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Patent Settlements in the Pharmaceutical Industry: What Can We Learn From Economic Analysis?

Severin Frank and Wolfgang Kerber*

(November 2015)

Abstract

Patent settlements between originator and generic firms in the pharmaceutical industry have been challenged by antitrust and competition authorities in the U.S. and the EU. Particularly settlements with large "reverse payments" to generic firms raise the concern of collusive behaviour for protecting weak patents and delaying price competition through generic entry and therefore harming consumers. However, it is still heavily disputed under what conditions such patent settlements are anticompetitive and violate antitrust rules. This article scrutinizes critically what economic analysis has so far contributed to our knowledge about the effects of these patent settlements and the possible rules for their antitrust treatment. An important claim of this paper is that the problem of patent settlements can only be understood, if we analyze it not only from a narrow antitrust perspective but also take into account its deep interrelationship with the problems (and the economics) of the patent system. Therefore we identify three different channels of effects, how patent settlements can influence consumer welfare: (1) price effects, (2) innovation incentive effects, and (3) effects via the incentives to challenge weak patents. The paper critically analyzes the existing economic studies and identifies a number of research gaps, especially also in regard to trade offs between different effects. It also suggests that policy solutions for these patent settlements should also be sought in combination with patent law solutions.

Keywords: Patent settlements, probabilistic patents, weak patents, pharmaceutical industry, generic competition

JEL classification: K40, L40, O34

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1. Introduction

Patent settlements between originator firms and generic firms in the pharmaceutical industry have been one the most disputed topics in competition and antitrust law discussions in recent years.[1] Particularly patent settlements with "agreed entry dates" in combination with "reverse payments" to generic firms ("pay-for-delay") were challenged by antitrust authorities in the U.S. and the EU as anticompetitive collusive behaviour between originators and generics delaying price competition through generic entry and harming consumers. Since settlement outcomes with large reverse payments can only occur in cases of potentially invalid patents ("weak patents"), this question is deeply linked to fundamental problems in the patent system. The controversies about patent settlements focus primarily on the role of reverse payments, i.e. whether they should be deemed as per se illegal, whether a (strong) presumption of illegality (with possibilities of rebuttals) should be applied or whether due to possible efficiency effects a rule of reason approach would be appropriate. Both in the US and the EU, so far no consensus could be reached among legal and economic scholars about the most appropriate antitrust solution.

In the U.S., the Federal Trade Commission (FTC) challenged such patent settlements with reverse payments in the pharmaceutical industry since 1999. The position of the FTC was and still is that patent settlements with reverse payments should be presumed as illegal with the possibility of a rebuttal by the parties, e.g. through litigation costs or other efficiencies (quick look rule).[2] After this policy of the FTC ran into much resistance in the U.S. courts (with contradictory decisions and reasonings; see Carrier 2012), the "Actavis" decision of the Supreme Court clarified that a large unexplained reverse payment can be a signal for the weakness of the patent and therefore the anticompetitiveness and illegality of such patent settlements. However, the Supreme Court also rejected the presumption of illegality approach of the FTC and wants the U.S. courts to apply a rule of reason approach, which also takes into account possible explanations for any value transfer from the originator to the generic firms.[3] In the EU, the European Commission (in its Pharmaceutical Sector Inquiry 2009, pp. 270) classified patent settlements and argued that the group of patent settlements with a restriction of entry and with a reverse value transfer requires closer competition policy scrutiny. This led the Commission to put this group of patent settlements under a special antitrust scrutiny in the newly adapted guidelines for the application of Article 101 (3) TFEU to Technology Transfer Agreements, and challenge and prohibit several patent settlements with reverse payments (e.g., in the case "Lundbeck"). Although the EU Commission acknowledges that settlements can have efficiency advantages like saving of litigation costs, time, and the resolution of uncertainty, it also emphasizes that society has an interest in removing wrongly granted patents to promote competition and innovation.[4]

