁴⁶ Novartis AG v Union of India, Supreme Court of India, Civil Appeal No.2706-2716 of 2013, (1 April 2013).

⁷⁴⁷ See Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994), Art. 27 (1).

*“ensure healthy lives and promote well-being for all at all ages”.*⁷⁴⁸

The SDGs proposed an array of targets from addressing non-communicable diseases, all the way to the material abuse to environmental health. Entrenched in the fulfilment of Goal 3 was the target to end the epidemics of tuberculosis, malaria, Acquired Immunodeficiency Syndrome (AIDS), hepatitis and other communicable diseases. The SDG's Goal 3 emphasizes the essential importance of access to medicines in the pursuit of sustainable human development; access to medicines is a fundamental component of the global promise to universal health coverage. Patent monopoly has been coupled with unaffordable prices of medicines that happen to be under patent protection.⁷⁴⁹ The worry, in this case, is that patents may be extended to medicines that may generally hardly qualify for protection, through the means of strategies involving evergreening, and this exacerbates the access to medicines challenge, notably in developing countries. Access to medicines forms an integral part of the right to health in international law, and this has been acknowledged in judgements regarding the enforcement of IPRs in India and Kenya.⁷⁵⁰ The UN Commission on Human Rights has further verified that access to essential medicines is a vital element of the right to health.⁷⁵¹ Other cases have also confirmed that the access to essential drugs issue is intently tied to other human rights, most

⁷⁴⁸ United Nations: Transforming our world the 2030 agenda for sustainable development. - <https://sustainabledevelopment.un.org/content/documents/21252030%20Agenda%20for%20Sustainable%20Development%20web.pdf>, DOA: 27.07.2017.

⁷⁴⁹ El Said, M./ Kapczynski, A.: Access to Medicines: The Role of intellectual Property Law and Policy. Working Paper prepared for the Third Meeting of the Technical Advisory Group of the Global Commission on HIV and the Law. 2011. -

<https://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/t/56547292e4b0e74bc872ee41/1448374930129/ACCESS-TOMEDICINESTHE-ROLE-OFINTELLECTUALPROPERTY-LAW-ANDPOLICY-1+%281%29.pdf>, DOA: 01.11.2017, pp. 1-19, p.13.

⁷⁵⁰ Owoeye, Olasupo/ Owoeye, Oluwabusayo: Intellectual Property, Access to Medicines and Universal Health Coverage Through a Health Rights Lens, in: European Intellectual Property Review (2018), Vol. 40, Is. 1, pp. 49-54, p. 49.

⁷⁵¹ United Nations Office of the High Commissioner for Human Rights: Access to Medicines - a Fundamental Element of the Right to Health. - <https://www.ohchr.org/EN/Issues/Development/Pages/AccessToMedicines.aspx>, DOA: 12.02.2016.

prominently the right to life. Importantly, the prices of many new medicines are beyond the financial reach of the majority of populace living in developing countries.⁷⁵² For instance, a newer medicine for the treatment of chronic HIV are priced at about \$30,000 a year, while the treatment for many rare illnesses can cost over \$200,000 a year.⁷⁵³

On another note, a multitude of the diseases require therapeutic treatment with the help of essential medicines. As we have seen above, essential medicines are those drugs that “*satisfy the priority healthcare needs of the population*”.⁷⁵⁴ As for the World Health Organization, essential medicines are selected based on their estimated current and future public health relevance, evidence of efficacy as well as safety, and cost-effectiveness.⁷⁵⁵ As a matter of convention, medicines that qualify to be classified as essential medicines are published in the WHO’s Model List of Essential Medicines. The list is updated biennially and is tailored in a bespoke manner according to needs, in an essential medicines list. Thus, national governments can use these lists as a tool to concentrate on their most pressing public health needs, when it comes to the public procurement and treatment of a limited and high-priority set of medicines.⁷⁵⁶

Over the course of past decades there has been some progress when it comes to accessing essential medicines. Despite the progress, there are still around two billion people in the world facing enormous

⁷⁵² El-Said, Mohammed: TRIPS-Plus, Public Health and Performance-Based Rewards Schemes Options and Supplements for Policy Formation in Developing and Least Developed Countries, in: American University International Law Review (2016), Vol. 31, Is. 3, pp. 373-444, p. 387.

⁷⁵³ Pollack, Andrew: High Cost of Sovaldi Hepatitis C Drug Prompts a Call to Void Its Patents. in: New York Times, 2015. - <https://www.nytimes.com/2015/05/20/business/high-cost-of-hepatitis-c-drug-prompts-a-call-to-void-its-patents.html>, DOA: 26.12.2017.

⁷⁵⁴ World Health Organisation: Health Topics: Essential Medicines. 2018. - http://www.who.int/topics/essential_medicines/en/, DOA: 27.07.2018.

⁷⁵⁵ World Health Organisation: Model List of Essential Medicines. 20th edition. 2017. - <https://www.who.int/publications/i/item/eml-20>, DOA: 29.08.2020.

⁷⁵⁶ World Health Organisation: Model List of Essential Medicines. - <https://list.essentialmeds.org/?indication=452>, DOA: 20.12.2020.

obstacles when it comes to accessing the medicines they need.⁷⁵⁷ The contemporary R&D model seems to be rather market-driven and thus ill-equipped to address the gaps when it comes to essential medications, especially those earmarked for the developing world. Furthermore, it should equally be noted that currently, more than ever before, the international community has begun to realise that higher prices for essential medicines have indeed evolved into a global problem, affecting every single country in the world, not just the developing ones. Significant price hikes for drugs have also been noticed in developed countries like the United States.⁷⁵⁸

⁷⁵⁷ World Health Organisation: Access to Medicine Foundation: The 2016 Access to Medicine Index: Methodology. 2015. –
<http://apps.who.int/medicinedocs/documents/s22176en/s22176en.pdf>, DOA: 27.04.2017.

⁷⁵⁸ Erman, Michael: Drug makers kick off 2021 with 500 U.S. price hike. in: Reuters. 2021. -
<https://www.reuters.com/article/us-usa-healthcare-drugpricing-idUSKBN2992IY>, DOA:
12.03.2021.

4.5. Initiative for Medicines, Access & Knowledge v. Abbott Laboratories

The Initiative for Medicines, Access & Knowledge (I-MAK) is a non-profit organisation consisting of both lawyers and scientists whose objective is to represent the rights of low-income patients worldwide.⁷⁵⁹ The organisation is convinced that everyone has the right to access affordable, life-saving medicines for HIV/AIDS and other diseases. I-MAK's aim is to increase access to generic medicines (generally lower in cost) by tackling policy and legal barriers. In doing so they tend to focus on patents that are without merit, such as those which are rooted on ever-greening. They also engage in the process of conducting evidence-based research on drug patents and prices.⁷⁶⁰

As early as 2006 Lopinavir/Ritonavir was considered among the best drug combination that was available for those patients who failed the first line of HIV therapy. Fortunately, the tablet form of the drug does not require to be refrigerated; equally, the intake of the tablet also does not necessitate adherence to a strict diet regime.⁷⁶¹ Unfortunately, access to Lopinavir/Ritonavir was impeded by a company named Abbott Laboratories, which was the main manufacturer and seller of the drug in question. Major US pharmaceutical company, Abbott Laboratories, was able to repeatedly file requests to secure patents on numerous formulations of Lopinavir/Ritonavir. This tactical approach permitted Abbott Laboratories to extend their exclusive rights, and therefore their influence when it comes to settling prices and control of the world

⁷⁵⁹ I-MAK: Solving The Drug Patent Problem: Policy Brief: How the Supreme Court Patent Case Could Raise Drug Prices. 2017. - http://www.i-mak.org/wp-content/uploads/2017/10/Policy-Brief_SCOTUS-Patent-Case -FINAL-TO-PDF.pdf, DOA: 02.02.2020.

⁷⁶⁰ Ibid.

⁷⁶¹ FXB Center Harvard University: Health and Human Rights Resource Guide: How is Access to Medicines a Human Rights Issue? 2019. - <https://www.hhrguide.org/2017/06/09/access-to-medicines-and-human-rights/>, DOA: 02.12.2019.

market, thereby outpricing the global patent-pool (particularly from the developing countries).⁷⁶²

I-MAK became concerned with the approach developed by the pharmaceutical companies' which, from their point of view, went on to multiple patents on essential drugs in a manner that was not justifiable. This approach represented one of the biggest dangers to individuals suffering from HIV.

In the case in question, Abbott filed a patent application with the Indian Patent Office and argued that its solid oral dosage formulation of Lopinavir/Ritonavir had only been modified minimally as an invention.⁷⁶³ This was essentially another effort of evergreening on already existing HIV medication. If Abbott Laboratories had secured a patent over the Lopinavir/Ritonavir formulation, the ramifications would have been severe. It would mean that other manufacturers operating within the Indian Union would have been barred from producing inexpensive generics. As a result, this would have meant that millions of the poor would be excluded from accessing the relevant medications.⁷⁶⁴ The steep price set by Abbott Laboratories for Lopinavir/Ritonavir would amount to \$2200 per patient per year (middle range) and \$500 (in the lower range).⁷⁶⁵ India, as the leading purveyor of cheap generic medicines designated to other developing and LDC would hardly be able to produce and deliver the patented HIV drug. Consequently, the people in multiple developing countries and in India would lack essential treatment.⁷⁶⁶ In 2006 Abbott Laboratories filed an application with the Indian Patent Office, asserting that its solid oral dosage formulation of Lopinavir/Ritonavir was a new invention that would not be known or obvious to anyone

⁷⁶² Ibid.

⁷⁶³ Chilton, Adam S.: India's Evolving Patent Laws and the WTO Obligations: The Rejection of Abbott Laboratories' Application for a New Kaletra Patent, in: Journal of Law, Medicine and Ethics (2011), pp. 296-300, p. 299.

⁷⁶⁴ Ibid, pp. 297-298.

⁷⁶⁵ Ibid.

⁷⁶⁶ Ibid, p. 299.

skilled in this area of work. It also claimed that its formulation was a substantial enhancement of efficacy in comparison to the already existing formulation.⁷⁶⁷

However, in 2007, I-MAK filed a patent opposition against Abbott's patent application, following three other patent oppositions I-MAK filed against Abbott on related patents that could also potentially have been in a position to block generic companies' production of the same tablet. I-MAK claimed that Abbott's formulation lacked the novelty criterion for an invention which could be considered patentable as per the Indian Patent Act. It also maintained that Abbott's drug was subject to Article 3(d) of the Indian Patent Act, which states:

*"the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant."*⁷⁶⁸

I-MAK also submitted scientific evidence certifying that Abbott's alleged new invention also lacked the claimed efficacy.⁷⁶⁹ Moreover, I-MAK's patent challenge stated the following:

"[S]hould a patent be granted for the application in question, it will unfairly impede others from looking to develop and/or offer Lopinavir/Ritonavir at more affordable prices. Moreover, it will

⁷⁶⁷ Ibid, p. 298.

⁷⁶⁸ Intellectual Property India: The Patents Act, 1970. -

https://ipindia.gov.in/writereadda/Portal/IPOAct/1_31_1_patent-act-1970-11march2015.pdf, DOA: 27.09.2017.

⁷⁶⁹ Chilton, Adam S.: India's Evolving Patent Laws and the WTO Obligations: The Rejection of Abbott Laboratories' Application for a New Kaletra Patent, in: Journal of Law, Medicine and Ethics (2011), pp. 296-300, pp. 298- 299.

*contribute to preventing HIV patients from accessing this particular treatment at a cost they can afford.”*⁷⁷⁰

Consequently, I-MAK reiterated that the Lopinavir/Ritonavir tablet did not amount to an invention and was not patentable under the Indian Patent Act. I-MAK’s challenge turned out to be successful and the Indian Patent Office undertook the brave step to deny Abbott’s a patent on the grounds that the new formulation lacked the inventive character.⁷⁷¹ As a consequence of this intervention Indian companies retain the ability to both produce and sell a much cheaper version of Lopinavir/Ritonavir to a multitude of developing nations. For Michelle Childs, former Director of Policy Advocacy of MSF Access Campaign, this development will have a significant impact. She stated that:

*“Access to the drug Lopinavir/Ritonavir is critical for people living with HIV who have become resistant to their first medicine combination.”*⁷⁷²

Prima facie, facilitating the introduction of generics into the market is an essential strategy in increasing access to medicines. I-MAK also stated that the Lopinavir/Ritonavir challenge meant that half a billion dollars in cost could now be saved over the period of three years. According to I-MAK, this ground breaking victory over Abbott has set an important precedent for their endeavour to prevent multinational pharmaceutical companies from misappropriating the patent system, thereby commemorating a new era of hope for millions of people living with HIV globally.⁷⁷³ In sum, the successful challenge of I-MAK against Abbott Laboratories can been seen as a constructive approach to

⁷⁷⁰ I-MAK: Solving The Drug Patent Problem: Policy Brief: How the Supreme Court Patent Case Could Raise Drug Prices. 2017. - http://www.i-mak.org/wp-content/uploads/2017/10/Policy-Brief_SCOTUS-Patent-Case -FINAL-TO-PDF.pdf, DOA: 02.02.2020.

⁷⁷¹ Ibid.

⁷⁷² Médecins Sans Frontières: Brazilians Demand Greater Access to Crucial HIV Drug. 2011. - <https://msfaccess.org/brazilians-demand-greater-access-crucial-hiv-drug>, DOA: 20.02.2021.

⁷⁷³ I-MAK: India Rejects Sham Patent Application for Lifesaving HIV Drug: Pharmaceuticals in India now free to help HIV patients worldwide. - <https://www.i-mak.org/2011/01/03/india-rejects-sham-patent-application-for-lifesaving-hiv-drug-pharmaceuticals-in-india-now-free-to-help-hiv-patients-worldwide/>, DOA: 28.02.2019.

prevent the exploitative measures employed, in the form of evergreening, by “Big Pharma” against the poor living in the global South. Perhaps this is an example of what the Nobel Prize winner Thomas Stearns Elliot pointed out that:

*“sometimes things become possible if we want them bad enough.”*⁷⁷⁴

Thus, the EU and other Western nations should work hand in glove to increase access to medicines, by tackling policy as well as legal barriers to the human right to health.

To conclude, *prima facie*, the right to health has arguably acquired the status of a human right. As have been discussed above, a multitude of international conventions mention protecting the right to health, from the UDHR, CEDAW, CRC, European Social Charter and ICESCR. Article 12 of the ICESCR recognises the right of all to enjoy the highest attainable standard of health. In this context is worth noting that the Office of the UN High Commissioner for Human Rights has stressed that access to medicines does indeed form a fundamental element of the right to health. Equally General Comment 14 also requires states to refrain from opposing the right to health or potentially limiting the same. Regarding the seizure of essential generic medicine from India, it would be difficult to establish that the actions undertaken by the EU border forces against the shipment of Losartan from India were deliberate attempts to violate the right to health. It seems that the EU could have potentially been in violation of the right to health due to two determining factors. The first being due to delays caused by the seizure of medicines that were in transit, the Brazilian patients were not able to access essential generic medicines and thereby not able to enjoy the highest attainable standard of health. Secondly, the repeated in transit seizures and detentions of generic

⁷⁷⁴ AZ Quotes: T.S. Eliot. - <https://www.azquotes.com/quote/349221>, DOA: 12.02.2021.

medicine from India designated to developing nations could potentially be classed as a system violation of the right to health.

Thus, by default the EU as the organisation that has caused these issues, it could arguably be held liable for violating the right to health. Brussels could, however claim, that it was protecting another set of norms, namely IP law and thus its actions were justified. Consequently, a conflict of norms would arise, whether the obligations under European Council Regulation 1383/2003 (IP law) would be superior to an obligation under international human rights law (right to health). Given the fact that there exists a conflict regarding the hierarchy of norms in the scenario in question, we shall first consider whether the right to health (access to medicines) is a *jus cogens* norm. Unfortunately, it has not acquired the status of *jus cogens*, the highest set of norms in international law, and would therefore not automatically supersede other legal norms. In this context, human rights advocates have proposed that to resolve this conflicting situation, international human rights law should take primacy over IP law, which in turn ought to be accepted where treaty obligations are in conflict. Policymaker have argued that in national as well as international fora, the human rights to health takes both moral and legal precedence over IP law which was also supported by UN Special Rapporteur Farida Shaheed. According to Shaheed in situations in which patent right and human rights are in conflict the latter should supersede. Given the potentially detrimental consequences of the seizure to the Brazilian patients, who allegedly are in desperate need of affordable medicines to treat their hypertension, it seems plausible that if a norm conflict between IP law and international human rights law arises (right to health), the latter should prevail. The detention of essential AIDS medicines from India designated to Nigeria would also render human rights superior to the EU's IP legislation.

The Maastricht Principles are based on two main pillars, the first being that international human rights law places particular obligations upon

states, when acting in a way that has real and predictable effects on human rights beyond their national border. In this situation, states must ensure that they “respect”, “protect” and in some situations, “fulfil” those rights. Given the fact that the EU, as mentioned above, by default is bound by international human rights law, it has the same duties as nation states. Thus, it would be duty-bound to respect and protect and, in some cases, to fulfil its human rights obligation. Brussels’ seizure of essential generic medicine from India designated to Brazil has by default predictable effects on the right to health, more precisely on the right to access to medicines for Brazilian citizens (patients). The seizure by the EU border agency has a predictable detrimental effect on the right to health of the Brazilian citizens as this meant that the shipment of Losartan got delayed for month. The second pillar of the Maastricht Principles requires states (EU) to act in such a manner as to realise human rights extraterritorially in the field of economic, social, and cultural rights, through international assistance and cooperation. This can be done directly and indirectly; regarding the seizure of generics by the EU through the employment of its enforcement actions, and the return of the shipment to India, has arguably curtailed Brazil’s ability to supply its vulnerable population with affordable essential generic medicines from India. As a result, Brussels’ actions are in violation of the Maastricht Principles.

Finally, for the most part evergreening consists of minor tweaks to existing patents, and the reapplication of patent protection would technically fall foul of the novelty requirement of Article 27.1 of TRIPS. In this context, the I-MAK case highlights the dangers that evergreening could have on the issue of affordability which by default has implications for accessibility of essential generic medicines seen in this case with Lopinavir/Ritonavir, for the treatment of HIV. It is worth noting that HIV medicine would fall into the category of essential medicine and would therefore be needed by millions of Indians. The price that has been set by Abbott (\$500-\$2200) can hardly be affordable by ordinary Indian citizens. The I-MAK case illustrates

rather well the extent to which Big Pharma is willing to go to maximise its profits, unfortunately to the detriment of the poor living in development countries. The victory of I-MAK over Abbott is promising, as it has illustrated how small NGOs can indeed win cases against multinational corporations and hinder them from limiting access to essential medicine due to financial limitations. The judgement will enable the production of generics of Lopinavir/Ritonavir which will benefit the less well-off and the poor on the subcontinent. Pharmaceutical corporations like Abbott have human rights duties, as per the former, to take all reasonable actions to make new medicines “as available as possible” to those countries in need. In sum, Brussels’ seizures appear to be in violation of international human rights law (right to health), and also qualifies as a violation of the Maastricht Principles.

5. TRIPS

This chapter will examine the matter of the TRIPS Agreement in the context of human rights. Given the fact that generic AIDS medicines from Nigeria were seized by EU border officials at Amsterdam airport, we shall analyse subject matter of affordable HIV/AIDS medicines.

The TRIPS Agreement entered into force on 1 January 1995.⁷⁷⁵ TRIPS is indeed a result of globalisation. Globalisation is hardly a new phenomenon and had begun as a process when trade started. Moreover, the obtaining of raw materials as well as markets developed more and more internationally. This process has been fast-tracked in the contemporary world, as the movement of goods as well as services have increased across international borders. The advent of information and communication technologies has further accelerated both international trade and globalisation.⁷⁷⁶ The WTO has the following mandate: the reduction of the obstacles to international trade, the administration as well as monitoring the rules for the trade in goods, services, and TRIPS. TRIPS established minimum requirements for the protection of IP rights in each of areas of IPRs, thereby implying that WTO Members are mostly eligible to provide higher but not lower standards of IPR protection. In this context, the TRIPS Agreement defines intellectual property rights: trademarks⁷⁷⁷, geographical indications⁷⁷⁸, industrial designs⁷⁷⁹, patents⁷⁸⁰, layout-

⁷⁷⁵ World Trade Organisation: TRIPS: A More Detailed Overview of the TRIPS Agreement. Overview: the TRIPS Agreement. 1995. -

https://www.wto.org/english/tratop_e/trips_e/intel2c_e.htm#:~:text=Overview%3A%20the%20TRIPS%20Agreement,multilateral%20agreement%20on%20intellectual%20property, DOA: 25.02.2021.

⁷⁷⁶ World Health Organization: Regional Office for South-East Asia, TRIPS, Intellectual Property Rights and Access to Medicines. 2017.-

<https://apps.who.int/iris/bitstream/handle/10665/258915/TRIPS.pdf?sequence=1>, DOA: 31.03.2021.

⁷⁷⁷ Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994), Arts. 15-21.

⁷⁷⁸ Ibid, Arts. 22-24.

⁷⁷⁹ Ibid, Arts. 25-26

⁷⁸⁰ Ibid, Art. 27.

designs (topographies)⁷⁸¹, undisclosed information⁷⁸² and well as copyright⁷⁸³ and related rights. Additionally, the incentive theory of the twentieth century justified IPR effectively regarding the technical and economic advancement of a nation.⁷⁸⁴ Given this subject matter, the US, the EU, and Japan, have been among the strongest proponents.⁷⁸⁵ It also entails the settlement of disputes among its members with regard to TRIPS.

Like other WTO Agreements, TRIPS establishes the general duty of national treatment and most-favoured-nation treatment (MFN).⁷⁸⁶ The MFN established that all members to the TRIPS Agreement must be treated equally.⁷⁸⁷ TRIPS also happened to be the most comprehensive multilateral agreement on intellectual property to date. WTO member states were issued different dates by which they had to modify their national laws and policies to enable the protection of patent rights regarding pharmaceuticals. The implementation of the policies and relevant legislation was subject to whether or not they were developing countries. Equally, the time frame for the implementation of the TRIPS Agreement was dependent on the fact whether or not the state in question had relevant patent laws in place.⁷⁸⁸ According to Article 66 (1), the LDC were initially given until 2006 to acknowledge and enforce patents on pharmaceutical products, even though this date has since been expanded to 1

⁷⁸¹ Ibid, Arts. 35-38.

⁷⁸² Ibid, Art. 39.

⁷⁸³ Ibid, Arts. 9-14.

⁷⁸⁴ Dreyfuss, R./ Ng, E. (eds.): *Framing Intellectual Property Law in the 21st Century: Integrating Incentives, Trade, Development, Culture, and Human Rights*. Cambridge: Cambridge University Press, 2018, pp. 241-242.

⁷⁸⁵ Voon, Tania/ Mitchel, Andrew: TRIPS (Trade-related aspects of Intellectual Property Rights), in: Bethlehem, Daniel/ Neufeld, Rodney et. al. (eds.): *The Oxford Handbook on International Trade Law*. Chapter: 8. Oxford: Oxford University Press, 2009, pp.186-208, p. 187.

⁷⁸⁶ Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994), Art. 4.

⁷⁸⁷ Ibid, Art. 3.

⁷⁸⁸ Ibid, Arts. 65-66.

January 2033.⁷⁸⁹ In two cases, the Council for TRIPS has granted a broader delay to the LDC to implement the substantive provisions of TRIPS most recently to 1 July 2021.⁷⁹⁰ Article 27 of the TRIPS maintains that patents shall be available for both processes as well as products, in every area of technology, provided they are novel, involve an inventive step and are capable of industrial application.⁷⁹¹ Likewise, Article 28 notes the rights of the patent owner consist of the right to deter third parties from “making, using, offering for sale, selling, or importing” the product without the patent owner’s permission.⁷⁹² As the WHO regards essential medicines not to be subject to patent protection, it follows from this logic that WTO member states would be duty bound to implement domestic patent legislations that do not form a barrier for accessing most essential drugs. This would also include drugs that are covered by the national list of essential medicine.⁷⁹³ For instance, antiviral drugs would fall into this category.⁷⁹⁴

In spite of their obligation to implement laws granting and enforcing patents on pharmaceutical products, WTO members do in fact possess substantial leeway to alter their patent laws to achieve eminent public health objectives.

While patent protection is still applicable, national governmental authorities and commercial entities are under obligation to negotiate

⁷⁸⁹ Council for Trade-Related Aspects of Intellectual Property Rights: Extension of the Transition Period Under Article 66.1 of the TRIPS Agreement for Least-Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products. 2015. - https://www.wto.org/english/tratop_e/trips_e/ldc_e.htm, DOA: 24.03.2021.

⁷⁹⁰ World Trade Organization: Intellectual Property: Least Developed Countries: Responding to least developed countries’ special needs in intellectual property. 2013. - https://www.wto.org/english/tratop_e/trips_e/ldc_e.htm, DOA: 25.03.2021.

⁷⁹¹ See Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994), Art. 27.

⁷⁹² Ibid, Art. 28 (1).

⁷⁹³ Attaran, A: How do patent and economic policies affect access to essential medicines in developing countries, in: Health Affairs (2004), Vol. 23, Is. 3, pp. 155-166, p. 159.

⁷⁹⁴ World Health Organization: Model List of Essential Medicines. 21st List. 2019. -

<https://apps.who.int/iris/bitstream/handle/10665/325771/WHO-MVP-EMP-IAU-2019.06-eng.pdf>, DOA: 25.03.2021, pp. 1-60, p.19.

with the patent owner on the contractual terms and costs at which medications are eligible to be imported into the states in question. Alternatively, they may enter into negotiations to produce medicines themselves domestically, provided that relevant generic medicines with a similar efficacy are available.⁷⁹⁵ Furthermore, Article 63 of TRIPS requires WTO member states to inform the Council for TRIPS about domestic laws, regulations, judicial, as well as administrative decisions that affect the scope of patent protection and other IPRs. Likewise, the relevant nation is required to reply to requests from other WTO member countries about the extent of their laws.⁷⁹⁶

A panel of experts deals with conflicts between WTO member states regarding compliance with TRIPS. The panel is appointed to hear every complaint. Decisions of the panel of experts may be appealed to the WTO Appellate Body. Additionally, TRIPS also allows member states to enact trade sanctions on a member nation in lieu of the patent owner, in cases where another WTO member failed to enact the decision of the panel or of the Appellate Body. The same is applied to cases in which the member nations did not comply with their duties under the TRIPS agreement.⁷⁹⁷

There are however exceptions to the rule in question, which can be found under Article 8 of TRIPS and offer the following alternative:

[m]embers may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development,

⁷⁹⁵ World Health Organization: Chapter 15: Access to essential medicines, TRIPS and the patent system, Advancing the right to health: the vital role of law. - <https://www.who.int/healthsystems/topics/health-law/chapter15.pdf>, DOA: 25.02.2021, p. 233.

⁷⁹⁶ Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994), Arts. 63 (1) – 63 (3).

⁷⁹⁷ Understanding on Rules and Procedures Governing the Settlement of Disputes, 15 April 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 2, 1869 U.N.T.S. 401; 33 I.L.M. 1226 (1994), Art. 22.

provided that such measures are consistent with the provisions of this Agreement.”⁷⁹⁸

In the context of TRIPS, human rights have been utilised by NGOs (non-governmental organisations) to construe the debate on the moral duty to enable the access to essential medicines to developing countries. This strategic approach benefited from the media, public and politicians who embraced the need to provide affordable anti-retroviral drugs (ARVs) to treat those suffering from HIV/AIDS in the developing world. The proponents of the “moral duty” approach came to the overwhelming conclusion that the TRIPS Agreement, in its original setting, did *de facto* hinder the access to affordable mediation for HIV/AIDS.⁷⁹⁹ The NGOs were able to highlight the intertwined nature between the HIV/AIDS crisis and intellectual property rights. This issue did indeed resonate with those living in the developing nations as well as the developed world.⁸⁰⁰ Access to affordable essential medicines and with it IPRs were now not only viewed through the lens of trade but also under the human right angle, namely the right to health.⁸⁰¹ This approach highlighted the dignity of those living with this health conditions. By framing TRIPS in the context of health and human rights, NGOs were able to push for accountability from politicians and thereby pressure international organisation and national governments which previously disregarded the linkage between the protection on IPRs and the right to health as a human right.⁸⁰² In the build up to the TRIPS agreement, corporate interests have depicted IPRs as a crucial tool when it comes to the investment in R&D, and also as an inalienable private property right. Likewise, corporate interests had linked copying essential medicines to theft and

⁷⁹⁸ Ibid, Art. 8 (1).

⁷⁹⁹ Matthews, Duncan: When Framing Meets Law: Using Human Rights as a Practical Instrument to Facilitate Access to Medicines in Developing Countries, in: World Intellectual Property Organization Journal (2011), Vol. 3, Is. 1, pp. 113-128, p. 115.

⁸⁰⁰ De Mello e Souza, Andre: The Power of the Weak: Advocacy Networks, Ideational Change and the Global Politics of Pharmaceutical Patent Rights, Stanford: Stanford University Press, 2005, p. 28.

⁸⁰¹ Ibid, p. 10.

⁸⁰² Ibid, p. 159.

piracy, even though these methods were completely legal in nature.⁸⁰³

By mimicking the strategies employed by the corporate interests when negotiating the TRIPS Agreement, the NGOs weakened the public perception of the legitimacy of TRIPS regarding access of essential HIV/AIDS medications. The campaigners of access to medicines shifted away from the ideas of the advocates who framed the TRIPS Agreement in the 1980s, and underlined the importance of saving the lives of the poor suffering from HIV/AIDS. This was in sharp contrast to notion of the founding fathers of TRIPS who viewed the agreement as a viable alternative to tolerating the piracy of private property of the pharmaceutical industry.⁸⁰⁴

The “framing strategy” employed by the NGOs challenged the traditional notion of patents being the catalyst for the development of new drugs through placing an emphasis on the debate around both human rights and the right to health. Thereby highlighting that the traditional patient regime provided by the TRIPS Agreement did indeed threaten both public health and access to essential medicine. The NGOs strategy to create a moral outrage worked and helped to generate a general sense of injustice of the original TRIPS Agreement.⁸⁰⁵ Fortunately, the NGOs were able to raise awareness that access to essential drugs was indeed a trade matter, and they also mobilised the media in developed nations, which in turn pressured the governments in these nations to pay adequate attention to the matter in question.⁸⁰⁶ For Duncan, the task of granting access to medicine under TRIPS benefitted from the guilty conscious of the

⁸⁰³ Sell, Susan/ May, Christopher: Moments in Law: Contestation and Settlement in the History of Intellectual Property, in: Review of International Political Economy (2001), Vol. 8, No. 3, pp. 467–500, p. 485.

⁸⁰⁴ Sell, Susan/ Odell, John: Reframing the Issue: The Coalition on Intellectual Property and Public Health in the WTO, in: Odell, John (ed.): Negotiating Trade: Developing Countries in the WTO and NAFTA. New York: Cambridge University Press, 2006, p. 93.

⁸⁰⁵ Matthews, Duncan: When Framing Meets Law: Using Human Rights as a Practical Instrument to Facilitate Access to Medicines in Developing Countries, in: World Intellectual Property Organization Journal (2011), Vol. 3 Is. 1, pp. 113-128, p. 116.

⁸⁰⁶ Drezner, Daniel W.: Gauging the Power of Global Civil Society: Intellectual Property and Public Health. 2005. - <http://danieldrezner.com/research/gaugingqcs.pdf>, DOA: 25.03.2021, p.15.

developed nations about the colonial legacy, especially with regard to sub-Saharan Africa.⁸⁰⁷ By linking the right to health to IPRs, the NGOs managed to put pressure on the leadership of both the developed and developing worlds that counterbalanced the role played by the pharmaceutical industry. This in turn opened the doors for a debate on IPRs and development policies.

In the following we shall consider the use of generics. The term “generic” is also used to identify copies of patented drugs or those drugs whose patents have already expired.⁸⁰⁸ In other words this is generic from a patent standpoint. The European Medicines Agency (EMA) noted that a generic drug would entail the same active substances as its patented counterpart.⁸⁰⁹ They are manufactured according to the same quality standards as the “original” or “branded” medicine.⁸¹⁰ Moreover, it is taken in the same dose in order to treat the same sickness.⁸¹¹ On the other hand, the name, appearance, packaging and the inactive ingredients of a generic medicines can be dissimilar to the patented counterpart.⁸¹² When copies of patent drugs are made by other manufactures, they are either sold under the name of the chemical ingredient (making them clearly generic), or under another brand name (which means they are still generics from the point of view of patents).⁸¹³ Generic medicines for the global market can only be developed after the expiry of the protection period for the “original” medicine. The protection period for patented medicines is,

⁸⁰⁷ Matthews, Duncan: When Framing Meets Law: Using Human Rights as a Practical Instrument to Facilitate Access to Medicines in Developing Countries, in: World Intellectual Property Organization Journal (2011), Vol. 3 Is. 1, pp. 113-128, p. 116.

⁸⁰⁸ World Trade Organization: Fact Sheet: TRIPS and Pharmaceutical Patents, What does “generic” mean? - https://www.wto.org/english/tratop_e/trips_e/factsheet_pharm03_e.htm, DOA: 19.03.2021.

⁸⁰⁹ European Medicines Agency: Generic and hybrid medicines. 2012. - <https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/generic-hybrid-medicines>, DOA: 19.03.2021.

⁸¹⁰ Ibid.

⁸¹¹ Ibid.

⁸¹² Ibid.

⁸¹³ World Trade Organization: Fact Sheet: TRIPS and Pharmaceutical Patents, What does “generic” mean? - https://www.wto.org/english/tratop_e/trips_e/factsheet_pharm03_e.htm, DOA: 19.03.2021.

according to Article 33 of TRIPS set to 20 years.⁸¹⁴ During this time, a generic medicine can only be brought into the market with the permission of the patent owner or under compulsory licences.^{815 816}

Similarly, it is worth pointing out that the Bolar provision permits the testing and regulatory approval of generic drugs before its patent expires.⁸¹⁷ Hence, generic manufacturers can prepare for production and sale of these medications once the patent expires. In this manner, the Bolar provision enables the quick entry of generic medications into a given market.⁸¹⁸

In the system of international exhaustion, the IPRs are exhausted once the pharmaceutical product has been placed by the owner of the IPRs anywhere in the world. Equally, the IPRs holder will not be able to prevent the pharmaceutical product from being imported from other nations. States do indeed have the liberty to determine their own exhaustion (parallel importation) regime of choice, and thereby they have the power to regulate the legal scale of parallel trade.⁸¹⁹ A debate has erupted over the most suitable exhaustion regime for developing nations. As a general rule, developing nations seem to prefer the system of international exhaustion as it does indeed permit these nations to import lower priced patented products globally. India, Thailand, Argentina, and various states in Latin America have recognised the international concept of international exhaustion, consequently allowing the parallel importation of patented

⁸¹⁴ TRIPS: Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994).

⁸¹⁵ This issue shall be explored in the next chapter in more detail.

⁸¹⁶ See Doha Declaration: World Trade Organization, Ministerial Declaration of 14 November 2001, WTO Doc. WT/MIN(01)/DEC/1, 41 ILM 746 (2002), paras. 5 & 6.

⁸¹⁷ World Health Organization: Regional Office for South-East Asia, TRIPS, Intellectual Property Rights and Access to Medicines. 2017. -

<https://apps.who.int/iris/bitstream/handle/10665/258915/TRIPS.pdf?sequence=1>, DOA: 31.03.2021.

⁸¹⁸ Ibid.

⁸¹⁹ Ariyarathna, Lasantha/ Kariyawasam, Kanchana: Pharmaceutical Patents and Access to Generic Medicines in Developing Countries, in: European Intellectual Property Review (2020), Vol. 42, Is. 2, pp. 108-118, p. 114.

pharmaceutical products. Likewise, the TRIPS Agreement accommodates parallel importation based on the doctrine of the exhaustion of IPRs. Article 6 of TRIPS stipulates that states have the discretion to implement their own policies and legislation with respect to the exhaustion of rights.⁸²⁰ Members of the WTO possess the flexibility to integrate the exhaustion of rights principle into their domestic legislation.⁸²¹

Furthermore, in this context the Report on the Commission of Intellectual Property Rights of the UK states:

*"Developing countries should not eliminate potential sources of low-cost imports, from other developing or developed countries. In order to be an effective pro-competitive measure in a scenario of full compliance with TRIPS, parallel imports should be allowed whenever the patentee's rights have been exhausted in the foreign country."*⁸²²

In conclusion, it remains to be stated that Article 8 of TRIPS enables the adoption of necessary measures to protect public health. Thus, each member state of the WTO may amend their domestic laws to permit access to essential medicine. Regarding the seizure of Losartan designated to Brazil and the AIDS drugs destined to Nigeria, particularly given the AIDS pandemic on the African continent, Article 8 of TRIPS became even more eminent when it came to meeting the public health needs of South Africa. A similar line of argument may also be explored in the case of the Losartan shipment.

⁸²⁰ Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994), Art. 6.

⁸²¹ Ariyarathna, Lasantha/ Kariyawasam, Kanchana: Pharmaceutical Patents and Access to Generic Medicines in Developing Countries, in: European Intellectual Property Review (2020), Vol. 42, Is. 2, pp. 108-118, p. 114.

⁸²² Monirul, Azam: Intellectual Property and Public Health in the Developing World. Cambridge: Open Book Publishers, 2016. - <https://www.openbookpublishers.com/product/476>, DOA: 13.03.2021, p. 171.

5.1. Compulsory Licenses

This subchapter will discuss the concept of compulsory license in the context of the TRIPS agreement. Likewise, the landmark case of Natco Pharma Ltd v. Bayer Corporation which rather nicely highlights the issue of compulsory licence shall be explored. It will further examine access to medicines to LDC and developing countries in the context of the Doha Declaration. Likewise, this subchapter will further discuss the issue of parallel importation when it comes to safeguard the affordability of essential generic medicines. It will also explore the concept of voluntary license agreement.

To begin with, the question which arises in the context of access to life-saving medicines is whether it would be possible to limit the extent of pharmaceutical patents for the distribution of affordable essential generic medicines. In particular, the supply of essential generic life-saving medicines for the developing, and least developed nations, are at the heart of this analysis. For instance, essential generic antiretroviral medications could become affordable to millions of people living in least-developed countries and developing nations. However, the distribution of medicine inevitably means the sale, selling and, more importantly, the importing of patented pharmaceutical products which constitute the nature of patents.⁸²³ In order to tackle this problem, public international law permits third parties to intervene with the rights of the patent holder, while ensuring that patent owners are not entirely deprived out of their pecuniary benefits. To do so a compulsory license under the TRIPS Agreement is typically issued. By exploiting compulsory licenses, the pharmaceutical entities either produce the generic version of patented medicines or import the

⁸²³ See Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994), Art. 28.

generic medications from a foreign pharmaceutical company.⁸²⁴ A compulsory licence is granted three years from the date of patent granted to an invention.

Before entering into the crux of the matter, it would be helpful to define the term compulsory licence. In this context, the compulsory licence is defined as:

[...] “*an authorisation by a competent government authority to use a patented invention by a third party without the consent of the patent holder, against a payment of “adequate remuneration.”* A ‘government use’ is a particular form of compulsory licence issued by the government for its own use or for the use of a third party.”⁸²⁵

Likewise, Article 30 of TRIPS provides for compulsory licences as a form of an outlined exclusion to patent rights. This treaty provides states with the right to determine the grounds for use of compulsory licences. Furthermore, Doha explicitly clarified the determination in Article 30 of TRIPS that WTO members are eligible to provide exceptions within limits to the rights bestowed by a patent.⁸²⁶

This declaration exemplifies the commitment of WTO members to grant access to medication. It asserts that TRIPS can and should be interpreted in a manner loyal to WTO countries’ right to protect public health, as well as to promote access to medicines for all”.⁸²⁷ In this manner, the Doha Declaration highlights that TRIPS should be a part of the developing country’s efforts to tackle public health challenges.

⁸²⁴ Arora, Shalini/ Chaturvedi, Rekha: Impact of TRIPS on Providing Easy Access to Affordable Medicines in India, in: Journal of Intellectual Property Rights (2017), Vol. 22, pp. 257-265, p. 261.

⁸²⁵ FXB Center Harvard University: Health and Human Rights Resource Guide: How is Access to Medicines a Human Rights Issue? 2019. - <https://www.hhrguide.org/2017/06/09/access-to-medicines-and-human-rights/>, DOA: 02.12.2019.

⁸²⁶ See Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994), Art. 30.

⁸²⁷ Doha Declaration: World Trade Organization, Ministerial Declaration of 14 November 2001, WTO Doc. WT/MIN(01)/DEC/1, 41 ILM 746 (2002), para 4.