How can the state of the academic discussion be briefly summarized? The large majority of scholars claim that patent settlements can be anticompetitive through delaying or impeding market entry and

[1] Janis/Hovenkamp/Lemley 2003, Bulow 2004, Hemphill 2006, Holman 2007, Carrier 2009, Brankin 2010, Edlin et al. 2013, Frank/Kerber 2013, Wang 2014.
[2] FTC Study 2002, p. vii; Case 570 U. S. ____ (2013) FTC v. Actavis, Inc. p. 20, Brankin 2010, p. 24, FTC Staff Study 2010, p. 9.
[3] Case 570 U. S. ____ (2013) FTC v. Actavis, Edlin et al. 2013, Wang 2014.
[4] EC Guidelines on the Appl. Of Art 101 to TTA, pp. 44.

therefore restricting generic competition.[5] There is a nearly unanimous consensus among these scholars that the size of reverse payments is a crucial criterion for its anticompetitive effects. The main discussion refers to the question whether a presumption of illegality of patent settlements with reverse payments should be used, or whether a rule of reason approach should be applied. Although nobody denies the possibility of efficiency advantages of patent settlements,[6] there is a wide range of opinions whether a stronger or weaker presumption of illegality of patent settlements with reverse payments (with a smaller or larger set of possible rebuttals) or a full-blown rule of reason with a deep case-specific analysis should be recommended.[7] There also seems to be a broad consensus that, vice versa, patent settlements are not seen as being anticompetitive, if the parties only agree on future entry dates without a reverse net value transfer.[8]

There is only a limited number of articles about patent settlements in which explicit economic analyses can be found. Some articles address the problem of patent settlements in the pharmaceutical industry directly (either with economic models,[9] or at least with explicit economic reasonings[10]). But also other economic contributions about the broader problems of weak ("probabilistic") patents and the design of the patent system are relevant for this patent settlement problem.[11] This article intends to analyze critically what economic analyses have so far contributed to our knowledge about the effects of patent settlements in the pharmaceutical industry and the possible rules for their antitrust treatment. On one hand, this entails a critical analysis of these economic models themselves (and the claims made by them), and, on the other hand, also an analysis of the gaps in our knowledge and the open research questions. One crucial claim of this paper is that the problem of patent settlements can only be understood, if we analyze it not only from a narrow antitrust perspective but also take into account its deep interrelationship with the (economics of the) patent system.[12]

The paper is structured as follows: Section 2 will present the general problem of weak patents as part of the discussion about the problems of the patent system. Section 3 will focus on the relevant normative antitrust standard (consumer welfare) and distinguish three channels of possible effects of patent settlements on consumer welfare. Section 4 deals with the effects on consumers via price competition, i.e. that patent settlements with reverse payments might harm consumers through the delay of generic entry. However, relevant for consumer welfare are also the effects of patent settlements on innovation incentives (section 5) and the incentives for generics to challenge potentially invalid patents (section

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[5] Balto 2000, Crane 2002, Morse 2002, Janis/Hovenkamp/Lemley 2003, McDonald 2003, Bulow 2004, Leffler/Leffler 2004, Hemphill 2006, Ponsoldt/Ehrenclou 2006, Holman 2007, Leary 2007, Davis 2009, Carrier 2009, Brankin 2010, Gratz 2012, Edlin et al. 2013, Piecht 2013, Carrier 2014b, Cotter 2014, Feldman 2014.

[6] Hemphill 2006, p. 121, Dickey/Orszag/Tyson 2010, p. 375, Brankin 2010, p. 23, Addanki/Butler 2014, p. 81.

[7] See, e.g., the "Actavis inference" as the most recent variant (Edlin et al. 2015).

[8] FTC Staff Study 2010, p. 1, EC Guidelines on the Appl. Of Art 101 to TTA, pp.44, EC Pharmaceutical Sector Inquiry Final Report, p. 524 at para. 1573.

[9] Willig/Bigelow 2004, Elhauge/Krüger 2012, Gratz 2012, Addanki/Daskin 2009, Yu/ Chatterji 2011.

[10] Schildkraut 2004, Hemphill 2006, Carrier 2009, Davis 2009, Kobayashi et al. 2015, Edlin et al. 2015.

[11] Shapiro 2003, Lemley/Shapiro 2005, Farrell/Shapiro 2008, Encaoua/Lefouili 2009.

[12] Please note that this is a general paper about patent settlements in the pharmaceutical industry. Therefore it does not take into account the specific institutional conditions of different legal and regulatory systems, as, e.g., the Hatch-Waxman Act in the U.S. or the specific institutional characteristics in the EU. Therefore we also do not want to derive specific policy conclusions in that regard.

6). The final section 7 will summarize our results, identify gaps of research, and discuss policy conclusions.

2. The Background Problem: Weak Patents and Defects of the Design of the Patent System

The problem of patent settlements in the pharmaceutical industry stems from the fact that a large number of granted patents are found invalid in patent litigation, which gives patent holders large incentives to defend their weak patents through settlements with reverse payments to challenging generic firms. An important reason is that patent offices do not invest enough time and resources in patent examination (esp. in regard to "prior art") and therefore tend to grant too many patents which often would not survive a challenge in patent litigation ("weak patents"). Empirical studies show that litigated patents are found invalid in 50% (or more) of all cases (Lemley/Shapiro 2005, p. 76). This result could be interpreted as a defect of the patent system. However, Lemley (2001) argued from an economic perspective, that such a result might also be efficient, because it might not be worthwhile to make deep and costly examinations of all patent applications, because many of the granted patents turn out as not valuable (rationally ignorant patent offices). But both interpretations lead to the conclusion that it is necessary that the patent system has effective legal instruments for challenging and weeding out invalid patents. It is an open question in the patent literature, whether and to what extent the institutional design of the entire patent system (with all its rules about granting, opposing, and challenging patents in courts) leads to an efficient patent system or - as in the meantime most legal and economic scholars claim - that the existing patent systems are deeply flawed and suffer from serious problems (Shapiro 2004, pp. 1018, Hall/Harhoff 2004, pp.4).

An economic perspective on this problem of weak patents has led to the development of the concept of "probabilistic" patents or “partial property rights” which has played a major role in the patent settlement discussion.[13] The basic idea is simple: Whereas from a legal perspective a patent right is either valid or not, the economic value of a granted patent right before litigation depends also crucially on the expected probability of defending it in patent litigation. If this probability is, e.g., $\theta = 0.25$, then the expected value of the patent for the patent owner is much lower than the value of a fully defendable (iron-clad) patent right. This probability θ is used for defining the strength of a patent. This "probabilistic" character of a patent has been used in the patent settlement discussion in two different ways: Since the patent strength θ reflects the winning probabilities of the settling parties in patent litigation, it influences the ranges of the settlements (in regard to agreed entry dates and/or the size of reverse payments). In the economic models but also in argumentations of legal scholars, this has led to conclusions that a 25% chance of defending a patent against a challenging generic firm would lead to a settlement on an agreed entry date without reverse payment of 25% of the remaining patent duration (e.g. Elhauge/Krüger 2012, pp. 295). However, it can also be used for the analysis of the innovation incentives that such a probabilistic patent offers (e.g. how large are the incentives for an innovation that allows for a patent with a patent strength of 25%). In their seminal paper "How Strong are Weak Patents?" Farrell/Shapiro (2008, p. 1348) assume that innovation incentives for probabilistic patents are optimal, if the proportionality principle is fulfilled, i.e. that incentives for an innovation from a probabilistic patent are proportional to its patent strength, i.e. that the rents from a patent with $\theta = 0.5$

[13] See Ayres/Klemperer 1999, Shapiro 2003, Farrell/Shapiro 2008.

should be half of the rents of an iron-clad patent ($\theta = 1$) and twice the rents for a patent with $\theta = 0.25$. Farrell/Shapiro (2008) have suggested that profits from weak patents might be relatively too large in comparison to stronger patents, leading to a distortion of innovation incentives in favour of "innovations" that only with a small probability are true innovations that should be rewarded by patent protection (see below section 5).