Additionally, even though intellectual property rights are essential for medical innovation, the prices of medication should not obstruct access in developing countries. Hence, the Doha Declaration establishes the sovereign right and legitimacy of WTO members to protect public health by compulsorily licensing patents and the liberty to determine grounds of compulsory licensing.⁸²⁸

WTO member states have stressed the importance of implementing and interpreting the TRIPS Agreement in a manner that supports public health by developing new drugs and granting access to already existing medicines.⁸²⁹ As a consequence, they adopted a separate Declaration on TRIPS and Public Health on 14 November 2001. The Doha Declaration, as it has been known, also recognises:

[...] the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.”⁸³⁰

The Declaration states that it should not prevent member countries from taking actions to safeguard public health.⁸³¹ It also tackles the matter of TRIPS' flexibility in the context of compulsory licencing, and exhaustion of the same.⁸³² It further defines the basis for extending the transition period for the LDC regarding pharmaceuticals until 2003. The Doha Declaration has been instrumental in demystifying the argument that the use of compulsory licences ought to be limited to emergency situations only. Doha has clearly extended the scope of the TRIPS by emancipating its members' legal capacity to determine

⁸²⁸ Ragavan, Srividhya: Drugs, Drugs Everywhere but Just Not for the Poor, in: World Intellectual Property Organization Journal (2016), Vol. 8, Is.1, pp. 41-53, p. 44.

⁸²⁹ World Trade Organization: Amendment to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), TRIPS: Factsheet. -

https://www.wto.org/english/tratop_e/trips_e/tripsfactsheet_e.htm, DOA: 20.03.2021.

⁸³⁰ Doha Declaration: World Trade Organization, Ministerial Declaration of 14 November 2001, WTO Doc. WT/MIN(01)/DEC/1, 41 ILM 746 (2002), para 1.

⁸³¹ Ibid, para. 4.

⁸³² See Doha Declaration: World Trade Organization, Ministerial Declaration of 14 November 2001, WTO Doc. WT/MIN(01)/DEC/1, 41 ILM 746 (2002), para. 4.

as per their discretion the legal basis upon which a compulsory license could be issued.⁸³³ Paragraph 5 (c) notes in this context:

[e]ach member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.”⁸³⁴

The TRIPS Agreement allows the utilisation of compulsory licenses as sort of a balancing act between providing access to already existing medicines, and the promotion of R&D into the development of new and improved medications.⁸³⁵

Under Article 31 of the TRIPS Agreement governments are permitted to utilise compulsory licensing without the authorization of the patent holder, to enable government use of a patent without the authorization of its owner, under a number of conditions aimed at protecting the legitimate interests of the patent holder. TRIPS also imposes a fair compensation scheme for the patent holder and limits the duration for the licence as well as the quantity that are allowed to be manufactured for the particular licence.⁸³⁶ Compulsory licensing is issued by the government of a WTO member state which authorises a commercial pharmaceutical company or government entity to manufacture a patented pharmaceutical or technical process without the patent owner's consent. The option to grant a compulsory licence under Article 31 for the purpose of manufacturing or import is accessible to

⁸³³ Ibid, para. 5 (b).

⁸³⁴ Ibid.

⁸³⁵ World Trade Organization: Amendment to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), TRIPS: Factsheet. - https://www.wto.org/english/tratop_e/trips_e/tripsfacsheet_e.htm, DOA: 20.03.2021.

⁸³⁶ Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994), Art. 31.

all member states.⁸³⁷ It extends to all products or technologies needed to treat diseases and even to combat a pandemic, such as the current SARS-CoV-2.⁸³⁸

The prerequisites in Article 31 obligate a commercial entity to apply for a compulsory licence, to have unsuccessfully attempted to obtain a voluntary licence from the patent owner on reasonable commercial terms and conditions.⁸³⁹ In the case of “national emergencies”, “other circumstances of extreme urgency” or “public non-commercial” use (or “government use”) or anti-competitive practices, the need to apply for a prior voluntary licence is not applicable.⁸⁴⁰ Additional requirements for granting compulsory licences apply and entail that such a licence may not be issued to Licensees.⁸⁴¹ Likewise, granting a compulsory license does not interfere with the patent owner’s right to manufacture a pharmaceutical product under the patent. Moreover, it must in principle be granted predominantly to the domestic market.⁸⁴² Compulsory licence may only be issued subject to application of procedural guarantees for importation has been applied.⁸⁴³ This would involve seeking voluntary licence ahead of being issued with a compulsory licence.

Voluntary licence agreements for essential medicines provide pharmaceutical companies that own patents or other IPRs the exclusive rights, with the power to distribute essential drugs to third parties. Among these third parties are generic producers that not only produce but also take care of the marketing and distribution of the

⁸³⁷ Ibid.

⁸³⁸ World Trade Organization: Amendment to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), TRIPS: Factsheet. -

https://www.wto.org/english/tratop_e/trips_e/tripsfacsheet_e.htm, DOA: 20.03.2021.

⁸³⁹ Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994), Art. 31 (b).

⁸⁴⁰ Ibid.

⁸⁴¹ Ibid., Art. 31 (e).

⁸⁴² Ibid., Art. 31 (f).

⁸⁴³ Ibid., Arts. 31 (a) & (b).

aforesaid pharmaceuticals. In some cases, the voluntary license foresees moderate royalties⁸⁴⁴, yet in other cases it is without royalties or in some incidences these have been waived.⁸⁴⁵ Voluntary licences have been used with a wide range of companies, including those manufacturing HIV drugs.⁸⁴⁶ It is, however, important to avert legal disputes for voluntary licences to set out unambiguously the actions that are allowed to be taken by the licensees, by paying due regard to the designated territories to which it is applied.⁸⁴⁷ Equally, voluntary licences present an opportunity for pharmaceutical firms to use them as part of their strategic approach when it comes to an area of corporate social responsibility. They are thereby contributing to the increased access to essential generic medicines at low costs. Yet additional approaches would include tiered pricing (selling drugs within a particular price range), non-filing of patents in LDCs, donation of medicines and the non-enforcement of existing patents.⁸⁴⁸ The pharmaceutical companies which own the patent are permitted to formalise their decision of non-enforcement of patent rights by issuing a non-assert declaration. Alternatively, they may also wish to enter into a non-assertive convention or an immunity-from-suit agreement. These treaties and agreements then outline the requirements under which the right holder would refrain from enforcing her patent rights.⁸⁴⁹ The International Drug Purchase Facility (UNITAID)⁸⁵⁰ established the Medicines Patent Pool⁸⁵¹ in 2006 in order to negotiate licence-related agreements with patent holders, with the aim of embarking into sublicensing agreements with generic pharmaceutical firms, in order to

⁸⁴⁴ See Art. 31 (h).

⁸⁴⁵ World Trade Organization: Amendment to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), TRIPS: Factsheet. -

https://www.wto.org/english/tratop_e/trips_e/tripsfacsheet_e.htm, DOA: 20.03.2021.

⁸⁴⁶ World Health Organization: Chapter 15 – Access to Essential Medicines, TRIPS and the Patent System. Advancing the Right to Health: The Vital Role of Law. World Health Organization. 2017, pp. 226-250. - <http://www.who.int/healthsystems/topics/health-law/chapter15.pdf>, DOA: 20.03.2021, p. 244.

⁸⁴⁷ Ibid.

⁸⁴⁸ Ibid.

⁸⁴⁹ Ibid.

⁸⁵⁰ UNITAID: World Health Organization. 2016. - <https://unitaid.org/#en>, DOA: 17.08.2018.

⁸⁵¹ Medicines Patent Pool: Medicines Patent Pool. 2016. - <http://www.medicinespatentpool.org/>, DOA: 19.07.2019.

manufacture licenced medications and combinations of medicines earmarked for LDC and developing nations. Such a licence agreement obliges the licensee to prove their production capacities to produce these particular components must be produced in line with the requalification standards of the WHO.⁸⁵²

Opponents have criticised the TRIPS Agreement for creating onerous legal barriers when it comes to obtaining a compulsory licence, and thereby barring this scheme from becoming a wide-ranging solution to confront the lack of life-saving medication for the less well-off nations.⁸⁵³ From another angle, the licence might also encourage competition between generic producers who intend to supply the authorised market with any given medicines at a lower cost.⁸⁵⁴

The Doha Declaration has allocated the task of providing extra flexibility to those member states that are unable to manufacture pharmaceuticals nationally to the TRIPS Council. These nations may, alternatively, obtain copies of patented medicines from other nations without the need to obtain consent from the patent holder.⁸⁵⁵ Moreover, paragraph 6 of the Doha Agreement recognises shortcomings when it comes to the production of drugs, and notes the following:

"We recognize that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face

⁸⁵² World Health Organization: Prequalification of medicines by WHO. Fact sheet no. 278. 2013. - <http://www.who.int/mediacentre/factsheets/fs278/en/>, DOA: 19.08.2018.

⁸⁵³ Halajian, Dina: Inadequacy of TRIPS & the Compulsory License: Why Broad Compulsory Licensing is Not a Viable Solution to the Access Medicine Problem, in: Brooklyn Journal of International Law (2013), Vol. 38, Is. 3, pp.1191-1231, p. 1205.

⁸⁵⁴ World Health Organization: Chapter 15 – Access to Essential Medicines, TRIPS and the Patent System. Advancing the Right to Health: The Vital Role of Law. World Health Organization. 2017, pp. 226-250. - <http://www.who.int/healthsystems/topics/health-law/chapter15.pdf>, DOA: 20.03.2021, pp. 243-244.

⁸⁵⁵ World Trade Organization: Amendment to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), TRIPS: Factsheet. - https://www.wto.org/english/tratop_e/trips_e/tripsfacsheet_e.htm, DOA: 20.03.2021.

difficulties in making effective use of compulsory licensing under the TRIPS Agreement.”⁸⁵⁶

Hence, the Doha Declaration has altered the scope of Article 31 (f) TRIPS, which specifically stated that compulsory licenses must predominantly be issued for the supply of the domestic market when it comes to nations that lack the capacity to produce pharmaceuticals goods in order to supply their own citizens.⁸⁵⁷ The legal obstacle for exporting countries of essential generic medicines was finally resolved on 30 August 2003⁸⁵⁸ when the member states of the WTO reached an agreement on the implementation of legislative changes to simplify the requirements for states wishing to import cheaper generic medicines made under compulsory licensing, in cases where they lack the capacity to manufacture the generic drugs domestically.⁸⁵⁹ Paragraph 6 of the Doha Declaration has indeed created a waiver of Art. 31 (f) of TRIPS, through which a nation that lacks the production facilities is now in a position to import a specific patented pharmaceutical drug from another member state that possesses both the technical know-how and the relevant manufacturing capabilities to produce the drug in question.⁸⁶⁰ As a result the Special Compulsory Licencing System was created.

Despite these rather optimistic developments due to the creation of the Special Compulsory Licencing System, terms and conditions are,

⁸⁵⁶ See Doha Declaration: World Trade Organization, Ministerial Declaration of 14 November 2001, WTO Doc. WT/MIN(01)/DEC/1, 41 ILM 746 (2002).

⁸⁵⁷ See Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994), Art. 31.

⁸⁵⁸ World Trade Organisation: Decision of the General Council of 30 August 2003, Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health. 2003. - https://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm, DOA: 21.07.2020.

⁸⁵⁹ World Trade Organization: Amendment to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), TRIPS: Factsheet. - https://www.wto.org/english/tratop_e/trips_e/tripsfactsheet_e.htm, DOA: 20.03.2021.

⁸⁶⁰ Ariyaratna, Lasantha/ Kariyawasam, Kanchana: Pharmaceutical Patents and Access to Generic Medicines in Developing Countries, in: European Intellectual Property Review (2020), Vol. 42, Is. 2, pp. 108-118, p. 115.

indeed, applicable when it comes to the products that are imported under this. A key objective for this system is that the relevant shipments with generic medications reach the beneficiary in question, with the goal to prevent the diversion of these medication to the wrong markets. Particularly, diverted generic medicines that land in the hands of "traders" that supply these to the illicit or black-market, could *prima facie* represent a potential reputational risk and loss of confidence in this system. Yet another challenge may emerge in the form of a parallel or grey market. Parallel importation is defined as following:

[...] *"the import and resale in a country, without the consent of the patent holder, of a patented product that has been legitimately put on the market of the exporting country. Parallel imports take place when there are significant price differences for the same good in different markets."*⁸⁶¹

Parallel import happens when a medicine is sold in various states at different rates, and an agent or intermediary in one country purchases the drugs and exports it to another country in competition with the producer.⁸⁶² Moreover, parallel importation can also be classed as a credible option to increase access to affordable generic medicine in LDC and developing countries.⁸⁶³ The central idea behind parallel importation is the notion of "exhaustion", which in essence asks the question whether a patent holder would be willing to abandon their ownership rights when they sell the pharmaceuticals product.⁸⁶⁴ The reasoning behind this principle is that the patent owner had financially

⁸⁶¹ FXB Center Harvard University: Health and Human Rights Resource Guide: How is Access to Medicines a Human Rights Issue? 2019. - <https://www.hhrguide.org/2017/06/09/access-to-medicines-and-human-rights/>, DOA: 02.12.2019.

⁸⁶² Ariyarathna, Lasantha/ Kariyawasam, Kanchana: Pharmaceutical Patents and Access to Generic Medicines in Developing Countries, in: European Intellectual Property Review (2020), Vol. 42, Is. 2, pp. 108-118, p. 114.

⁸⁶³ Ibid.

⁸⁶⁴ Halajian, Dina: Inadequacy of TRIPS & the Compulsory License: Why Broad Compulsory Licensing is Not a Viable Solution to the Access Medicine Problem, in: Brooklyn Journal of International Law (2013), Vol. 38, Is. 3, pp.1191-123, p. 1199.

fully benefitted from the sale of their patentee product. Consequently, the patent holder should not have yet again another option to further control the resale of the products in which their patents are essentially incorporated.⁸⁶⁵ Subsequently, WTO members are free to authorise parallel imports.⁸⁶⁶

An example of a parallel or grey import would be if entity A has a medicine patented in the State B and State C, which it sells at a lower rate to State C. If a second entity was to purchase the medicine in State C and import the same into State B at a lower cost than entity A's price, that would be the case of parallel or grey import.⁸⁶⁷ The majority of developing countries view parallel importation not just as an opportunity for economic development but equally as a means to prevent possible anti-competitive actions by an exclusive distributor.⁸⁶⁸ Likewise, parallel importation permits a state to make use of the price differences in various markets, where substantial price differences can be found among the same pharmaceutical commodities.⁸⁶⁹ For instance, on the one hand, 100 units of Bayer's ciprofloxacin (500 mg) are priced at Shilling 74,000 in Mozambique. On the other hand, in India, 100 units of the same drug are sold for Shilling 1,500. This is due to local competition from the generic pharmaceutical

⁸⁶⁵ Owoeye, Olasupo: Access to Medicines and Parallel Trade in Patented Pharmaceuticals, in: European Intellectual Property Review (2015), Vol. 37, Is. 6, pp. 359-368, p. 360.

⁸⁶⁶ Ariyarathna, Lasantha/ Kariyawasam, Kanchana: Pharmaceutical Patents and Access to Generic Medicines in Developing Countries, in: European Intellectual Property Review (2020), Vol. 42, Is. 2, pp. 108-118, p. 114.

⁸⁶⁷ See World Trade Organisation: Fact Sheet: TRIPS and Pharmaceutical Patents, Obligations and exceptions. 2006. - https://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm, DOA: 21.08.2018.

⁸⁶⁸ Lijadu, Femi: Parallel Importation: How to Manage the Problem, quoted in: Yetunde Okojie, Parallel Importation and the Exhaustion of Rights Principle under the 'TRIPS Agreement' and the 'Doha Declaration. - <http://www.spaajibade.com/resources/wp-content/uploads/2016/03/Website-article-on-Parallel-Importation-and-the-Exhaustion-of-Rights-Principle-under-the-1.pdf>, DOA: 17.08.2020.

⁸⁶⁹ World Health Organization: Essential Medicines and Health Products: Declaration on the TRIPS Agreement and Public Health. - http://www.who.int/medicines/areas/policy/doha_declaration/en/, DOA: 21.04.2020.

manufacturers. Consequently, Mozambique can import the product from India without Bayer's consent.⁸⁷⁰

To apply the system under paragraph 6 of the Doha Declaration, the government of a member state wishing to make use of the system are expected to notify the WTO. There are the following three types of notification when it comes to the special compulsory licences in order to export medicines:

- “*importing Member's one-off general notification of its intention to use the System (not required for least-developed country Members);*
- *importing Member's specific notification of the details of the needed pharmaceutical products and other details required under the System;*
- *exporting Member's notification of grant of a compulsory licence for export and conditions attached to it.*”⁸⁷¹

There is however no requirement to get approval from a WTO body in order to apply the system in question. However, there are limitations, for instance, “reasonable measures within their means” and “proportionate to their administrative capacities” to prevent these conditions from becoming burdensome as well as impractical for the importing nation.⁸⁷² The system also requires that developed members states are obliged to supply both pecuniary and technical cooperation upon request, and subject to mutually agreed conditions, in order to aid countries using the system to avoid trade diversion away from earmarked beneficiaries.⁸⁷³ While all members of the WTO are eligible to export under this system, developed nations have committed

⁸⁷⁰ News: Plan to lower cost of imported drugs. 2016. - <http://mobile.nation.co.ke/news/Plan-to-lowercost-of-importeddrugs/1950946-3262536-format-xhtml-i2ibbs/index.html>, DOA: 19.06.2019.

⁸⁷¹ World Trade Organisation: TRIPS: Special Compulsory Licences for Export of Medicines: Guide to Notifications. 2003. -

https://www.wto.org/english/tratop_e/trips_e/guidenotifications_e.pdf, DOA: 21.08.2018.

⁸⁷² World Trade Organization: Amendment to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), TRIPS: Factsheet. -

https://www.wto.org/english/tratop_e/trips_e/tripsfacsheet_e.htm, DOA: 20.03.2021.

⁸⁷³ Ibid.

themselves not to make use of this scheme. As a somewhat pleasant development, the WTO agreed on 6 December 2005 to incorporate the 2003 waiver decision into the TRIPS Agreement for good, and the amendment entered into force on 23 January 2017. Consequently, additional flexibility to protect public health has become part and parcel of the TRIPS Agreement.⁸⁷⁴ Notably, the compulsory licensing provisions represent a balance that goes to the root of the tenets and aims enshrined in arts 7 and 8 of the TRIPS Agreement. The quintessence of Article 7 is to outline the protection, as well as enforcement, of intellectual property rights, which in turn are supposed to contribute to technological advancements that are beneficial to the economic and social welfare of the member countries. Similarly, mutual advantages and benefits should be extended to both manufacturers and consumers.⁸⁷⁵ Additionally, Article 8 considers the doctrines under which the objectives of Article 7 will can be fulfilled. The principles under Article 8 recognises member states entitlement to embrace measures that are in line with public health, and public interest, in sectors that are crucial to economic, social and technological development of the WTO nations.⁸⁷⁶ Both Articles 7 and 8 have wide-ranging political and social consequences for the LDC and developing countries of the WTO, and permit them to customise actions that facilitate world-wide trade, while at the same token also realising their domestic goals.⁸⁷⁷ For example, significantly less well-off nations may utilise compulsory licences in crucial technologies such as life-saving medicines in order to promote “downstream innovations”, which if not would be blocked every so often by the strict implementation of intellectual property rights. Downstream innovation is classed as:

⁸⁷⁴ Ibid.

⁸⁷⁵ See Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994), Art. 7.

⁸⁷⁶ Ibid, Art. 8.

⁸⁷⁷ Ragavan, Srividhya: Patents and Trade Disparities in Developing Countries. Oxford: Oxford University Press, 2012, p. 366.

"[...] the process of turning the inventions and processes into economic value".⁸⁷⁸

Thus, manufacturers of generic medicines could play a key role in altering the objective and use of paragraph 6 of the Doha Declaration when it comes to compulsory licences. They could guarantee the reliance of developing countries upon this provision without worry about negative political and economic ramifications.⁸⁷⁹ Furthermore, Doha Declaration declares, *inter alia*, that:

*"each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles."*⁸⁸⁰

The connection between IPRs and public health have a significant impact on access to drugs in developing countries. The WHO has recognised that the success of the Doha Decision depends on its implementation.⁸⁸¹ Members of the WTO will have to amend their national legislation to integrate the amendment to the TRIPS Agreement. Regrettably, observers have declared that the Doha decision has seen little practical implementation among WTO members. The failure of industrialised nations to distribute essential generic medicines to the countries that urgently need them meant that the Doha Declaration could hardly reverse the current dissatisfactory situation in a meaningful manner. Unfortunately, *prime facie*, there seems to be very little enthusiasm, on the part of the Industrialised

⁸⁷⁸ See Bhardwaj, Gunjan: Innovation Management: Collaborating Downstream in Emerging Markets. 2010. - <https://innovationmanagement.se/2010/05/24/collaborating-downstream-in-emerging-markets/#:~:text=Downstream%20innovation%20is%20the%20process,like%20Bosch%2C%20Mahle%20or%20BASF>, DOA: 24.03.2021.

⁸⁷⁹ Lee, S.: Can Incentives to Generic Manufacturers Save the Doha Declaration's Paragraph 6?, in: Georgia Journal of International Law (2013), Vol. 44, Is. 4, pp. 1387-1422, p. 1387.

⁸⁸⁰ See Doha Declaration, World Trade Organization, Ministerial Declaration of 14 November 2001, WTO Doc. WT/MIN(01)/DEC/1, 41 ILM 746 (2002), para 5 (a).

⁸⁸¹ Statement of the World Health Organization on WTO Access to Medicines Decision, 1 September 2003. 2003. -

<https://www.who.int/mediacentre/news/statements/2003/statement10/en/>, DOA: 09.01.2020.

world, when it comes to the implementation of the Doha mechanisms to supply the low-cost or no-cost pharmaceuticals to LDC and developing nations.⁸⁸²

⁸⁸² Ariyaratna, Lasantha/ Kariyawasam, Kanchana: Pharmaceutical Patents and Access to Generic Medicines in Developing Countries, in: European Intellectual Property Review (2020), Vol. 42, Is. 2, pp. 108-118, p. 116.

5.1.1. Natco Pharma Ltd v. Bayer Corporation

This section will consider the landmark case of Natco Pharma Ltd v. Bayer Corporation. The dispute between the Indian pharmaceutical company Natco Pharma (an Indian company based in Hyderabad) and Bayer on the subject matter of a compulsory licence was contested before the Indian Patent Office and the Intellectual Property Appellate Board in India (IPAB). Almost a decade ago, in March 2012, India issued its first compulsory licence favouring a generic drug producer with respect to a pharmaceutical patent granted to Bayer in 2008.⁸⁸³ Bayer had applied for an Indian patent for the medicine Sorafenib Tosylate four years earlier, which it was marketing under the brand name Nexavar. Nexavar has proven to be effective when it comes to treating certain forms of liver as well as kidney cancer.⁸⁸⁴

The application for the compulsory licence to manufacture Sorafenib was filed by Natco Pharma and the compulsory licensing application was based on the three grounds (three step-test). The first ground was that the reasonable requirements of the public with respect to the patented drug were not satisfied by the patent holder. Secondly, by the fact that the patented drug was not available at a reasonable price. Thirdly, that the invention was not worked in India itself.⁸⁸⁵

As for the first, the Controller relied on details that were issued by the patent holder and observed that only about two percent of the total number of kidney and liver cancer patients were able to make use of the medicine.⁸⁸⁶ For the Controller this was indeed a valid ground for concluding the reasonable requirements of the public with respect to the patented drug were not satisfied by the patent holder with regard

⁸⁸³ Natco Pharma Ltd v. Bayer Corp (2012) C.I.A. No. 1. 2011. -

http://www.ipindia.nic.in/ipoNew/compulsory_License_12032012.pdf, DOA: 13.04.2014.

⁸⁸⁴ Ibid, para. 3.

⁸⁸⁵ Ibid, para. 9.

⁸⁸⁶ Ibid, para 22.

to the patented invention.⁸⁸⁷ Regarding the second subject matter, the controller remarked that the sales for the drug were extremely low, when comparing the patents that were in dire need of the drug. As Bayer charged around Rs. 280 000 rupees (\$3862) for a month therapy. Thus, this was evidence enough for the Controller to conclude that it was simply not affordable for the general public to purchase the medicine due to the rather exorbitant cost.⁸⁸⁸ Concerning the third ground, the Controller found that simply importing the drug into India would not satisfy the qualification that the invention has been worked in India as it was not manufactured to any significant extent in India.⁸⁸⁹

Interestingly, the Controller noted that, though possessing manufacturing facilities in India, the patent holder had decided not to produce the patented medicine India even as four years had passed since the granting of the patent.⁸⁹⁰ In sum, the Controller issued a compulsory license in favour of Natco Pharma with a royalty rate fixed at 6% of the net sales on a quarterly basis.⁸⁹¹

The decision of the Controller on the compulsory license was challenged before the IPAB. The decision was, however, upheld by the IPAB subject to some modifications, *inter alia*, it increased the royalty rate from six to seven percent of the next sales.⁸⁹² Dissatisfied with the decision of the IPAB, Bayer challenged the decision of the IPAB at the Bombay High Court. The Bombay High Court broadly agreed with almost all the points decided by the Controller as well as of the IPAB and dismissed the case.⁸⁹³ Bayer filed petition for Special Leave to Appeal before the Supreme Court of India, challenging the decision of the Bombay High Court. The Supreme Court dismissed the

⁸⁸⁷ Ibid, paras. 23-24.

⁸⁸⁸ Ibid, para 36.

⁸⁸⁹ Ibid, para 45.

⁸⁹⁰ Ibid.

⁸⁹¹ Ibid, para 61.

⁸⁹² *Bayer v. Union of India and Natco OA/35/2012/PT/MUM. -*

<http://www.gnaipr.com/CaseLaws/OA352012PTMUM.pdf>, DOA: 13.03.21, para. 43.

⁸⁹³ Ibid, para. 45.

petition and was not willing to intervene with the decision of the Bombay High Court.⁸⁹⁴ While the judicial and other governmental bodies that deal with IPRs have clearly given permission for manufacturing Nexavar under compulsory license, we have seen in Chapter 4 that the management of Bayer was anything but amused by this decision.

Though compulsory licence under TRIPS has found little appreciation by Bayer, it had, however, produced the diametrically opposite outcome from what was, *prima facie*, feared by Bayer. For example, the price reduction meant that more and more people in India could now afford the medicine and consequently that boosted the sales volume.⁸⁹⁵ However, against all odds, Bayer did indeed profit from compulsory licenses and the legally lowered price for Nexavar, a medication for the treatment of kidney and liver cancer. The increase in volume, when it comes to sales, ended up rectifying the revenue losses which Bayer feared would arise as a consequence of the compulsory licence.⁸⁹⁶ In sum, it turned out to be a win-win situation for all those involved, including Bayer; the instrument of compulsory licence itself, as a crucial legal instrument for making life-saving drugs affordable; and last but not least, for the patients in the developing world. The increase in volume, when it comes to sales, ended up rectifying the revenue losses which Bayer feared would arise as a consequence of the compulsory licence.⁸⁹⁷

Finally, the Natco Pharma Ltd v. Bayer Corporation has showcased the positive impact which compulsory licence had on the affordability of essential cancer medicine Nexavar. Compulsory licence has made

⁸⁹⁴ Petition for Special Leave to Appeal (C) NO(S). 30145/2014. - <http://www.lawyerscollective.org/updates/supreme-court-says-no-to-bayer-upholds-compulsory-license-on-nexavar.html>, DOA: 19.07.2016.

⁸⁹⁵ Bayer Corp v Union of India M.P. Nos.74–76 of 2012 and No.108 of 2012; OA/35/2012/PT/MUM. -

https://www.jetro.go.jp/ext_images/world/asia/in/ip/pdf/compulsory_en.pdf, DOA: 24.03.2021.

⁸⁹⁶ Ragavan, Srividhya: Drugs, Drugs Everywhere but Just Not for the Poor, in: World Intellectual Property Organization Journal (2016), Vol. 8, Is. 41, pp. 41-53, p. 44.

⁸⁹⁷ Ibid.

Nexavar affordable for the Indian masses, as \$3862 per month are even at the time of writing only affordable by a tiny number of the Indian population. Given the win-win situation in which both the Indian patients and Bayer profited from the compulsory licence means that compulsory licences are indeed working when it comes to proving access to essential generic medicines. Bayer had hardly made any profit on the cancer drug before the compulsory licence was issued, however, after the granting of the licence its sales went up considerably. The Bayer example showcases rather nicely both the importance of compulsory licences, and that selling affordable medicines does not lead to a pecuniary disadvantage of the producer of generic medicines. Multinational pharmaceutical companies from Europe, together with the EU, should take a leaf out of Bayer's book and be more inclined to issue both voluntary licences as well as compulsory licence to developing countries as and when needed. If anything, the Nexavar example demonstrates that issuing compulsory licences does not need to come at a loss for the multinational corporation. It would be advisable for both the European pharmaceutical industry and for the EU to work on opportunities to issue compulsory licences rather than to engage in the seizure of essential medicines. In sum, the Doha Declaration has opened doors full of opportunities to protect the human right to affordable medicines; it would now be the turn of Brussels to open a window and to encourage its pharmaceutical industry to make sure of it.

6. Traditional Knowledge

“Every town’s our hometown; every man, our kinsman; good and evil happen not because of others.”⁸⁹⁸

The misappropriation of traditional knowledge, also referred to as biopiracy, when it comes to the use of ancient traditional knowledge and seems to be an important issue of contention. This chapter will examine the intellectual misappropriation of medical and other traditional knowledge from India primarily by Western multinationals. The medical patents and other intellectual property protection based on traditional knowledge shall be discussed. Multinationals located in West have managed to secure patents in the United States and in the European Union. However, *prima facie* there seems to be hardly any protection for the actual owners of medical traditional knowledge, who in most cases happened to be the indigenous communities of the Indian subcontinent. The issue at hand seems to be that the West is keen in research investigation and patent medical traditional knowledge when it comes to plants, thereby bioprospecting the biodiversity of 45,500 different plant species located in India.

While, *prima facie*, Brussels is not necessarily actively directing the efforts of the Western pharmaceutical industry in their endeavours to exploit Indian medicinal traditional knowledge, the question does indeed arise whether the EU is silently condoning the exploitative measures undertaken by Western multinationals from the pharma industry. This chapter shall also investigate whether the indigenous community, as the actual owner of the intellectual property right in question, have pecuniarily been compensated by the relevant multinationals for the commercial exploitation of their IPRs. This chapter shall also examine whether the illegitimate exploitation of

⁸⁹⁸ Poongunranar, Kaniyan: Puranaanooru – Verse 192, Old Tamil Poetry Translations of Tamil Poetic works that span 2000 years. - <https://oldtamilpoetry.com/2016/05/05/puranaanooru-192/>, DOA: 01.01.2020.

traditional knowledge from India would potentially be in violation of international human rights law.

This chapter will examine the bioprospecting of the following items: neem (*Azadirachta indica*), turmeric (*Curcuma longa*), basmati (*Oryza sativa*), *Trichopus zeylanicus* (Arogya pacha) and yoga. Most of the items discussed in the chapter are plants, except for yoga. This final aspect of consideration will be the subject matter of property rights. While all examples are medically relevant or medicines on their own right, basmati represents an exception. Basmati does, however, have high nutritional level and excellent health benefits. While there would have been many more examples that are available, the limited scope of this work when it comes to matters of traditional knowledge and biopiracy in and of Indian biodiversity and medical practice has led to the selection of the exhibits. A key reason for choosing the five examples is due to their quintessential Indian nature, in which, *T. zeylanicus* is admittedly less commonly known. This is indeed also the reason for selecting *T. zeylanicus* as it showcases the harsh reality and the blatant injustice when it comes to biopiracy of indigenous traditional knowledge in the area of medicinal plants. The *T. zeylanicus* incident visualises the detrimental effects that biopiracy has on indigenous traditional knowledge, if the same is not adequately safeguarded through the means of IP protection. The aim of this chapter is therefore to examine the interplay between traditional knowledge and biopiracy and its consequences for the IP owners. We shall consider whether the notion of colonialisation of the South by the West, through the “nuclear missiles” of patents and other IP protection is indeed warranted. The alternative would entail that this is in fact mere hyperbole.

Having discussed the objective of this chapter it would now be advisable to define the multiple terms that are of significance for this section. To begin with, it would be advisable to define the term

traditional knowledge. While there is no widely accepted definition for the term traditional knowledge, however, the definition used by the WIPO, which works in the field of traditional knowledge protection, provides the following definition:

*"tradition-based literary, artistic or scientific works; inventions; scientific discoveries; design; marks, names and symbols; undiscovered information; and all other tradition-based innovations and creations, resulting from intellectual activity in the industrial, scientific, literary or artistic fields."*⁸⁹⁹

The WIPO definition is the most widely recognised version. Thus, traditional knowledge appears to be defined in a rather broad manner. It includes the whole of the culture of those people living in local as well as in indigenous communities. The aforesaid culture is a combination of the practice carried out in order to survive in a given environment, together with long-standing traditions. The spiritual meaning and beliefs of the communities are yet other key factors.⁹⁰⁰ It can be both oral and written, as long as traditional knowledge is transmitted. The name 'traditional' does not necessarily have to imply that that the item is old, it should, however, be transmitted from one generation to another and be rooted on traditions or norms. Traditional stands for the manner in which knowledge have been preserved, created as well as disseminated. Thus, traditional knowledge includes information about genetic materials dealing with the growth and the use of plants for medical treatment and for nutritional purposes.⁹⁰¹ It is also a collective knowledge; hence it is the joint property of indigenous people.⁹⁰²

⁸⁹⁹ Finetti, Claudia: Traditional knowledge and the patent system: Two worlds apart? in: World Patent Information (2011), Vol. 33, Is. 1, pp. 58-66, p. 58.

⁹⁰⁰ Ibid.

⁹⁰¹ Ibid.

⁹⁰² Ibid.

Moreover, Anu Bala provides defines traditional knowledge as the following:

*"Traditional knowledge (TK) refers to knowledge that people of an indigenous community, in one or more society, based on experience and adaptation to a local culture and environment, have developed over time, and constantly shaped by innovations and practices of each generation."*⁹⁰³

Having defined the term traditional knowledge extensively it would be now appropriate to turn our attention to the term biopiracy. Biopiracy is defined as the following:

*"[as] a "political" definition given to the behaviour of some corporations, belonging both to the developed countries and to the traditional knowledge holders' countries, which commercially exploit the information got by traditional knowledge as the biological material or the specific knowledge about a topic, without any compensatory benefit to the stakeholder of such a knowledge. Sometimes, the TK has been duplicated as such, in patents."*⁹⁰⁴

Yet another definition describes biopiracy as following:

*"[...] therefore can be described as the unjustified extraction of the environmental heritage and traditional knowledge from various regions of the earth for economic exploitation and industrial monopolization."*⁹⁰⁵

Yet another term that is worth defining is the terms biodiversity. The term is defined as following:

⁹⁰³ Bala, Anu: Traditional Knowledge and Intellectual Property Rights: An Indian Perspective. 2019. - <http://ssrn.com/abstract=1954924>, DOA: 19.02.2020.

⁹⁰⁴ Finetti, Claudia: Traditional knowledge and the patent system: Two worlds apart? in: World Patent Information (2011), Vol. 33, Is. 1, pp. 58-66, p. 59.

⁹⁰⁵ Udgaoonkar, Sangeeta: The Recording of Traditional Knowledge: Will it Prevent 'Bio-Piracy'? , in: Current Science (2002), Vol. 82, No. 4, pp. 413-419, pp. 414-415.

“The diversity in the living organism presents on the earth, collectively in land water and air is called biological diversity or biodiversity. Biodiversity includes millions or races, local variants of species and subspecies, and ecological processes and cycles that link organism into populations, communities, ecosystems and ultimately the entire biosphere.”⁹⁰⁶

Moreover, we shall look at the definition for the bioprospecting which is defined as following:

“[bioprospecting] involves ‘the systematic search for genes, natural compounds, designs and whole organisms in wild-life with a potential for product development.”⁹⁰⁷

⁹⁰⁶ Krishnamoorthy, Venkataraman/ Swarna, Latha: Intellectual Property Rights, Traditional Knowledge and Biodiversity of India, in: Journal of Intellectual Property Rights (2008), Vol. 13, pp. 326-335, p. 326.

⁹⁰⁷ Mateo, N./ Nader, W./ Taayo, G.: Bioprospecting in Encyclopaedia of Biodiversity. Vol. 1, New York: Academic Press, 2001, p. 471.

Exhibit A. Neem

The biological or rather Latin name of the neem tree is *Azadirachta indica* but in Sanskrit the same tree is referred to as *sarva-roga nivarini* or the “curer of all ailments”.⁹⁰⁸ In English some may refer to it as the wonder tree. It is also referred to as the Indian lilac.⁹⁰⁹ Among the plants which are capable of standing humidity are only a few, ranging from the coconut palm, bamboo to the neem tree. The neem tree has made its home in the more arid parts of the Indian subcontinent and reaches the height of up to 20 meters.⁹¹⁰

Now the question arises on why this tree has been given such a magnificent name. The answer seems very much convincing, the neem tree offers abundance when it comes to the subject matter of biodiversity. The neem tree is the source of much goodness and offers a variety of natural products produced by utilising the plants' seed-oil. Neem seed oil has been used as an organic chemical and finds itself to be put to good use as an agricultural, medicinal, pesticide as well as in the cosmetic sector.⁹¹¹ Juice from neem leaves is used as a cure against skin disorders, parasitic infections, and psoriasis. Equally neem extract has been used as an antidote to malaria, neem oil as a form of a contraceptive⁹¹² if applied intravaginal ahead of the intercourse. Moreover, it has been known to be a spermicide with a 100% effectiveness.⁹¹³ Likewise, neem's leaves, bark, seeds, fruit pulp and flowers are used to treat a wide range of sicknesses and other

⁹⁰⁸ Shiva, Vandana: The neem tree - a case history of biopiracy. Third World Network. 2013. - www.twnside.org.sg/title/pir-ch.htm, DOA: 25.05.2015.

⁹⁰⁹ Ghosh, Shubha: Globalization, Patents, and Traditional Knowledge, in: Columbia Journal of Asian Law (2003), Vol. 17, pp. 73-120, p. 106.

⁹¹⁰ Shiva, Vandana: The neem tree - a case history of biopiracy. Third World Network. 2013. - www.twnside.org.sg/title/pir-ch.htm, DOA: 25.05.2015.

⁹¹¹ Kadidal, Shayana: Subject-Matter Imperialism: Biodiversity, Foreign Prior Art and the Neem Patent Controversy, in: IDEA (1996), Vol. 37, pp. 371-403, pp. 372-373.

⁹¹² Marden, Emily: The Neem Tree Patent: International Conflict Over the Commodification of Life, in: Boston College International and Comparative Law Review (1999), Vol. 22, pp. 279-295, p. 283.

⁹¹³ Song, Olnsoon: Old knowledge into New Patent Law: The Impact of United States Patent Law on Less-Developed Countries, in: Indiana International & Comparative Law Review (2005), Vol. 16, Is. 1, pp. 261-293, p. 271.

physical complications as well as complaints, which typically range from diabetes, leprosy, ulcers, regular constipation to skin disorders.⁹¹⁴

With regard to dental use, it is worth mentioning that the grandfather of the author has been substituting neem twigs for a toothbrush, over the course of years, due to its medicinal nature in the area of oral hygiene and dental care.⁹¹⁵ The neem stick has been used for the aforesaid purpose for centuries.⁹¹⁶ This particular method of tooth cleaning by chewing sticks has been commonly observed on the Indian subcontinent.⁹¹⁷ Neem sticks contain antiseptic ingredients required for dental hygiene.⁹¹⁸ Moreover, neem powder is put to good use in order to brush teeth as well as massage gums. Ayurvedic and other toothpastes used in India tend to contain neem extracts.⁹¹⁹ Research in Germany has shown that neem extracts prevent periodontal disease and tooth decay.⁹²⁰ Furthermore, the following medical conditions have been successful treated with daily use of neem mouth rinse or neem leaf extract added to the water: tooth decay, bleeding, sore gums and infections.⁹²¹

Neem has indeed been known in India for more than 2000 years and has been studied there for years.⁹²² The tree is indeed intertwined with

⁹¹⁴ Shiva, Vandana: The neem tree - a case history of biopiracy. Third World Network. 2013. - www.twnside.org.sg/title/pir-ch.htm, DOA: 25.05.2015.

⁹¹⁵ Ibid.

⁹¹⁶ Ibid.

⁹¹⁷ Bhambal, Ajay/ Jain, Manish/ Kothari, Sonal/ Sudhanshu, Saxena: A Comparative Effect of Neemstick and Tooth Brush on Plaque Removal and Gingival Health: A Clinical Trial, in: Journal of Advanced Oral Research (2011), Vol. 2, Is. 3, pp. 51-56, p.51.

⁹¹⁸ Ibid.

⁹¹⁹ Ibid, p. 51; Miraherba: Ayurvedic herbal-toothpaste with Neem. 2021. -

<https://www.miraherba.de/en/dental-care/1380-dabur-herbal-neem-toothpaste-100g-5022496101325.html>, DOA: 19.01.2021.

⁹²⁰ Neem: A Tree for Solving Global Problems. in: Office of International Affairs. 1992. - <http://darwin.nap.edu/books/0309046866/html>, DOA: 05.12.2005.

⁹²¹ Naveed, Niha/ Murthykumar, Karthikeyan/ Soundarajan, Subasree/ Srinivasan, Sripradha: The Use of Neem in Oral Health, in: Research Journal of Pharmacy and Technology (2014), Vol. 7, Is. 9, pp. 1060-1064. -

<https://riptonline.org/HTMLPaper.aspx?Journal=Research+Journal+of+Pharmacy+and+Technology%3bPID%3d2014-7-9-14>, DOA: 19.01.2021.