It is well known that the challenging of potentially invalid patents can suffer from serious incentive problems. Since all patent systems rely on private litigation for challenging patents, the private incentives for challenging patents suffer from a public good problem, because the costs and risks of patent litigation is borne by the challenging firm, whereas the benefits of having eliminated an invalid patent right accrues to everybody.[14] This externality of challenging patents cannot only lead to too small incentives for challenging firms, but also implies that patent settlements between originator and generic firms can have negative (external) effects on third parties, because the settlement helps to maintain an unjustified exclusive right. Due to these third-party effects, the usual normative notion that private parties should be free how to settle their conflicts in private litigation is problematic in the case of patent litigation. Therefore rules for critically scrutinizing and limiting the scope of patent settlements are justified also from an economic perspective. However, this is not only a problem of patent settlements. Shapiro (2003) showed that patent owners can achieve the same result of defending their weak patents also through licensing agreements (with too low license fees), mergers, and patent pools leading him to the conclusion that all of these transactions should be put under antitrust scrutiny.[15]

3. Assessing Antitrust Rules for Patent Settlements: Normative Questions and the Distinction Between Three Groups of Effects

What is the correct normative criterion for assessing antitrust rules for patent settlements? Most influential and representing also the ex- or implicit opinions of many other scholars is the criterion that a patent settlement should not lead to a lower consumer welfare than it can be expected from litigation (Shapiro 2003, p. 396).[16] According to him, "... consumers have a 'property right' to the level of competition that would have prevailed, on average, had the two parties litigated the patent dispute to a resolution in the courts. So long as the consumers' rights to this level of competition/benefits are respected, the two parties are permitted to negotiate more profitable arrangements that they each prefer to litigation" (ibid.).[17] In line with the "probabilistic" perspective on patents, this also implies that “patent holders are not entitled to the same level of profits that would result from an ironclad patent covering the same patent claims" (ibid.).

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[14] See Farrell/Merges 2004, pp. 952, Hemphill 2006, pp. 150. This is the reason why in the U.S. the Hatch-Waxman Act intended to increase the incentives of generic firms by giving the first challenging firm a 180-days-exclusivity right in regard to market access (in comparison to other generic firms). However, the 180-day mechanism is also critically discussed, since it might open opportunities for making collusive settlement agreements with the first filer while others are excluded (Janis/Hovenkamp/Lemley 2003, p. 1755, Hemphill 2006, p. 108, Carrier 2009, pp. 61).

[15] Closely related to this problem is also the discussion about the antitrust assessment of "non-challenge clauses" in licensing agreements (Janis/Hovenkamp/Lemley 2003, pp. 1721).

[16] E.g. Blair/Cotter 2002, Janis/Hovenkamp/Lemley 2003, Schildkraut 2004, Elhauge/Krüger 2012, Gratz 2012.

[17] However, this is not the same as the "less-restrictive alternative" standard, which is also used in Art. 101 (3) of the European competition rules.

The manifold effects of antitrust rules for patent settlements can affect the welfare of consumers through three different channels:

(1) The discussion so far focussed mainly on the (static) price effects through the potential delay of competition by generic entry. The question here usually is whether patent settlements lead to such a late entry of generics that the benefits of future lower prices through generic competition for the consumers are less than what could be expected in the case of patent litigation.

(2) Antitrust rules on patent settlements can also influence the innovation incentives, i.e. the question is whether more restrictive rules for defending patents through reverse payments might lead to lower innovation incentives for originator firms (dynamic efficiency) and therefore also harm consumers in the future.