⁹²² Shiva, Vandana: The neem tree - a case history of biopiracy. Third World Network. 2013. - www.twnside.org.sg/title/pir-ch.htm, DOA: 25.05.2015.

the fabric of Indian culture, and there is respect for the neem tree that in some parts of the country the tree is revered and considered holy.⁹²³ Yet in other regions of the nation people consume tender shoots of the neem tree in celebration of the New Year.⁹²⁴ Farmers in India had realised long time ago that, while being a powerful insecticide, the plant extract was harmless for human beings.⁹²⁵ Neem oil also finds its use as lamp oil substitute. The fruit pulp is useful in the manufacture of methane.⁹²⁶

Unfortunately, no patents have been issued for neem products to Indian farmer, tribes, neither by governmental institutions nor by Non-Governmental Organisations (NGOs). The reason for this was that back in the early 90s India's patent regime failed to recognise the patentability of pharmaceutical and agricultural products under Indian domestic law.⁹²⁷

While exclusion under Indian patent law was applicable, this was not the case when it comes to the application of patent protection abroad or more precisely overseas. This particular subject matter allows us to contemplate the issuing of a neem patent to W.R. Grace, more accurately a patent which was based on a method to enhance neem oil extract in the United States.⁹²⁸ The creators of this patent state that they have conducted a somewhat unassumingly sounding innovation, which was developed through the extracting of neem oil, an organic pesticide in its own right, from crushed seeds into some form of a chemical solvent contrary to what has been used by the Indian farmers (to which, traditionally, water has been added in order to use it as a

⁹²³ Marden, Emily: The Neem Tree Patent: International Conflict Over the Commodification of Life, in: Boston College International and Comparative Law Review (1999), Vol. 22, pp. 279-295, p. 285.

⁹²⁴ Ibid, p. 283.

⁹²⁵ Shiva, Vandana: The neem tree - a case history of biopiracy. Third World Network. 2013. - www.twnside.org.sg/title/pir-ch.htm, DOA: 25.05.2015.

⁹²⁶ Ibid.

⁹²⁷ Legislative Department: The Patent Act. 1970, Chapter II. -

<http://legislative.gov.in/actsofparliamentfromtheyear/patents-act-1970>, DOA: 14.01.2021.

⁹²⁸ Charles G. Carter et al., storage stable Azadirachtin Formulation, US Pat. No. 5,124,349 (June 23, 1992).

solvent).⁹²⁹ In order to use it as pesticide, the native farmers would break up the seeds and subsequently soak them in water or alcohol and use the remaining solution to sprinkle crops. The only disadvantage of this organic pesticide is that it has a short shelf life.⁹³⁰ Unlike its organic counterpart, the American invention guarantees a shelf life of up to 24 months.⁹³¹

A controversy with regard to the granting of this patent has erupted as many Indians were claiming that such an invention was blatantly obvious and lacks credible novelty when it comes to the subject matter of innovation.⁹³² Grace's patent was successful in obtaining patents from both the European Patent Office and the US Patent and Trademark Office.⁹³³

The United States Patent Office issued a patent to W.R. Grace & Co, for this specific substance, to an agro-chemical multinational with headquarters in Bogo Raton, Florida, United States.⁹³⁴ To be more precise, the patent has been issued due to the following characteristics:

*"for the storage of stable insecticidal composition comprising neem seeds extract [which permits] increasing the shelf-life stability of azadirachtin solution."*⁹³⁵

⁹²⁹ Kadidal, Shayana: Subject-Matter Imperialism: Biodiversity, Foreign Prior Art and the Neem Patent Controversy, in: IDEA (1996), Vol. 37, pp. 371 – 403, p. 374.

⁹³⁰ Marden, Emily: The Neem Tree Patent: International Conflict Over the Commodification of Life, in: Boston College International and Comparative Law Review (1999), Vol. 22, pp. 279-295, p. 283.

⁹³¹ Shiva, Vandana: The neem tree - a case history of biopiracy. Third World Network. 2013. - www.twnside.org.sg/title/pir-ch.htm, DOA: 25.05.2015.

⁹³² Kadidal, Shayana: Subject-Matter Imperialism: Biodiversity, Foreign Prior Art and the Neem Patent Controversy, in: IDEA (1996), Vol. 37, pp. 371 – 403, p. 375.

⁹³³ Global Patent Index - EP 0436257 B1, European Patent Office. -

<https://data.epo.org/gpi/EP0436257B1-Method-for-controlling-fungi-on-plants-by-the-aid-of-a-hydrophobic-extracted-neem-oil>, DOA: 29.01.2020.

⁹³⁴ U.S. Patent No. 5,124,349; Global Patent Index - EP 0436257 B1, European Patent Office. - <https://data.epo.org/gpi/EP0436257B1-Method-for-controlling-fungi-on-plants-by-the-aid-of-a-hydrophobic-extracted-neem-oil>, DOA: 29.01.2020.

⁹³⁵ U.S. Patent No. 5,124,349.

Apart from the above-mentioned patent W. R. Grace has registered yet another patent on neem covering the following physiognomies:

*"for improving the storage of stability of neem seeds extracts containing azadirachtin, a chemical that is an active agent in neem."*⁹³⁶

Apart from the patents issued to Grace, there are over 130 patents that have been granted by the USPTO on both processes and products comprising extracts from the neem tree.⁹³⁷ Moreover, in 1994 the US Environmental Protection Agency registered Neemix, the stabilised azadirachtin solution developed by Grace for use on food crops.⁹³⁸ Consequently, Neemix became the first manufactured product based on the neem tree to, officially, obtain a patent in the United States of America.

The patenting of Neemix *prima facie* appears to be an example of biopiracy due to Grace's exploitation of traditional knowledge of neem being a powerful insecticide. The knowledge regarding the qualities of neem has been known in India for more than thousand years. Grace has also not provided any adequate compensation, nor has it entered into a profit-sharing arrangement with the farming community.

For Indian activists opposing the granting of this patent by American as well as European institutions adds even more insult to injury. The globally renowned activist, Vandana Shiva, is disappointed by Grace's claims over the intellectual property (IP) developed by the Indian indigenous farmers over the course of centuries. In Shiva's eyes, this once again proves the ignorance on the part of the rich Western nations, which take a massive commercial cut, profit-wise, while only

⁹³⁶ U.S. Patent No. 4,946,681.

⁹³⁷ Ghosh, Shubha: Globalization, Patents, and Traditional Knowledge, in: Columbia Journal of Asian Law (2003), Vol. 17, pp. 73-120, p. 106.

⁹³⁸ Marden, Emily: The Neem Tree Patent: International Conflict Over the Commodification of Life, in: Boston College International and Comparative Law Review (1999), Vol. 22, pp. 279-295, p. 284.

handing over peanuts to those who deserve all the credits.⁹³⁹ From her point of view, nothing is new under the sun, and the West is, in this particular case, thieving a centuries old Indian invention and passing it on as their own. One could refer to this phenomenon as colonisation by other means.⁹⁴⁰ For Shiva, the economic inequalities have emerged between the well-to-do industrialised Western nations and the poor developing countries as a direct result of 500 years of colonialism and its ongoing “supply chains” for the extraction of resources and wealth from the developing nations as well as LDC until date.⁹⁴¹ In other words, the Western innovators are committing biopiracy by robbing, in most cases, illiterate tribal Indian population of their century old knowledge about neem and its biological characteristics.⁹⁴² Shiva’s position seems to be in line with the criticism that had been brought forward by the protagonist of legal postcolonialism, Antony Anghie, who criticised the European (Spaniards) for their claim, based on natural law, to trade freely in the territory of the native Indians.⁹⁴³ For the colonisers, commercial exploitation necessitated war and likewise international law was vital for commerce.⁹⁴⁴ This way exploitation-based history and colonisation by other means repeats itself in which the rich are getting richer and the poor are getting poorer. To quote T.S. Eliot:

*“If you haven’t the strength to impose your own terms upon life, then you must accept the terms it offers you.”*⁹⁴⁵

⁹³⁹ Kadidal, Shayana: Subject-Matter Imperialism: Biodiversity, Foreign Prior Art and the Neem Patent Controversy, in: IDEA (1996), Vol. 37, pp. 371-403, p. 375.

⁹⁴⁰ Jacoby, Craig D./ Weiss, Charles: Recognizing Property Rights in Traditional Biocultural Contribution, in: Stanford Environmental Law Journal (1997), Vol.16, Is. 1, pp. 74-124, pp. 89-91.

⁹⁴¹ Marden, Emily: The Neem Tree Patent: International Conflict Over the Commodification of Life, in: Boston College International and Comparative Law Review (1999), Vol. 22, p. 287.

⁹⁴² Ibid.

⁹⁴³ Anghie, Antony: The Evolution of International Law: Colonial and Postcolonial Realities, in: Third World Quarterly (2006), Vol. 27, Is. 5, pp. 739-753, p. 743.

⁹⁴⁴ Ibid, p. 744.

⁹⁴⁵ BBC America: Anglophenia: Happy Birthday, T. S. Eliot: 20 of His Most Life-Affirming Quotes. 2015. - <https://www.bbcamerica.com/anglophenia/2014/09/happy-birthday-t-s-eliot-20-quotes>, DOA: 16.01.2021.

Consequently, the indigenous farming population needs to live with the terms offered by the American multinational if they cannot challenge the patent in their favour. One could compare the recurrence of this process to a notion in Hinduism which is referred to as *samsara* (cycle of reincarnation) for which no *nirvana* (release from the cycle of rebirth) is envisaged. According to Ms Shiva, the US has merely come along to fill in the gap that has been left by the retreat of the British Empire, once again keen and willing to exploit yet another Indian natural recourse, this time opting for neem.⁹⁴⁶ Emily Marden seems to be convinced that opposing the use of biological resources poses a genuine threat for the advancement of the biotechnology industrial sector.⁹⁴⁷ Article 15 of the Convention on Biological Diversity (CBD) seems to follow this line of argument by only recognising the rather limited nature of sovereignty with regard to property rights when it comes to genetic materials and resources found within the domestic border.

Yet another critique of granting a patent for a neem by-product to Grace has been former Indian MP George Fernandes who compared patenting neem to doing the same to cow dung.⁹⁴⁸ Little did he know that his claim, whilst being somewhat imaginative, has somewhat been close to reality, as has been shown above, regarding patenting distilled cow urine.⁹⁴⁹ Inventors have come a long way when it comes to granting patent processes and products based on biodiversity, starting from by-products and ending with waste products. Others are objecting to patenting neem on purely ethical grounds, given the fact the neem tree has been worshipped and revered for its holy character.⁹⁵⁰ This would result in commercialising something that is quintessential to Indian identity. The increase in price for neem seeds

⁹⁴⁶ Marden, Emily: The Neem Tree Patent: International Conflict Over the Commodification of Life, in: Boston College International and Comparative Law Review (1999), Vol. 22, p. 280.

⁹⁴⁷ Ibid, p. 281.

⁹⁴⁸ Ibid, p. 293.

⁹⁴⁹ See Chapter on "Holy Cow".

⁹⁵⁰ Shiva, Vandana: The neem tree - a case history of biopiracy. Third World Network. 2013. - www.twnside.org.sg/title/pir-ch.htm, DOA: 25.05.2015.

as a result of increased demand in neem products meant that, in many cases, a free resource has been turned in a costly raw material. Now the local consumers are forced to compete for the neem seed with multinationals producing for the agricultural sectors in the West.⁹⁵¹ The local farmer cannot afford the price of the seeds which the industry is capable of paying; this situation depicts the danger which many from the indigenous farming community are deeply worried about.

One might argue that something which is obvious to India may not necessarily as obvious to those sitting in in the US Patent Office. As per U.S. law, both the modification and purification of an organic substance may have the effect of obtaining a patent with legal ownership to the purified solution.⁹⁵² Consequently, Grace's patent, *prima facie*, seems to satisfy the relevant legal criteria as per the U.S. Patent Act. It seems to fulfil the following requirements applicable as the 1994 version of 35 U.S Code sections 101,102 and 103. The requirements are as following:

- (1) *has some practical use;*
- (2) *is novel in relation to the “prior art”*
- (3) *Is not obvious from the “prior art” to a person of ordinary skill on the art at the time the invention was made and;*
- (4) *Provides a description that is adequate to enable a knowledgeable person to practice the invention in the best mode.*⁹⁵³

Unfortunately, the obvious nature of the patent as claimed above by Fernandes does, not defeat the patentability in the United States.⁹⁵⁴

⁹⁵¹ Ibid.

⁹⁵² Marden, Emily: The Neem Tree Patent: International Conflict Over the Commodification of Life, in: Boston College International and Comparative Law Review (1999), Vol. 22, pp. 279-295, p. 281.

⁹⁵³ U.S. Patent Act of July 4, 1836, ch. 357, § 12, 5 Stat. 117, §§ 101-103.

⁹⁵⁴ Marden, Emily: The Neem Tree Patent: International Conflict Over the Commodification of Life, in: Boston College International and Comparative Law Review (1999), Vol. 22, pp. 279-295, p. 284.

On another note, Section 102 of the U.S. Patent Act is rather cautious when it comes to the legal notion of foreign prior art.⁹⁵⁵ Foreign prior art in this context merely means that there is evidence that a particular invention, which has been set out for patent registration is already known abroad.⁹⁵⁶ Section 102 (a) and (b) of the 1994 version of 35 U.S.C addresses the issue of invoking foreign patents and its applicability in the following manner:

“(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, or[...].”⁹⁵⁷

Unlike the EU patent code, as mentioned above, its US counterpart did, at least in its 1994 version, not provide for a definition of the term “prior art”. As listed above, Section 102 discusses prior foreign activity only in anticipating an American patent when the aforesaid activity is tangible. Moreover, it must be accessible in the form of a description of the invention in a printed publication or in a document related to either the applicant’s own foreign patent or another person’s foreign patent. Yet a potential option to challenge Grace’s patent would be to search for printed articles on the use of neem in scientific journals, we shall see below whether this is a viable alternative. In other words, the only other viable option would be to introduce Indian prior knowledge, use

⁹⁵⁵ United States Code [USC02] 35 USC §102: Conditions for Patentability: Novelty. 2021. - <https://uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title35-section102&num=0&edition=prelim>, DOA: 01.01.2021.

⁹⁵⁶ European Patent Office: What is Prior Art? 2015. - <https://www.epo.org/learning/materials/inventors-handbook/novelty/prior-art.html>, DOA: 01.01.2021.

⁹⁵⁷ U.S. Patent Act of July 4, 1836, ch. 357, § 12, 5 Stat. 117.; Kadidal, Shayana: Subject-Matter Imperialism: Biodiversity, Foreign Prior Art and the Neem Patent Controversy, in: IDEA (1996), Vol. 37, pp. 371-403, p. 379.

or invention whilst disputing Grace's claim and filing an opposing petition with the court against Grace's patent. In order to succeed, evidence would need to be shown that a party in India had a printed and broadly circulated depiction of the invention.⁹⁵⁸ For Kadidal, biodiversity rarely leaves traces in the form of patentable records behind. He suggests that the reason for this is that most of biodiversity occurs in countries in which the organic products and their advancement are not subject to patentability. In many cases it was the tribal and farming communities which often were losing out in the patent race that these agro-products are part of *opus dei*. The relevant rules and regulations of the Indian Union on its own constitutes a position based on opacity for the previously mentioned community, this circumstance together with underdevelopment creates a considerable hurdle to gain a patent in India let alone overseas.

At this point, it would be advisable to make a brief historical excursion into foreign activity exclusion with the aim of seeing how this legal norm has developed over the past centuries. To begin with, both Patent Acts of 1790 as well as 1793 prohibited patents on inventions that have been known or are being used in the public domain.⁹⁵⁹ No geographic restrictions were foreseen in the 1790 Act. This act was amended in 1793 and limited the patent application to US citizens only.⁹⁶⁰ The nationality-based approach when it comes to patent applications was abolished in the next amendment of the Patent Act in 1836.⁹⁶¹ Yet another requirement was that the applicant must be in the position to believe herself or himself to be the first inventor, and not simply an importer.⁹⁶² The previously mentioned omission from prior art of foreign knowledge, invention or use by other made it until date.

⁹⁵⁸ Kadidal, Shayana: Subject-Matter Imperialism: Biodiversity, Foreign Prior Art and the Neem Patent Controversy, in: IDEA (1996), Vol. 37, pp. 371-403, p. 393.

⁹⁵⁹ U.S. Patent Act of 1790, Ch. 7, 1 Stat. 109-112 (April 10, 1790).; Patent Act of 1793, Ch. 11, 1 Stat. 318-323 (February 21, 1793).

⁹⁶⁰ Patent Act of 1793, Ch. 11, 1 Stat. 318-323 (February 21, 1793).

⁹⁶¹ U.S. Patent Act of July 4, 1836, ch. 357, § 12, 5 Stat. 117.

⁹⁶² Ibid, § 121-122.

It is, however, interesting that the Patent Act of 1836 distinguished between what can be regarded as discovery and between mere importation.⁹⁶³ The mere import of an existing invention from abroad is not patent-worthy as per the old law. *Prima facie* back then existed the rather convincing rational that solely independent discoveries and inventions fulfil the required eligibility of being considered patent worthy. Shayana Kadidal seems to detect the notion that the drafter of the 1836 Act has been driven by the ideal that patent protection ought to be earmarked as a form of reward for creative geniuses.⁹⁶⁴ *Prima facie* the drafters of the 1836 Act seem to believe the mere importing or copying would not be fit for purpose, as novelty and originality remains the cornerstone of industrial accomplishments.⁹⁶⁵

While nearly every national has prior knowledge but use of invention is considered against a later US patent; the situation is rather different when it comes to the same activities that have been undertaken abroad. This circumstance displays the rather unfortunate technical issue with foreign patents somewhat nicely. Professor Margo Bagley of Emory University School of Law in the United States does not share this position, he views this geographic limitation as unconstitutional and, simply put, as a matter of bad policy. He advocates permitting foreign knowledge and its use as prior art to protect the developing nations as well as indigenous peoples from the Western nation's patent rights.⁹⁶⁶ He also deems that indigenous people deserve to be adequately compensated by Western companies for the commercial exploitation of their traditional knowledge.⁹⁶⁷

The US patent owned by WR Grace did not initially have national implications regarding the applicability of the same patent in India. At

⁹⁶³ Cuno Eng'g Corp. v. Automatic Devices Corp., 314 U.S. 84, 91 (1941).

⁹⁶⁴ Kadidal, Shayana: Subject-Matter Imperialism: Biodiversity, Foreign Prior Art and the Neem Patent Controversy, in: IDEA (1996), Vol. 37, pp. 371 – 403, p. 394.

⁹⁶⁵ Cuno Eng'g Corp. v. Automatic Devices Corp., 314 U.S. 84, 91 (1941).

⁹⁶⁶ Nard, Craig Allen: In Defence of Geographic Disparity. in: Faculty Publications 278. (2003). - https://scholarlycommons.law.case.edu/faculty_publications/278, DOA: 10.01.2015.

⁹⁶⁷ Ibid.

the initial stage of the patent application in the USA, Indian legislation did not facilitate the patentability of biodiversity, organic and its by-products.⁹⁶⁸ The reason for this might be based on the fact that, traditionally, Hinduism promotes the respect for any form of life on mother earth. Hence, the traditional point of view would be contrary to patenting and commercially exploiting biodiversity. The American school of thought, with regard to its willingness to patent “living beings” and their extracts, happen to be rooted in the Unitarian notion that all forms of innovations ought to be both promoted and protected.⁹⁶⁹

Prima facie from the American legislator’s point of view, a continued stream of innovations means progress, which leads to wealth accumulation through royalties acquired by owning the relevant patent. Thus, the U.S. American patent system endorses the concept of reaping the fruits of an individual’s efforts and to promote scientific progress to justify the patent protection of living organisms.⁹⁷⁰ To apply this concept to the current Covid-19 pandemic, the research and development department of BioNTech & Pfizer, in line with the American school of thought, deserve to profit from the royalties for patenting their vaccination against Covid-19. BioNTech & Pfizer should profit from the financial gain for investing millions of U.S. dollars into their research and development department to develop the relevant vaccination. The promoters of this approach believe that the winner, in our case the creator, should enjoy absolute ownership over his property, subject to her willingness to grant a licence to a third party to use the patent against adequate pecuniary compensation. Therefore, patent protection fuels innovation; without such a right of ownership an adequate incentive for generating innovations would not exist.⁹⁷¹ Moreover, if competing companies would be allowed to use the inventions, free of charge, from one another there would be no

⁹⁶⁸ Marden, Emily: The Neem Tree Patent: International Conflict Over the Commodification of Life, in: Boston College International and Comparative Law Review (1999), Vol. 22, pp. 279-295, p. 285.

⁹⁶⁹ Ibid, p. 290.

⁹⁷⁰ Ibid, p. 291.

⁹⁷¹ Ibid.

incentive to invest huge sums of money, time and energy in order to develop new products.⁹⁷² The Unitarian perspective would argue that everybody profits from Grace's patent, even the Indian farmers, as they have the possibility by using the need-based solution to free up time and labour in order to pursue other endeavours.⁹⁷³ This argument seems hardly convincing if one was to consider it from the point of view of the indigenous agricultural communities of India. While machinery and production methods are worthwhile when it comes to patent protection, the same does not necessarily apply for living plants. For Shiva, the origins of this argument lay in the fact that it is essential to keep the living organisms free from technological manipulatory efforts. The reason for this appears to be simple, as technological manipulation or, if one were to take the contemporary debate on bioengineered crops and corn, have a rather unsounding effect on both the self-organisational and self-healing characteristics of neem and other plants.⁹⁷⁴ In fact, the crucial challenge to intellectual property protection is deeply rooted in Indian tradition. Traditional Indian values incorporate cultural and religious aspects and infuse flora and fauna with symbolic meanings. For example, in Hinduism, a multitude of plants, animals, lakes, rivers and hills are considered to be sacrosanct representations of God.⁹⁷⁵ Commodifying the various representations of the Almighty goes against the very notion of Indian traditional values. Patenting life would indeed undermine the moral and cultural fabric of the Indian Union, as ownership of living beings is profoundly immoral and constitutes a serious challenge to Indian values. Thus, the neem tree has both cultural and religious significance for the Indian nation. Indian communities have devoted centuries to cultivate and to gain knowledge of the plant.⁹⁷⁶

⁹⁷² Ibid.

⁹⁷³ Ibid.

⁹⁷⁴ Shiva, Vandana: *Biopiracy: The Plunder of Nature and Knowledge*. Boston: South End Press, 1997, pp. 32-39.

⁹⁷⁵ Marden, Emily: *The Neem Tree Patent: International Conflict Over the Commodification of Life*, in: *Boston College International and Comparative Law Review* (1999), Vol. 22, pp. 279-295, p. 293.

⁹⁷⁶ Ibid.

This situation changed when India became party to the TRIPS convention in 2005. In anticipation of this advent of India's membership of the TRIPS Grace summarily declared that they were not going to apply for the same patent protection in India. They blamed the slow operation of the patent process as the reason for this decision.⁹⁷⁷ Moreover, WR Grace was only purchasing 3 percent of all the neem seeds harvested on the subcontinent and thereby leaving the remainder to be utilised by both the domestic population as well as the relevant industry.⁹⁷⁸ It remained unclear for the course of multiple years whether the neem patent obtained by Grace would have any detrimental socio-economic effects for the Indian agricultural sector as a whole, and for the indigenous population in particular.⁹⁷⁹ On the contrary, from Grace's point of view, the patent is actually beneficial for Indian farmers. The multinational was also convinced that its patent brought considerable benefits to the Indian economy in general, and for the Indian farmers in particular, when considering the rise in remuneration due to the steady increase in price for neem seeds.⁹⁸⁰ In addition, W. R. Grace has also pointed out the increase in available job opportunities at regional and local levels for the agricultural communities, which once again showcase the economic significant of the patent not only for Grace but also for the indigenous agricultural communities of Hindustan.⁹⁸¹ For them it is indeed a double whammy or a Win-Win situation. Apart from using the needed seed for their personal use, all Indian farmers now have the opportunity to sell their harvested surplus to Grace and thereby gain additional income.⁹⁸²

⁹⁷⁷ Ibid, p. 285.

⁹⁷⁸ Kadidal, Shayana: Subject-Matter Imperialism: Biodiversity, Foreign Prior Art and the Neem Patent Controversy, in: IDEA (1996), Vol. 37, pp. 371-403, p. 376.

⁹⁷⁹ Marden, Emily: The Neem Tree Patent: International Conflict Over the Commodification of Life, in: Boston College International and Comparative Law Review (1999), Vol. 22, pp. 279-295, p. 285.

⁹⁸⁰ Shiva, Vandana: The neem tree - a case history of biopiracy. Third World Network. 2013. - www.twnside.org.sg/title/pir-ch.htm, DOA: 25.05.2015.

⁹⁸¹ Marden, Emily: The Neem Tree Patent: International Conflict Over the Commodification of Life, in: Boston College International and Comparative Law Review (1999), Vol. 22, pp. 279-295, p. 285.

⁹⁸² Ibid.

Moreover, the price of neem seeds have gone up, thereby guaranteeing higher remunerations for the local agricultural communities.⁹⁸³ Thus, neem, from Grace's perspective, has the potential of becoming Hindustan's cash crop; it has also provided significant employment opportunities for the local Indian population.⁹⁸⁴

Yet, the fear remains that Grace's share in the harvest might rise considerably to meet demands from the global farming community. In doing so, Grace could potentially create a monopsony⁹⁸⁵ in the organic raw material market, given its position, when it comes to controlling the biggest market for the final neem by-product.⁹⁸⁶

At the same time, the US patent might in future deny, native Indian companies, access to the American market. Indian producers of the same neem by-product would need to pay a considerable sum to Grace in exchange for licences to be able to sell their agro-product to potential US customers. In sum, the consequence would be the accumulation of a massive market share of the US agro-market for neem by-products and thus establishing a *de facto* monopoly for the American patent holder. Thereby making Grace, above all, judge, jury, and executioner, in a market unquestionably large in size, and very profitable in commercial terms, due to its multitude of beneficial factors.⁹⁸⁷ Thus, the neem-based pesticide's beneficial qualities are the following: it is organic, biodegradable, and sustainable.⁹⁸⁸

The unequal distribution of the pecuniary resources in Grace's favour turned out to be rather disconcerting for the India farming community. Neem is not the only subject matter of contention another plant known

⁹⁸³ Shiva, Vandana: The neem tree - a case history of biopiracy. Third World Network. 2013. - www.twnside.org.sg/title/pir-ch.htm, DOA: 25.05.2015.

⁹⁸⁴ Ibid.

⁹⁸⁵ A commercial position in which there is a single buyer, namely Grace.

⁹⁸⁶ Kadidal, Shayana: Subject-Matter Imperialism: Biodiversity, Foreign Prior Art and the Neem Patent Controversy, in: IDEA (1996), Vol. 37, pp. 371-403, p. 378.

⁹⁸⁷ Ibid, p. 377.

⁹⁸⁸ Ibid, p. 378.

by its Latin name *Rauwolfia serpentina*, Indian snakeroot or devil pepper, which has been used as the basic ingredient for a medicine against hypertension, and which in turn generated the sum total of \$260 million. In all these cases, the indigenous and domestic farmers do not see a single penny or rupee.⁹⁸⁹ For what it is worth, the former President of Tanzania, Ali Hassan Mwinyi, was talking about the asymmetry of inequality of opportunity when it comes to the free flow of biodiversity. According to President Mwinyi, on the one hand, developing countries are expected to almost guarantee free access to biodiversity to industrialist nations (the West). On the other hand, the same industrial nations go on to patent those goods produced utilising those organic resources, which they regard as private property of their multinationals. A considerable number of the developing world seems to struggle to purchase these agricultural products although the organic raw materials and knowledge and the processing technics used were taken from these developing countries.⁹⁹⁰ The Indian farmers are losing out on the sum total of \$5,4 billion p.a. on royalties which would have been owed to them for exploitation of the agricultural products by the West.⁹⁹¹ Yet, the neem patent has raised the question whether living beings ought to be patentable. The U.S. position on this matter appears to be following a rather Unitarian concept, while promoting a stable stream of innovation. In other words, the American position seems believe that the fruits of one's labour supersedes the patent protection over living organisms.⁹⁹² If one was to employ a reasoning for the validation of a patent, based on constitutional grounds, aiming to promote scientific progress as well as the use of art.

⁹⁸⁹ Marden, Emily: The Neem Tree Patent: International Conflict Over the Commodification of Life, in: Boston College International and Comparative Law Review (1999), Vol. 22, pp. 279-295, p. 287.

⁹⁹⁰ Ibid, p. 288.

⁹⁹¹ Ibid, p. 287.

⁹⁹² Ibid, pp. 290-291.

Having discussed the rather dissatisfactory and unfair outcome for the indigenous farming community on the subcontinent due to W.R. Grace's acquisition of the patent on the neem extract, in 1995, a "coalition of the willing" consisting of 225 agricultural, trade and scientific groups and over 100,000 Indian farmers, under the leadership of the NGO the Foundation on Economic Trends petitioned the U.S. Patent and Trademark office. The petition asks for the revocation of the neem patent on the following two grounds:

- a) *Immorality*; and
- b) *lack of novelty*.⁹⁹³

The Indian "coalition of the willing" was eager to go the extra mile in their fight against biopiracy, as the British-American poet and play writer T.S. Eliot's famously wrote:

*"Only those who will risk going too far can possibly find out how far one can go."*⁹⁹⁴

Thus, the coalition pledged to transform the patent matter into a full-fledged international dispute (in the area of intellectual property). They have absolutely been convinced that the Western world was guilty as charged, and the charge being IP theft and biopiracy.⁹⁹⁵ While the coalition was not successful when it came to their demands, it had, however, opened the eyes of the Indian government to the injustice.

Due to the drastic injustice and W.R. Grace's international reputation and prominence in the context of the chemical and pharmaceutical industry, the Indian government went on to file an objection against W. R. Grace with the U. S. patent office blaming the same for copying an

⁹⁹³ Ibid, p. 289.

⁹⁹⁴ Goodreads: T.S. Eliot Quotes. -

https://www.goodreads.com/author/quotes/18540.T_S_Eliot, DOA: 15.02.2021.

⁹⁹⁵ Marden, Emily: The Neem Tree Patent: International Conflict Over the Commodification of Life, in: Boston College International and Comparative Law Review (1999), Vol. 22, pp. 279-295, p. 286.

invention belonging to the Indian Union. The Indian Union withdrew after finding out that Grace had invented a novel process which was not grounded on Hindustani traditional knowledge.⁹⁹⁶

Against these odds, yet another challenge against the neem patent was brought forward at the European Patent Office's head office in Munich. The patent was challenged by the groups of the following three entities: the International Federation of Organic Agriculture, the European Parliament's Green Party, and Dr. Vandana Shiva of the Research Foundation for Science, Technology and Ecology (RFSTE) of India. They went on to request the patent revocation due to the following grounds:

- a) *Lack of novelty*; and
- b) *Lack of an inventive step*.⁹⁹⁷

The group *inter alia* also demanded the annulment of the patent as, in their opinion, the fungicide qualities of neem and its use have been known on the subcontinent for more than 2000 years.⁹⁹⁸ Unlike its American counterpart the European Patent Office turned out to be less receptive to the Grace's argument. After the course of two consecutive days of hearings before the Opposition Board of the European Patent Office and after five years since commencement of the legal dispute, the Board withdrew, on 11 May 2000, the patent granted to W. R. Grace by the European Patent Office and the U. S. Department of Agriculture for a process to extract oil from the neem tree.⁹⁹⁹ The Board found in favour of the claimants ruling that the patent, at hand,

⁹⁹⁶ Ghosh, Shubha: Globalization, Patents, and Traditional Knowledge, in: Columbia Journal of Asian Law (2003), Vol. 17, pp. 73-120, p. 106.

⁹⁹⁷ Shiva, Vandana: Biopiracy from Neem to Rice to Atta, Gates and Monsanto Influence IPR Policy. 2016. - <https://www.thecitizen.in/index.php/en/NewsDetail/index/1/7840/Biopiracy-From-Neem-to-Rice-to-Atta-Gates-and-Monsanto-Influence-IPR-Policy>, DOI: 20.01.2018.

⁹⁹⁸ Ibid.

⁹⁹⁹ Global Patent Index - EP 0436257 B1, European Patent Office. - <https://data.epo.org/gpi/EP0436257B1-Method-for-controlling-fungi-on-plants-by-the-aid-of-a-hydrophobic-extracted-neem-oil>, DOI: 29.01.2020.

did indeed lack novelty.¹⁰⁰⁰ Based on these judgements, *pirma facie*, it appears that there seems to be differential treatment when it comes to the requirement for novelty at the international level. If the reasoning that was exploited by EU Patent Office regarding novelty would have been applied by its U.S. counterparts, then Grace would have had its licence revoked.¹⁰⁰¹ Interestingly, the EU patent had been an incremental improvement in comparison to the U.S. patent and, at the same time, it provided a protection for an application of the processes that had already been patented in America.¹⁰⁰² The patents obtained in the U.S. to the one acquired in the EU epitomises the development sequence of the invented product, starting from the process to the application phase. *Prima facie*, it seems safe to argue that it is comparatively easy to obtain such a patent in the United States of America than in pretty much in any other part of the world. It seems that India has learned its lesson from the above-mentioned ordeal and finally the chicken has come to roost. In line with James Russell Lowell's motto:

*"the foolish and the dead alone never change their opinions."*¹⁰⁰³

The government in New Delhi, neither being foolish nor diseased or ineffective, went on to consider potential amendments to the Indian Patent Act in 1999, with the aim to expressly grant patent protection to indigenous people.¹⁰⁰⁴ The proposed amendment would protect multitudes of plant varieties to any given individual and communities of persons or any governmental or non-governmental organisations acting on behalf of local groups or a particular village.¹⁰⁰⁵

¹⁰⁰⁰ Ghosh, Shubha: Globalization, Patents, and Traditional Knowledge, in: Columbia Journal of Asian Law (2003), Vol. 17, pp. 73-120, p. 107.

¹⁰⁰¹ Ibid.

¹⁰⁰² Ibid.

¹⁰⁰³ Russell, Lowell James: Brainy Quote. -

https://www.brainyquote.com/quotes/james_russell_lowell_122661, DOA: 02.01.2021.

¹⁰⁰⁴ Ghosh, Shubha: Globalization, Patents, and Traditional Knowledge, in: Columbia Journal of Asian Law (2003), Vol. 17, pp. 73-120, p. 107.

¹⁰⁰⁵ Ibid.

Prima facie the neem dispute has exposed both fear and anger against the multinationals from the West transforming, and in the worst-case scenario, taking over Hindustan, thereby seriously challenging the Indian way of life. Arguably this is yet again an extension of Huntington's "West v Rest" stretching all the way to IP. Huntington's observation of the Muslim world displayed the fact that the Muslim world is reverting to their own values. Interestingly, Indian activists, and VIP's (Bollywood actors, sport personalities etc.) are all promoting organic farming, traditional food, crafts, clothing etc. The same applies for the Western educated Indian middle class; they either have enjoyed a Western style education at a reputable Indian university or have completed the university education in the West and are turning their hearts and minds back to the indigenous Indian culture. 'Made in India' has seen a considerable boost in contemporary Indian history. Arguably, this trend is directed again at both the West and the Republic of China.

Exhibit B. Turmeric

Turmeric is a plant, which is native to India, Pakistan, and Sri Lanka. The pecuniary worth of the plant is rooted in the rhizome (roots) of the plant, out of which a yellow-coloured substance in the form of a powder is extracted by means of a complicated boiling process. The root's powder itself is used to colour cotton, confectionaries, calico (cotton cloth) and leather goods.¹⁰⁰⁶ Sanjay Kumar, in *The Lancet*, referred to turmeric as grandma's remedies.¹⁰⁰⁷ As early as in 1995 Drs. Hari Har Cohly and Suman Das, both Indian-American scientists from the University of Mississippi, were granted a patent by the United States Patent and Trademark Office (USPTO) for "the use of turmeric in wound healing".¹⁰⁰⁸ The aforesaid patent was granted for the following attributes:

- "1. A method of promoting healing of a wound in a patient, which consists essentially of administering a wound-healing agent consisting of an effective amount of turmeric powder to said patient.*
- 2. The method according to claim 1, wherein said turmeric is orally administered to said patient.*
- 3. The method according to claim 1, wherein said turmeric is topically administered to said patient.*
- 4. The method according to claim 1, wherein said turmeric is both orally and topically administered to said patient.*
- 5. The method according to claim 1, wherein said wound is a surgical wound.*
- 6. The method according to claim 1, wherein said wound is a body ulcer."*¹⁰⁰⁹

¹⁰⁰⁶ Ghosh, Shubha: Globalization, Patents, and Traditional Knowledge, in: Columbia Journal of Asian Law (2003), Vol. 17, pp. 73-120, p. 93.

¹⁰⁰⁷ Kumar, Sanjay: India Wins Battle with USA over Turmeric Patent, in: *The Lancet* (1997), Vol. 350, Is. 9079, p. 724.

¹⁰⁰⁸ U.S. Patent No. 5,401,504; Justia Patents, Use of turmeric in wound healing, Dec 28, 1993. - <https://patents.justia.com/patent/5401504>, DOA: 21.01.2020.

¹⁰⁰⁹ USPTO patent full-text and image database, United States Patent No. 5,401,504., Use of turmeric in wound healing. - <http://patft.uspto.gov/netacgi/nph->

Cohly and Das, the respective patent inventors depicted turmeric as a yellow-coloured powdery substance extracted from the plant *Curcuma Longa*.¹⁰¹⁰ Turmeric, so the investors claim, is routinely used to colour and to flavour dishes natives to the Indian cuisine. In fact, turmeric imparts a bitter taste and is also used in prepared mustard.¹⁰¹¹ Despite being a dietary agent it has been known to be used in Indian traditional medicine as an anti-inflammatory drug and to treat multiple sprains.¹⁰¹² Both scientists describe the active agent in turmeric, together with their experimental approach when establishing the healing capacities turmeric when treating ulcers and wounds through oral and topical applications. Every patent application must be accompanied by a statement of prior art in which the applicants discuss the relevant prior attempts to test the healing character of turmeric and on how to separate the active agent.¹⁰¹³ A statement of prior art is a written statement made by the person during a patent application, listing the scope of the relevant claims.

However, on 1998, the India Council of Scientific and Industrial Research challenged the patent which lead the United States Patent and Trademark Office (USPTO) to cancel all the above mentioned six claims in the patent on the wound healing qualities of the turmeric powder.¹⁰¹⁴ The Council of Scientific and Industrial Research contested the validity of the patent due to the lack of novelty, citing the prior art in the traditional knowledge of India. Evidence of traditional knowledge, including ancient Sanskrit texts and a paper published in 1953 in the Journal of the Indian Medical Association was submitted to

[Parser?Sect1=PTO2&Sect2=HIOFF&p=1&u=%2Fnetahmtl%2FPTO%2Fsearch-bool.html&r=1&f=G&l=50&co1=AND&d=PTXT&s1=5,401,504.PN.&OS=PN/5,401,504&RS=PN/5,401,504](http://www.uspto.gov/patent/parse?Sect1=PTO2&Sect2=HIOFF&p=1&u=%2Fnetahmtl%2FPTO%2Fsearch-bool.html&r=1&f=G&l=50&co1=AND&d=PTXT&s1=5,401,504.PN.&OS=PN/5,401,504&RS=PN/5,401,504), DOA: 03.12.2020.

¹⁰¹⁰ Ibid.

¹⁰¹¹ Ibid.

¹⁰¹² Ibid.

¹⁰¹³ Ibid.

¹⁰¹⁴ Ghosh, Shubha: Globalization, Patents, and Traditional Knowledge, in: Columbia Journal of Asian Law (2003), Vol. 17, pp. 73-120, p. 94.

establish that the findings of the innovators have been known in India for centuries.¹⁰¹⁵

Whilst the Patent Office was willing to cancel the patent, however, it did not issue a written opinion.¹⁰¹⁶ The turmeric case once again proves that unjustified patents can indeed be challenged based on traditional knowledge. This case also highlights the difficulty in verifying whether a specific patent that existed and constituted common knowledge in one country (India) could be checked in the United States.¹⁰¹⁷

In any case the, the US decision caused a great sense of excitement amongst the grass root activists. Vandana Shiva saw, in the annulment of the patent, a victory for the fight against biopiracy. In other terms the robbery of local traditional knowledge and biology in general by multinationals in the western world.¹⁰¹⁸ Dr. Shiva believes that The USPTO's interpretation of prior art has led to the transformation of all living resources and life under the cartel of the multinational corporations.¹⁰¹⁹ She is also convinced that global recognition of patents without attaching the same recognition for prior art would be disastrous and amount to a recipe for biopiracy.¹⁰²⁰ While the TRIPS Agreement went on to impose multiple Western concepts, due to the fact that they existed on the relevant lead countries to this agreement, it did somewhat expand the parameters with regard to the definition of prior art. Thus, the turmeric case displays the fact that an invention in state A cannot disregard the prior existence of the same invention in state B. TRIPS thereby permits the use of traditional knowledge and history as a means to fight their expropriations

¹⁰¹⁵ Bala, Anu: Traditional Knowledge and Intellectual Property Rights: An Indian Perspective. 2011. - <http://dx.doi.org/10.2139/ssrn.1954924>, DOA: 10.10.2016.

¹⁰¹⁶ USPTO Reexam. No. 90/004,433, Oct. 28, 1996.

¹⁰¹⁷ Ghosh, Shubha: Globalization, Patents, and Traditional Knowledge, in: Columbia Journal of Asian Law (2003), Vol. 17, pp. 73-120, p. 95.

¹⁰¹⁸ Shiva, Vandana: Free Tree, in: The Hindustan Times. 2000. -

<http://www.hindustantimes.com/nonfram/080600/detOPI10.htm>, DOA: 19.05.2017.

¹⁰¹⁹ Ibid.

¹⁰²⁰ Ibid.

efforts.¹⁰²¹ The turmeric patent seems to have been a product of biopiracy, as traditional knowledge from India about Turmeric was taken and patented without the provision of any form of compensation.

Moreover, while the battle has been won but the war is not over, as there are multiple turmeric-based patents in existence in the United States,¹⁰²² which cover a host of illnesses, starting from turmeric treatments against skin disorders, as well as turmeric used as an anti-irritant just to name two.¹⁰²³ Moreover, as recent as in 2018 Arjuna Natural was granted a second European patent for the BCM-95 turmeric extract by the EPO (EP2755987 B1).¹⁰²⁴

For Shiva, these patents would lack novelty and are subject to prior art restriction, as these entire patents involve traditional knowledge from India. In any case, the patent cancellation does indeed provide hope for future challenges of multiple turmeric patents and proves that a well-argued and well-supported case, based on techno-legal grounds can indeed lead to the aspired success.¹⁰²⁵

¹⁰²¹ Ghosh, Shubha: Globalization, Patents, and Traditional Knowledge, in: Columbia Journal of Asian Law (2003), Vol. 17, pp. 73-120, p. 96.

¹⁰²² Ibid.

¹⁰²³ Ibid.

¹⁰²⁴ Chu, Will: Arjuna Natural granted second European patent for turmeric extract. Natura. 2018. - [https://www.nutraingredients.com/Article/2018/05/11/Arjuna-Natural-granted-second-European-patent-for-turmeric-extract#:~:text=The%20European%20Patent%20Office%20\(EPO,rheumatoid%20arthritis%20and%20Alzheimer's%20disease](https://www.nutraingredients.com/Article/2018/05/11/Arjuna-Natural-granted-second-European-patent-for-turmeric-extract#:~:text=The%20European%20Patent%20Office%20(EPO,rheumatoid%20arthritis%20and%20Alzheimer's%20disease), DOA. 19.08.2019.

¹⁰²⁵ Kumar, Sanjay: India Wins Battle with USA over Turmeric Patent, in: The Lancet (1997), Vol. 350, Is. 9079, p. 724.

Exhibit C. Basmati

According to the Oxford Learner's Dictionaries, basmati is defined as "*a type of rice with long grains and a pleasant taste*".¹⁰²⁶ The name 'basmati' itself derives from the Hindi name sugandhit, which may be translated as 'fragrant'.¹⁰²⁷ This meaning seems to be rather apt, as the rice is known for its nut-like aromatic smell. Basmati is traditionally native to India, as well as Pakistan, and to a lesser extend to Thailand. Basmati refers to a specific class of rice of which there are around 400 different species in existence in Pakistan and India. As early as in 1997 Rice Tec, a Texas-based company acquired a patent in the method of breeding a long grain fragrant rice, and a novel method of preparing as well as cooking the rice.¹⁰²⁸ The patent issued contained 20 claims.¹⁰²⁹ Given, the limited scope of this chapter, it will not be possible to consider all of the claims individually and in detail, this section shall therefore consider those that protrude out of those claims.¹⁰³⁰ One such claim *inter alia* states the following:

"A rice plant, which plant when cultivated in North, Central or South America, or Caribbean Island has a mature height of about 80 cm to about 140 cm." 1031 It also has "an average starch index of about 29." 1032

¹⁰²⁶ Oxford Learner's Dictionaries: Basmati. -

<https://www.oxfordlearnersdictionaries.com/definition/english/basmati>, DOA: 05.02.2021.

¹⁰²⁷ Ghosh, Shubha: Globalization, Patents, and Traditional Knowledge, in: Columbia Journal of Asian Law (2003), Vol. 17, pp. 73-120, p. 97.

¹⁰²⁸ Chouhan, Vishwas Kumar: Protection of Traditional Knowledge in India by Patent: Legal Aspect, in: Journal of Humanities and Social Science (2012), Vol.3, Is. 1, pp. 35-42, p. 38.

¹⁰²⁹ Rai, Saritha: India-U.S. Fight on Basmati Rice Is Mostly Settled. in: The New York Times. 2001. - <https://www.nytimes.com/2001/08/25/business/india-us-fight-on-basmati-rice-is-mostly-settled.html>, DOA: 05.02.2021.

¹⁰³⁰ Yemi, Adewumi: Who owns It?: US-India Basmati Rice Dispute in WTO. -

<http://www.american.edu/projects/mandala/TED/basmati.html>, DOA: 05.02.2021.

¹⁰³¹ U.S. Patent No. 5,663,484; Bibliographic data: US5663484 (A) - 1997-09-02, European Patent Office. -

https://worldwide.espacenet.com/publicationDetails/biblio?CC=US&NR=5663484&KC=&FT=E&locale=en_EP#, DOA: 05.12.2021.

¹⁰³² Ibid.

The company RiceTec's issued those 20 claims for a particular rice plant (Claims 1-11,114), for the seeds that germinate that patented rice (Claim 12), for the grain that is produced by the rice plant (Claims 13, 15-17) and for the method of choosing plants for breeding and propagating specific rice grains (claims 18-20).¹⁰³³ In essence, the patent was issued for the following three aspects:

*“growing rice plants with certain characteristics identical to basmati; the grain produced by such plants, and the method of selecting the rice plant based on a starch index (SI) test devised by RiceTec.”*¹⁰³⁴

While the patents validity is limited to the United States, it does affect other varieties that have been grown anywhere in the Western Hemisphere.¹⁰³⁵ Moreover, the U.S. market forms around ten percent of the total basmati exports originating from Indian and Pakistan.¹⁰³⁶

The basmati patent was given to RiceTec just at the time when the Council of Scientific and Industrial Research (CSIR) was challenging the patent on turmeric successfully. The allotting of the patent to RiceTec lead to an instant challenge of the basmati rice patent. The attorneys for the Indian government stated that RiceTec was holding a patent for the following three aspects: “growing rice plants with relevant attributes that are identical to Basmati, for the grains produced by such plants as well as the method used to select rice

¹⁰³³ Ghosh, Shubha: Globalization, Patents, and Traditional Knowledge, in: Columbia Journal of Asian Law (2003), Vol. 17, pp. 73-120, p. 101.

¹⁰³⁴ Song, Olnsoon: Old knowledge into New Patent Law: The Impact of United States Patent Law on Less-Developed Countries, in: Indiana International & Comparative Law Review (2005), Vol. 16, Is. 1, pp. 261-293, p. 276.

¹⁰³⁵ Jamil, Uzma: Biopiracy: The Patenting of Basmati by Ricetec. Commission on Environmental, Economic and Social Policy - South Asia and Sustainable Development Policy Institute. in: Working Paper Series # 37. 1998. -

https://www.academia.edu/27094302/Biopiracy_The_Patenting_of_Basmati_by_Ricetec_Commission_on_Environmental_Economic_and_Social_Policy_South_Asia_And_Sustainable_Development_Policy_Institute, DOA: 27.05.2018, p. 2.

¹⁰³⁶ Song, Olnsoon: Old knowledge into New Patent Law: The Impact of United States Patent Law on Less-Developed Countries, in: Indiana International & Comparative Law Review (2005), Vol. 16, Is. 1, pp. 261-293, p. 277.

based on the starch index, and the test devised by RiceTec Inc.¹⁰³⁷ The attorneys were confident that their claim was based on the plant varieties that were already in existence as a staple on the Indian subcontinent. Moreover, the attorneys outline the fact that two-third of the rice imports were from Thailand and the remaining 1/3 was divided between Indian and Pakistan respectively. Ironically, neither variety of the rice could be cultivated in the United States where the patent was issued.¹⁰³⁸ The law dictates that for a patent to be granted there needs to exist a novelty,¹⁰³⁹ which the lawyers for the Indian government argued, was not evident in the case in hand, as the *so-called* invention itself is *de facto* imported into the United States. They also objected to the use of the name basmati in combination with the patent, as well as the marketing of the same. Not surprisingly, such patents would have detrimental effects for the good will and recognition of the domestic basmati rice from India; moreover, it also creates unnecessary confusion when it comes to the subject matter of geographic origin.

Fortunately, as a direct consequence of the request filed for re-examination application by APEDA (Agricultural and Processed Food Products Export Development Authority) an NGO acting on the behest of the Indian administration, RiceTec caved in and agreed to proceed with a patent withdrawal. As late as in 2021 the United States Patent and Trademark Office issued a Reexamination certificate cancelling numerous claims *inter alia* (claims 1-7, 10 and 14-20). In essence, the consequences for RiceTec are the loss of its claims over the written description of the plant previously owned by the company.¹⁰⁴⁰

On yet another note, RiceTec has in the meantime also filed a trademark application with the “intent to use” the mark Basmati USA in

¹⁰³⁷ Ghosh, Shubha: Globalization, Patents, and Traditional Knowledge, in: Columbia Journal of Asian Law (2003), Vol. 17, pp. 73-120, p. 102.

¹⁰³⁸ Ibid.

¹⁰³⁹ Conditions for patentability. Novelty. 35 U.S. Code. -

<https://www.law.cornell.edu/uscode/text/35/102>, DOA: 12.02.2021, § 102.

¹⁰⁴⁰ Ghosh, Shubha: Globalization, Patents, and Traditional Knowledge, in: Columbia Journal of Asian Law (2003), Vol. 17, pp. 73-120, p. 102.

the United States as early as in 1992.¹⁰⁴¹ The term Trademark is defined by WIPO as following:

*"A trademark is a sign capable of distinguishing the goods or services of one enterprise from those of other enterprises. Trademarks are protected by intellectual property rights. ...[A] trademark registration will confer an exclusive right to the use of the registered trademark. This implies that the trademark can be exclusively used by its owner or licensed to another party for use in return for payment. Registration provides legal certainty and reinforces the position of the right holder, for example, in case of litigation."*¹⁰⁴²

The trademark exploitation by the RiceTec is yet another example for biopiracy. Surprisingly enough, the relevant trademark was abandoned in 1994. Moreover, a California based firm issued a file application for the mark "Maryam Premium Aromatic Basmati Rice".¹⁰⁴³ Its endeavors to secure the trademark rights to the term "basmati" were futile. Consequently, the firm ended up abandoning the trademark claim in June 2001.¹⁰⁴⁴ Trademark law itself has the possibility to become the foundation for challenging the use of the term basmati. Thus, RiceTec could well be prohibited from marketing basmati rice in such a form that causes a confusion with its counterparts from India. Yet to successfully obtain a judgment against RiceTec, the Indian administration would have to prove that there was a high likelihood of confusion for the consumer between RiceTec's basmati and the rice

¹⁰⁴¹ Official Gazette of the United States Patent and Trademark Office: Trademarks, U.S. trademark application no. 74,305,936. - https://books.google.de/books?id=3wbAQAAMAAJ&pg=RA5-PA224&lpg=RA5-PA224&q=U.S.+trademark+application+no.+74,305,936&source=bl&ots=QeqA-99vMc&sig=ACfU3U0-RS9tqcRdFFlqzLX_9kIZe4yhKg&hl=de&sa=X&ved=2ahUKEwi5ueqjy9XuAhUPP-wKHZ6hAAsQ6AEwDnoECBoQAg#v=onepage&q=U.S.%20trademark%20application%20no.%2074%2C305%2C936&f=false, DOA: 06.02.2021.

¹⁰⁴² Trademarks: What is a trademark? - <https://www.wipo.int/trademarks/en/>, DOA: 07.02.2021.

¹⁰⁴³ U.S. trademark application no. 76,081,451.

¹⁰⁴⁴ Ghosh, Shubha: Globalization, Patents, and Traditional Knowledge, in: Columbia Journal of Asian Law (2003), Vol. 17, pp. 73-120, p. 101.

grown and marketed in India.¹⁰⁴⁵ RiceTec *prima facie* seems to have taken a rather smart move when it explicitly avoided using the term “basmati” in its marketing endeavors. The reason for this seems to be rooted in the intention to avoid claims for the violation of geographic indication (GI).¹⁰⁴⁶

According to the World Intellectual Property Organization, the term geographical indication consists of a sign that is primarily used on products that have a specific geographical origin.¹⁰⁴⁷ Equally, the products possess attributes and reputations that have been attached because they hailed from a particular region. Moreover, to be considered as a GI, a particular sign is intended to identify a product as being from a particular place. Correspondingly, the place of origin also dictates qualities, and characteristics, as well as the reputation of any given product. There exists a causal link between a product and where it has been produced, as the qualities are subject to the place of origin of a given product.¹⁰⁴⁸

Moreover, Article 22 (1) defines the term geographical origin as following:

“...identify a good as originating in the territory of a Member, or a region or locality in that territory, where a given quality, reputation or other characteristic of the good is essentially attributable to its geographical origin.”¹⁰⁴⁹

On another note, traditionally, liquors and wines have rather commonly associated with GI. For instance, the name “champagne” could only be

¹⁰⁴⁵ Ibid, p. 103.

¹⁰⁴⁶ Ibid.

¹⁰⁴⁷ World Intellectual Property Organization: Geographical Indications: What is a geographical indication? - https://www.wipo.int/geo_indications/en/, DOA: 06.02.2021.

¹⁰⁴⁸ Ibid.

¹⁰⁴⁹ World Trade Organization: Uruguay Round Agreement: Trips, Part II - Standards concerning the availability, scope and use of Intellectual Property Rights. 1994. -

https://www.wto.org/english/docs_e/legal_e/27-trips_04b_e.htm, DOA: 05.07.2020.

used to describe wine that has been produced in the Champagne region of France, the name of the region the product derives from. Any other wine with similar attributes from another part of the world cannot be branded as “champagne”; the brand “champagne” remains the exclusive IP of the champagne producers in France.¹⁰⁵⁰ “Scotch” whisky highlights, yet another case of GI.¹⁰⁵¹ Only whisky produced in the Scottish Highlands is allowed to be branded Scotch whisky.¹⁰⁵²

RiceTec has taken a different approach when it comes to marketing its products on the Europe continent. The company markets its product under the name Texmati rice, as the law of the United Kingdom has long gone over to provide trademark protection to the rice originating from India and Pakistan.¹⁰⁵³ Great Britain has become the largest market for basmati rice in Europe. Moreover, the European Union recognises Indian and Pakistani geographically indicated rights permitting only basmati rice that has been grown in these two states to be labelled as the same.¹⁰⁵⁴ RiceTec in the USA has also used the same name without making use of the name basmati in its product packaging. In American supermarkets, basmati is traded under the

¹⁰⁵⁰ Jamil, Uzma: Biopiracy: The Patenting of Basmati by Ricetec. Commission on Environmental, Economic and Social Policy - South Asia and Sustainable Development Policy Institute. in: Working Paper Series # 37. 1998. -

https://www.academia.edu/27094302/Biopiracy_The_Patenting_of_Basmati_by_Ricetec_Commission_on_Environmental_Economic_and_Social_Policy_South_Asia_And_Sustainable_Development_Policy_Institute, DOA: 27.05.2018, p.4.

¹⁰⁵¹ Bakhru, Rachna: Basmati, pashminas and the law: A guide to protecting geographical indications in India. Trademark World #221. 2009. - <http://rnaip.com/wp-content/uploads/2014/09/1125205335news.pdf>, DOA: 05.05.2018, pp.44-46, p. 45.

¹⁰⁵² Jamil, Uzma: Biopiracy: The Patenting of Basmati by Ricetec. Commission on Environmental, Economic and Social Policy - South Asia and Sustainable Development Policy Institute. in: Working Paper Series # 37. 1998. -

https://www.academia.edu/27094302/Biopiracy_The_Patenting_of_Basmati_by_Ricetec_Commission_on_Environmental_Economic_and_Social_Policy_South_Asia_And_Sustainable_Development_Policy_Institute, DOA: 27.05.2018, p.4.

¹⁰⁵³ Ghosh, Shubha: Globalization, Patents, and Traditional Knowledge, in: Columbia Journal of Asian Law (2003), Vol. 17, pp. 73-120, p. 103.

¹⁰⁵⁴ Jamil, Uzma: Biopiracy: The Patenting of Basmati by Ricetec. Commission on Environmental, Economic and Social Policy - South Asia and Sustainable Development Policy Institute. in: Working Paper Series # 37. 1998. -

https://www.academia.edu/27094302/Biopiracy_The_Patenting_of_Basmati_by_Ricetec_Commission_on_Environmental_Economic_and_Social_Policy_South_Asia_And_Sustainable_Development_Policy_Institute, DOA: 27.05.2018, p.5.

following names: Calmati, Kasmati and Texmati. Indian basmati exporters have dismissed these variations as mere imitations.

As for the Indian government, *prima facie* it appears to be wise to argue that that the term basmati has been a subject of confusion for the average consumer. An argument that could be brought forward by RiceTec is that, unlike feta cheese, the term was not likely to trigger trademark protection, as it is *de facto* a descriptive mark.¹⁰⁵⁵

Having mentioned feta cheese, it would now be of interest to consider what a European GI entails. Article 1 of the Ministerial Order 313025/1994 of the Greek government provides some indication when it comes to the production of feta cheese, the milk used for the production must be exclusively from goats and sheep from the following Greek regions: Central Macedonia West Macedonia, East Macedonia, Epirus, Thrace, Thessaly, Central Greece, Lesbos, and Peloponnese. The reason for this is rooted in the climate of those regions, which play a significant role in the production chain. The chemistry between the flora and the climate meant that the milk from these regions had developed a chemically rich composition, as well as organoleptic properties.¹⁰⁵⁶ This in combination with traditional production methods has made Greek Feta cheese into what it has become today - a cheese that is flavoursome, unique aroma-wise, in characteristics as well as in consistency.¹⁰⁵⁷

Basmati only means fragrant, which, is a mere descriptive when it comes to the product. To put it differently, the word "basmati" essentially describes a particular scent of the rice and not the specific geographic origin; as in the case of feta cheese, the distinct aroma

¹⁰⁵⁵ World Intellectual Property Organization: Defining a Name's Origin: The Case of Feta. 2016. - <https://www.wipo.int/ipadvantage/en/details.jsp?id=5578>, DOA: 06.02.2021.

¹⁰⁵⁶ Ibid.

¹⁰⁵⁷ Ibid.

and texture of basmati rice originates from the Indian soil watered by the Himalayan rivers.¹⁰⁵⁸

For Vandana Shiva, RiceTec has stolen the following three aspects:

- the collective IP and the biodiversity heritage of Indian farmers
- misappropriation from Indian exporters and farmers whose markets are being taken over by RiceTec Inc.
- misrepresentation when it comes to consumers since RiceTec is using the stolen name, Basmati, for a rice which originated from India, without growing the same in India, which in turn does not constitute the same quality.¹⁰⁵⁹

Saritha Rai calls it “piracy of emerging nations’ indigenous products”. For the average Indian, basmati was more than an economic power play between US and India. Basmati can literally be found in every kitchen on the subcontinent and can be regarded as part of Indian national heritage.¹⁰⁶⁰ A community of Indian farmers were frustrated with the endeavors of RiceTec to patent basmati, which has been substantial for the survival of Indian farmers on the subcontinent. This led to a mass protest in which more than 50, 000 people went to demonstrate in front of the U.S. Embassy in New Delhi.¹⁰⁶¹ Finally, the Basmati issue is yet another example for the exploitation traditional knowledge of Indian rice cultivation by the Western multinationals.

¹⁰⁵⁸ Rai, Saritha: India-U.S. Fight on Basmati Rice Is Mostly Settled. in: The New York Times. 2001. - <https://www.nytimes.com/2001/08/25/business/india-us-fight-on-basmati-rice-is-mostly-settled.html>, DOA: 05.02.2021.

¹⁰⁵⁹ Song, Olnsoon: Old knowledge into New Patent Law: The Impact of United States Patent Law on Less-Developed Countries, in: Indiana International & Comparative Law Review (2005), Vol. 16, Is. 1, pp. 261-293, p. 276.

¹⁰⁶⁰ Rai, Saritha: India-U.S. Fight on Basmati Rice Is Mostly Settled. in: The New York Times. 2001. - <https://www.nytimes.com/2001/08/25/business/india-us-fight-on-basmati-rice-is-mostly-settled.html>, DOA: 05.02.2021.

¹⁰⁶¹ Ibid.

Exhibit D. *Trichopus Zeylanicus*

The discovery of *Trichopus zeylanicus* highlights the importance of the South Asian medical tradition Ayurveda, which has been a key reason for establishing the Indian Ministry of AYUSH. AYUSH stands for Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy. These are the six Indian systems of medicine, both prevalent and practiced in India. The Indian government has engaged in efforts to safeguard Ayurvedic knowledge (a source of traditional knowledge), one of which was the creation of an electronic database known as the Traditional Knowledge Digital Library (TKDL).¹⁰⁶² Another method is the discovery of an Ayurvedic drug as part of a bioprospecting benefit-sharing scheme.¹⁰⁶³

In 1988 the Tropical Botanical Garden and Research Institute (TBGRI), a governmental research institution, undertook an ethnobotanical field study in the Agastyar forest of the Southwestern part of the Indian Union. The forest has been the home of the Kani, a nomadic tribe, consisting of around 17, 000 people who lead a settled life in tribal hamlets.¹⁰⁶⁴ For the researchers of the TBGRI, the Kani people became persons of interest as to their use of wild plants which provide them with energy, which were identified by TBGRI's researchers as *T. zeylanicus*.¹⁰⁶⁵

The exploitation of the plant was only possible through the divulgence of this precious information by the Kani people to the TBGRI's researchers. The researchers went on to isolate the pharmacological elements, as well as developed from there a restorative herbal

¹⁰⁶² This shall be considered further below.

¹⁰⁶³ Reddy, Sita: Making Heritage Legible: Who Owns Traditional Medical Knowledge?, in: International Journal of Cultural Property (2006), Vol. 13, Is. 2, pp. 161-188, p. 161.

¹⁰⁶⁴ Madassery, Joseph/ Kottakkal, Martin/ Pradeep, A.K.: High Frequency In Vitro Propagation of *Trichopus Zeylanicus* subsp. *travancoricus* using Branch-Petiole Explants, in: Acta Physiologiae Plantarum (2011), Vol. 33, pp. 1141-1148, pp. 1141-1142.

¹⁰⁶⁵ Reddy, Sita: Making Heritage Legible: Who Owns Traditional Medical Knowledge?, in: International Journal of Cultural Property (2006), Vol. 13, Is. 2, pp. 161-188, p. 177.

medicine and issued two patent applications. TBGRI later sold for the sum total of 25,000 USD, to the manufacturing licence to a Ayurvedic company, called Arya Vaidya Pharmacy, located on the subcontinent.¹⁰⁶⁶ Having obtained the licence, Arya Vaidya Pharmacy moved on to produce and market a new form of drug named Jeevani, which is an anti-fatigue sports medicine. To benefit the Kani community, whose traditional knowledge in question was the fundamental source of the medicine, TBGRI entered into an agreement for a benefit-sharing model with the Kani people.¹⁰⁶⁷ In this context, it would be worth mentioning that TBGRI's approach has been in line with Art. 8 (j) of the Convention of Biological Diversity, which obligates the state parties to the following:

*"Subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote the wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices."*¹⁰⁶⁸

The CBD has been ratified by more than 168 countries from all over the world. Through the act of ratification, the member states agree to abide by the following principles: the conservation of biodiversity, the sustainable use of its components; and the fair as well as equitable sharing of the benefits arising out of the utilization of genetic resources.¹⁰⁶⁹

¹⁰⁶⁶ Ibid.

¹⁰⁶⁷ Ibid.

¹⁰⁶⁸ Secretariat of the Convention on Biological Diversity: Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity. 2011. - <https://www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf>, DOA: 15.08.2017.

¹⁰⁶⁹ CBD Secretariat: List of Parties to the Convention on Biological Diversity. - <https://www.cbd.int/information/parties.shtml>, DOA: 15.02.2021.

The benefit-sharing system was introduced by the Nagoya Protocol which itself is an ancillary accord to the CBD. A core obligation includes the following: benefit-sharing obligations, access obligation, and compliance obligations. These models have been devised to warrant a structure to access genetic resources and the equitable sharing of benefits. Art. 5 of the Nagoya Protocol states the following:

"1. In accordance with Article 15, paragraphs 3 and 7 of the Convention, benefits arising from the utilization of genetic resources as well as subsequent applications and commercialization shall be shared in a fair and equitable way with the Party providing such resources that is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention. Such sharing shall be upon mutually agreed terms."

"4. Benefits may include monetary and non-monetary benefits, including but not limited to those listed in the Annex."¹⁰⁷⁰

Art. 5 of the protocol emphasises the importance of undertaking the commercial exploitation of genetic resources in a fair and equitable manner with the party that had provided the relevant resources. The hearing was going to go swiftly due to it being carried out subject to a mutual agreement. Art. 10 of the Nagoya Protocol propagates a global benefit sharing system in cases where a prior consent from the owning party is not possible. It states the following:

"Parties shall consider the need for and modalities of a global multilateral benefit sharing mechanism to address the fair and equitable sharing of benefits derived from the utilization of genetic resources and traditional knowledge associated with genetic resources that occur in transboundary situations or for which it is not

¹⁰⁷⁰ Secretariat of the Convention on Biological Diversity: Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity. 2011. - <https://www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf>, DOA: 15.08.2017.

possible to grant or obtain prior informed consent. The benefits shared by users of genetic resources and traditional knowledge associated with genetic resources through this mechanism shall be used to support the conservation of biological diversity and the sustainable use of its components globally.”¹⁰⁷¹

In the present case, TBGRI was willing to settle on a benefit-sharing model, adding 50% of the license fee, together with 2% of the royalty when it comes to profits with the Kani people for the duration of eight years. *Prima facie*, this seemed to be in line with the Nagoya Protocol and to reflect a fair and equitable compensation model for the exploited tribal medical knowledge. The first payment was issued in 1999 for the drug Jeevani in the sum of 12,500 USD. The amount was to be shared between the research institute and the Kani people.¹⁰⁷²

Unfortunately, this also marks a point of contention, namely raising the question of whose traditional knowledge must be compensated. As things stand, collective ownership appears to be the assumed component when it comes to benefit-sharing contracts.¹⁰⁷³

The first issue of contention that arose in the correlation with the Kani people was based on how to define the term community; the source of contention began with the formation of a trust, named Kani Smudaya Kshema Trust. The trust was established to help administer the benefit-sharing process under the guidance of another NGO working in the local area.¹⁰⁷⁴ There existed immense suspicion about the trust on the part of the Kani people, which meant that the trust had only managed to have 500 members in 1998; the Kani people even refused to attend tribal meetings organised by the TBGRI. A clear point of contention was the CBD itself, which combines both locals and

¹⁰⁷¹ Ibid.

¹⁰⁷² Reddy, Sita: Making Heritage Legible: Who Owns Traditional Medical Knowledge?, in: International Journal of Cultural Property (2006), Vol. 13, Is. 2, pp. 161-188, pp. 177-178.

¹⁰⁷³ Ibid, p. 178.

¹⁰⁷⁴ Ibid.

indigenous people in its community definition together. The indigenous community of the Kani have little in common with the local Indian community; equally, TBGRI, while intending to include the Kani community in the decision-making process, only included those Kani people that were in one *panchayat* area (local village government). Arguably this is what T.S. Eliot meant when he wrote the following:

*"Most of the evil in this world is done by people with good intentions."*¹⁰⁷⁵

Unlike the *panchayat* system which is rooted on the Indian constitution and its decision-making organs are democratically elected, the Kani rely on a tribal chief-based form of governance.¹⁰⁷⁶ The fact that TBGRI's staff only interacted with one Kani *panchayat* meant that the people in the remaining other two were offended and considered the TBGRI's approach culturally insensitive and outright biased.¹⁰⁷⁷ Things came to head when in 1995 nine Kani medicine men (tribal healers), dissatisfied with the lack of a participatory approach by TBGRI, not only boycotted the meeting but also complained in writing to the CM of the south Indian state of Kerala. The tribal healer owned a customary right to medical knowledge and rejected in their letter the sale of their traditional knowledge to a private enterprise.¹⁰⁷⁸

Yet another issue of contention arose over the procurement of the plant in question, namely *T zeylanicus*. A key factor which TBGRI's researchers only discovered at a later stage is that *T. zeylanicus* only preserves its medicinal qualities if it grows under the natural conditions of the Agastyar tropical forest of Southwest India. They did, however, enter into a contractual agreement with Arya Vaidya Pharmacy for the supply of cultivated raw plants for the duration of seven years. In an

¹⁰⁷⁵ Goodreads: T.S. Eliot Quotes. -

https://www.goodreads.com/author/quotes/18540.T_S_Eliot, DOA: 15.2.2021.

¹⁰⁷⁶ Reddy, Sita: Making Heritage Legible: Who Owns Traditional Medical Knowledge?, in: International Journal of Cultural Property (2006), Vol. 13, Is. 2, pp. 161-188, p. 178.

¹⁰⁷⁷ Ibid.

¹⁰⁷⁸ Ibid.

attempt to rectify this, the institute went on to enlist 50 Kani families who were living in the forest, with the aim to cultivate *T. zeylanicus* under the supervision of the researchers.¹⁰⁷⁹ To make it sound more appealing the program was pitched as a creative employment generation program; the program entailed an option for each family to manage the semiwild plant by cultivating one or two acres with an estimated income of around 715 USD per acre. The harvest was further anticipated to increase in the subsequent years for the anticipated timeframe of 20-30 years.¹⁰⁸⁰ Given their rather unique nature as the quintessential forest residents, Kani would have had a strong bargaining chip at the negotiating tables when it came to the regulation and control of the harvest.¹⁰⁸¹ As with any proper thriller, life had thrown in a twist in the form of the state forest department, under whose jurisdiction the area of the Agastyar tropical forest falls. Despite having hardly contributed any material or pecuniary resources for the research endeavours, the forest department demanded a cut of the licence fees as well as the royalties, based on the fact that the collected crops are endemic to the forest. Consequently, TBGRI had no other choice than to renegotiate the terms and conditions of the initial agreement and it included the forest department, which in turn meant that the Kanis had to endure significant cuts in their share of the profit.¹⁰⁸²

As for the main outcome, the manufacturing process continued as planned. That the benefit sharing scheme, which had been sponsored by the government, established a compensation scheme relying on tribal medicinal knowledge without the consent of the whole community of Kani people did not disturb the production chain of Jeevani. Jeevani was delivered to both national and international markets, and relevant fees and royalties were issued to the Trust

¹⁰⁷⁹ Ibid.

¹⁰⁸⁰ Ibid.

¹⁰⁸¹ Ibid, p. 179.

¹⁰⁸² Ibid.

dedicated to the Kani community.¹⁰⁸³ The trust had, however, lost all credibility among the entire body of the Kani people.¹⁰⁸⁴

Eight years after the benefit-sharing agreement had been signed, the Kani people finally wanted to take their future in their own hands. The licence expired in August 2006, prompting criticism from NGOs about the benefit-sharing agreement generated by the TBGRI leading to the privatisation of common traditional knowledge of humanity. In an interesting twist, Kani *panchayat* leaders, in conjunction with the group of all the tribal healers, refused to renew the licence to Arya Vaidya Pharmacy. Instead of outsourcing their traditional medical knowledge to manufacturers outside, who are usually out to make a profit for themselves, they announced plans to start a factory themselves with the assistance of the three *panchayats*.¹⁰⁸⁵

Having discussed the struggle of the Kani community for ownership of their traditional knowledge and obtaining the same after waiting for eight years, the struggle did, unfortunately, not end here for the Kani community. For more than a decade, none of the key actors: the Kani Community, TBGRI, the State government of Kerala, thought to apply for an international patent or trademark securing the IP rights over the traditional knowledge of the Kani people. The leading U.S. food supplement manufacturer and vitamin store chain owner, the Great Earth Companies Inc. used the gap in the market and secured the trademark for Jeevani.¹⁰⁸⁶ As mentioned above, Jeevani was the name under which the drug had been marketed in India. The Great Earth Companies Inc. went on to use the trademark for its products “Jeevani Jolt 1000”, without infringing on the IP rights of its Indian competition.¹⁰⁸⁷ It appears to be an irony of fate, that after eight years of research which was based on traditional knowledge and the issuing

¹⁰⁸³ Ibid.

¹⁰⁸⁴ Ibid.

¹⁰⁸⁵ Ibid.

¹⁰⁸⁶ Ibid.

¹⁰⁸⁷ Ibid.

of a benefit-sharing agreement that was accompanied by the slogan “to give back equitable returns to the South”, Jeevani is now also viable in the West. Jeevani is marketed here as an anti-stress adaptogen, energiser, and an immune system supporter, available for only 21,99 USD.¹⁰⁸⁸ *Prima facie*, it seems that traditional knowledge and medicinal heritage can be discovered and commodified by an entity in one location, and owned by an entity in yet a completely different location.¹⁰⁸⁹ Consequently, one could refer to this phenomenon as the continuation or perhaps even the expansion of West colonialism, through other means, of the South.¹⁰⁹⁰ “Jeevani Jolt 1000” represents the most obvious form of biopiracy, and was undertaken with minimal effort and at low cost, thereby misappropriating the traditional knowledge of the Kani tribal community.

¹⁰⁸⁸ Ibid.

¹⁰⁸⁹ Ibid.

¹⁰⁹⁰ Krishnamoorthy, Venkataraman/ Swarna, Latha: Intellectual Property Rights, Traditional Knowledge and Biodiversity of India, in: Journal of Intellectual Property Rights (2008), Vol. 13, pp. 326-335, p. 329.

Exhibit E. Yoga

Yoga is a philosophical tradition that is thousands of years old, hailing from South Asia. It is an exercise regime that trains body and soul through a combination of mental and physical practices.¹⁰⁹¹ The name yoga derived from the Sanskrit word *yuj*, which could be translated as yoke, union or join together. Yoga and its associated ascetic practices are part of multiple religious traditions that are rooted in the South Asian subcontinent. These religions include the following: Sikhism, Hinduism, Buddhism and Jainism.¹⁰⁹² In particular, yoga has been associated with the Hinduist tradition and represents one of the six key philosophies of religious orthodoxy (referred to as darsanas). As early as 2000 years ago, local yoga expressions were classed into eight different and separate limbs of practice by the ancient sage, referred to as per his namesake *Pantanjali*. This the Yoga Sutras of *Pantanjali* include the following limbs: *dharana* (concentration), *dhyanā* (meditation), *samadhi* (trance), *yama* (abstentions), *niyama* (observances), *asana* (postures), *pranayama* (breath control) and *pratyahara* (abstraction).¹⁰⁹³ Regardless of whether the yoga school is transnational, modern or esoteric, it tends to have a distinctive practice style with its unique interpretation and combinations of certain subsets of limbs. In this context, it is worth mentioning that not even in the Indian Union did a single traditional yoga style exist. On the contrary, multiple yoga traditions have always existed side by side on the subcontinent.¹⁰⁹⁴

Transnational yoga only gained momentum in the last five decades among its cosmopolitan customers hailing from Europe, Australia,

¹⁰⁹¹ Fish, Allison: The Commodification and Exchange of knowledge in the Case of Transnational Commercial Yoga, in: International Journal of Cultural Property (2006), Vol.13, No. 2, pp. 189-206, p. 191.

¹⁰⁹² Flood, Gavin D.: An Introduction to Hinduism. Cambridge: Cambridge University Press, 1996, p. 6.

¹⁰⁹³ Ibid, p. 95.

¹⁰⁹⁴ Ibid.

Japan, and the United States. These predominately Western customers were absorbed by the indigenous and oriental alternatives to both health and exercise practice and have consequently generated a market demanding transnational commercial yoga.¹⁰⁹⁵ The market was drawing from Hatha yoga, a style that places a considerable importance on the physical aspects of the yoga practice based on *pranayamas*, *pratyahara* and *asanas*. The key objectives of Hatha yoga are both sensory withdrawal and more advanced steps of meditation.¹⁰⁹⁶ More precisely, the transnational commercial Hatha focuses on gymnastics with the accompanying physical effects, which includes weight loss the reduction of physical stress, physical flexibility, and muscle toning. In the recent version, yoga has developed as a commodity of success that managed to fulfil the increasing demands of Western customers for the enhancement general health and physique through exercise. In the context of wellness culture, yoga has evolved into a lucrative industry as an uncomplicated alternative to the, in many cases, much dreaded gym workout. In the same token, yoga's positive side effect of reducing stress is a positive concomitant. In fact, yoga has gained momentum as an efficient workout routine that can still be added at the end of a long day at work.¹⁰⁹⁷ The transnational commercial yoga market in the U.S. was valued north of \$30 billion and had been practiced by around 20 million people as of 2004.

Given yoga's popularity and increase in commercial value it would now be advisable to consider whether yoga, as a health enhancer, might be eligible for IP protection. Thus, it seems hardly surprising that given its profitability, various players on the commercial market of the U. S. went on to register thousands of IP claims regarding yoga-related services as well as goods. In this regard, patent applications

¹⁰⁹⁵ Fish, Allison: The Commodification and Exchange of knowledge in the Case of Transnational Commercial Yoga, in: International Journal of Cultural Property (2006), Vol.13, No. 2, pp. 189-206, p. 191.

¹⁰⁹⁶ Ibid.

¹⁰⁹⁷ Ibid.

on yoga devices, mats and other apparatuses have been subjected to patent application in China, Russia and Canada. Thus, multiple CD's, DVD's and books on yoga are protected by copyright.¹⁰⁹⁸

In 2002, a prominent case involving IP rights in relation to yoga drew much public attention. The case involved Bikram Choudhury, the founder and president of BYCI, went on to enforce trademark and copyrights against a “renegade” infringer studio. Choudhury has been involved in multiple U.S. federal court lawsuits; he has settled many of these cases out of court with a nondisclosure agreement.¹⁰⁹⁹ This section will consider three of those cases which are of importance for this research, as they highlight the significance of a health-related practice. While it is not medicinal in the purest sense of the word, it does however highlight the injustice and cultural misappropriation of indigenous or something that is quintessential Indian, in the present case, the therapeutic and health-related use of yoga. One might immediately ask whether the traditional knowledge of yoga can be protected by a person or a commercial entity located in the United States. In other words, should the traditional knowledge of yoga remain in the public domain and hence should never be subject to IP registration by individuals or commercial entities? The Bikram Choudhury case once again highlights the exploitation of traditional knowledge by multinationals like the pharmaceutical companies, as seen above, that happened to patent the traditional use of indigenous botanical remedies. They do so by means of laboratory research and subsequent documentation to vindicate their IP ownership.¹¹⁰⁰

¹⁰⁹⁸ Srinivas, Krishna Ravi: Intellectual Property Rights and Traditional Knowledge: The Case of Yoga, in: Economic & Political Weekly (2007), Vol. 47, No. 27 & 28, pp. 2866-2871. - <http://ssrn.com/abstract=1005298>, DOA: 31.12.2019, p. 2868.

¹⁰⁹⁹ Fish, Allison: The Commodification and Exchange of knowledge in the Case of Transnational Commercial Yoga, in: International Journal of Cultural Property (2006), Vol.13, No. 2, pp. 189-206, p. 192.

¹¹⁰⁰ Hayden, Cori. When Nature Goes Public: The Making and Unmaking of Bioprospecting in Mexico. Princeton: Princeton University Press, 2003, pp. 125-135.

Bikram Yoga has often been called the McDonald's version of yoga.¹¹⁰¹ Choudhury established a version of transnational commercial Yoga that has evolved into a highly profitable venture; Bikram style of yoga involves 26 postures (asanas) and two breathing exercises (pranayamas), practiced over the duration of around 90 minutes in a studio heated to 105 Fahrenheit (40,6 centigrade).¹¹⁰² During the exercise each individual pose is held for a precise time frame, performed twice and accompanied by scripted instruction from the yoga instructor.¹¹⁰³ While the attributes of each studio might differ to some extent, there remains a rather restricted space for deviation, so that the Bikram style is easily distinguishable.¹¹⁰⁴ The Bikram studios are part of a group of around 800 franchises, the BYCI, which is being operated in 33 states. As part of the franchise agreement, a studio must have entered into an agreement to teach only Bikram Yoga classes, which in turn had to be taught by Bikram certified instructors only. Thus, a particular form of yoga had to be physically set up in a programmed manner that was not in competition with other Bikram studios. Finally, any such studio must be owned by a Bikram-certified teacher. On top of this, to become a certified instructor at Bikram, an individual must be permitted into and graduated from the BYCI training program. The program itself is undertaken on a full-time basis and lasts for two months. The program is only offered twice a year at BYCI headquarters in Los Angeles, and it costs \$6,000.¹¹⁰⁵

Choudhury's career is that of a quintessential American success story, one from rags to riches. He was born in Kolkata, India, where he had been immersed in the practice of yoga from age four onwards. At age 17 he became the champion of the world in yoga, he managed to

¹¹⁰¹ Fish, Allison: The Commodification and Exchange of knowledge in the Case of Transnational Commercial Yoga, in: International Journal of Cultural Property (2006), Vol.13, No. 2, pp. 189-206, p. 194.

¹¹⁰² Ibid.

¹¹⁰³ Ibid.

¹¹⁰⁴ Ibid.

¹¹⁰⁵ Ibid.

choreograph the renowned “Bikram Beginning Yoga Series”, while recovering from a knee injury. Soon his series of yoga gained international popularity which earned him a special invitation from former U.S. president Richard Nixon to visit the United States in the 1970s. As it happened, Nixon himself had been a student of Bikram. Once he arrived in the United States, Choudhury managed to open his first yoga studio in Los Angeles, which drew many wealthy customers.¹¹⁰⁶

As early as 2002 Bikram started to register both trademarks and copyrights protection for his publications. One aspect that seems to have an overarching scheme is that, in multiple cases involving IP rights protection, Indian natives who settled in the U.S. or other western counties have secured for IP protection for traditional knowledge they grew up with in India.

One such publication is Bikram’s “Beginning Yoga Class”, as well as related images produced by him since 1970. Bikram and his legal counsel continually maintained that his yoga sequence was a specific arrangement of postures and is hence eligible for copyright protection. His legal counsel insisted that the arrangement of those postures deserves legal protection as it is comparable to other choreographed performances that are aesthetic, like for instance in the case of dance.¹¹⁰⁷ In order to cement his IP claims, Bikram sends forceful cease and desist letters to studios that teach Bikram Yoga without prior approval.

In 2002, Bikram started his first copyright suit against a studio located in Orange County, California, against his former student and the student’s spouse.¹¹⁰⁸ Both parties went on to settle their claims out of court. Consequently, there is no court decision on the validity of

¹¹⁰⁶ Ibid, p. 195.

¹¹⁰⁷ Ibid.

¹¹⁰⁸ Ibid.

Bikram's claims to copyright protection. During the lawsuit, Choudhury asserted that his legal action was ethically justified as he had authored both the famous and profitable series under his own blood sweat and tears.¹¹⁰⁹ He likewise claimed that his brand name was in danger of being tarnished due to competition by uncertified and untrained yoga instructors. Choudhury further argued that the comparative inferior instructions would potentially endanger the life and limb of the students.¹¹¹⁰ *Prima facie*, Bikram's rather aggressive and threatening style forced multiple yoga studios throughout the U.S. to either change the sequences or completely stop offering the same.

Bikram seemed to have won the battle, yet the war was far from over. In this regard, two yoga organisations, named "Hot yoga Alliance" and the "Society of Betterment of Humanity" merged into a single organisation by the name of "Open-Source Yoga Unity" (OSYU). OSYU was started by lawyers, studio owners, teachers, and students. Unlike in the case of Choudhury, OSYU's mission is to protect the public access of yoga. Thus, they went to issue a lawsuit challenging Choudhury, with the aim of defeating his copyright and trademark claims over yoga, which in turn would enable unfettered access and development of yoga.¹¹¹¹ OSYU went on to collectively argue that yoga has always been a source of open access, and was only controlled by a guild-like organizational structure. This organisation is convinced that yoga should not be privately owned, instead they propagated that yoga should be in the public domain. Bikram, on the other hand, was arguing that his identity as an authentic Indian guru who happened to be taught from an early age by an acclaimed Master meant that he never had maintained a homogenous style and had

¹¹⁰⁹ Ibid.

¹¹¹⁰ Bikram Choudhury v. Kim Schreiber Morrison, Mark Morrison, and Prana Incorporated, case No. SA02-565 DOC(ANX) (USDC Central District of CA, Southern Division).

¹¹¹¹ Yoga Unity v. Bikram Choudhury case No. C 03-03182 PJH (USDC Northern District of CA, San Francisco Division).

thus created a successful commodity in this segment.¹¹¹² The case was settled out of court in April 2005 and both parties managed to sign a nondisclosure agreement. While, understandably, very little of the nondisclosure agreement has been leaked, one aspect of the agreement seemed to be evident, namely, that OSYU would cease to teach the Bikram Beginning Series and in return Choudhury would agree not to sue the individual members of OSYU for IP violations.¹¹¹³

The lawsuits involving Bikram, and their media reports gained traction in Choudhury's place of birth India, in particular the Indian government and the Art of Living Foundation, and they were not necessarily amused about the privatisation of yoga. Both parties are convinced that yogi knowledge is indeed traditional knowledge due to its ancient tradition and historical context. Consequently, they also share OSYU's opinion that yoga should remain in the public domain.¹¹¹⁴ As for the Indian government it had already registered a small section relating to yoga in the Traditional Knowledge Digital Library (TKDL). The Bikram lawsuits had triggered the government's desire to create a separate digital yoga library to avoid future IP claims. The library contains thousands of ancient scripts and texts, in combination with illustrations of more than 1,500 Yogic postures.¹¹¹⁵ Moreover the TKDL has collected relevant descriptions about plants, from the ancient languages: Sanskrit, Tamil, Urdu, Arabic and Persian.¹¹¹⁶ Equally due to the numerous patent applications over Indian traditional knowledge based inventions, the Indian government was forced to translate the information which was available in the Indian language into those languages which are internationally known. The aforesaid languages are the following five languages: English, German, French,

¹¹¹² Fish, Allison: The Commodification and Exchange of knowledge in the Case of Transnational Commercial Yoga, in: International Journal of Cultural Property (2006), Vol.13, No. 2, pp. 189-206, p. 195.

¹¹¹³ Ibid.

¹¹¹⁴ Ibid, p. 198.

¹¹¹⁵ Ibid, p. 201.

¹¹¹⁶ World Intellectual Property Organization: About the Traditional Knowledge Digital Library. - https://www.wipo.int/meetings/en/2011/wipo_tkdl_del_11/about_tkdl.html, DOA: 22.02.2021.

Japanese and Spanish. The relevant information is also available on the public domain. The knowledge available in the public domain cannot be considered for a patent. Since its creation, 220 patent applications relating to Indian medicinal systems have been refused or withdrawn by applicant due to TKDL.¹¹¹⁷

In 2011 Bikram filed a third lawsuit against Mark Drost and Zefea Samson, the founders of Evolution Yoga and *inter alia* due to copyright infringement. Drost had been employed as a senior member of Choudhury's training staff, in this capacity he worked closely with him. Both Samson and Drost enrolled and successfully completed the compulsory three-month yoga teachers' training course.¹¹¹⁸ However, in 2008 he left Choudhury's studio to establish his own studio under the name of Evolution studio.¹¹¹⁹ Evolution studio was offering various styles and types of yoga, which also included "hot Yoga" and related sequences, something that is characteristic for "Bikram's Basic Yoga System". Choudhury described the sequence of yoga poses depicted in his Yoga book as a system or method which was designed to systematically work every inch of the body. He also claimed that he had done extensive research into common diseases and postures before arriving at this sequence.¹¹²⁰ Bikram's book described that through the application of the methods prescribed in the hardback, participants were able to attain distinguishable psychological and spiritual results in the form of a sense of endless energy and well-

¹¹¹⁷ Ansari, M.S.: Role of Traditional Knowledge Digital Library (TKDL) in Preservation and Protection of Indigenous Medicinal Knowledge of India, in: Chakraborty, R./ Sen, S. (eds): Herbal Medicine in India. Singapore: Springer, 2020, pp. 613-617.

¹¹¹⁸ Bikram's Yoga Coll. Of India, Ltd. P'ship v. Evolution Yoga, Ltd. Liab. Co. – 803 F.3d 1032 (9th Cir. 2015) Case Brief: Law School Case Brief. -

https://www.lexisnexis.com/community/casebrief/p/casebrief-bikram-s-yoga-coll-of-india-ltd-p-ship-v-evolution-yoga-ltd-liab-co_, DOA: 08.02.2021.

¹¹¹⁹ Friedman D'Angelo, Jennifer: What the Bikram Copyright Rejection Means for Yoga. in: Yoga Journal. 2015. - <https://www.yogajournal.com/lifestyle/yoga-trends/rejection-bikram-copyright-upheld-means-future-yoga/#:~:text=%20Yoga%20is%20different%20from%20choreography,an%20idea%20or%20a%20fact.>, DOA: 09.02.2021.

¹¹²⁰ Case Brief: Bikram's Yoga Coll. Of India, Ltd. P'ship v. Evolution Yoga, Ltd. Liab. Co. – 803 F.3d 1032 (9th Cir. 2015). - https://www.lexisnexis.com/community/casebrief/p/casebrief-bikram-s-yoga-coll-of-india-ltd-p-ship-v-evolution-yoga-ltd-liab-co_, DOA: 08.02.2021, p. 11.

being.¹¹²¹ Based on this knowledge, Choudhury's Bikram's Yoga College of India issued a lawsuit against Evolution Yoga, alleging them of copyright violations. He once again claimed that he had obtained copyright protection, under Section 102 (b) of the Copyright Act 1976, for the sequences of yoga poses and breathing exercises (hot yoga).

Section 102 (b) of the Copyright Act 1976 states the following:

*"In no case does copyright protection for an original work of authorship extend to any idea, procedure, process, system, method of operation, concept, principle, or discovery, regardless of the form in which it is described, explained, illustrated, or embodied in such work."*¹¹²²

The Court of Appeal for the Ninth Circuit held that sequence of poses and breathing exercises that were developed by Choudhury were to be regarded as an idea, and therefore expressly excluded from the copyright protection.¹¹²³ The court regard the sequence of yoga poses as an idea, process or system that was designed to improve health. Copyright would in this case only extend to expression of this idea, the pictures and words used to depict the sequence, however, not the idea of the sequence itself. Moreover, the yoga Alliance, an international trade association, also filed an *amicus* brief supporting Evolution Yoga's position, arguing that granting Bikram's claim would be devastating for the yoga community.¹¹²⁴

¹¹²¹ National Law Review: The Idea of Yoga Versus the Expression of It: Bikram's Yoga College of India v. Evolution Yoga, LLC. 2015. - <http://www.natlawreview.com/organization/mcdermott-will-emery>, DOA: 13.02.2021.

¹¹²² Case Brief: Bikram's Yoga Coll. Of India, Ltd. P'ship v. Evolution Yoga, Ltd. Liab. Co. – 803 F.3d 1032 (9th Cir. 2015). - <https://www.lexisnexis.com/community/casebrief/p/casebrief-bikram-s-yoga-coll-of-india-ltd-p-ship-v-evolution-yoga-ltd-liab-co>, DOA: 08.02.2021.

¹¹²³ Case Brief: Bikram's Yoga Coll. Of India, Ltd. P'ship v. Evolution Yoga, Ltd. Liab. Co. – 803 F.3d 1032 (9th Cir. 2015). - <https://www.lexisnexis.com/community/casebrief/p/casebrief-bikram-s-yoga-coll-of-india-ltd-p-ship-v-evolution-yoga-ltd-liab-co>, DOA: 08.02.2021, pp. 20-23.

¹¹²⁴ National Law Review: Hold That Pose: Can the Bikram Yoga Sequence Be Protected by Copyright Law? 2015. - <http://www.natlawreview.com/author/joseph-mleccese>, DOA: 13.02.2021.

Consequently, as the sequence of yoga poses fell within the meaning of Section 102 (b)'s exclusion, the court went on to grant Evolution's motion for summary judgment and held that the collection of facts and ideas was not sufficient to give the right to copyright protection.¹¹²⁵ The ninth circuit court was of the opinion that extending copyright protection to the sequences would have led to a frustration of Choudhury's book, thereby encouraging readers to practice that particular method described in the same. The purchaser of Choudhury's book would have little to no reason to purchase Bikram's book if, after getting the book, practicing the described yoga poses would automatically turn the owners of this book into copyright infringers.¹¹²⁶ In the EU exercise mats for yoga have been patent by the EPO.¹¹²⁷ In sum, the Bikram Yoga case appears to be yet another example of biopiracy, and the commercial exploits are sadly not shared with the Indian government which, as had been discussed in the chapter on Hindu nationalism, is the biggest supporter of yoga globally.

¹¹²⁵ Case Brief: Law School Case Brief, Bikram's Yoga Coll. Of India, Ltd. P'ship v. Evolution Yoga, Ltd. Liab. Co. - 803 F.3d 1032 (9th Cir. 2015). - <https://www.lexisnexis.com/community/casebrief/p/casebrief-bikram-s-yoga-coll-of-india-ltd-p-ship-v-evolution-yoga-ltd-liab-co.>, DOA: 08.02.2021.

¹¹²⁶ National Law Review: The Idea of Yoga Versus the Expression of It: Bikram's Yoga College of India v. Evolution Yoga, LLC. 2015. - <http://www.natlawreview.com/organization/mcdermott-will-emery>, DOA: 13.02.2021.

¹¹²⁷ European Patent Office: European patent for recreation mats, European Patent Specification, Patent No: EP 2 640 479 B1. - <https://data.epo.org/publication-server/document?iDocId=5038450&iFormat=0>, DOA: 18.02.2021.

Exhibit F. Property Rights

In this section we shall consider the subject of property rights in the context of IP ownership. This part will also examine the concept of property possession as endorsed by Morris Raphael Cohen, American philosopher, lawyer, and legal scholar. For Cohen, property rights and mere physical possession are not one and the same. Moreover, a property right according to Morris Cohen is not a relation between an owner and a thing, but rather between an owner and other persons in relation to items; a right could be extending against one or more persons.¹¹²⁸ This is even more prevalent when it comes to the subject matter of our interest, patents, and arguably other IP rights such as trademarks, copyrights, etc. This constitutes a large part of the capitalised assets of the globe's commercial businesses and industry. If one were to apply Cohen's point to the issue of traditional knowledge, there exists a relation between the owner of the traditional knowledge, for instance, in Exhibit D, the Kani tribe who are the property owner and consequently have a right against TBGRI or Great Earth Companies Inc. By default, the Kani tribe should be compensated for the exploitation of their traditional knowledge by Great Earth Companies Inc., ideally through a benefit sharing model or through royalties.

The Cohen also argues that the quintessential component of private property provides an exclusive right to exclude others; the law may indirectly assist oneself by removing certain general hindrances to the enjoyment of property. At the same time property law only assists an individual in their endeavor to exclude others from using the items designated to that individual. Thus, to use a person's property, land or in our case the IPRs a prior consent of the owner would be

¹¹²⁸ Cohen, Morris R.: *Property and Sovereignty*, in: Cornell Law Review (1927), Vol. 13, Is. 1, pp. 8-30, p. 12.

required.¹¹²⁹ Staying with the Kani example, both the IP law and international human rights law would assist the tribe in their potential endeavor to exclude Great Earth Companies Inc. using their IPRs and would remove, as per Cohen, any hindrances as to the enjoyment of their IP rights. The international human rights law angle when it comes to property will be discussed further below. Cohen reminds us not to ignore the fact that authority over things is equal to that over our fellow humans.¹¹³⁰ Protecting the property rights of a landlord provides him with the right to accumulate rental income and ensure that your property is protected. The rental income could also be substituted with royalties or license fees in the Kani case. Moreover, the legal ownership of, take for instance, land or industrial machinery, with a right to draw an income, also affects the allocation of goods that will come into existence in the future. Equally it determines what portion of the relevant goods each person should be entitled to.¹¹³¹ This aspect of Cohen's analyses on the right to possession depicts rather well the distribution of the share originating from the license fee as well as the royalties as discussed in Exhibit D. Sadly, the Kani community, as the actual owner of the traditional knowledge for the patented "medicine", were mere shareholders or partners who were given a share which was preapproved by TBGRI's researchers and other governmental institutions. This means that the landlord or the patent owner has been granted certain legal powers to demand financial compensation for a social product that is being developed in the future.¹¹³² Such a future product could be a medicine or a trademark that has been subject to IP protection. The sovereign rights possessed by the modern-day IP right holder tends to have, to some extent, a different format from the one formerly possessed by a landowner.¹¹³³

¹¹²⁹ Ibid.

¹¹³⁰ Ibid, p. 13.

¹¹³¹ Ibid.

¹¹³² Ibid.

¹¹³³ Ibid.

It would now be prudent to analyse if property ownership should be justifiable as per the occupation theory. An old and most influential defence for the possession of private property was created on the assumption that it was the right of the initial inventor and occupant to dispose of the property which had become his own. This has been the majority opinion of Roman jurists and modern philosophers alike. Modern philosophers from Grotius to Kant promoted the right of the labourer to the product of his labour. This was defended based on the fact that the labourer was in possession of the raw material that was designed for the creation of the finished good.¹¹³⁴

Undoubtedly one may find flaws in such arguments, particularly as only a tiny portion of substantial wealth was discovered in a rather straightforward manner. In most cases, they were obtained through the labour of a multiple people, yet in other cases, by business manipulation and in the colonial context by conquest, to name a few instances. In the contemporary world it has become much harder, and only a few goods that are of commercial value are obtained by discovery or first occupancy.¹¹³⁵

For Cohen, there appears to be little ethical self-evidence when it comes to the concept of finders keepers. He also finds no issue with legislation which promotes that a treasure trove shall belong to the states or the monarch rather than to the finder. This would be the case whenever a natural resource would have been found below an individual's property which would as a matter of good law, automatically, belong to the crown or country. Cohen wonders in this context, whether the discoverer of a river should be entitled to all its water.¹¹³⁶ If one was to say for the sake of the argument that the finder should be entitled to full possession that would, according to Cohen, not mean that the owner should use his or her possession arbitrarily or

¹¹³⁴ Ibid, p. 15.

¹¹³⁵ Ibid.

¹¹³⁶ Ibid.

that such an ownership should prevail indefinitely posthumously. However, providing protection for the first occupant or discoverer appears to be in line with the general principle that such possession ought to be protected. Cohen views this general principle as highly relevant for the economy. He also believes that there should be a limit to any given possession, which would mean that the possession is only that of an individual until someone else with a better claim comes along. For Morris Cohen, this is a justifiable position, as it provides security and certainty when it comes to transactions. It also guarantees public peace if there exists relevant legislation that confiscates possession in circumstances which would endanger the public order of a nation. Cohen believed that the distribution of property must always be subject to law and that the law itself must be subject to modifications or amendments. He compares this issue to that of political power, and argues that it would be *ad absurdum* to say that this should never change.¹¹³⁷

We shall now turn our attention to the labour theory as proposed by Cohen. For philosopher Cohen, economic commodities are never the output of a single person but that of the hard labour of many. He also argues that in line with the labour theory, productivity needs to be encouraged and to achieve this aim property must be subject to distribution. Property, therefore, should be distributed with adequate consideration to the productivity needs of the community. He also acknowledges the fact that on the one hand, a considerable amount of property is accumulated by those who are hardly productive, while on the other hand he argues that a considerable number of productive communities do not receive their rewards in the property.¹¹³⁸ According to social activists, like Shiva, Western multinationals are less like innovators and more like pirates of biodiversity.¹¹³⁹ Thus, the

¹¹³⁷ Ibid, p. 16.

¹¹³⁸ Ibid, p. 17.

¹¹³⁹ Marden, Emily: The Neem Tree Patent: International Conflict Over the Commodification of Life, in: Boston College International and Comparative Law Review (1999), Vol. 22, pp. 279-295, p. 280.

multinationals from the pharmaceutical industry have exploited both the plant resources and the traditional knowledge on how to produce relevant medical products.

Morris Cohen draws on the Judeo-Christian religious belief that the first assertion over property is by an individual who needs it rather than the one who has created the same.¹¹⁴⁰ He believes that the only means to justify the dissemination of property in accordance with labour is by proving that it serves the greater social need.¹¹⁴¹ For Cohen, property as one of many human interests cannot be absolute to the detriment of human life in general. He departs from Montesquieu's position that private property is sacrosanct in nature and any interference by the state with these rights should be avoided against all odds. The neem case, does however, showcase that in the context of IPRs an interference by the state (here India) may turn out to be useful. In general, he believes that private property should roam freely and should only be subject to restriction in cases where it collides with the common good.¹¹⁴² While individuals enjoy an inalienable right over private property, the state must intervene for the right not to be denigrated into, for instance, public nuisance. For Cohen, an absolute right over private property would mean that the creation of smell, fire, noise, or other danger would render such property worthless; to avoid such a scenario, property rights must either be limited or attached with positive obligations, which in turn ought to be enforced by the state itself.¹¹⁴³

Moreover, Sir William Searle Holdsworth, a professor of English legal history, noted that the nation state can never be indifferent to the use of the owner over his property. He outlines, what has made its way into various international treaties, that the aforesaid restrictions by the

¹¹⁴⁰ Cohen, Morris R.: *Property and Sovereignty*, in: Cornell Law Review (1927), Vol. 13, Is. 1, pp. 8-30, p. 17.

¹¹⁴¹ Ibid.

¹¹⁴² Ibid, p. 21.

¹¹⁴³ Ibid.

state should not only be applied between the owner of a private property and that of other property owners, but also regarding interest affecting the community as a whole. Such interests would include the following: safety, morals, health, religion, and general welfare. Cohen believes that no community can afford to be indifferent to the exploitation of its disadvantaged and needy citizens by those who wish to indulge their commercial greed.¹¹⁴⁴ In this regard the Indian government should intervene on behalf of the Kani tribe against the U.S. multinational.

Morris Cohen highlights in his work “Property and Sovereignty”, the example of slavery. He raises the question on the consequences of abolishing slavery, and the slave owner having their “property” confiscated. He wonders whether, in such a case, the state would be under the obligation to compensate the slave owners with the full current market value for their slaves. Such a scenario would unquestionably administer shockwaves to the system, and also to the affected community, as a considerable amount of slave owners would be dispossessed of their source of revenue. They would also have lost their status of cultural leader within society. Yet, critiques of the abolitionist movement would argue that it would not necessarily be a desirable outcome for the slave, after a lifetime of servitude, to be released to freedom with all its challenges. Protagonists of the abolitionist movement would counterargue that the slaves have been violently and involuntarily uprooted from their home in Africa and have been subject to unimaginable human rights violations.¹¹⁴⁵ If one were to take both arguments into consideration, one cannot but argue that the slaves must be compensated first. Compensation for Cohen must not be in the form of direct financial reparations, it could, however, be in the form of educational measures and rehabilitation schemes. This

¹¹⁴⁴ Ibid, p. 23.

¹¹⁴⁵ Ibid, p. 24.

may indeed take precedence overcompensation for former slave owners.¹¹⁴⁶

This aspect is even more eminent in contemporary U.S. politics, in which the son of a former slave and first African American, was elected to the U.S. senate from the state of Georgia. Reverend Senator Raphael Gamaliel Warnock also happened to be the senior pastor of Ebenezer Baptist Church in Atlanta, the church which was formerly pastored by none other than Martin Luther King, Jr. Paying tribute to his mother during the Georgian runoffs Rev. Warnock famously stated:

*"Because this is America, the 82-year-old hands that used to pick somebody else's cotton went to the polls and picked her youngest son to be a United States senator,"*¹¹⁴⁷

It suffices to say that the United States has come a long way as a highly educated descendant, with two PhD's, managed to be elected Senator. In this incident, education has at least for the descendent of a slave worked true miracles. In the Kani case, compensation could also take the form of creating schools or hospitals for the community, which could then be financed by Great Earth Companies Inc.

Unsurprisingly, there exists a debate whether international human rights instruments do in fact recognise the right to property.¹¹⁴⁸ A debate has also arisen over whether IPRs should be regarded as personal property.¹¹⁴⁹ Yet, many observers even went a step further to

¹¹⁴⁶ Ibid, p. 25.

¹¹⁴⁷ Karimi, Faith: Raphael Warnock honors the journey of his 82-year-old mother, who as a teen 'used to pick somebody else's cotton'. in: CNN, 2021. - <https://edition.cnn.com/2021/01/06/us/verlene-warnock-pick-cotton-trnd/index.html>, DOA: 23.02.2021.

¹¹⁴⁸ Yu, Peter: Ten Common Questions about Intellectual Property and Human Rights, in: Georgia State University Law Review (2007), Vol. 23, pp. 709-753, pp. 731-736.

¹¹⁴⁹ Raustiala, Kal: Density and Conflict in International Intellectual Property Law, in: UC David Law Review (2007), Vol. 40, pp. 1021-1038, p. 1032.

compare the protection of IPRs with the protection of human rights.¹¹⁵⁰ *Prima facie*, this position seems to be in line with the interpretation of the ECtHR's of Article 1 of Protocol No.1 to the ECHR.¹¹⁵¹ IPRs have also been covered in the right to property as entailed in Article 17 (2) of the Charter of Fundamental Right of the EU.¹¹⁵² Even for those that have been rather reluctant to place IPRs and human rights on equal footing, there seems to be a consensus that the charter does indeed protect the significant human rights attributes of IPRs.¹¹⁵³ Moreover, Article 15 (1) (c) of the ICESCR states that: [t]he States Parties to the present Covenant recognize the right of everyone... [t]o benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.¹¹⁵⁴ Arguably, the original inventor deserves to profit from his labour or invention. Thus, in the Kani case it would be the community that would be profiting from their property rights of the IP, as they have a material interest as a result of their scientific discovery.

The protection of traditional knowledge as well as cultural expression could equally preserve the way of life and economic and cultural heritage of both persons and peoples.¹¹⁵⁵ The promotion of equitable benefit sharing also supports the following rights: self-determination, development, scientific progress well as cultural participation and

¹¹⁵⁰ Yu, Peter: EU Economic Partnership Agreements and International Human Rights, in: Drexel, Josef/ Grosse Ruse-Khan, Henning/ Nadde-Phlix, Souheir (eds.): EU Bilateral Trade Agreements and Intellectual Property: For Better or Worse? Heidelberg: Springer, 2014, pp. 109-131, p. 115.

¹¹⁵¹ Council of Europe: Protocol 1 to the European Convention for the Protection of Human Rights and Fundamental Freedoms, 20 March 1952, ETS 9.

¹¹⁵² See European Union: Charter of Fundamental Rights of the European Union, 26 October 2012, 2012/C 326/02.

¹¹⁵³ Yu, Peter: EU Economic Partnership Agreements and International Human Rights, in: Drexel, Josef/ Grosse Ruse-Khan, Henning/ Nadde-Phlix, Souheir (eds.): EU Bilateral Trade Agreements and Intellectual Property: For Better or Worse? Heidelberg: Springer, 2014, pp. 109-131, p. 115.

¹¹⁵⁴ United Nations Office of the High Commissioner for Human Rights: International Covenant on Economic, Social and Cultural Rights. Adopted and opened for signature, ratification and accession by General Assembly resolution 2200A (XXI) of 16 December 1966 entry into force 3 January 1976. - <https://www.ohchr.org/EN/ProfessionalInterest/Pages/CESCR.aspx>, DOA: 03.03.2021.

¹¹⁵⁵ Graeme, Austin/ Helfer, Laurence: Human Rights and Intellectual Property: Mapping the Global Interface. Cambridge: Cambridge University Press, 2011, p. 3.

development at large of the above-mentioned group. Biodiversity, seeds, the genetic resources of plants, as well as traditional agricultural practices, could be covering rights to health and food. The protection of traditional, as well as cultural knowledge, is significant from a human rights point of view.¹¹⁵⁶ The Declaration on the Rights of Indigenous People, adopted by the UNGA in September 2007, mentioned that:

[i]ndigenous people have the right to maintain, control and develop their cultural heritage, traditional knowledge and traditional cultural expressions, as well as the manifestations of their sciences, technologies and cultures, including human and genetic resources, seeds, medicines, knowledge of the properties of fauna and flora, oral traditions, literatures, designs, sports and traditional games and visual and performing arts. They also have the right to maintain, control, protect and develop their intellectual property over such cultural heritage, traditional knowledge, and traditional and cultural expressions. In conjunction with indigenous peoples, States shall take effective measures to recognize and protect the exercise of these rights.”¹¹⁵⁷

Similarly, UN Declaration on the Rights of Indigenous People, *prima facie*, indicates that there are significant implications for the IPRs protection. Yet this Declaration echoes the wording of UDHR, ICCPR and ICESCR. In this context, Article 27 of the UDHR notes:

[e]veryone has the right freely to participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits. Everyone has the right to the protection of the moral

¹¹⁵⁶ Yu, Peter: EU Economic Partnership Agreements and International Human Rights, in: Drexel, Josef/ Grosse Ruse-Khan, Henning/ Nadde-Phlix, Souheir (eds.): EU Bilateral Trade Agreements and Intellectual Property: For Better or Worse? Heidelberg: Springer, 2014, pp. 109-131, p. 116.

¹¹⁵⁷ United Nations Declaration on the Right of Indigenous People, 13 September 2007. - https://www.un.org/development/desa/indigenouspeoples/wp-content/uploads/sites/19/2018/11/UNDRIP_E_web.pdf, DOI: 01.04.2021, Art. 31 (1) & (2).

and material interests resulting from any scientific, literary or artistic production of which he is the author.”¹¹⁵⁸

Article 27 of the UDHR, although not legally binding, can be used as soft law in arguing that the Kani people do indeed have the IPRs over herbal medicine as their material interest due to their scientific authorship.

In conclusion, as we have seen in previous chapters of this research, the West, in particular the EU, seems to be mindful when it comes to the protection of its own pharmaceutical market and the avoidance of direct competition of the much cheaper generic medication from the Indian subcontinent. Regardless of whether in the case of neem, turmeric, basmati rice, *T. zeylanicus*, or yoga, Indian traditional knowledge has been exploited and patented or otherwise protected by IPRs. While, *prima facie*, Brussels is not necessarily actively directing the efforts of the Western pharmaceutical industry in their endeavours to exploit Indian medicinal traditional knowledge, Brussels seems to be silently condoning the exploitative measures undertaken by Western multinationals from the pharma industry. Brussels’ passive involvement can, in this regard, arguably be seen in its approval of the patent registration by Western multinationals and companies at the EPO. While the EPO, in the neem case, changed its mind and withdrew the challenge, it did however take considerable time and money to archive this, both of which were in short supply for indigenous people, tribal communities and for poor farmers which happened to be the owners of the relevant traditional knowledge.

With regard to financial compensation for the exploitation of the traditional knowledge or more particular, the IPRs of the patented product the situation is rather dim. Arguably in all the exhibits that

¹¹⁵⁸ UN General Assembly, Universal Declaration of Human Rights, 10 December 1948, 217 A (III). - <https://www.refworld.org/docid/3ae6b3712c.html>, DOA: 01.04.2021, Art. 27 (1) & (2).

have been discussed in this chapter there exists an element of biopiracy, given the fact that corporations have commercially exploited the information they gained by traditional knowledge, either in the form of the biological material or in the form of the specific knowledge about a topic itself. The multinational companies were reluctant to provide appropriate compensation to the owner of the traditional knowledge in question. As a matter of fact, the indigenous community have only on exceptional occasions been asked for their consent for the IPRs exploitation. Sadly, willingness by multinationals to compensate the actual owner of the IPRs in question seems to be a rarity. Only in the case of *T. zeylanicus* has the indigenous tribal community of the Kani, as the owner of the traditional knowledge, been compensated by its licensee the Indian manufacturer Arya Vaidya Pharmacy. The U.S. multinational, Great Earth Companies Inc, had indeed purloined the international IPRs of the Kani community without entering a profit-sharing model, as required by the Art. 8 (j) of the CBD and by Art. 5 of the Nagoya Protocol. Cohen seems to concur with this interpretation. He seems to believe that the owner of the IPR in general and the Kani community in particular, ought to be compensated for the exploitation of their traditional knowledge by Great Earth Companies Inc. From a Hindu nationalist point of view every plant, animal, lake, river and hill are considered to be sacrosanct representations of God. The neem tree is considered sacred and is to date being worshipped by Hindu devotees in India. Similarly, yoga has also been claimed by Hindu nationalists as something that is quintessential Indian. Any exploitation of the plant, and Indian traditional knowledge regarding the use of the same by western multinational corporations or companies, would be worth protecting from a Hindu nationalist perspective. Moreover, the illegitimate exploitation of traditional knowledge seems to be in violation with Article 1 of Protocol No.1 to the ECHR, Article 17 (2) of the Charter of Fundamental Right of the EU, and in violation of Article 15 (1) (c) of the ICESCR. Consequently, one could argue that the illegitimate exploitation of traditional knowledge, without prior consent of the owner or rights holder, would qualify as a violation of

international human rights law. Thus, in the Kani case, a violation of the right to property is rather evident. As per the exhibits that have been analysed above, the EU seems to take a laissez-faire approach when it comes to the protection of traditional knowledge and the related IPRs rights for biodiversity from India. In this regard, it is critical to acknowledge that the EPO has issued EU patents to the majority of the exhibits that have been discussed in this chapter. Finally, given the violation of IPRs in the context of traditional knowledge, it seems that the EU would be advised to take a stronger stance when it comes to the protection of traditional knowledge, in order to avoid time-consuming and costly litigations for the owners of traditional knowledge.

7. EU Trade Agreements

Today the EU has emerged as a major economic player on the world stage, with its single currency and its economic influence, as it strives for democracy and human rights. For what it is worth, the Union views itself primarily as both a norm based and responsible international actor. This chapter will consider aspects of international trade agreements of the EU; more precisely, it will look into the higher IPRs (“TRIPS plus”) standards that seem to be part and parcel of both bilateral and multilateral trade agreements of the EU. In doing so, this segment will consider both FTA’s and Economic Partnership Agreements (EPA) of the EU with LDC and developing nations. It will also examine whether the IPRs that are applied by the Brussels could potentially obstruct the full enjoyment of human rights. Finally, this section will also explore whether the EU has acquired the status of a leading global actor.

Before embarking on the subject matter of the EU Trade Agreements, we shall briefly consider the nature of Brussels’ foreign policy. The EU, as a nonstate actor, was *per se* not recognised by other nations, consequently, it could not become a member of all international organisations. Similarly, it has had difficulties in participating in international negotiations. Yet a crucial question for the Union was whether it had indeed acquired the status of an international actor. The Treaty of Maastricht in 1993 turned the informal gathering of EU members into the Common Foreign and Security Policy (CFSP).¹¹⁵⁹ While economic integration within the European Union was possible, for Waltz, the cooperation in foreign and security matters is yet a completely different ballgame.¹¹⁶⁰ According to Hedley Bull, the EU is not an actor in international matters, and it seems unlikely to become such an actor. For Bull, the European Union is indeed a union of

¹¹⁵⁹ Dijkstra, Hylke/ Vanhoonacker, Sophie: The Common Foreign and Security Policy. Oxford Research Encyclopedia of Politics. 2017. -

<https://doi.org/10.1093/acrefore/9780190228637.013.155>, DOA: 12.09.2019.

¹¹⁶⁰ Waltz, Kenneth: Theory of international politics. Reading: Addison-Wesley, 1979, p. 152.

nation states.¹¹⁶¹ Likewise, according to Sjöstedt, in order for the EU to be considered as an international actor, it must indeed behave as one and needs to stick out as an individual unit, in the international system, separate from its member nations.¹¹⁶² After the end of the Cold War and the fall of the Soviet Union in 1991, the EU continued to take a stronger stance in the area of foreign policy. Have said this, it would be a matter of prevarication to indicate that the involvement of the Union in the Yugoslavian civil war was a successful endeavour in Brussels' global politics. Equally, Brussels foreign policy was boosted in 1999 through the formation of novel institutions like the High Representative.¹¹⁶³ Traditionally, the EU has been deemed a civilian power which happened to be an economic powerhouse in the long term, and an armed force in the short run.¹¹⁶⁴ Due to its trade and development policies, Brussels was in a position to place its economic power behind its political ambitions. For instance, the utilisation of economic sanctions has emerged into a beloved foreign policy of Brussels. Similarly, as a civilian power the Union has been focused to settle international differences primarily through diplomatic means, while placing importance to international law.¹¹⁶⁵ Beginning with the subject of fundamental human rights all the way to strong institutions, the Union has been striving to depict its norms on the international community.¹¹⁶⁶ In line with the EU's approach, Manners argues that the ability to convince other states to accept one's norms will equate to

¹¹⁶¹ Bull, Hedley: Civilian power Europe: A contradiction in terms?, in: *Journal of Common Market Studies* (1982), Vol. 21, Is. 2, pp.149–164, p. 151.

¹¹⁶² Sjöstedt, Gunnar: *The external role of the European Community*. Farnborough (UK): Saxon House, 1977, p. 66.

¹¹⁶³ Dijkstra, Hylke/ Vanhoonacker, Sophie: *The Common Foreign and Security Policy*. Oxford Research Encyclopedia of Politics. 2017. -
<https://doi.org/10.1093/acrefore/9780190228637.013.155>, DOA: 12.09.2019.

¹¹⁶⁴ Duchêne, François: *The European Community and the uncertainties of interdependence*, in: Kohnstamm, M./ Hager, W. (eds.): *A nation writ large? Foreign policy problems before the European Community*. Basingstoke (U.K.): Macmillan, 1973, p. 19.

¹¹⁶⁵ Dijkstra, Hylke/ Vanhoonacker, Sophie: *The Common Foreign and Security Policy*. Oxford Research Encyclopedia of Politics. 2017. -

<https://doi.org/10.1093/acrefore/9780190228637.013.155>, DOA: 12.09.2019.

¹¹⁶⁶ Ibid.

the greatest power of all.¹¹⁶⁷ For Brussels, being considered a civilian power has been rather convenient, as it was lacking the relevant military capacity. This notion was anything but controversial, as Hedley Bull has considered the term civilian power as contradictory in nature. For Bull, military might is a prerequisite to obtain an international power status.¹¹⁶⁸

Critics have remarked that the EU is indeed a realist power, hence acting similarly to any other nation on the globe.¹¹⁶⁹ According to Sjursen, both human rights and democracy have also been endorsed by the US.¹¹⁷⁰ Moreover she remarked that there is a very thin line between Brussels displaying itself as a force for good and being a fully fletched imperial power.¹¹⁷¹ The drastic shifting in every rotating world stage, in which emerging powers gradually enter into a competition for power does indeed pose a novel challenge for Brussels as a global actor. This situation, in turn, obliges the Union to reconsider the importance of both norms and interests in the field of foreign policy. Multiple emerging nations have, like New Delhi, attached significance to sovereignty.¹¹⁷² This is indeed complicated, as it is a complex issue, given the unconventional global actor stance of the EU.

It would now be appropriate to turn our attention to the matter of trade agreements. Mostly the mighty, dominant, and ever so powerful multinationals tend to operate in local markets and have enormous financial means; they are not only in the position to lobby governments but to engage in vast marketing operations which aim to undermine

¹¹⁶⁷ Manners, Ian/ Whitman, Richard (eds.): *The foreign policies of European Union member states*. Manchester: Manchester University Press, 2000, p. 253.

¹¹⁶⁸ Bull, Hedley: Civilian power Europe: A contradiction in terms?, in: *Journal of Common Market Studies* (1982), Vol. 21, Is. 2, pp.149–164, p. 151.

¹¹⁶⁹ Hyde-Price, Adrian: “Normative” power Europe: A realist critique, in: *Journal of European Public Policy* (2006), Vol. 13, Is. 2, pp. 217–234, p. 218.

¹¹⁷⁰ Sjursen, Helene: The EU as “normative” Power: How can this be?, in: *Journal of European Public Policy* (2006), Vol. 13, No. 2, pp. 235–251, p. 240.

¹¹⁷¹ Ibid, pp. 241-242.

¹¹⁷² Ibrahim, Azeem: Europe Is Ready for Its Own Army: As the United States retreats, the EU is shaping its own military. in: *Foreign Policy*, 2019. - <https://foreignpolicy.com/2019/09/05/europe-is-ready-for-its-own-army/>, DOA: 10.04.2021.

the flexibility of the TRIPS Agreement.¹¹⁷³ *Prime facie*, multiple developing nations are acting in a reverse manner when it comes to utilising compulsory licenses due to the fear of potential reprisals from Western countries. These states appear to be rather reluctant owing to the fear that foreign direct investors might react in a negative fashion if developing countries were to grant compulsory licences.¹¹⁷⁴ Both the internal pressure, regarding the need to obtain cost effective generic and life-saving drugs, together with the external pressures from the developed nations should by no means be underestimated. Developed nations have indeed mobilised their collective bargaining powers, in addition to their legal instruments, in order to follow through with their partial IPRs regulations when entering into trade agreements.¹¹⁷⁵

There are two global players that have opted to enforce their own IPRs in a strict manner and have thereby furthered their own interests. One such global player is the US and the other being the EU, a supranational organisation. The US has previously entered into bilateral trade agreements with the Asian nations Cambodia and Vietnam; Washington required that these Asian nations would adhere by and comply with IPRs standards which are in line with the TRIPS Agreement.¹¹⁷⁶ *Prim facie*, these appear to be routinely employed terms and conditions. However, this impression should very-well shift once one concludes that neither Cambodia nor Vietnam have been

¹¹⁷³ Ariyarthna, Lasantha/ Kariyawasam, Kanchana: Pharmaceutical Patents and Access to Generic Medicines in Developing Countries, in: European Intellectual Property Review (2020), Vol. 42, Is. 2, pp. 108-118, p. 117.

¹¹⁷⁴ Sulander, Jaakko: The Role of Compulsory Licensing in Improving Access to Essential Medicines in Developing Countries. 2002. - <https://sckool.org/lw-556-intellectual-property-law-20012002.html>, DOA: 24.03.2021.

¹¹⁷⁵ Ariyarthna, Lasantha/ Kariyawasam, Kanchana: Pharmaceutical Patents and Access to Generic Medicines in Developing Countries, in: European Intellectual Property Review (2020), Vol. 42, Is. 2, pp. 108-118, p. 117.

¹¹⁷⁶ Annex to the Trade and Investment Framework Agreement between the United States and Cambodia. 2006. - https://ustr.gov/sites/default/files/uploads/agreements/tifa/asset_upload_file152_9651.pdf, DOA: 23.03.2021.; Annex to the Trade and Investment Framework Agreement between the United States and Vietnam. 2007. - https://ustr.gov/sites/default/files/uploads/agreements/tifa/asset_upload_file81_12935.pdf, DOA: 23.03.2021.

members of the WTO when the bilateral trade agreement was signed.¹¹⁷⁷ Consequently, compliance would not have been compulsive for these nations. This example showcases rather nicely the unsurprising fact that bilateral pressures have also been exercised on developing countries regarding the use of the TRIPS Agreement.

The TRIPS Agreement does indeed offer various instruments that allow developing countries and LDC a degree of flexibility, and enable them to create a balance between pharmaceutical patent protection and their relevant socio-economic aims.¹¹⁷⁸ The flexibilities *inter alia* cover the components of compulsory licences, parallel importation, and transition periods. These flexibilities provided by the TRIPS Agreement were sharpened by the regional and bilateral trade treaties, which were negotiated between the EU and other development countries. A similar approach has been taken by Washington when signing bilateral and regional treaties; the relevant treaties by Brussels are referred to as “TRIPS Plus” agreements. This is since the IPRs’ protection regime contained in these “TRIPS Plus” agreements are stricter than the one provided for by the original TRIPS conventions.¹¹⁷⁹ Equally, IPRs’ protection regimes require that the relevant developing nations that are party to the convention implement TRIPS entirely before the expiry of the transition period offer to developing nations. Alternatively, these developing countries would also be compelled to either join or abide by multilateral IPRs’ treaties.¹¹⁸⁰ To be more precise, by negotiating treaties with developing nations in a bilateral legal or with a group of the developing countries, the EU and the United States do in fact utilise their greater negotiating clout to step up IPRs, and to advance the harmonisation of

¹¹⁷⁷ Ariyarthna, Lasantha/ Kariyawasam, Kanchana: Pharmaceutical Patents and Access to Generic Medicines in Developing Countries, in: European Intellectual Property Review (2020), Vol. 42, Is. 2, pp. 108-118, p. 117.

¹¹⁷⁸ Helfer, Laurence: Pharmaceutical Patents and the Human Right to Health: The Contested Evolution of the Transnational Legal Order on Access to Medicines, in: Halliday, Terence C./ Shaffer, Gregory (eds.): Transnational Legal Orders, in: Duke Law School Public Law & Legal Theory Series No (2015), pp. 311-339, p. 323.

¹¹⁷⁹ Ibid.

¹¹⁸⁰ Ibid.

those rights at a speed that is superior to what is possible under the WTO mechanism.¹¹⁸¹ Moreover, they also conveniently incorporate the patent offices of a variety of developing nations in a system of global governance, which in turn mimics the patent model of major industrialised countries.¹¹⁸² Additionally, in order to negotiate agreements that strengthen the IPRs protection of pharmaceutical patents, both Brussels and Washington launched initiatives for a multilateral treaty in order to enforce civil and criminal enforcement of IPRs. One of the most rigid agreements ranks Anti-Counterfeiting Trade Agreement (ACTA); the following states have been signatories to ACTA: Australia, Canada, Japan, Mexico, Morocco, New Zealand, Singapore, South Korea, Switzerland, USA and the EU. ACTA was seeking to create a new gold standard globally when it comes to IPRs enforcement. It does indeed apply to all types of IPRs and goes beyond the level of protection offered by TRIPS. What appears to be suspicious is that the draft text was kept under wraps until the very last minute, and thereby lacked transparency.¹¹⁸³ A key concern among those who advocated for access to medicine was the fear that the ACTA would impede trade in essential medicine and other pharmaceutical products, by providing the patent holders of essential generic medicines to seize those medicines in transit between states that are members to ACTA.¹¹⁸⁴ This ACTA Agreement was voted down in 2012 by the EU parliament and is no longer applicable for the EU.¹¹⁸⁵

¹¹⁸¹ Organization for Economic Co-operation and Development (OECD): Regionalism and Multilateral Trading Systems. 2003. - <https://www.oecd-ilibrary.org/docserver/9789264101371-en.pdf?expires=1616865116&id=id&accname=oid010942&checksum=12029FB28A9C1690F4BF3DB63DC51276>, DOA: 25.02.2021, pp. 7-169, p.112.

¹¹⁸² Ibid.

¹¹⁸³ Geist, Michael: ACTA Guide, Part Three: Transparency and ACTA Secrecy. 2010. - <https://www.michaelgeist.ca/2010/01/acta-guide-part-three/>, DOA: 25.02.2020.

¹¹⁸⁴ Grosse Ruse - Khan, Henning: A Trade Agreement Creating Barriers to International Trade? ACTA Border Measures and Goods in Transit, in: American University International Law Review (2011), Vol. 26, No. 3, pp. 645-726, p. 650.

¹¹⁸⁵ European Parliament: Everything you need to know about ACTA: Information society. 2012. - <https://www.europarl.europa.eu/sides/getDoc.do?type=IM-PRESS&reference=20120220FCS38611&format=XML&language=EN#title1>, DOA: 25.01.2020.

On another note, a FTA between the EU and Vietnam entered into force in August 2020. Under this FTA, Vietnam is required to commit to a high level of IPRs protection, even beyond those standards that are required by the TRIPS Agreement; the FTA extended the scope of patentability, data protection and patent terms.¹¹⁸⁶ Unlike the EU, the US only has a very limited number of FTA's, namely those with South Korea and Singapore; the US has indeed regularly curtailed the TRIPS flexibility. Washington's FTAs have expanded the scope of patentability, data protection, data exclusivity and patent terms; at the same time, it puts constraints on compulsory licensing and patent revocation. Equally, it also enforces a complete prohibition of parallel imports.¹¹⁸⁷ Sadly, more often than not, health considerations are being used as a trade off in exchange for tariff benefits and preferential market access. Unsurprisingly, these trade agreements are negotiated in a non-transparent manner and often through the means of *in camera* negotiations.¹¹⁸⁸

Consequently, *prima facie*, almost any state that enters an FTA would likely be subject to their TRIPS Agreement flexibilities being curtailed. As these FTAs formally comply with Article 1 (1) of TRIPS, they therefore allow developed nations to mobilise their bargaining power as well as their legal mechanism to limit the flexibilities granted under TRIPS.¹¹⁸⁹ By the same token, the developed nations tend to

¹¹⁸⁶ European Union–Vietnam Free Trade Agreement Ch.12 (Agreed text as of January 2016). 2016. - <http://ceecvn.org/eu-vietnam-free-trade-agreement-agreed-text-as-of-january-2016/>, DOA: 24.03.2017.

¹¹⁸⁷ Burri, Mira/ Serrano, Omar: Making Use of Trips Flexibilities: Implementation and Diffusion of Compulsory Licensing Regimes in Brazil and India. in: World Trade Institute Working Paper No. 1. 2016. - <http://dx.doi.org/10.2139/ssrn.2748447>, DOA: 24.03.2021.

¹¹⁸⁸ El Said, M./ Kapczynski, A.: Access to Medicines: The Role of intellectual Property Law and Policy. Working Paper prepared for the Third Meeting of the Technical Advisory Group of the Global Commission on HIV and the Law. 2011. - <https://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/t/56547292e4b0e74bc872ee41/1448374930129/ACCESS-TOMEDICINESTHE-ROLE-OFINTELLECTUALPROPERTY-LAW-ANDPOLICY-1+%281%29.pdf>, DOA: 01.11.2017, pp. 1-19, p.13.

¹¹⁸⁹ See Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994), Art. 1 (1).

implement stronger IPRs protection that goes far beyond the requirements of TRIPS; in order to resist this eminent pressure from developed nations, developing countries are forced to develop a significant degree of economic and political clout. This is indeed something that is lacking on the part of the developing nations.¹¹⁹⁰ Unfortunately, it becomes evident that the flexibilities provided by TRIPS are not broad enough, while at the same time, they are subject to procedural and other limitations, thereby resulting in underutilisation of those flexibilities earmarked by the agreement.¹¹⁹¹

As examined above, pressures have been employed by developed nations through multiple means, starting from bilateral trade agreements and through the underutilisation of flexibilities offered by the TRIPS Agreement. Moreover, multilateral bodies have also engaged in endeavours to curtail the flexibilities granted by the TRIPS Agreement. It is therefore unsurprising that developing countries have rather been circumspect when it comes to the utilising the flexibilities offered by TRIPS.¹¹⁹² In this context, it would be worth noting that the EU is indeed a member of the WTO and of the TRIPS Agreement itself.¹¹⁹³

It would now be apt to turn our attention to the subject matter of Economic Partnership Agreement (EPA) of the EU, in order to investigate whether IPRs and human right are included in these EPA's, and whether there are potential complexities, hurdles and ambiguities, and challenges in the interplay between both rights. The EU has an EPA or a plurilateral with the following regions: EU-CARIFORUM, EU-Pacific, EU-ESA, EU-Cameroon, EU-SADC and

¹¹⁹⁰ Ariyaratna, Lasantha/ Kariyawasam, Kanchana: Pharmaceutical Patents and Access to Generic Medicines in Developing Countries, in: European Intellectual Property Review (2020), Vol. 42, Is. 2, pp. 108-118, p. 117.

¹¹⁹¹ Ibid.

¹¹⁹² Ibid.

¹¹⁹³ European Commission: Access to Markets, Intellectual property rights and geographical indications. - <https://trade.ec.europa.eu/access-to-markets/en/content/intellectual-property-rights-and-geographical-indications>, DOA: 01.04.2021.

EPAs with West Africa.¹¹⁹⁴ EPAs of the EU contains the provisions that cover the abuse of IPRs and provisions on competition law; it is obvious that principally competition can be healthy when it comes to the enhancement of the value chain. Competition does indeed improve productivity, product quality and the reduction in costs. This could eventually become a win-win situation for the consumer who would receive a high-quality product for an affordable price. Arguably, the beneficial nature of competition law can easily be pursued, provided there exists a level playing field regarding competitions among equals; however, the case would be considerably different when it comes to competitors that are not on unequal footing. For instance, this is the case with regard to the EPA's between developing nations or LDC and the EU.

According to the EU Commission, the EU trade policy supports strong IPR standards that have an impact on both the Union and oversees. The IPR legal framework for international trade of the European EPA entails IP rights that promote innovation, an origin of product guarantees and ensure the genuine character, supplemented by prohibiting measures against any violations of the rights in question.¹¹⁹⁵ Through its trade policy, the EU is not only promoting the protection of IPRs, but also protecting consumers against counterfeit goods (including medicines) that are not in compliance with the health and safety regulation of the Union.¹¹⁹⁶ In its trade negotiations with both other states and regions the EU aims to establish IP standards. EU's IP standards tend to go beyond those issued by the WTO and the TRIPS Agreement. In fact, they happen to address specific IPRs

¹¹⁹⁴ Berger, Axel/ Brandl, Clara/ Schwab, Jakob et. al.: The Trade Effects of the Economic Partnership Agreements between the European Union and the African, Caribbean and Pacific Group of States: Early Empirical Insights from Panel Data. in: German Development Institute, Discussion Paper. 2020. - https://www.die-gdi.de/uploads/media/DP_7.2020.pdf, DOA: 01.04.2021.

¹¹⁹⁵ European Commission: Access to Markets, Intellectual property rights and geographical indications. - <https://trade.ec.europa.eu/access-to-markets/en/content/intellectual-property-rights-and-geographical-indications>, DOA: 01.04.2021.

¹¹⁹⁶ Ibid.

concerns and issues of the state in question.¹¹⁹⁷ Brussels also promotes the improvement of IPR standards in developing nations. The EU Commission further argues that IPR protection is significant for European businesses and would likewise attract foreign investment, technology transfer¹¹⁹⁸, research as well as innovation, which inevitably is beneficial for developing nations and LDCs.¹¹⁹⁹

Moreover, Brussels also aims to facilitate access to medicines in developing countries. According to the EU Commission, the EU wants to strike the right balance between IPR protection of R&D of pharmaceutical enterprises into new medicines, with the requirement to ensure global access to these medications.¹²⁰⁰ In order to strike the right balance, the EU modified its policies on IPRs linked to medicines as per the development level and needs of its treaty partners. In doing so, Brussels argues to support low- and middle-income countries in the following areas: R&D of medicines, their public health system, and trade rules facilitating access to medicines with global health organisations.¹²⁰¹

The intellectual property chapter in the EPA acts as a two-edged sword when it comes to the issue of human rights. It can either promote human rights or frustrate the same; yet many commentators seem to be rather convinced of the latter.¹²⁰² On the normative level, the language used in the IPRs chapter of the EPA itself can lead to tensions. More precisely, it can either create inconsistencies or

¹¹⁹⁷ Ibid.

¹¹⁹⁸ See Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994), Arts 66 (2) & 67.

¹¹⁹⁹ European Commission: Access to Markets, Intellectual property rights and geographical indications. - <https://trade.ec.europa.eu/access-to-markets/en/content/intellectual-property-rights-and-geographical-indications>, DOA: 01.04.2021.

¹²⁰⁰ Ibid.

¹²⁰¹ Ibid.

¹²⁰² Yu, Peter: EU Economic Partnership Agreements and International Human Rights, in: Drexl, Josef/ Grosse Ruse-Khan, Henning/ Nadde-Phlix, Souheir (eds.): EU Bilateral Trade Agreements and Intellectual Property: For Better or Worse? Heidelberg: Springer, 2014, pp. 109-131, p. 115. 109-131, p. 118.

conflicts between the IPRS chapter and international human rights instruments. These may also result in lost prospects because of the EPA's failure to unambiguously promote human rights protection, despite the fact that such a protection would not directly be in dispute with the IPRs chapter. Unfortunately, *prima facie*, there seems to be an erroneous and non-evidenced supposition that an increase in IPRs are always a better option.¹²⁰³ Accordingly, developed nations have, against all odds, strengthened both their safeguarding and enforcement capacities of IPRs without paying due consideration to the side effects when it comes to the field of human rights.¹²⁰⁴

Given the fact that there are a multitude of areas in which there exists a tension between IPRs and human rights, we shall also consider access to medicine for LDCs and developing countries. This area of patent protection is characterised by a strong patent protection, limiting parallel importation, clinical trial data, and last, but not least, the mandate for seizing in transit generic medicines.¹²⁰⁵ While virtually all economists would concur that any level of IPRs protection is better than none, it does not mean that by the same token that a strong level of IPRs protection is better than a moderate one.¹²⁰⁶ In this context, it is hardly surprising that in comparison to the intellectual property system, it is the human rights counterpart that does indeed consist of a dissimilar language, culture and forum; this dissimilarity also extends to the field of conflict resolution and negotiation. Human rights advocates find themselves, at times, diametrically opposed to the IPRs' holders and their supportive governments.¹²⁰⁷ The latter is often subject to a trade-based perspective while adopting the approach predefined by the TRIPS. This situation has led to harsh criticism by

¹²⁰³ Ibid.

¹²⁰⁴ Ibid.

¹²⁰⁵ Ibid.

¹²⁰⁶ Lerner, J: The patent system in a time of turmoil, in: WIPO Journal (2010), No. 2, pp. 28–37, p. 32.

¹²⁰⁷ Gervais, Daniel: Intellectual property and human rights: Learning to live together, in: Torremans PLC (ed.): Intellectual Property and Human Rights. Alphen aan den Rijn: Kluwer Law International, 2008, p. 22.

human rights protagonist who have critiqued both the WTO and its Appellate Body for its shortcomings in the field of human rights protection.¹²⁰⁸ Equally, UN human rights bodies have engaged in harsh criticism of the TRIPS Agreement itself. Resolution 2000/7 of the UN Sub-Commission on the Promotion and Protection of Human Rights declared that:

*[t]he implementation of the TRIPS Agreement does not adequately reflect the fundamental nature and indivisibility of all human rights.*¹²⁰⁹

The UN Sub-Commission noted the conflict between the TRIPS Agreement and International human rights law. Similarly, it highlighted the social functions of the IP and reminded governments about the superiority of human right duties over economic agreements and its accompanied policies. Moreover, it requires that all, domestic, regional and international economic policies take international human right norms and standards, in their entirety, into consideration when creating global economic policies.¹²¹⁰ Former UN High Commissioner for Human Rights, Mary Robinson, while criticising the TRIPS Agreement mentioned, that by requiring a minimum standard of IPRs protection TRIPS has circumvented a high-level of autonomy, as well as room for adequate human rights policies from the WTO members. Likewise, TRIPS contained human rights protection that have been established in industrialised nations, and not in those with lesser degrees of development.¹²¹¹ More importantly, LDCS and other developing nations are required to undertake a level of IPR protection which in turn does not account for those states' domestic needs, conditions or national interests. Robinson also mentioned that human

¹²⁰⁸ Broude, Tomer: It's Easily Done: The China - Intellectual Property Rights Enforcement Dispute and the Freedom of Expression, in: Journal of World Intellectual Property (2009), Vol.13, pp. 660–673, p. 664.

¹²⁰⁹ Commission on Human Rights: Report of the High Commissioner on Economic, Social and Cultural Rights: The Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights (2001) - E/CN.4/Sub.2/2001/13.

¹²¹⁰ Ibid.

¹²¹¹ Ibid.

rights' aspects, such as the promotion of public health, are an exception in the TRIPS provisions rather than being a guiding principle of the agreement.¹²¹² The former Human Rights Commissioner recognised the fact that those flexibilities that have been provided for by the TRIPS Agreement were nonetheless a vital tool that would help balance the international IP system; WTO members would, however, require both relevant expertise and pecuniary, as well as other resources, in order to fully benefit from these flexibilities.¹²¹³ The United Nations Conference on Trade and Development (UNCTAD) mentioned the utilisation of the flexibilities offered by TRIPS have been problematic, due to high costs linked to the complicated and onerous technical prerequisites for both enactment and execution of adequate domestic legislation.¹²¹⁴ Apart from the normative and legislative constraints, the obligations contained in the TRIPS Agreement could redirect already scarce fiscal resources from other vital areas, such as public health.¹²¹⁵

Before embarking on the subject of bilateral and plurilateral treaties, we shall consider the relevant guiding principles and objectives of the EU Trade Policy. According to Article 207 (1) Treaty on the Functioning of the European Union (TFEU), the trade policy (common commercial policy) of the EU ought to "be conducted in the context of the principles and objectives of the Union's external action."¹²¹⁶ Both the relevant principles and objectives are defined further in Article 21 of Treat of the European Union (TEU). Moreover, Article 21 (2) of the TEU entails multiple principles and objectives. However, for the

¹²¹² Ibid.

¹²¹³ Ibid.

¹²¹⁴ UNCTAD: The Least Developed Countries Report 2007: Knowledge, Technological Learning and Innovation for Development. Geneva, 2007.

¹²¹⁵ Yu, Peter: EU Economic Partnership Agreements and International Human Rights, in: Drexel, Josef/ Grosse Ruse-Khan, Henning/ Nadde-Phlix, Souheir (eds.): EU Bilateral Trade Agreements and Intellectual Property: For Better or Worse? Heidelberg: Springer, 2014, pp. 109-131, p. 123.

¹²¹⁶ See Consolidated Versions of the Treaty on European Union and the Treaty on the Functioning of the European Union (TFEU) [2016] OJ C202/1.

purpose of this research we shall limit our focus on two aspects only. The relevant two aspects are:

“to consolidate and support democracy, the rule of law, human rights and the principles of international law”¹²¹⁷ and to “foster the sustainable economic, social and environmental development of developing countries, with the primary aim of eradicating poverty.”¹²¹⁸

Thus, the principles and objectives of the European trade policy include human rights as well as the sustainable economic and social development of developing countries.

We shall now turn our attention to the bilateral and plurilateral trade agreements of the EU. As has been mentioned above, the EPAs have established considerable tensions between IPRs and human rights; similarly, the bilateral and plurilateral agreements of the EU have also raised further apprehensions. Entering into treaties outside the multilateral system has, at times, resulted in weakening the multilateral approach to international rules setting in the fields of IPRs and human rights.¹²¹⁹ By encouraging states to provide higher standards of IPRs protection in comparison to multilateral treaties, such as the TRIPS Agreement, the EPAs, *prima facie*, have caused considerable challenges to the stability of international human rights and the international trading system.¹²²⁰ Such bilateral and plurilateral treaties, between the EU and another state or a group of states, may indeed estrange a state’s other trading partners, thereby making it increasingly challenging for a third country to enter into a multilateral

¹²¹⁷ Ibid, Art. 21 (2) (b).

¹²¹⁸ Ibid, Art. 21 (2) (d).

¹²¹⁹ Yu, Peter: EU Economic Partnership Agreements and International Human Rights, in: Drexel, Josef/ Grosse Ruse-Khan, Henning/ Nadde-Phlix, Souheir (eds.): EU Bilateral Trade Agreements and Intellectual Property: For Better or Worse? Heidelberg: Springer, 2014, pp. 109-131, p. 124.

¹²²⁰ Yu, Peter: Sinic Trade Agreement, in: U.C. Davis Law Review (2011), Vol. 44, pp. 953-1028, p. 976.

trade discussions with that state in the future.¹²²¹ The fragmentation of the international legislative structure in the form of the EPA has compelled countries to redirect their meagre resources, energy, time and concentration from other international intergovernmental initiatives; this would also include the expansion of the global human rights system. Particularly, in less-developed nations with limited resources both financially, and in terms of personnel, it could mean that there would be a potential overlap between the resources earmarked for negotiation of international human rights conventions, and those dedicated to developing IPRs. In this context, the EPA negotiations would unavoidably further diminish the resources that could otherwise be utilised for strengthening the safeguarding of human rights.¹²²² Moreover, supranational organisations like the EU are not able to dedicate the same level of energy, time and attention to negotiations if they had been placed into the position to negotiate bilateral-, plurilateral- and multilateral agreements alongside each other.¹²²³ In this regard, both Benvenisti and Downs have observed international regulatory organisations with overlying jurisdiction and boundaries could assist powerful states and supernational organisations, such as the EU, to maintain their supremacy in the international domain.¹²²⁴ Raustiala has noted that the increasing complexity could also cause what could be termed as a form of “strategic inconsistency”, which assists with the alteration, as well as weakening, unfavourable legislation in the field of international human rights. The complex situation could significantly disturb the current dynamic between both international institutions and actors. This

¹²²¹ Ibid.

¹²²² Yu, Peter: EU Economic Partnership Agreements and International Human Rights, in: Drexl, Josef/ Grosse Ruse-Khan, Henning/ Nadde-Phlix, Souheir (eds.): EU Bilateral Trade Agreements and Intellectual Property: For Better or Worse? Heidelberg: Springer, 2014, pp. 109-131, p. 124.

¹²²³ Directorate General for Trade: European Commission. Strategy for the Enforcement of Intellectual Property Rights in Third Countries. OJ 2005 C 129. - <https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2005:129:0003:0016:EN:PDF>, DOA: 01.09.2020.

¹²²⁴ Benvenisti, Eyal/ Downs, George: The Empire's New Clothes: Political Economy and the Fragmentation of International Law, in: Stanford Law Review (2007), Vol. 60, pp. 595–631, p. 603.

situation in turn could diminish collective bargaining capacity, as well as the influence that was attained by the LDC and developing countries through their collective bargaining initiatives in the past.¹²²⁵ In order to rectify this situation, a state can request the inclusion of human rights impact assessments before adopting new EPAs or the introduction of new regulations that seek to execute those conventions. In fact, states can take advantage of the existing human rights structure to monitor the effects of IPRs on human rights protection. For instance, analysts have proposed to use UN monitoring mechanism to relieve the conflict between IPRs and human rights.¹²²⁶ While these monitoring mechanisms are perhaps not as effective as to resolve the conflict, they do, however, have a substantial benefit. Despite the fact that these institutions lack rewarding as well as sanctioning powers when it comes to the human rights compliance, the human rights record of states is published through the state reporting system, which provided LDC and developing nations with the ability to expose and challenge other nation states and the EU for their shortcoming when it come to the protection of human right standards.¹²²⁷ Finally, a greater utilisation of the international human rights system could assist both LDC and developing nations to make use of the flexibilities provided by the TRIPS treaty.

Finally, multiple developing countries seem to be reluctant to apply the flexibilities that have been permitted by the EU, for instance compulsory licences with regard to medicine. Developing nations fear that if they fail to comply with the EU's higher IPRS standards,

¹²²⁵ Raustiala, Kal: Density and Conflict in International Intellectual Property Law, in: UC David Law Rev (2007), Vol. 40, pp. 1021-1038, pp. 1027-1028.

¹²²⁶ Yu, Peter: EU Economic Partnership Agreements and International Human Rights, in: Drexl, Josef/ Grosse Ruse-Khan, Henning/ Nadde-Phlix, Souheir (eds.): EU Bilateral Trade Agreements and Intellectual Property: For Better or Worse? Heidelberg: Springer, 2014, pp. 109-131, pp. 127-128.

¹²²⁷ Beutz Land, Molly: Protecting Rights Online, in: Yale Journal of International Law (2009), Vol. 34, pp. 1–46, pp. 29-30.

Brussels appears to be willing to retaliate by withholding foreign direct investment that were earmarked for the state in question. Brussels appears to push for the “TRIPS plus” standard of IPRs protection, which is indeed higher than is required by the WTO. Such a requirement is placing an undue burden on LDC and developing nations that have entered into trade agreements with the EU, and at the same time these agreements tend to curtail, Brussels’ contracting partners, from utilising the flexibility provided by the WTO. In this context, one needs to keep in mind that the utilisation of the flexibilities provided by the WTO are, for instance, fundamental when it comes to the acquisition of affordable medicine. The EU claims to promote strong IPRs standards with the view to protect consumers against, for instance, counterfeit medicines and other substandard goods. It also maintains that the high IPRs standards are quintessential for its businesses, and for the promotion of international trade. In doing so, the EU is possibly covertly creating a level playing field with regard to IPRs standards, which are both higher than is required by the WTO and highly beneficial for itself. Arguably, in requiring the implementation of the higher IP standards from the nations that are party to the EU trade agreements, Brussels is protecting itself against cheaper competition from developing countries and LDC. This in turn is beneficial for the EU, to say the least. While the EU is well accustomed to its own IP standards, the developing nations tend to struggle with the burden to comply and implement the higher IP standards. In order to comply with the EU’s high level of IPRs protection, these poor nations require time, money and resources, all of which are undeniably in short supply for most of the LDC and developing nations. In summary, the IP requirements issued by the EU in its trade agreements tend to be burdensome for the other contracting nations, and go way beyond what is required by the WTO.

7.1. EU-India FTA

A comprehensive FTA between the EU and India seems to be rather apt, as both have emerged as major global actors in the area of trade at the beginning of the 21st century. This section will investigate both the potential and the challenges for such an agreement to come to fruition. To begin with, we shall turn our attention to EU-Indian negotiations on access to medicine, in the context of an FTA between the two unions. A key question that arises, in this context, is whether an FTA between the EU and India would restrict access to affordable medicines in developing nations. The EU Commission states that it has recognised New Delhi's right, as well as capability, for the production and export of lifesaving (essential) generic medicines to other developing nations. As for Brussels, the IPR provision has not been intended to dilute these rights. The Commission further argues that it has suggested an exemption clause in the FTA negotiations with New Delhi, which would guarantee India's liberty to produce, as well as export, essential drugs in harmony with the TRIPS Agreement, Doha Declaration and the utilisation of compulsory licensing, which is essential for LDC and developing nations.¹²²⁸ For the EU, data exclusivity remains a crucial factor, given its relevance to the development and marketing of new drugs, and demands that the inventor conducts vast and cost intensive research and testing. The completion of the R&D process routinely takes more than ten years, and justifies appropriate legal protection in accordance with Art 39 (3) of the TRIPS Agreement.¹²²⁹ The European Commission, *prime facie*, appears to be committed to issue the required flexibility, and it is showing the willingness to take the Indian legal system into consideration. Equally, the commission seems to be ready to take New Delhi's status as a development country, and its role as the

¹²²⁸ Third Word Resurgence: The EU-India free trade agreement and access to medicines. 2010. - <https://www.twn.my/title2/resurgence/2012/259/cover04.htm>, DOA: 04.05.2019.

¹²²⁹ See Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994), Art. 39 (3).

world's largest producer of generic medicine, into consideration.¹²³⁰ With regard to the enforcement of border measures, the EU intends to include in the proposed FTA the provision that in transit generic medicine will not be dealt with. The Commission has been willing to modify the relevant Regulation to elucidate the relevant enforcement measures when it comes to in transit generic medicines. The aim, according to Brussels, would be to prevent unnecessary impediment to the access of medicine while transiting through its territory.¹²³¹

The EU also asserts that it had engaged in an initiative to introduce a mechanism regarding inexpensive medicine through the eradication of importation tariffs on generic medicines. Brussels encourages measures directed at cooperative procurement of drugs, as well as vaccinations, both severally by individual members states, and jointly by the Union through its contributions to the Global Fund to Fight AIDS, Tuberculosis and Malaria and to GAVI (Vaccine Alliance).¹²³²

Moreover, the Union supports global health organisations and initiatives in various forms. Brussels provides financing for the provision of quality medicines, vaccines, and commodities directly to developing countries, and supports the relevant supply chain with the aim of assisting with the distribution of medicines.¹²³³ Brussels has also purported to possess a strong voice when it comes to the access of drugs on the global stage, such as with the WHO. In this context, Brussels supports the endeavours of the WHO in putting together a list of essential medicines, together with the provision of guidance when it

¹²³⁰ Statista: Value of Indian pharmaceutical exports from financial year 2012 to 2020. 2021. - <https://www.statista.com/statistics/1038136/india-value-of-pharmaceutical-exports/>, DOA: 01.03.2021.

¹²³¹ Third Word Resurgence: The EU-India free trade agreement and access to medicines. 2010. - <https://www.twn.my/title2/resurgence/2012/259/cover04.htm>, DOA: 04.05.2019.

¹²³² Prats Monné, Xavier: European Commission: United Nations Secretary-General's, High-Level Panel on Access to Medicines. 2016. - <http://www.unsgaccessmeds.org/inbox/2016/2/16/contributioneuropean-commission>, DOA: 03.08.2019.

¹²³³ European Commission: Access to Medicines EU global health actions for low- and middle-income countries. Fact sheet. 2016. - https://trade.ec.europa.eu/doclib/docs/2016/april/tradoc_154443.pdf, DOA: 21.09.2018.

comes to rational use of the same. The Union also endorses, as part of the WHO's Global Strategy on R&D, the initiative to identify and assist the research into developing new, or more targeted, drugs to fight neglected diseases in developing nations with 2 million EUR.¹²³⁴ The EU has also been contributing to the Global Fund to Fight AIDS, Tuberculosis and Malaria; equally, the Union jointly with its member states has, with USD 3.5 billion per annum, emerged as the largest contributor to this Global Fund.¹²³⁵ Brussels has also acknowledged the fact that developing countries often lack the capacity to evaluate and pre-qualify medicines for entry into their markets. In fact, most of these developing nations rely on the pre-qualification procedures undertaken by the WHO, the US, or the EU; on behalf of the EU, the EMA addresses this lack of capability in developing countries. For Brussels, the EMA's efforts, *prima facie*, could lead to the fact that medicines reach the markets of developing countries, and ensure the safety, efficacy and quality of these medicines.¹²³⁶

The EU and India have been struggling to agree on an FTA since 2007. Diplomatic relations between the EU and the Indian Union were established as early as in 1962. In 1994, both Unions signed a Cooperation Agreement, which in turn provided the legal basis for bilateral relations. This agreement has improved cooperation in the area of politics and economy. The strategic partnership between both entities was initiated in 2004.¹²³⁷ After 16 rounds of talks between 2007-2013, the negotiations between both entities came to a halt amidst strong differences, in particular, due to the demands of the EU for a reduction in import duties on automotive and wines by New Delhi. Both cuts would have been *inter alia* highly beneficial for Germany and

¹²³⁴ Ibid.

¹²³⁵ Ibid.

¹²³⁶ Ibid.

¹²³⁷ European Union External Action: Facts Sheet. EU-India relations. 2016. - https://eeas.europa.eu/archives/docs/factsheets/docs/eu-india_factsheet_en.pdf, DOA: 10.09.2019.

France.¹²³⁸ Moreover, *prima facie*, as discussed above, the competition arising from the export of cheap generic medicine from India to the EU represents a major obstacle for the creation of an FTA between the EU and India.

Nonetheless an FTA between both unions would bring a substantial benefit for India. However, New Delhi is not willing to agree with Brussels conditions regarding India's pricing of agricultural products, procurement policies, data protection and IPRs.¹²³⁹ India has perceived that if an FTA became reality, it would grant Brussels unprecedented power to interfere with the subcontinent's sovereignty; another side effect would be that the inequality between developing nations and developed countries would further be underpinned.¹²⁴⁰ New Delhi appears to be anything other than amused when it comes to agreeing on the minutiae of the FTA, as the subcontinent is not amongst equals when negotiating with Brussels. The EU's push to come up with an FTA in a speedy manner seems to have misjudged the Indian concept of fairness, equality, and the legitimacy of processes and outcomes.¹²⁴¹ The BJP government had previously interrupted bilateral FTA negotiations due to the ban of Indian generic drugs in 2015.¹²⁴² With regard to a fully-fledged FTA, there seem to be more potholes than smooth pastures ahead; the EU will have to come up with more innovative solutions in order to conclude an FTA with the Indian Union.

¹²³⁸ Indian Global Business: Brexit clears the decks for India's FTAs with UK and EU. 2021. - <https://www.indiaglobalbusiness.com/analyses/snap-analysis/brexit-clears-the-decks-for-indias-ftas-with-uk-and-eu>, DOA: 27.12.2020.

¹²³⁹ Nataraj, Geethanjali: Why can't India and the EU sign an FTA. East Asia Forum. 2013. - <https://www.eastasiaforum.org/2013/06/14/why-can-t-india-and-the-eu-sign-an-fta/>, DOA: 18.08.2019.

¹²⁴⁰ Dutta, Sagnik: Negotiating a sell-out. in: Frontline. 2013. - <https://hillel.org/2013/05/01/negotiating-a-sell-out/>, DOA: 13.12.2016.

¹²⁴¹ Kavalski, Emilian: The EU–India Strategic Partnership: Neither Very Strategic, Nor Much of a Partnership, in: Cambridge Review of International Affairs (2016), Vol. 29, Is. 1, pp. 192-208, p. 203.

¹²⁴² See chapter 8.1. for more details.

Finally, Brussels has initiated negotiations with New Delhi aiming to establishing an FTA. As a consequence of the seizure of generic medicine from India, the EU seems to be willing to ease restrictions of generic drugs from India that are only entering the EU in-transit. Brussels has also acknowledged New Delhi's position as the largest producer of generic medicines in the world, which in turn will be highly significant during FTA negotiations. At the time of writing, the FTA negotiations happen to be at a standstill. Bilateral negotiations are on hold due to the 2015 ban of Indian generics, which in turn has led to further scepticism regarding the signing of an FTA. While in the long run an FTA appears to be beneficial for both entities, the EU's obsession with IPRs protection, particularly in the area of generic medicine, there remains a considerable obstacle for the signing of such an agreement.

8. Impact Factors

The following three sub-chapters will consider the impact factors that influence the bilateral relations between the EU and India. These impact factors will highlight issues that are both beneficial and counterproductive when it comes to the bilateral relations between both entities. The first sub-chapter will cover the 2015 dispute between India and the EU over ban of 700 generic medicines from India. Moreover, this section will also consider the EU's unwillingness to waive the IPRs protection of the Covid-19 vaccines. The second sub-chapter will examine Brexit and its consequences, or the UK's relations with the EU and Indian. It will also consider the Covid-19 vaccine distribution issues on the backdrop of the Covid-19 pandemic. In particular, the dispute between Brussels and London over the distribution of the Covid vaccine. The third and final sub-chapter will cover aspects of both unilateralism and multilateralism; it will examine whether the EU and India are taking a unilateral or multilateral position when engaging in international relations.

8.1. Economic Interests v. Protectionism

In 2015, the European Union banned the marketing of approximately 700 generic medicines due to suspected manipulation of clinical trials conducted by the Indian pharmaceutical research company GVK Biosciences based in Hyderabad.¹²⁴³ It was the biggest EU-wide interruption, as well as suspension of sales and distribution of generic medicines ordered by the EU Commission. The ban on sale and distribution encompassed pharmaceutical firms, drug stores, outlets, and wholesale dealers. Thus, the drugs affected by the ban lost their eligibility to be used in the Union from 21 August 2015 onward. Most of these banned generic medicines were copies of drugs that had once been patented and were at the time of the ban off patent protection. The aforementioned Hyderabadi generics were retailed in the European market for numerous years without any complaints having been raised regarding the quality or effectiveness of the drugs or any adverse reports.¹²⁴⁴ Unfortunately, Brussels decision was yet another setback when it comes to the goodwill of New Delhi's pharmaceutical industry. The Indian pharmaceutical manufacturing sector has gained a steady share of the global generics market (around 40%) due to India's ability to make a large amount of affordable generic medicines.¹²⁴⁵ Indian-made generics had considerable impact on reducing the global costs for pharmaceuticals. This result did not only have positive consequences, as pharmaceutical companies from Europe and the United States were exasperated and lobbied their respective governments to cease, what

¹²⁴³ The Hindu: EU bans 700 generic drugs for manipulation of trails by GVK Biosciences. 2018. - <https://www.thehindubusinessline.com/companies/eu-bans-700-generic-drugs-for-manipulation-of-trials-by-gvk/article7464217.ece>, DOA: 20.03.2018.

¹²⁴⁴ Sen, Amiti: India may drag EU to WTO if drugs ban is not lifted. in: The Hindu. 2018. - <https://www.thehindubusinessline.com/economy/india-may-drag-eu-to-wto-if-drugs-ban-is-not-lifted/article7508529.ece>, DOA: 20.03.2018.

¹²⁴⁵ Financial Times: Generic drugs ban prompts India to freeze EU trade talks: Brussels to stop selling the drugs amid concerns about the integrity of clinical trials in India. 2015. - <https://www.ft.com/content/4ded8ca4-3b8a-11e5-bbd1-b37bc06f590c>, DOA: 20.03.2018.

was considered by them, a means by India to suppress patent innovation.¹²⁴⁶

The government in New Delhi has made it clear that it had found no proof of data manipulation from the Hyderabadi company and engaged in talks with EU authorities in order to lift the ban.¹²⁴⁷ The subcontinent seemed to be anxious, as that the decision of the Union was rooted on commercial considerations, instead of health reasons. This might be because Indian generic medicines have been available at a fractional cost of the patented versions of the drugs that had been offered by major pharmaceutical companies which are *inter alia* based in the EU.¹²⁴⁸ Moreover, the Indian drug exports are worth around \$15 billion annually.¹²⁴⁹ According to an Indian official, the key notion behind this move might have been to discourage the manufacturing of generic medicines from India (veiled protectionism). For New Delhi, Brussels' move appears to be protectionism in disguise in support of the major pharmaceutical producers in the EU. Indian Ministry of Commerce and Industry spokesperson, Rajinder Chaudhary, expressed the subcontinent's concern about Brussels' imposition of a ban on the sale of medicines.¹²⁵⁰ As a consequence, India considered the possibility of suing the EU, in front of the WTO, for the unjustified banning of 700 Indian medicines which had been clinically examined

¹²⁴⁶ EURACTIV: EU, India working to resolve trade row over generic drugs. 2015. - <https://www.euractiv.com/section/trade-society/news/eu-india-working-to-resolve-trade-row-over-generic-drugs/>, DOA: 20.03.2018.

¹²⁴⁷ EURACTIV: India suspends trade talks with the EU over generic drugs ban. 2015. - <https://www.euractiv.com/section/health-consumers/news/india-suspends-trade-talks-with-the-eu-over-generic-drugs-ban/>, DOA: 20.03.2018.

¹²⁴⁸ EURACTIV: EU, India working to resolve trade row over generic drugs. 2015. - <https://www.euractiv.com/section/trade-society/news/eu-india-working-to-resolve-trade-row-over-generic-drugs/>, DOA: 20.03.2018.

¹²⁴⁹ Sen, Amiti: India may drag EU to WTO if drugs ban is not lifted. in: The Hindu. 2018. - <https://www.thehindubusinessline.com/economy/india-may-drag-eu-to-wto-if-drugs-ban-is-not-lifted/article7508529.ece>, DOA: 20.03.2018.

¹²⁵⁰ EURACTIV: EU, India working to resolve trade row over generic drugs. 2015. - <https://www.euractiv.com/section/trade-society/news/eu-india-working-to-resolve-trade-row-over-generic-drugs/>, DOA: 20.03.2018.

by GVK Biosciences.¹²⁵¹ Finally, as a sign of protest against the ban, New Delhi deferred talks on the FTA between both entities.¹²⁵²

Based on its previous negative experience when it comes to the export of generic medicine to developing nations, India took a stance when it came to making Covid-19 vaccines available to both the developing countries and LDC. As early as in October 2020, both India and South Africa requested WTO members waive protections offered by the TRIPS Agreement when it comes to the issue of patents, industrial design, copyrights and trade secrets (undisclosed secrets) in order to prevent, contain, and treat Covid-19.¹²⁵³ The subject matter of trade secrets concerning pharmaceuticals have been covered under Article 39 (3) of the TRIPS Agreement.¹²⁵⁴ The waiver should have been made available until widespread vaccination has been established and the majority of the global population has obtained the relevant immunity level.¹²⁵⁵ The waiver from the use of such trade secrets would permit regulatory authorities to utilise the relevant data of the Covid-19 vaccine in the public interest, and enable the speedy entry of a multitude of vaccine producers into the international

¹²⁵¹ Sen, Amiti: India may drag EU to WTO if drugs ban is not lifted. in: The Hindu. 2018. - <https://www.thehindubusinessline.com/economy/india-may-drag-eu-to-wto-if-drugs-ban-is-not-lifted/article7508529.ece>, DOA: 20.03.2018.

¹²⁵² EURACTIV: EU, India working to resolve trade row over generic drugs. 2015. - <https://www.euractiv.com/section/trade-society/news/eu-india-working-to-resolve-trade-row-over-generic-drugs/>, DOA: 20.03.2018.

¹²⁵³ World Trade Organization: Council for Trade-Related Aspects of Intellectual Property Rights. Waiver from certain provisions of the TRIPS Agreement for the prevention, containment and treatment of Covid-19: Communication from India and South Africa. 2020. - <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True>, DOA: 21.04.2021, para. 2.

¹²⁵⁴ Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994), Art. 39 (3).

¹²⁵⁵ World Trade Organization: Council for Trade-Related Aspects of Intellectual Property Rights. Waiver from certain provisions of the TRIPS Agreement for the prevention, containment and treatment of Covid-19: Communication from India and South Africa. 2020. - <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True>, DOA: 21.04.2021, para. 13.

market.¹²⁵⁶ New Delhi and Pretoria endeavoured to provide all WTO member states with the liberty to grant or refuse the enforcement of IPRs related to Covid-19 vaccines, diagnostics, drugs as well as other technologies for the duration of the pandemic.¹²⁵⁷ As part of their waiver request both India and South Africa have argued that:

[a]n effective response to the COVID-19 pandemic requires rapid access to affordable medical products including diagnostic kits, medical masks, other personal protective equipment and ventilators, as well as vaccines and medicines for the prevention and treatment of patients in dire need.”¹²⁵⁸

The bilateral proposal mentioned that IPRs have been an impediment to affordable Covid medical products. Thus, an interim suspension would permit numerous actors to commence production sooner, instead of concentrating vaccine production on the shoulders of a tiny number of patent owners.¹²⁵⁹ Both countries have also mentioned that:

[a]s new diagnostics, therapeutics and vaccines for COVID-19 are developed, there are significant concerns, how these will be made available promptly, in sufficient quantities and at affordable prices to meet global demand.”¹²⁶⁰

¹²⁵⁶ Dhar, Biswajit/ Gopakumar, K. M.: Towards more affordable medicine: A proposal to waive certain obligations from the Agreement on TRIPS. in: ARTNeT Working Paper Series. No. 200. 2020. - <https://www.econstor.eu/handle/10419/226692>, DOA: 02.01.2021.

¹²⁵⁷ World Trade Organization: Council for Trade-Related Aspects of Intellectual Property Rights. Waiver from certain provisions of the TRIPS Agreement for the prevention, containment and treatment of Covid-19: Communication from India and South Africa. 2020. - <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True>, DOA: 21.04.2021, para. 11.

¹²⁵⁸ Ibid, para. 5

¹²⁵⁹ Usher, Ann Danaiya: South Africa and India push for COVID-19 patents ban: They want the WTO to temporarily suspend intellectual property rights so that COVID-19 vaccines and other new technologies are accessible for poor countries, in: The Lancet (2020), Vol. 396, Is. 10265, pp. 1790-1791. - [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(20\)32581-2/fulltext#:~:text=South%20Africa%20and%20India%20have,needed%20to%20control%20the%20pandemic](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)32581-2/fulltext#:~:text=South%20Africa%20and%20India%20have,needed%20to%20control%20the%20pandemic), DOA: 26.03.2021, p. 1790.

¹²⁶⁰ World Trade Organization: Council for Trade-Related Aspects of Intellectual Property Rights. Waiver from certain provisions of the TRIPS Agreement for the prevention, containment and treatment of Covid-19: Communication from India and South Africa. 2020. -

Unfortunately, by October 2020, the member states of the WTO failed to come up with the necessary consensus to enact the proposed waiver. Yet again the EU, along with the US, Switzerland and Japan (all countries with a strong pharmaceutical sector) have ferociously opposed the proposal by New Delhi and Pretoria.¹²⁶¹ Likewise, pharmaceutical companies have been rather speedy in articulating their rejections to the proposed IPRs waiver for the duration of the pandemic. These multinationals have noted that granting permission to copy Covid-19 vaccines without adequate consent through the means of the compulsory licensing would, in their mind, undercut innovation and increase the risk of spreading unsafe viruses.¹²⁶² An EU spokesperson has further underpinned the attitude of the pharmaceutical heavyweights and stated that credible evidence was lacking for the claim that IPRs were impeding access to covid-19 related medications and technologies.¹²⁶³ Brussels has a strong protectionist stance when it comes to sharing the vaccine recipes and production procedures, particularly with manufacturers in the developing nation and LDC.

Despite rejecting the waiver proposal from India and South Africa by, *inter alia*, the EU, there has been considerable support from approximately 100 nations out of the 164-member states according to Doctors without Borders.¹²⁶⁴ The support by 100 nations is further

<https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q/IP/C/W669.pdf&Open=True>, DOA: 21.04.2021, para. 7.

¹²⁶¹ Eliassen, Ingeborg: Europe blocks move that would massively expand Covid vaccine production capacity. Why? 2021. - <https://www.investigate-europe.eu/en/2021/europe-blocks-trips-waiver-proposal-india-south-africa-wto-covid-vaccine/>, DOA: 11.02.2021.

¹²⁶² Buccus, James: An Unnecessary Proposal: A WTO Waiver of Intellectual Property Rights for COVID-19 Vaccines. CATO Institute. in: Free Trade Bulletin No. 78. 2020. - https://www.cato.org/sites/cato.org/files/2020-12/FTB_78.pdf, DOA: 01.01.2021.

¹²⁶³ Usher, Ann Danaia: South Africa and India push for COVID-19 patents ban: They want the WTO to temporarily suspend intellectual property rights so that COVID-19 vaccines and other new technologies are accessible for poor countries, in: The Lancet (2020), Vol. 396, Is. 10265, pp. 1790-1791. - [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(20\)32581-2/fulltext#:~:text=South%20Africa%20and%20India%20have,needed%20to%20control%20the%20pandemic](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)32581-2/fulltext#:~:text=South%20Africa%20and%20India%20have,needed%20to%20control%20the%20pandemic), DOA: 26.03.2021, p. 1790.

¹²⁶⁴ Eliassen, Ingeborg: Europe blocks move that would massively expand Covid vaccine production capacity. Why? 2021. - <https://www.investigate-europe.eu/en/2021/europe-blocks-trips-waiver-proposal-india-south-africa-wto-covid-vaccine/>, DOA: 11.02.2021.

endorsed by Article 8 of TRIPS which provides that WTO member states that:

*"[m]embers may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development."*¹²⁶⁵

On a similar note, Article 7 of TRIPS Agreement highlights both the protection, as well as enforcement of IPRs, ought to be done in a way that is beneficial to economic and social welfare.¹²⁶⁶ Thus, in no event should IPRs emerge as a legal obstacle when it comes to guaranteeing early access to inexpensive Covid medications for everyone on the globe during a pandemic that has already killed millions.¹²⁶⁷ In this context, WHO chief Tedros Adhanom Ghebreyesus said that "vaccine nationalism" could lead to a prolongation of the pandemic.¹²⁶⁸ Ghebreyesus has asked, when if not now, the world community would be willing to provide access to the much needed Covid vaccines.¹²⁶⁹ He also reminded the global community that the virus continued to mutate into contagious variants, with the potential to be more deadly in nature, and with disastrous consequences.¹²⁷⁰ Adding insult to injury, New Delhi has criticised the dichotomy, or some might say the hypocritical nature, of the rich nations. The subcontinent states that:

¹²⁶⁵ Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994), Art. 8 (1).

¹²⁶⁶ Bucchus, James: An Unnecessary Proposal: A WTO Waiver of Intellectual Property Rights for COVID-19 Vaccines. CATO Institute. in: Free Trade Bulletin No. 78. 2020. - https://www.cato.org/sites/cato.org/files/2020-12/FTB_78.pdf, DOA: 01.01.2021.

¹²⁶⁷ Ibid.

¹²⁶⁸ Lee, Gavin: Coronavirus: WHO criticises EU over vaccine export controls. in: BBC News, 2021. - <https://www.bbc.com/news/world-europe-55860540>, DOA: 26.03.2021.

¹²⁶⁹ Eliassen, Ingeborg: Europe blocks move that would massively expand Covid vaccine production capacity. Why? 2021. - <https://www.investigate-europe.eu/en/2021/europe-blocks-trips-waiver-proposal-india-south-africa-wto-covid-vaccine/>, DOA: 11.02.2021.

¹²⁷⁰ Ibid.

[o]n the one hand, these countries are buying up as much of the limited supply as they can, leaving no vaccines in the pie for developing and least-developed countries. On the other hand, and very strangely, these are the same countries who are arguing against the need for the waiver that can help increase the global manufacturing and supply to achieve not just equitable, but also timely and affordable access to such vaccines for all countries.”¹²⁷¹

In this context, it is interesting to note that German Chancellor Angela Merkel bemoaned that the EU had “permitted” India to become a major pharmaceutical producer in the world, while the industry has deteriorated in on the continent.¹²⁷² Merkel also highlighted the vaccine shortage in the EU, and mentioned that she was worried about the situation in India, due to the uncertainty whether the pharmaceutical products from the subcontinent would still be delivered to the EU. Merkel also clarified that if India was not abiding by its commitment to supply Covid-19 medicines then Brussels needed to reconsider its pharmaceutical supply chain.¹²⁷³ Merkel’s protectionist perspective regarding the European pharmaceutical industry came to light when she stated that the EU had failed to treat their pharmaceutical industry well for multiple years. She further added that despite these shortcoming, Brussels manged to maintain pharma industries in the Netherlands, Belgium and Germany.¹²⁷⁴ The statement issued by the German Chancellor led to backlash from the Indian media which was anything but amused by Merkel’s words, and

¹²⁷¹ Usher, Ann Danaiya: South Africa and India push for COVID-19 patents ban: They want the WTO to temporarily suspend intellectual property rights so that COVID-19 vaccines and other new technologies are accessible for poor countries, in: *The Lancet* (2020), Vol. 396, Is. 10265, pp. 1790-1791. - [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(20\)32581-2/fulltext#:~:text=South%20Africa%20and%20India%20have,needed%20to%20control%20the%20pandemic](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)32581-2/fulltext#:~:text=South%20Africa%20and%20India%20have,needed%20to%20control%20the%20pandemic), DOA: 26.03.2021, p. 1791.

¹²⁷² OpIndia: Angela Merkel laments that they ‘allowed’ India to become pharmacy of the world, fears that they will not get Covid-19 medicine. 2021. - <https://www.opindia.com/2021/04/angela-merkel-laments-they-allowed-india-to-become-pharmacy-of-world/>, DOA: 10.05.2021.

¹²⁷³ Ibid.

¹²⁷⁴ Ibid.

accused the Chancellor of putting Berlin first.¹²⁷⁵ Likewise, her comments have attracted sharp comments from commentators and experts from around the globe. They were of the opinion that the statements on India were not only a diplomatic faux pas, but also tone deaf and very patronising. In other words, the EU was showing its ugly and selfish side. Amidst the backlash, the German embassy went on a charm-offensive and issued multiple tweets expressing Berlin's sympathy for India's Covid crisis.¹²⁷⁶ It appears that Germany only backpedalled due to global outrage and criticism. The whole campaign *prima facie* appears to be a dishonest and covert attempt to save face.

Against the backdrop of this, the EU Commission and the member states of the EU, are increasingly under pressure to re-examine their strong disapproval of the proposed waiver, which could open the doors for an increase in vaccine on the globe.¹²⁷⁷ 115 Members of the EU Parliament have urged the Commission and the Council of the EU to reconsider the proposed waive of TRIPS, while both Commission and Council have paid lip-service by stating that Covid-19 medical products ought to be regarded as "global public goods" without proper enforcement.¹²⁷⁸ EU lawmakers had also acknowledged the fact that the EU will not be able to defeat Covid-19 until it has been defeated universally.¹²⁷⁹ It is, however, important to clarify that at the time of writing, the EU has committed itself to deliver 1.3 billion doses of

¹²⁷⁵ WION Gravitas: Angela Merkel says Europe "Allowed India" to become a pharma hub. 2021. - <https://www.msn.com/en-in/news/other/gravitas-angela-merkel-says-europe-allowed-india-to-become-a-pharma-hub/vi-BB1fYZM9?li=AAggbRN>, DOA: 12.05.2021.

¹²⁷⁶ OpIndia: After chancellor Angela Merkel's snide remarks on India, German Embassy quickly moves to make amends. 2021. - <https://www.opindia.com/2021/04/after-chancellor-angela-merkels-statements-india-german-embassy-quickly-moves-to-make-amends/>, DOA: 15.05.2021.

¹²⁷⁷ Human Rights Watch: The EU Should Stop Blocking Efforts to Increase Global Vaccine Access. 2021. - <https://reliefweb.int/report/world/eu-should-stop-blocking-efforts-increase-global-vaccine-access>, DOA: 25.03.2021.

¹²⁷⁸ Eliassen, Ingeborg: Europe blocks move that would massively expand Covid vaccine production capacity. Why? 2021. - <https://www.investigate-europe.eu/en/2021/europe-blocks-trips-waiver-proposal-india-south-africa-wto-covid-vaccine/>, DOA: 11.02.2021.

¹²⁷⁹ Human Rights Watch: The EU Should Stop Blocking Efforts to Increase Global Vaccine Access. 2021. - <https://reliefweb.int/report/world/eu-should-stop-blocking-efforts-increase-global-vaccine-access>, DOA: 25.03.2021.

vaccine and 2.2 billion in funds for the developing world as Covid-19 relief measures.¹²⁸⁰ While is a commendable effort, it is merely a drop in the ocean, as the only way to tackle this pandemic would be to waiver the strong IPRs protection on Covid-19 vaccines and other related drugs. Brussels should come to terms with the fact that vaccine nationalism (protectionism) will not be the remedy against a global pandemic of such magnitude.

Unlike the EU, the Indian Union has taken the diametrically opposite approach to what WHO chief Ghebreyesus termed as "vaccine nationalism" and has offered the distribution of millions of domestically manufactured coronavirus vaccines free of charge. New Delhi has dubbed its vaccine diplomatic initiative "Vaccine Maitri" (Hindi for vaccine friendship). Indian PM Modi stated that his nation had been deeply honoured to be able to meet the healthcare needs of the world community.¹²⁸¹ The distribution of the Covishield, the AstraZeneca vaccine made by the Serum Institute of India, commenced to the nations that are located in the subcontinent's immediate neighbourhood, and to some important partner states in the Indian Ocean. The doses were supplied as a gift, consistent with New Delhi's "Neighbourhood First" policy. Other nations that have received the relevant vaccine are states that are located in Africa, Latin America and CARICOM (Caribbean), the Middle East and Northern America.¹²⁸² Moreover, according to the Indian Foreign Ministry, the nation had dispatched more than 15.6 million doses to 17 countries.¹²⁸³ The deliveries of Indian vaccines had helped New Delhi

¹²⁸⁰ European Commission (press release): EU doubles contribution to COVAX to €1 billion to ensure safe and effective vaccines for low and middle-income countries. 2021. - https://ec.europa.eu/commission/presscorner/detail/en/IP_21_690, DOA: 22.02.2021.

¹²⁸¹ Deutsche Welle: Is India's COVID vaccine giveaway risky diplomacy? 2021. - <https://www.dw.com/en/is-indias-covid-vaccine-giveaway-risky-diplomacy/a-56590143>, DOA: 21.03.2021.

¹²⁸² Laskar, Rezaul: India sends 22.9 mn doses of Covid-19 vaccines to 20 countries, more in pipeline. in: Hindustan Times. 2021. - <https://www.hindustantimes.com/india-news/india-sends-22-9-mn-doses-of-covid-19-vaccines-to-20-countries-more-in-pipeline-101613142400644.html>, DOA: 20.04.2021.

¹²⁸³ Deutsche Welle: Is India's COVID vaccine giveaway risky diplomacy? 2021. -

to push ahead of Beijing in its “vaccine diplomacy”.¹²⁸⁴ In this context, it is worth mentioning that Canada had thanked India for delivering 500,000 doses of coronavirus vaccines in March 2021, only a week after approval by the Canadian regulator.¹²⁸⁵ Besides, in 2020 the Indian Republic has supplied hydroxychloroquine to 55 coronavirus-hit countries, both on humanitarian bases as well as commercial grounds. UN chief Antonio Guterres’ spokesperson saluted New Delhi for supplying the global community with Hydroxychloroquine in their efforts to combat the pandemic.¹²⁸⁶

The “Swadeshi” or “Make in India”, campaign launched by the Modi government to encourage Indian companies to manufacture their products in India and provide significant incentives to, *inter alia*, the pharmaceutical sector in India seem to have indeed taken off.¹²⁸⁷ Indian generic vaccines appear to be in demand more than ever. With the vaccine initiative New Delhi seems to underline its statute as the world largest medicine cabinet.

According to legal postcolonialism, the character of international law has been undeniably European in nature. For legal historian JHW Verzijl, the body of international law as it stands to date is both the

<https://www.dw.com/en/is-indias-covid-vaccine-giveaway-risky-diplomacy/a-56590143>, DOA: 21.03.2021.

¹²⁸⁴ Laskar, Rezaul: India sends 22.9 mn doses of Covid-19 vaccines to 20 countries, more in pipeline. in: Hindustan Times. 2021. - <https://www.hindustantimes.com/india-news/india-sends-22-9-mn-doses-of-covid-19-vaccines-to-20-countries-more-in-pipeline-101613142400644.html>, DOA: 20.04.2021.

¹²⁸⁵ Business Standard: Canada thanks India for sending 500,000 doses of COVID-19 vaccines: Canada on Wednesday (local time) thanked India for sending coronavirus vaccines, of which 500,000 doses reached on March 4, a week after the AstraZeneca vaccine was approved. 2021. - [https://www.business-standard.com/article/current-affairs/canada-thanks-india-for-sending-500-000-doses-of-covid-19-vaccines-121030400127_1.html#:~:text=Canada%20on%20Wednesday%20\(local%20time,vaccine%20is%20now%20in%20Canada](https://www.business-standard.com/article/current-affairs/canada-thanks-india-for-sending-500-000-doses-of-covid-19-vaccines-121030400127_1.html#:~:text=Canada%20on%20Wednesday%20(local%20time,vaccine%20is%20now%20in%20Canada), DOA: 25.03.221.

¹²⁸⁶ OpiIndia: Angela Merkel laments that they ‘allowed’ India to become pharmacy of the world, fears that they will not get Covid-19 medicine. 2021. - <https://www.opindia.com/2021/04/angela-merkel-laments-they-allowed-india-to-become-pharmacy-of-world/>, DOA: 10.05.2021.

¹²⁸⁷ Firstpost: Make In India, Ayushman Bharat, Swachh Bharat: NDA campaign likely to showcase flagship programmes to attract voters. 2019. - <https://www.firstpost.com/india/make-in-india-ayushman-bharat-swachh-bharat-a-look-at-various-schemes-and-polices-of-narendra-modi-government-6237911.html>, DOA: 20.02.2021.

cognisant efforts of the European brain, and has drawn its key components from the common European belief system.¹²⁸⁸ Likewise, in line with legal postcolonialism, international law consists of a series of doctrines and principles that were developed in Europe. These doctrines, as well as principles that emerged out of European experience and history, which in due time were expanded to the non-European world which existed outside the sphere of European international law.¹²⁸⁹ In this respect the non-European world played a trivial role within each of these schemes.¹²⁹⁰ Furthermore, the sovereignty doctrine neglects the non-European world from its realm, and further proceeds to vindicate imperialism that was a consequence of the integration of the non-European world into the system of international law.¹²⁹¹ This doctrine has been used as a preface of a project of grandeur to bequeath sovereignty on the “dark places on the globe”.¹²⁹² In other words, the sovereignty of a Eurocentric international law over the non-European peasantry had been propagated. Thus, international law has been utilised to bridge the gap between European and non-European peoples and cultures. In this context, the European cultures and peoples have been viewed largely as civilised, in comparison to the non-Europeans who have been regarded as uncivilised.¹²⁹³ Having established this gap, what followed was the formation of doctrines that were deigned to wipe out the gap between the civilised and the non-civilised cultures and peoples. The aim was to bring the uncivilised, backward, aberrant, violent, and oppressed peoples into a sphere of civilisation, an order of a universal nature that is administrated by (European) international law.¹²⁹⁴ For Anghie, this distinction between the civilised and the uncivilised, the

¹²⁸⁸ Verzijl, JHW: International Law in Historical Perspective. Vol 1. Leiden: AW Sijthoff, 1968, pp. 435 - 436.

¹²⁸⁹ Anghie, Antony: The Evolution of International Law: Colonial and Postcolonial Realities, in: Third World Quarterly (2006), Vol. 27, Is. 5, pp. 739-753, p. 740.

¹²⁹⁰ Ibid, p. 741.

¹²⁹¹ Ibid.

¹²⁹² Kosekenniemi, Martti: The Gentle Civilizer of Nations: The Rise and Fall of International Law, 1870-1960. Cambridge: Cambridge University Press, 2003, p. 115.

¹²⁹³ Anghie, Antony: The Evolution of International Law: Colonial and Postcolonial Realities, in: Third World Quarterly (2006), Vol. 27, Is. 5, pp. 739-753, p. 741.

¹²⁹⁴ Ibid, p. 742.

animating difference of imperialism, is vital to the creation of the sovereignty doctrine; this could be understood as providing some cultures with all the prerogatives of sovereignty, whilst excluding these prerogatives to others. Cultural dissimilarities have been instrumental in shaping the sovereignty doctrine,¹²⁹⁵ and the sovereignty doctrine views Colonialism as a central component to the creation of international law. Colonialism was fundamental for the universality of international law. Both the dynamics of dissimilarities and the West's mission to civilise the uncivilised continues until date.¹²⁹⁶ At the beginning of the 15th and 16th centuries the presence of Europeans in non-European territories intensified, and consequently the interaction between both classes of states intensified. Appropriate legal doctrines were developed to regulate the complex modes of interaction between the aforementioned different groups of nations; these doctrines were inevitably developed to rectify the obtainment of sovereignty over non-Europeans.¹²⁹⁷

The first texts of modern international law by Francisco de Vitoria's "on the Indians lately discovered", addresses the complex legal issues that surfaced from Spanish claims to sovereignty over the Americas after the voyage of Columbus.¹²⁹⁸ Vitoria relied on the naturalist and theological jurisprudence of that time, and claimed that all peoples were subject to fundamental natural law including Indians (the indigenous population). Others portrayed native Indians as animals, heathens that were lacking any discernible rights; Victoria believed that the native Indians lacked adequate government, which ought to be established over the Indians by the Spanish. He claimed that the Spaniards had to rule as trustees over the uncivilised Indians¹²⁹⁹ - for Victoria, Indians are children who are in need of a guardian. *Prima facie*, it seems that Indians can only be rectified by the intervention of

¹²⁹⁵ Ibid.

¹²⁹⁶ Ibid.

¹²⁹⁷ Ibid.

¹²⁹⁸ De Victoria, Francisco: *De Indis et de Iure Belli Relectiones* (translated by John Pawley Bate). Washington, DC: Carnegie Institute of Washington, 1917, p. 150.

¹²⁹⁹ Ibid

the Spaniards, who are portrayed as representatives of natural law itself.¹³⁰⁰ As the “self-proclaimed saviour” of the uncivilised non-Europeans, the Spanish obtained the right to travel to the lands of the Indians and to reside there, as long as they did not commit any harmful acts; they may not be barred from their endeavours by the Indians.¹³⁰¹ Obviously these supposedly “innocent” rights to travel as well as trade have tremendous consequences for the Indians.¹³⁰² Francisco de Victoria’s book showcases, *inter alia*, the central importance of commerce to international law and how the obstruction of commercial exploits dictates war.¹³⁰³ Little appears to have changed in the 21st century except for the notion of war; in connection with this research, the EU uses the legal instruments of seizures, detentions and bans to protect its domestic pharmaceutical market against cheap generic medicines from India.

When it comes to the matter of treaties, imperial powers claimed that native chiefs had entered into contracts which in turn gave the European powers sovereignty over non-European peoples and lands. However, the legal capacity of the indigenous people to enter into legally binding agreements was contradictory at best, as the natives lacked relevant legal capacity for the most part. What is clear from an examination of the treaties, however, is that international lawyers granted the natives such status, quasi-sovereignty, for purposes of transferring rights, property and sovereignty.¹³⁰⁴ According to Vitoria, the ability of the indigenous population to hand over their resources was as a result guaranteed by these treaties. In this regard Western or European standards were proclaimed to be universally applicable, and the failure of non-Western and non-European countries to abide by

¹³⁰⁰ Anghie, Antony: The Evolution of International Law: Colonial and Postcolonial Realities, in: Third World Quarterly (2006), Vol. 27, Is. 5, pp. 739-753, p. 743.

¹³⁰¹ De Victoria, Francisco: *De Indis et de Iure Belli Relectiones* (translated by John Pawley Bate). Washington, DC: Carnegie Institute of Washington, 1917, p. 150.

¹³⁰² Anghie, Antony: The Evolution of International Law: Colonial and Postcolonial Realities, in: Third World Quarterly (2006), Vol. 27, Is. 5, pp. 739-753, p. 743.

¹³⁰³ Ibid, p. 744.

¹³⁰⁴ Ibid, p. 745.

these principles meant a lack of civilisation that, in turn, warranted both an intervention as well as the invasion of the natives' lands.¹³⁰⁵ In this context, it is rather telling that at the Berlin Conference of 1884, 85 of the major European powers of that time met in Berlin with the set goal to engage in talks on how to divide the African content amongst themselves. The consequence was the division of the African continent, which transpired without paying due consideration to the complexity of the political administration that operated within that territory, and has created enduring problems. Towards the end of the 19th Century, the European expansionism meant that the European-influenced international law had gained world-wide reach as the one and only system that applied to every society; this was also the method through which European international law became universally applicable.¹³⁰⁶ Moreover, a main issue of contention between the West and the emerging new nations became international economic law. The newly emerged nations contended that this particular *corpus juris* had been formed by Western nations in their endeavour to advance their own interests; the emerging states themselves had hardly played a role in the creation of this legislation.¹³⁰⁷ Various scholars from the West recognised the validity of the allegations made by the newly emerged nations, however, the Western nations contended that the Third World nations were nevertheless legally bound by the older terms of international economic law that the West had drafted. Likewise, the West made the recognition of these and other legislations of the international system a prerequisite to become an independent sovereign nation.¹³⁰⁸ In this context, the EU seemed to utilise European international law, more precisely, European legislation, in order to seize, detain, and, in other cases, to ban generic medicine from India designated to developing nations as well as to the EU market. This was the case, in 2008, in which in transit

¹³⁰⁵ Ibid.

¹³⁰⁶ Ibid, p. 746.

¹³⁰⁷ Ibid, p. 748.

¹³⁰⁸ Ibid.

essential generic medicines from India, designated to developing countries, was subject to seizure and detention by EU border officials due to suspected IPRs violations. Similarly, in 2015, Indian export of 700 generic medicines was banned due to suspected data manipulation.

Another contentious subject has been international human rights law, as it validated the imposition of international law in the internal relations of any given state; international law was used to warrant additional interference by the Western World in the affairs of the Third World. The characteristic of this interference became apparent after the downfall of the Soviet Union and the advent of globalisation.¹³⁰⁹ Additionally, the evolution of neoliberal economic policy, and the establishment of the WTO, posed new issues for Third World countries. Likewise, the International Monetary Fund and the World Bank increasingly occupied an invasive position when it came to the economies of these Third World countries. The efforts of the aforesaid financial institutions have utilised their considerable powers to reform the social and political structure of the Third World nations. In doing so, they utilised the umbrella of good governance, in which they drew on a variety of strategic techniques which entailed the application of international human rights law.¹³¹⁰ While, *prima facie*, the merits of good governance seem to be obvious, the meaning of this term is subject to contention. The aforesaid organisation endeavoured to utilise a modified version of international human rights law for the furtherance of their neoliberal policies under the guise of good governance, instead of facilitating genuine empowerment of the citizens of the Third World.¹³¹¹ The notion of good governance seemed to be applied by the EU when it signed international treaties, such as FTA, with developing nations in which it required that developing nations abide by the higher IPRs standards than is

¹³⁰⁹ Ibid, p. 749.

¹³¹⁰ Ibid.

¹³¹¹ Ibid.

generally been required under TRIPS by the WTO. Regarding international human rights law and access to essential generic medicine, as a human right to health, designated to developing countries, the EU seemed to give precedence to IPRs over international human rights law, even in cases in which the drugs are not designated to the international market of the EU.

In sum, *prima facie*, by extension one might conclude that Merkel's statement is rather telling and shows the true colours of the EU. First Brussels used the legal instrument of "manufacturing fiction" to arguably, possibly dissuade Indian manufacturers from competing with the EU's domestic industry through arbitrary seizure and detention of generic medicines. Now the EU, via Merkel, leader of the most influential EU member state, might have underlined this stance by publicly stating that Brussels should not have allowed New Delhi to become the biggest producer of pharmaceuticals on the globe. Markel's statement did indeed invite considerable backlash from India and international media. A seasoned politician of such grandeur like Angela Merkel should have known better not to utter these words amid the second Coronavirus wave in India, with a death toll of more than 4500 people daily.¹³¹² The EU's protectionism of its domestic pharmaceutical industry has never been more blatantly obvious than in the case of Angela Merkel's recent statement. Finally, it seems obvious that the EU has strong economic interests when it came to the protection of its domestic pharmaceutical market against cheap generic medicines from India. On the part of Brussels, there seems to be an economic policy objective to reduce the EU's dependency on pharmaceutical products from India, which is rather evident from Merkel's statement on the neglect of the EU's pharma industry. Brussels appears to take a protectionist stance when it comes to

¹³¹² Choudhury, Saheli Roy: India's daily death toll crosses 4,500 as Covid-19 cases stay below 300,000. in: CNBC. 2021. - <https://www.cnbc.com/2021/05/19/india-covid-crisis-cases-may-have-peaked-but-deaths-hit-new-record.html>, DOA: 21.05.2021.

fending off international competition from cheap Indian generic medicines from India. The seizure of in transit generic Indian medicines due to IPRs violation, by EU officials, and the application of the legal concept of “manufacturing fiction”, gives rise to the suspicion that the EU might be following a hidden protectionist agenda against the cheap competition from India. This suspicion has further been supported by the ban of 700 generic medicines from India. European protectionism meant that Brussels has also taken a strong stance against the issuance of a waiver to the IPRs on Covid-19 vaccines. While Brussels is willing to support the WHO’s Covax programme financially and donate considerable vaccines, it seems to be eager to protect the vaccines’ IPRs. Unlike the EU, India has been more than willing to donate and sell vaccines to developing countries from around the world. Its “Vaccine Maitri” has been placed the India on the map as a responsible emerging global player. The nation has certainly increased both its reputation as well as its soft power on the international stage.

8.2. Brexit

“You can't do Europe a la carte [...] Imagine Europe is a football club and you join, once you're in it you can't say 'Let's play rugby.’”¹³¹³

Laurent Fabius, former French foreign minister

This sub-chapter aims to briefly examine the consequences of Brexit¹³¹⁴ for both the EU and India. The United Kingdom (UK) has traditionally been accused of cherry picking whilst a member of the EU, and during the Brexit talks.¹³¹⁵ During the referendum, which was held on 23 June 2016, a 52% majority of British voters voted to leave the European Union; part of the reason was due to the fact that a small majority of Brits considered the EU a dysfunctional economic entity. Many Brits also felt that the Union was increasingly incapable to deal with economic crises since 2008 and the attached 20% unemployment rate in southern Europe.¹³¹⁶ Yet, the UK has been the second largest net contributor to the Unions' budget.¹³¹⁷ Equally, by default, the EU has lost its second permanent seat at the UN Security Council (UNSC).

On 29 March 2017, PM Theresa May issued a letter to the European Council President Donald Tusk, in which she triggered Article 50 of the Treaty of the EU, which commenced the two-year long countdown to

¹³¹³ BBC News: Brexit day: The story of the UK leaving the EU in key quotes. 2020. - <https://www.bbc.com/news/uk-46920529>, DOA: 19.01.2021.

¹³¹⁴ (Britain's exit from the European Union)

¹³¹⁵ Harries, Daniel: EU's Barnier warns UK it can't 'cherry pick' benefits in Brexit negotiations. in: China Global Television Network. 2020. - <https://newseu.cgtn.com/news/2020-06-11/EU-s-Barnier-warns-UK-it-can-t-cherry-pick-benefits-in-Brexit-talks-RdD3Y4EbOU/index.html>, DOA: 10.12.2020.

¹³¹⁶ Friedman, George: 3 Reasons Brits Voted for Brexit. in: Forbes. 2016. - <https://www.forbes.com/sites/johnmauldin/2016/07/05/3-reasons-brits-voted-for-brexit/?sh=37a710ec1f9d>, DOA: 13.09.2019.

¹³¹⁷ Kovacevic, Tamara: EU budget: Who pays most in and who gets most back? in: BBC News. 2019. - <https://www.bbc.com/news/uk-politics-48256318>, DOA: 03.03.2020.

the UK leaving the EU. The Article 50 process is also referred to as Brexit. In this context, Article 50 TEU states the following:

[a]ny Member State may decide to withdraw from the Union in accordance with its own constitutional requirements.

*A Member State which decides to withdraw shall notify the European Council of its intention. In the light of the guidelines provided by the European Council, the Union shall negotiate and conclude an agreement with that State, setting out the arrangements for its withdrawal, taking account of the framework for its future relationship with the Union. That agreement shall be negotiated in accordance with Article 218(3) of the Treaty on the Functioning of the European Union. It shall be concluded on behalf of the Union by the Council, acting by a qualified majority, after obtaining the consent of the European Parliament.”*¹³¹⁸

The UK was eventually expected to leave the EU on 29 March 2019. However, after a vote at the House of Commons on 14 March 2019, the British government issued a request to extend the Article 50 process until 30 June 2019.¹³¹⁹ The possibility for an extension is provided in Article 50 (3) of TEU which states the following:

*[t]he Treaties shall cease to apply to the State in question from the date of entry into force of the withdrawal agreement or, failing that, two years after the notification referred to in paragraph 2, unless the European Council, in agreement with the Member State concerned, unanimously decides to extend this period.”*¹³²⁰

¹³¹⁸ See Consolidated Versions of the Treaty on European Union and the Treaty on the Functioning of the European Union (TFEU) [2016] OJ C202/1, Art. 50 (1) & (2).

¹³¹⁹ BBC News: Brexit day: The story of the UK leaving the EU in key quotes. 2020. - <https://www.bbc.com/news/uk-46920529>, DOA: 19.01.2021.

¹³²⁰ Consolidated Versions of the Treaty on European Union and the Treaty on the Functioning of the European Union (TFEU) [2016] OJ C202/1, Art. 50 (3).

Subsequently, the 27 leaders of the EU member states agreed to grant the extension request. During the Brexit chaos, and increasing extensions to the Article 50 process, European Council president Donald Tusk became increasingly frustrated and issued the following statement:

*"I've been wondering what the special place in hell looks like [...] for those who promoted Brexit without even a sketch of a plan of how to carry it safely."*¹³²¹

Additionally, on 2 April 2019, the UK's PM sought yet another extension to the Article 50 process until 31 October 2019, which was later granted by the European Council.¹³²² On 19 October 2019, PM May's withdrawal bill failed to pass the House of Commons and the British PM issued a further extension request on 28 October 2019; this request was once again granted by the EU.¹³²³ On 12 December 2019, Boris Johnson was elected PM of the UK, securing a majority in the general elections. Following the electoral success of PM Johnson, the EU Withdrawal Agreement Act 2020 received Royal Assent on 23 January 2020. Consequently, on 31 January 2020 the UK finally left the EU and entered a transitional period. Boris Johnson stated in this context:

*"[s]ome people think that it [Brexit] is the end of the world. It's not. On the contrary, it's a massive opportunity for this country."*¹³²⁴

Finally on 31 December 2020, the transitional period came to an end and the UK left the single market, as well as the customs union of the

¹³²¹ Schaart, Eline: Donald Tusk: 'Special place in hell' for those who backed Brexit with no plan, Politico. 2019. - https://www.politico.eu/article/_trashed-21/, DOA: 19.07.2020.

¹³²² BBC News: Brexit day: The story of the UK leaving the EU in key quotes. 2020. - <https://www.bbc.com/news/uk-46920529>, DOA: 19.01.2021.

¹³²³ Ibid.

¹³²⁴ Johnson, Boris: AZ Quotes. - <https://www.azquotes.com/quote/1504812>, DOA: 14.02.2021.

EU.¹³²⁵ Following the Brexit deal, a three-month grace-period was granted, during which the post Brexit deals would not have been enforced on food items that were being brought into Northern Ireland. The reason for this is that Northern Ireland essentially remains part of the EU's single market for goods.¹³²⁶ Moreover, under the Northern Ireland Protocol all products are ordinarily authorized for export from the EU to Northern Ireland without checks at the border.¹³²⁷

In this context, a somewhat curious event occurred as a consequence of Brexit, when border guards confiscated ham sandwiches and other food items from British lorry drivers at the Dutch border in the Netherlands. This event occurred after new border controls were put in place between the EU and UK. Dutch border agents also explained to travellers, as well as lorry drivers that diary and meat products from outside the EU had essentially been banned. In a rather amusing scenario, a lorry driver from the UK who arrived by ferry at Hook Holland seaport asked an official if he was allowed to at least keep the bread from the sandwiches as the importation of ham was not permitted.¹³²⁸ The border guard issued the following comment:

“No, everything will be confiscated- welcome to the Brexit, sir, I am sorry.”¹³²⁹

¹³²⁵ BBC News: Brexit day: The story of the UK leaving the EU in key quotes. 2020. - <https://www.bbc.com/news/uk-46920529>, DOA: 19.01.2021.

¹³²⁶ Campbell, John: Brexit: How Northern Ireland is different. in: BBC News. 2020. - <https://www.bbc.com/news/uk-northern-ireland-55488686>, DOA: 03.01.2021.

¹³²⁷ The Irish Times: What is article 16 of the Northern Ireland protocol? Brexit deal clause triggered by EU to place controls on export of Covid vaccines to Northern Ireland. 2021. - <https://www.irishtimes.com/news/ireland/irish-news/what-is-article-16-of-the-northern-ireland-protocol-1.4472868>, DOA: 12.04.2021.

¹³²⁸ O'Reilly, Luke: Dutch border officials confiscate ham sandwiches from UK lorry drivers: ‘Welcome to the Brexit’. in: Evening Standard. 2021. - <https://www.standard.co.uk/news/uk/border-guards-sandwiches-confiscated-brexit-b845171.html>, DOA: 12.01.2021.

¹³²⁹ See Krever, Mick/ Woodyatt, Amy: Driver's sandwich confiscated on Dutch border because of Brexit. in: CNN. 2021. - <https://edition.cnn.com/travel/article/sandwich-brexit-netherlands-intl-scli-gbr/index.html>, DOA: 12.01.2021.

Against the backdrop of the soon to conclude three-month period, the UK unilaterally decided to extend the grace period until October 2021. The EU was anything but amused about this unilateral, and some might say obstreperous, move by the UK, and has launched a legal action before the ECJ, claiming that the UK's unilateral move did indeed break international law.¹³³⁰ PM Johnson asserted that the government's move was lawful.¹³³¹ This happened against the backdrop of Union politicians in Northern Ireland demanding that the Northern Ireland Protocol to be scrapped, and further appealed that the UK government to invoke Article 16 of the Northern Ireland Protocol, which permits both the UK and the EU to unilaterally suspend any part of the agreement that causes "economic, societal or environmental difficulties".¹³³² The issue went from bad to worse over the supply of Covid-19 vaccines and promoted even more outrage. In a unilateral manoeuvre, Brussels itself announced, on 29 January 2021, that it would utilise the Article 16 of the Northern Ireland Protocol to implement export controls on vaccines produced in the EU. This would also apply to vaccines moving between Northern Ireland and the Republic of Ireland.¹³³³ This move could be seen as part of Brussels' endeavour to curb export Covid vaccine controls, bearing in mind of Union row with AstraZeneca over its supply contract. The EU was fearful of the fact that London would use Northern Ireland as a back portal to circumvent export controls from Brussels, and transport vaccines into the UK unchecked, thus triggering Article 16 of the Protocol which would have closed that gap in the system.¹³³⁴ The

¹³³⁰ Edgington, Tom/ Morris, Chris: Brexit: What is the Northern Ireland Protocol and why are there checks? in: BBC News. 2021. - <https://www.bbc.com/news/explainers-53724381>, DOA: 10.04.2021.

¹³³¹ Ibid.

¹³³² See Protocol on Ireland/Northern Ireland. 2020. - [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/840230/Revised Protocol to the Withdrawal Agreement.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/840230/Revised%20Protocol%20to%20the%20Withdrawal%20Agreement.pdf), DOA: 17.02.2021, Art. 16.

¹³³³ Edgington, Tom/ Morris, Chris: Brexit: What is the Northern Ireland Protocol and why are there checks? in: BBC News. 2021. - <https://www.bbc.com/news/explainers-53724381>, DOA: 10.04.2021.

¹³³⁴ The Irish Times: What is article 16 of the Northern Ireland protocol? Brexit deal clause triggered by EU to place controls on export of Covid vaccines to Northern Ireland. 2021. -

Union said that such actions were justified in order to avert issues with the supply chain of the Covid vaccines. *Prima facie*, it appears that Brussels had increasingly been under pressure due to the chaos surrounding the Union's sluggish vaccine rollout, and was threatening to block exports from the AstraZeneca plant in the Netherlands.¹³³⁵

Multiple EU member states have blamed Brussels for its incapability to sign vaccine contracts with pharmaceutical multinationals.¹³³⁶ Interestingly, it was the EU which previously lectured the UK to respect the Northern Irish Protocol and its importance when it came to guaranteeing the terms of the Good Friday Agreement.¹³³⁷ Yet the EU, *prima facie*, appeared to be rather quick when it came to undermining the same agreement and failing to listen to their own advice. According to Conservative MP and former secretary for Northern Ireland, Julian Smith, Brussels lacked understanding about the sensitive nature of the Good Friday Agreement.¹³³⁸ He dubbed it an "almost Trumpian act".¹³³⁹ EU member Ireland been stunned by Brussels unconsolidated and unilateral move by the Union. After heavy criticism from both the PM of Ireland and from the Northern-Irish government, the EU was forced to reverse its decision within the course of hours.¹³⁴⁰ The Spanish Foreign Minister acknowledged that

<https://wwwirishtimes.com/news/ireland/irish-news/what-is-article-16-of-the-northern-ireland-protocol-1.4472868>, DOA: 12.04.2021.

¹³³⁵ Boffey, Daniel: EU leaders push back against bloc's plans to halt Covid vaccine exports: More sceptical member states hope 'stick will never be used' amid concerns over supply chain. in: The Guardian. 2021. - <https://www.theguardian.com/world/2021/mar/25/eu-leaders-push-back-against-blocs-plans-to-halt-covid-vaccine-export>, DOA: 13.04.2021.

¹³³⁶ Adler, Katya: EU vaccine export row: Bloc backtracks on controls for NI. in: BBC News, 2021. - <https://www.bbc.com/news/uk-55865539>, DOA: 17.03.2021.

¹³³⁷ Ibid.; Northern Ireland Peace Agreement (The Good Friday Agreement), 10. April 1998. - https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/136652/agreement.pdf, DOA: 13.03.2018.

¹³³⁸ Adler, Katya: EU vaccine export row: Bloc backtracks on controls for NI. in: BBC News, 2021. - <https://www.bbc.com/news/uk-55865539>, DOA: 17.03.2021.

¹³³⁹ Ibid.

¹³⁴⁰ Edgington, Tom/ Morris, Chris: Brexit: What is the Northern Ireland Protocol and why are there checks? in: BBC News. 2021. - <https://www.bbc.com/news/explainers-53724381>, DOA: 10.04.2021.

this situation has not necessarily assisted the EU Commission's reputation.¹³⁴¹

Another associated issue might have been London's refusal to grant fully-fledged diplomatic status to the EU's mission. According to the UK Foreign Office, granting Brussels a diplomatic status would set a dangerous precedent thereby treating an international body identically to a sovereign nation.¹³⁴² However, 142 nations on the globe have granted the EU full diplomatic status.¹³⁴³

As a final point, it would now be fitting to look at the possibility of a FTA between the UK and India post Brexit. After Singapore and Vietnam, now it is India that is looking into entering into an FTA with the UK. Both New Delhi and London are on the brink of intensifying their negotiations in order to sign what could be regarded as one of the globe's most comprehensive trade agreements.¹³⁴⁴ According to Indian officials, the bilateral trade agreement is expected to compromise pharmaceuticals, petroleum, chemicals, defence manufacturing, fintech and food items; both nations will finally be able to cut the shackles of the EU. Unlike the trade talks between both entities, it will hardly be subject to the same type of difficulties that exist in trade negotiations between the EU and India, according to the president of the Federation of Indian Export Organisations.¹³⁴⁵ Moreover, in the fiscal year 2020, the UK accounted for 16% of India's \$53.7 billion exports to the EU.¹³⁴⁶ During the same period, India

¹³⁴¹ Adler, Katya: EU vaccine export row: Bloc backtracks on controls for NI. in: BBC News. 2021. - <https://www.bbc.com/news/uk-55865539>, DOA: 17.03.2021.

¹³⁴² Boffey, Daniel/ Wintour, Patrick: UK insists it will not grant EU ambassador full diplomatic status. The Guardian. 2021. - <https://www.theguardian.com/world/2021/jan/21/uk-insists-it-will-not-grant-eu-ambassador-full-diplomatic-status>, DOA: 14.04.2021.

¹³⁴³ Ibid.

¹³⁴⁴ Indian Global Business: Brexit clears the decks for India's FTAs with UK and EU. 2021. - <https://www.indiaglobalbusiness.com/analyses/snap-analysis/brexit-clears-the-decks-for-indias-ftas-with-uk-and-eu>, DOA: 27.12.2021.

¹³⁴⁵ Ibid.

¹³⁴⁶ Ibid.

exported pharma products, garments, gems, jewellery, organic chemicals, and footwear in large quantities to the UK.¹³⁴⁷

In sum, in the aftermath of Brexit, both the Brussels and London appear to need to get used to the new reality; Brussels is not amused to see the second largest net contributor to its budget go. Similarly, by default the EU has lost its “second permanent seat” at the UNSC. The Union seems to regret seeing the UK leave and was determined not to concede when the UK tried to unilaterally extend the post-Brexit grace period until October 2021. Having been subject to considerable criticism due to the lack of Astra Zeneca vaccines, Brussels, to save face, triggered Article 16 of the Northern Ireland Protocol which permits both the UK and the EU to unilaterally suspend any part of the agreement in question. The EU had to revert due to increased pressure; the UK refused to grant full-diplomatic status to EU’s mission in London.

Finally, it is early days since the withdrawal by the UK from the EU and at the same time both entities have entered unprecedented terrain in their bilateral relations. Regarding India, London has entered promising negotiations over an FTA with New Dehli. *Prima facie*, unlike in the case of an FTA with the EU, India and the UK appear to be confident that a bilateral trade agreement would be achieved much more easily.

¹³⁴⁷ Ibid.

8.3. Unilateralism v. Multilateralism

This sub-chapter shall explore the concepts of unilateralism and multilateralism. In this regard, unilateralism is used to describe the circumstances in which a powerful and dominant state disregards multilateral norms and adopts a self-centred approach to foreign policy.¹³⁴⁸ The level of power defines how unilateral a state might be. Thus, unilateralism seems to be the preferred *modus operandi* for mostly major powers and tends to be, more likely than not, used by a hegemonic state.¹³⁴⁹ Namely, a powerful state that can accomplish its policy using its own resources without the prerequisite of international assistance can pursue its foreign policy objective disregarding recognised international norms. Having said this, however, such unilateral actions are usually subject to political expenses.¹³⁵⁰ Unilateralism is frequently identified as selfish and illicit behaviour that damages the soft power of the unilateralist country. An outstanding example of unilateralism can be seen in the actions of former President Donald Trump, who declared before being inaugurated in 2016, that the Trans-Pacific Strategic Economic Partnership Agreement (TPP) was nullified, without consulting the other involved nations. As the largest economy in the TPP, the U.S. had the capability to act in a unilateral manner due to its status as the largest economy out of the TPP nations, without obliterating the multilateral international free trade agreement.¹³⁵¹ In general the U.S. seems to fit the description of a unilateral power, the same would apply to the former Soviet Union. In the context of the Covid-19 pandemic,

¹³⁴⁸ Wedgwood, Ruth: Unilateral action in a multilateral world, in: Forman, Shepard/ Patrick, Stewart (eds.): *Multilateralism and U.S. Foreign Policy: Ambivalent Engagement*. Boulder: Lynne Rienner Publishers, 2002, pp. 167–189, p. 168.

¹³⁴⁹ Wallace, William: U.S. unilateralism: A European perspective, in: Forman, Shepard/ Patrick, Stewart (eds.): *Multilateralism and U.S. Foreign Policy: Ambivalent Engagement*. Boulder: Lynne Rienner Publishers, 2002, pp. 141–164.

¹³⁵⁰ Thompson, Alexander: *Channels of power: The UN Security Council and U.S. statecraft in Iraq*. Ithaca (New York): Cornell University Press, 2009, p. 35.

¹³⁵¹ Tago, Atsushi: *Multilateralism, Bilateralism, and Unilateralism in Foreign Policy*, Graduate School of Law, Kobe University. 2017. -

<https://oxfordre.com/politics/view/10.1093/acrefore/9780190228637.001.0001/acrefore-9780190228637-e-449#acrefore-9780190228637-e-449-biblitem-0056>, DOA: 27.08.2019.

unilateralism, or rather unilateralist policies, regarding the approval of the Corona vaccine would provide relevant examples to cases in which unilateralism has worked. A prominent example of a unilateral policy, when it comes to the approval and distribution of Covid-19 vaccines, would be the U. S. “Operation Warp Speed”.¹³⁵² As part of “Operation Warp Speed” the FDA approved, as one of the first nations, the BioNTech/Pfizer vaccine.¹³⁵³ Washington’s unilateral approach with regard to vaccine procurement, distribution as well as administration has been considerably successful;¹³⁵⁴ similarly, Britain’s unilateral vaccine approval and rollout have been a considerable success. The UK’s Medicines and Healthcare products Regulatory Agency was quick to approve the Corona virus vaccine early, and ordered relevant quantities of the vaccine at an early stage. Consequently, it was able to rollout the vaccines early and in a successful manner.¹³⁵⁵ The vaccine rollout success of both the UK and US seems to suggest that a unilateral approach with regard to vaccine acquisition appears to be a viable solution for the short-term.¹³⁵⁶ It would be worth investigating whether unilateralism would also qualify as a credible solution for the global vaccine distribution in the long run, however before doing so, we shall consider the term multilateralism.

Multilateralism, in terms of a numerical definition, consists of a “three-state minimum” criterion, which is seen as a reasonable and practical

¹³⁵² Deutsch, Jillian/ Wheaton, Sarah: How Europe fell behind on vaccines: The EU secured some of the lowest prices in the world. At what cost? in: Politico. 2021. - <https://www.politico.eu/article/europe-coronavirus-vaccine-struggle-pfizer-biontech-astrazeneca/>, DOA: 23.02.2021.

¹³⁵³ Ibid.

¹³⁵⁴ Beltekian, Diana/ Ortiz-Ospina, Esteban/ Ritchie, Hannah: Coronavirus (COVID-19) Vaccinations, Our World in Data. 2021. - <https://ourworldindata.org/covid-vaccinations>, DOA: 15.05.2021.

¹³⁵⁵ Hutton, Will: Yes, Britain’s vaccine rollout is a triumph. But let’s not kid ourselves it proves the Brexit case. in: The Guardian. 2021. - <https://www.theguardian.com/commentisfree/2021/feb/07/britains-vaccine-rollout-a-triumph-lets-not-kid-ourselves-it-proves-brexit-case>, DOA: 19.02.2021.

¹³⁵⁶ Ibid.

definition.¹³⁵⁷ Thus, by definition, the WTO, as an international institution, would undoubtedly be classified a multilateral actor on the global stage.¹³⁵⁸ The concept of multilateralism comprises, transmits, and transports, norms and values. It acknowledges the appropriate requirements to conduct foreign policy and is regarded advantageous when it comes to the international order. Multilateralism, in terms of foreign policy, stands for the commitment to particular principles, substantive aims, and a value-based foreign policy. It also refers to a foreign policy approach that pursues the creation, maintenance and further building of a specific, normative international order through the means of international diplomacy.¹³⁵⁹ In this context, multilateralism does not reveal much about the exact nature of the values, norms, principles, rules, organisations, and procedures that ought to be followed when conducting international relations. Multilateralism, in this sense, is therefore no longer primarily about acting together with others, but rather about securing certain objectives and interests that are closely associated with a specific concept of the international order.¹³⁶⁰ Multilateralism is based on norms and rules that sustain predictability in the international system.¹³⁶¹ Brussels presents itself as a normative power which could be seen as rather attractive to other nations.¹³⁶² *Prime facie*, both Brussels and New Delhi display their dedication to efficient multilateralism; however, for India this involves the utilisation of the international platform in the quest for the

¹³⁵⁷ Corbetta, Renato /Dixon, William: Multilateralism, major powers, and militarized disputes, in: Political Research Quarterly (2004), Vol. 57, Is.1, pp. 5–14, p. 6.

¹³⁵⁸ Tago, Atsushi: Multilateralism, Bilateralism, and Unilateralism in Foreign Policy, Graduate School of Law, Kobe University. 2017. -

<https://oxfordre.com/politics/view/10.1093/acrefore/9780190228637.001.0001/acrefore-9780190228637-e-449#acrefore-9780190228637-e-449-bibItem-0056>, DOA: 27.08.2019.

¹³⁵⁹ Maull, Hanns: Multilateralism: Variants, Potential, Constraints and Conditions for Success. SWP Comment 2020/C 09. 2020. - <https://www.swp-berlin.org/10.18449/2020C09/>, DOA: 18.10.2020.

¹³⁶⁰ Ibid.

¹³⁶¹ Tago, Atsushi: Multilateralism, Bilateralism, and Unilateralism in Foreign Policy, Graduate School of Law, Kobe University. 2017. -

<https://oxfordre.com/politics/view/10.1093/acrefore/9780190228637.001.0001/acrefore-9780190228637-e-449#acrefore-9780190228637-e-449-bibItem-0056>, DOA: 27.08.2019.

¹³⁶² Bendiek, Annegret: A Paradigm Shift in the EU's Common Foreign and Security Policy: From Transformation to Resilience. in: SWP Research Paper 2017/RP 11 (2017), pp. 5 – 29, p. 7.

advancement of its national interests. Moreover, for India non-interference and sovereignty in its internal affairs are main aspects of multilateralism.¹³⁶³ According to Christian Wagner, New Delhi, *prima facie* appears to abide by multilateral agreements only to the degree that these agreements boost its sovereign autonomy and its global prestige.¹³⁶⁴ Brussels' position is almost diametrically opposed, as it believes in creating a law-based international order in the long run.¹³⁶⁵ Critics have argued that the EU has not evolved as a fully-fledged sovereign international actor from the standpoint of international law, and consequently its ability to live up to such a membership in the international legal order has not yet been established.¹³⁶⁶

For India, a traditional great power, the EU is predominantly a union of nation states instead of a regional supernational entity. Therefore, New Delhi seems to feel more comfortable engaging in bilateral talks. Critiques have noted that New Delhi's little interest when it comes to the EU comes down to lack of fundamental understanding, as well as rudimentary knowledge of the EU and its functions. This may be a consequence of being hardly exposed to EU affairs.¹³⁶⁷ Paris has, in this context, steadily surfaced as New Delhi's closest partner and traditional power; the bilateral relationship dates back to Gaullism, which reverberated strongly with India's nuclear ambitions and its role in the non-alignment movement - Paris also happens to be New Delhi's arms seller and a major player when it comes to the area of

¹³⁶³ Kavalski, Emilian: The EU–India strategic partnership: neither very strategic, nor much of a partnership, in: Cambridge Review of International Affairs (2016), Vol. 29 Is. 1, pp. 192-208, p. 202.

¹³⁶⁴ Wagner, Christian: India moves into the spotlight. in: Deutschland Online. 2006. - https://www.magazine-deutschland.de/magazin/OZ-India_6.06_ENG_E4.php, DOA: 12.4.2010.

¹³⁶⁵ Grevi, Giovanni / De Vasconcelos, Álvaro (eds.): Partnerships for effective multilateralism. EU relations with Brazil, China, India and Russia, in: Chaillot Paper No. 109. Paris: Institute for Security Studies, 2008, pp. 87-103, p. 90.

¹³⁶⁶ Bendiek, Annegret: A Paradigm Shift in the EU's Common Foreign and Security Policy: From Transformation to Resilience. in: SWP Research Paper 2017/RP 11 (2017), pp. 5 – 29, p. 11.

¹³⁶⁷ Benaglia, Stefania: How to Boost EU–India Relations. in: CEPS Policy Brief No. 341. 2016. - <https://ssrn.com/abstract=2766216>, DOA: 27.08.2017.

space.¹³⁶⁸ Additionally, France also happens to be a maritime nation with around one million of its nationals residing in the Indian Ocean.¹³⁶⁹

We shall take a brief look at the Strategic Partnership between the EU and India at this point; EU and India entered into a Strategic Partnership in 2004. In bilateral relations, multilateralism has been promoted by the EU; the partnership implied a strategic alliance for the advancement of an effective multilateral approach in international relations.¹³⁷⁰ During the various EU-India Summits, both unions propagated common norms and values, *inter alia*, democracy, human rights, and climate protection.¹³⁷¹

Notwithstanding its status as the largest single market on the globe, and despite sharing democratic beliefs, Brussels seems to be another commercial partner of New Delhi amongst several nations.¹³⁷² While the EU likes to believe that India sees it as a relevant player in the field of defence and security, in actuality, from the Indian perspective, Brussels is perceived as a weak actor which is far too disunited to develop a comprehensive strategy. It is seen as a follower of US security strategy, rather than as a leader.¹³⁷³ Critics have noted the complexity and potential of the EU as a global player has not fully been grasped to the full extent by India; this perception is mutual as Brussels seems to lack knowledge of New Delhi's perspective on the

¹³⁶⁸ Howorth, Jolyon: EU Global Strategy in a changing world: Brussels' approach to the emerging powers, in: Contemporary Security Policy (2016), Vol. 37, Is. 3, pp. 389-401, p. 393.

¹³⁶⁹ Racine, Jean-Luc: The Indo-French strategic dialogue: Bilateralism and world perceptions, in: Journal of Strategic Studies (2002), Vol. 25, Is. 4, pp.157-191, p. 165.

¹³⁷⁰ Kavalski, Emilian: The EU-India strategic partnership: neither very strategic, nor much of a partnership, in: Cambridge Review of International Affairs (2016), Vol. 29 Is. 1, pp. 192-208, p. 202.

¹³⁷¹ Ibid, p. 204.

¹³⁷² Howorth, Jolyon: EU Global Strategy in a changing world: Brussels' approach to the emerging powers, in: Contemporary Security Policy (2016), Vol. 37, Is. 3, pp. 389-401, p. 393.

¹³⁷³ Gippner, Olivia/ Lutz, Anja/ Mohan, Garima/ Stumbaum, May-Britt U./ Zhao, Jizhou: Does Europe Matter? The EU as a Security Actor in the Asian Century. NFG Working Paper Series, No. 18. 2015. - https://refubium.fu-berlin.de/bitstream/handle/fub188/18922/NFG_final_report_151111.pdf?sequence=1&isAllowed=y, DOA: 16.09.2017.

EU.¹³⁷⁴ The EU seems to be widely known in India for its approach to human rights and methods of seeking dialogue, rather than focusing on concrete projects at hand. The Union's policies are tied to its self-perception as a soft power; it views itself as a norm-based power that is committed to both multilateral institutions and international law.¹³⁷⁵ As part its effective multilateralism agenda, the EU believes in the strengthening of the UN.¹³⁷⁶ In this context, the Indian Union appears to be rather unhappy that merely 50% of EU members are committed to support New Delhi's bid for a seat at the UN Security Council. Washington, on the other hand, seems to be more committed in supporting India's bid for a permanent seat at the Security Council.¹³⁷⁷ In this context, India's nuclear power status and its status as part of the top five global economies do, *prima facie*, support this demand.¹³⁷⁸

Besides, Brussels has also been viewed by New Delhi as an entity that has been engaged to undermine the democratic composition of governance in India.¹³⁷⁹ Such sentiments also underline the fact that there seems to be some sort of disregard for the legitimacy of the EU's normative power on the Indian subcontinent; this, in turn, questions the very notion of Brussels' international identity.¹³⁸⁰

On another note, regarding the procurement and allocation of Covid-19 vaccines, in comparison to other nations, the EU's multilateral

¹³⁷⁴ Benaglia, Stefania: How to Boost EU–India Relations. in: CEPS Policy Brief No. 341. 2016. - <https://ssrn.com/abstract=2766216>, DOA: 27.08.2017.

¹³⁷⁵ Jaffrelot, Christophe: India and the European Union: The Charade of a Strategic Partnership. 2006. - <https://hal-sciencespo.archives-ouvertes.fr/hal-01065630/document>, DOA: 12.05.2017.

¹³⁷⁶ Ibid.

¹³⁷⁷ Howorth, Jolyon: EU Global Strategy in a Changing World: Brussels' Approach to the Emerging Powers, in: Contemporary Security Policy (2016), Vol. 37, Is. 3, pp. 389-401, p. 392.

¹³⁷⁸ Bajpai, Prableen: The 5 Largest Economies in The World And Their Growth in 2020. Nasdaq. 2020. - <https://www.nasdaq.com/articles/the-5-largest-economies-in-the-world-and-their-growth-in-2020-2020-01-22>, DOA: 15.04.2021.

¹³⁷⁹ Dutta, Sagnik: Negotiating a sell-out. in: Frontline. 2013. - <https://hillel.org/2013/05/01/negotiating-a-sell-out/>, DOA: 13.12.2016.

¹³⁸⁰ Kavalski, Emilian: The EU–India strategic partnership: neither very strategic, nor much of a partnership, in: Cambridge Review of International Affairs (2016), Vol. 29 Is. 1, pp. 192-208, p. 204.

approach has been suboptimal, to say the least. The EU as a multilateral organisation, *prime facie*, was unable to act swiftly and on short notice when it came to the procurement of life-saving vaccines. The EMA as a pan-European institution has been acting slowly when it comes to vaccine approval, and European bureaucracy appears less flexible when it comes to vaccine approvals. In other words, Brussels has prioritised process over speed when it comes to vaccine distribution.¹³⁸¹ The EU Commission has been criticised for its self-assumed position of a vaccine procurer and distributor in a Soviet-like manner.¹³⁸² The Commission lacked both expertise and experience in the procurement and supply of Covid vaccines, and, as a result, the EU has been largely left behind both the UK and the US in its vaccine rollout.¹³⁸³ With regard to vaccine procurement and supply a unilateral approach appears to be most promising, at least, in the short run. This is because national regulators and nation states seem to be capable of acting swiftly and dealing with vaccine approval on a short notice through emergency approvals, and thereby forgo the painstaking bureaucratic apparatus used by the EU.

Finally, *prime facie*, in the short run, unilateralism seems to be an effective approach when it comes to quickly vaccinating the population of an individual state. However, as we have examined, in the penultimate preceding sub-chapter¹³⁸⁴, in the long-term perspective a multilateral approach, when it comes to vaccines, is imperative and “vaccine nationalism” is indeed detrimental, given that we are living in

¹³⁸¹ Deutsch, Jillian/ Wheaton, Sarah: How Europe fell behind on vaccines: The EU secured some of the lowest prices in the world. At what cost? in: Politico. 2021. - <https://www.politico.eu/article/europe-coronavirus-vaccine-struggle-pfizer-biontech-astrazeneca/>, DOA: 23.02.2021.

¹³⁸² Hutton, Will: Yes, Britain’s vaccine rollout is a triumph. But let’s not kid ourselves it proves the Brexit case. in: The Guardian. 2021. - <https://www.theguardian.com/commentisfree/2021/feb/07/britains-vaccine-rollout-a-triumph-lets-not-kid-ourselves-it-proves-brexit-case>, DOA: 19.02.2021.

¹³⁸³ Deutsch, Jillian/ Wheaton, Sarah: How Europe fell behind on vaccines: The EU secured some of the lowest prices in the world. At what cost? in: Politico. 2021. - <https://www.politico.eu/article/europe-coronavirus-vaccine-struggle-pfizer-biontech-astrazeneca/>, DOA: 23.02.2021.

¹³⁸⁴ For details see the sub-chapter on Economic Interests and Protectionism.

a globalised and interconnected world. As the Covid-19 pandemic does not stop at national borders, it is necessary to take a multilateral approach when it comes to vaccine distribution. Only if the global community works together on a multilateral level can the pandemic be tackled successfully; in this regard, it seems to be imperative to waive the IPRs on Covid-19 vaccines, as advocated by India and South Africa before the WTO. Thus, vaccine nationalism is disproportionate and will have a detrimental effect on poorer nations. In sum, only multilateral efforts by the global community regarding the provision of access to essential vaccines can bring an end to the pandemic.

9. Conclusion

To begin with, if one were to contemplate Modi's remarks (see introduction) about the world considering India as the land of snake charmers and of black magic, this does, on the one hand, beg the question whether there had been much of a change given the so called "Gomutra parties", in which the consumption of cow urine in order to fend off Covid-19 was practiced by the Hindu nationalists in India. On the other hand, the Indian Union has indeed come a long way, and has established its status as the world's largest medicine cabinet.

With regard to the research question of whether access to essential generic medicines would qualify as an element of the right to health, the Office of the UN High Commissioner for Human Rights has stressed that access to medicines does indeed form a fundamental element of the right to health. Equally, given the fact that Losartan does indeed also fall under the WHO's list of essential medicine, one may argue that access to Losartan would fall under the cluster of the right to health. Likewise, generic medicines as cost-effective versions of patented drugs would fall under the second element of the AAAQ framework, as per the General Comment 14, namely accessibility (implying affordability). Having established this, we would also need to establish whether the right to health can be classified as a human right. In this regard, a multitude of international conventions have made the right to health part of the international human rights treaty. They *inter alia* cover the following conventions: UDHR, CEDAW, CRC, European Social Charter and ICESCR. Article 12 of the ICESCR recognises the right of all to enjoy the highest attainable standard of health. General Comment 14 also requires states to refrain from opposing the right to health or limiting the same. Thus, it can be deduced from the legislation above that the right to health does indeed fall into the category of human rights.

Regarding the seizure of essential generic medicines from India by the EU, it would be difficult to establish that the actions undertaken by the EU border forces against the shipment of Losartan from India were deliberate attempts to violate the right to health. It seems, however, that the EU would potentially be in violation of the right to health due to two decisive factors. Firstly, as a result of the delays caused by the seizure of medicines that were in transit, Brazilian patients were not able to access essential generic medicines and thereby barred from enjoying the highest attainable standard of health. Secondly, repeated in transit seizures and detentions of generic medicine from Indian designated to developing nations could potentially be classed as a systematic interference with the right to health. Thus, the EU has been at the root cause of these actions and has therefore arguably acted in violation of the right to health. As has been shown above, the right to health forms part of international human rights law and consequently, by default, the EU appears to be violating international human rights law. The seizures also appear to be in violation of the Maastricht Principles.

With regard to the question of the hierarchy of legal norms in instances in which a conflict between two legal norms arises as in the scenario in question, here between IP law (in the form of Council Regulation 1383/2003) and international human rights law (right to health), the issue at hand is which legal norm ought to be superior. Human rights advocates have proposed that to resolve this conflicting situation, international human rights law should take primacy over IP law, which in turn ought to be accepted where human rights obligations conflict with other norms. Policymakers have argued that both on the national, as well as on the international fora, the human right to health should take both moral and legal precedence over IP law. This argument was also supported by UN Special Rapporteur Farida Shaheed. According to Shaheed, in situations in which patent right and human rights are in conflict, the latter should supersede; thus, given the fact that for many in Brazil access to Losartan is a

matter of life and death, this argument seems to be convincing. As a result, it seems plausible that if a norm conflict between IP law and international human rights law (right to health) arises, the latter should prevail.

Pertaining to the issue of sanctions creating a barrier to trade, it appears that Council Regulation 1383/2003 does indeed violate Article V (2) of the GATT Agreement which mandates the freedom of transit. Similarly, Council Regulation 1383/2003 also seems to be in violation of Article 52 of TRIPS as, in the instance in question, it has obstructed legitimate trade. The Indian manufacturer entered into legitimate trade relations, as upon seizure the EU authorities found no issue with this point. As per Article 52 TRIPS the law of the country of importation, namely Brazil, would have been applicable and not that of the EU. According to Brazilian IP law the imported generic medicines were permissible, and by default, the EU border agency's seizure of generic medicines from India did indeed represent a potential barrier to trade. Interestingly, Brussels seems, at its own fruition, to have voluntarily assumed the position of an "IP watchdog" when it comes to the policing of IPRs on the international stage.

As for the question whether Brussels is using the seizure of generics from Indian in a protectionist manner, it can be deduced that Brussels seems to have two courses of action, which can be depicted as a two-edged sword, to fend off competition from developing nations in the area of pharmaceuticals. The first strategy that Brussels seems to employ is to make it a mandatory requirement, in its FTAs with developing countries, to implement the EU's IPRs standards which are typically higher than is required by the WTO under the TRIPS Agreement ("TRIPS Plus"). By making the implementation of these higher IP standards a prerequisite for an FTA with the EU, Brussels is protecting itself against much cheaper competition from developing countries, *inter alia*, in the area of pharmaceuticals. While the EU is obviously well accustomed to its own IP standards, developing nations

tend to struggle with the burden to comply and implement these higher IP standards. Implementation of the IP standards that are required by these FTAs tend to necessitate considerable time, finances and other resources, all of which are in short supply for developing countries. Secondly, as no FTA has been in place between the EU and India at the time of writing, the EU seems to have employed another strategy regarding Indian generics. In cases in which Brussels does not have FTAs in place, it appears to use its own domestic IP legislation to seize generic medicines suspected of IPR infringement, as seen in the case of generic medicines from India. The measures employed by the EU appear to be utilised to curtail competition from New Delhi against Brussels' domestic pharmaceutical industry. To achieve this objective, the EU appears to, strategically, utilise both its European Council Resolution 1383/2003 and its jurisprudence (manufacturing fiction) to rubber stamp its domestic IP standards in this particular case on Indian generics, which tend to utilise transit through European shores in order to cut transportation costs. The IP standards applied by the Council Regulation are higher than is required by TRIPS. Merkel's statement that Brussels should not have allowed New Delhi to become the biggest producer of pharmaceuticals in the world seems to elucidate the protectionist agenda of the EU. Similarly, the statement by Bayer CEO Dekkers that Bayer did not develop Nexavar for the Indians, but for Western patients who could "actually" afford the drug, seems to strike the same note. To argue with Huntington, Merkel's statement seems to create an "us" versus "them" scenario along religious and cultural lines between the Europeans and Indians.

Another incident that supports this line of argument would be the ban of 700 generic drugs from India by the EU due to suspected manipulations of clinical trials. The same generics were retailed in the European market for numerous years without any complaints having been raised regarding the quality or effectiveness of the drugs. A reason for this ban, according to the Indian side, might have been to stifle competition of Indian generics, which are typically available at a

fractional cost of its European counterpart. Indian generics present stark competition against the local pharmaceutical industry of the EU. Given the fact that Indian drug exports are worth around \$15 billion annually, it seems hardly surprising that New Delhi views this move as veiled protectionism. For Huntington, Brussels' protectionist policies make much sense and fit rather well into the categorisation of "West" versus the "Rest". The West (EU) is endorsing its economic interests together with the intention to inflict upon India the economic policies it deems fit, in the case in question, the extraterritorial application of the Council Resolution 1383/2003. It seems that, according to Huntington, the EU is utilising international institutions (WTO) and its economic position to shift and shake global trade in such a way as to guarantee the EU's dominance, promote its political and economic values, as well as to protect its trade interests.

Huntington's concept of global Western (EU) economic dominance could also be seen in the exploitation of Indian traditional knowledge by multinationals from the West. While in these instances the EU does not seem to actively promote the efforts of the Western pharmaceutical industry to exploit Indian traditional knowledge, it seems, however, to take a *laissez-faire* attitude when it comes to patent registration with the EPO by these Western companies. Regarding financial compensations for the exploitation of the traditional knowledge the situation is rather dire. As a matter of fact, the indigenous community have only on exceptional occasions been asked for their consent by the companies in question. Consequently, compensation for the exploitation of traditional knowledge remains an exception. The illegitimate exploitation of traditional knowledge without prior consent of the owner would qualify as a violation of international human rights law. Given the violation of IPRs in the context of traditional knowledge, it seems that the EU would be advised to take a stronger stance when it comes to the protection of traditional knowledge in order to avoid time-consuming and costly litigations for the mostly local and/or indigenous owners of traditional knowledge.

The traditional knowledge owners tend to be part of poor communities without adequate knowledge of their rights.

With regard to Brexit, Brussels' protectionist agenda could be seen in the triggering of Article 16 of the Northern Ireland Protocol to implement export controls on vaccines produced in the EU. The EU was fearful of the fact that London would use Northern Ireland as a back portal to circumvent export controls from Brussels and transport vaccines into the UK unchecked. It stated that such actions were justified to avert issues with the supply chain of Covid-19 vaccines. In actual fact, Brussels' measures appeared to be twofold, on the one hand they represented a form of protectionism, and, on the other they were utilised to save face given the EU's slow vaccine rollout. In this context, Huntington's theory appears to be outdated and requires a considerable overhaul, in particular the us-versus-them hypothesis. Religion and culture, being an important common denominator for Huntington, seem to be a weak argument, as can be seen in the case of the EU and Brexit. Although at the time of writing, a trade deal between the EU and the United Kingdom has been agreed upon, Brexit again highlights the shortcomings of Huntington's theory. In this instance, the common culture and religion neither acted as a safety pin nor could they be used as some sort of superglue to hold, in global terms, the UK in a brittle alliance with the EU.

Prima facie, protectionism or unilateralism seem to be effective when it comes to swiftly vaccinating the population of an individual state or territory; however, in the long run a multilateral approach to vaccines is imperative. Vaccine nationalism as *inter alia* practiced by the EU is indeed detrimental in a globalised and interconnected world. As the Covid-19 pandemic does not stop at national borders, it is necessary to take a multilateral approach when it comes to vaccine distribution. Only if the global community works together on a multilateral level can the pandemic be tackled successfully. Thus, it seems to be imperative to waive IPRs on Covid-19 vaccines as advocated by India and South

Africa, and only multilateral efforts by the global community regarding the provision of access to essential vaccines can bring an end to the pandemic.

In comparison to Brussels, New Delhi seems to have taken the high road with its “vaccine maitri” initiative. While the West is keeping its best, prohibiting the export of Covid-19 vaccines, India seems to be more than willing to share its vaccine with the rest of the world. The Hindu nationalist elite perceives India as the Vishwa Guru and are trying to market these ambitions through large scale soft power initiatives rather than through hard power capacities. The “vaccine maitri” initiative by New Delhi, through which Indian *inter alia* donated Covid-19 vaccines to developing countries, appears to be another move of the BJP government to become a respected major player on global stage. The “vaccine maitri” initiative will, from the perspective of the BJP elites, boost India’s status as a Vishwa Guru in science and technology, as envisaged by RSS founder Dr. Hedgewar. The BJP government has received considerable appreciation for its vaccine diplomacy from world leaders.¹³⁸⁵ Another initiative to boost India’s global standing was the International Yoga Day through which New Delhi was expecting to gain prestige on the international stage.

Finally, India’s post-imperial victimhood approach seems to be in line with the European border agency’s seizure of Indian generic medicines, and would, *prima facie*, fit into the description of victimisers, as they were restricting India from obtaining the status of a Vishwa Guru (world leader) in the global pharmaceutical industry. For the RSS, the seizure of generic Indian medicines by an EU border official, due to suspected violations of IPRs, could be interpreted as yet another effort by the West (EU) to continue with the never-ending

¹³⁸⁵ Sibal, Sidhant: World leaders thank PM Narendra Modi as India sends COVID-19 vaccines to 47 countries. in: Zee News. 2021. - <https://zeenews.india.com/india/world-leaders-thank-pm-narendra-modi-as-india-sends-covid-vaccines-to-47-countries-2345750.html>, DOA: 01.05.2021.

downgrading of India. Similarly, the ban of around 700 Indian generic medicines in 2015 seems to further confirm the determination by the EU to curtail India from becoming an economic power from RSS' point of view. Likewise, Brussels would be seen from a Hindu nationalist perspective as utilising the seizure to culturally induce poverty in India or staying with the topic, to hinder India's growth as the pharmacy of the world. As per the RSS' ideology, India would need to regain self-confidence in this matter and challenge the suppressor.

On another note, the Hindu nationalist's propaganda regarding the medical capacities of Gomutra and the organisation of Coronavirus parties might, arguably, have caused some amusement in the EU and around the world. From both the BJP's and Hindu nationalist's standpoint, the position of Gomutra seems to follow a rational that is designed to rally the Indian public behind the Hindu nationalist (Hindutva) agenda and of a symbolic nature. The Hindu nationalist policies to promote Gomutra could have cast doubts as to the quality, as well as the credibility, of Indian medicines and the pharmaceutical industry as whole. While reasonable scepticism and objectivity needs to be at the forefront of any scientific research, overall, the Hindu nationalist Gomutra remedy against Covid-19 seems not to have caused significant damage to the reputation of the domestic pharmaceutical industry of India from the EU's perspective. This can be deduced from Merkel's statement regarding Brussels needing to procure essential COVID-19 vaccines from New Delhi. Another issue of concern has been AMR in India, and its spread to the EU has been rather discomforting. Multiple Indian manufacturers of pharmaceutics have been tested for superbugs, which are resistant to antibiotics, in the water of production sites. Given the fact that India has been at the epicentre of the global drug resistance crisis, Brussels' response could have been triggered by the potential health hazard originating from New Delhi, to ban generic medicines from India out of precaution. These sanctions seem to have been short lived and were settled via bilateral consultations sooner rather than later.

It follows from this research that, for the foreseeable future, arguably the biggest area of contention when it comes to negotiations about an FTA between the EU and India is going to be IP protection in the field of pharmaceuticals. To tackle this issue of much discontent, the EU would be advised to learn from the consequences of German Pharmaceutical multinational Bayer losing its case against Natco Pharma Ltd. In this context, the Natco Pharma Ltd v Bayer Corporation case illustrates the beneficial aspects that compulsory licences could have for both the European pharmaceuticals industry and vulnerable patients in developing countries. Ironically, as a consequence of losing the case against Natco Pharma Ltd and issuing a compulsory licence, Bayer was able to obtain more profit than before, while at the same time, a large portion of the Indian population gained access to affordable and essential generic medicines. If anything, the Nexavar example demonstrates that issuing compulsory licences does not need to come at a loss for the multinational corporation. It would be advisable for both EU and India to work on opportunities that are similar to compulsory licences rather than to engage in the seizure of essential medicines. Thus, compulsory licences, or other knowledge and benefit sharing initiatives, provide an excellent tool that would enable EU pharmaceuticals to share their knowledge with the domestic pharmaceutical industry in India, and at the same time to make more profit than ever in the segment in question in India. Applying this idea to the EU would mean to make contractual arrangements with India through an FTA that would be beneficial for the pharmaceutical industries of both unions and for those with ill-health in developing countries.

If anything, the Bayer example shows that compulsory licences may turn out to be a win-win situation for both the consumer in the developing world and the multinational cooperation. By the same token, instead of blocking the Indo-South African initiative, at the WTO, to suspend IPRs related to Covid-19 in order to make Covid-19 vaccines available for both LDC and developing countries, Brussels'

would be strongly advised to actively promote the Indo-South African initiative. Admittedly, at the time of writing, the EU has committed itself to deliver 1.3 billion doses of vaccine and 2.2 billion in funds for the developing world as Covid-19 relief measures. While this is commendable, it is merely a drop in the ocean. The only way to tackle this pandemic would be to waive the strong IPRs protection on Covid-19 vaccines and other related drugs. Regarding the actions against generic medicines from India due to suspected IP infringement, the EU would be advised to hold regular consultations with their Indian counterparts, prior to the implementation of seizures, to clarify potential contentious matters and agree on a *modus operandi*.

To conclude, it would be worth noting that further research ought to be undertaken in four areas that will be detailed below. Firstly, access to essential generic medicines as human right is a topic of longevity and, due to the strong protectionist stance of the pharmaceutical industry, when it comes to the subject of IPR, this issue will remain a contentious matter in the international arena for the foreseeable future. If anything, the contemporary global Covid-19 vaccine shortage has once again highlighted this issue rather nicely. As a result, further research should be encouraged in this field. Secondly, the commercial exploitation of traditional knowledge, particularly, in the areas of Indian traditional medicine and medicinal remedies, is an emerging field and requires considerable research in the foreseeable future. Scholarly and interdisciplinary work should *inter alia* focus on the protection and guarantees of ownership rights of the IPR's holder who, in most cases, happen to be the indigenous and rural population of India. In this context, future scholarly research should both encourage and focus on recommendations for stricter domestic, regional, and international legislation that aim to provide a higher level of protection for traditional knowledge. Thirdly, research should be undertaken as to the creation of an FTA between the EU and India. In doing so, particular importance should be given to both the IPRs regime and the pharmaceutical sector, as this has been a thorn in the flesh of both

entities. Lastly, the engagement of both unions regarding the distribution of Covid-19 vaccines would be another area that is worth investigating. It would, particularly, be worth examining whether Brussels will eventually have a change of heart amidst both the rising death tolls due to Covid-19 (globally) and the increasing criticism of the EU's vaccine nationalism. In sum, future research in the above-mentioned topics would be highly beneficial for the development of scholarship in this field of research.

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