(3) The third channel for effects on consumer welfare are the effects of antitrust rules on patent settlements for the incentives of generics to challenge weak patents. If patent settlements, for example through reverse payments, can also increase the incentives for challenging potentially invalid patents, then a lower number of monopolistic market positions are protected by unjustified patents until the expiration date, leading to higher consumer welfare through more generic competition.

Should the last two groups of effects be relevant for an assessment of patent settlements from an antitrust perspective? The argument might be made that they relate both to effects on innovation and the patent system, and should therefore not be a concern of competition law. However, the problem is more complex: First, although the main discussion focusses on the static price effects, also the other effects have been discussed and mentioned as relevant both from legal and economic scholars in the antitrust discussion about patent settlements. In the EC Guidelines on Technology Transfer Agreements the "general public interest to remove invalid intellectual property rights as an unmerited barrier to innovation and economic activity"[18] was explicitly mentioned. In the U.S., it is the Hatch-Waxman Act which explicitly intended to increase the incentives of generic firms for challenging invalid patents of originator firms. Therefore the second and third group of effects have always been present in this discussion. Secondly, from an economic perspective, the criterion of using the consumer welfare in the case of litigation as normative standard would also entail the effects on innovation incentives and incentives to challenge invalid patents. However, this touches the difficult and hotly disputed issue of the proper delineation between problems that should be dealt with in competition law or in patent law. We will come back to this discussion at the end of this paper.

4. Effects on Consumer Welfare via Prices

Nearly the entire literature on patent settlements in the pharmaceutical industry has focussed on the effects that settlements with or without reverse payments might have on the entry date of generics and therefore on the question when generic competition does lead to lower prices for drugs. Since there is a broad consensus that settlements should be preferred to litigation due to litigation costs, the crucial question concerns the antitrust limits that should be set for settlements in order to avoid negative effects for consumers via prices. In the following, we summarize and analyze the results of this discussion from an economic perspective. It is surprising that - despite all the controversies - most of the

[18] EC Guidelines on the Appl. Of Art 101 to TTA, p. 44 at para. 235.

contributions both from economic and legal scholars use roughly the same basic economic model, either explicitly or implicitly.[19] Therefore it is useful to present briefly the assumptions, reasonings, and conclusions of this basic model.

The basic patent settlement model

It is assumed that an originator firm A has a patent which allows for annual monopoly profits M_A for the remaining patent duration T, and there is only one firm B that can challenge the patent. If this generic firm B would enter the market at entry date E, both firms have annual duopoly profits D_A and D_B.[20] Since duopoly prices are lower than monopoly prices, the annual welfare of consumers under duopoly (W_D) is larger than under monopoly (W_M). If we assume that the true patent strength (probability of defending successfully the patent in litigation) is θ, then the consumers can expect with probability θ a lower consumer welfare due to high monopoly prices and with probability 1 - θ a higher consumer welfare due to lower duopoly prices after revocation of the patent.[21] According to the normative criterion of Shapiro the consumer welfare in the settlement case should not be smaller than in the litigation case ($W_S \geq W_L$). If in the settlement both parties have agreed on an entry date E (e.g., in 2 years), the consumer welfare in the case of settlements is $W_S = E\ W_M + (T - E)\ W_D$, i.e. for two years consumers suffer from the low consumer welfare under monopoly prices before their welfare is increased through lower duopoly prices for the rest of the patent duration. This implies that under these assumptions the normative criterion is fulfilled, if the entry date of the generic is not later than the strength of the patent θ multiplied with the remaining patent duration T (i.e., $E \leq \theta\ T$ (for the following analysis, we define: $E^* = \theta\ T$). For example, this would mean that a patent strength of 20% would translate into an entry date after 20% of the remaining patent duration T, i.e. if T = 10 years, i.e. generic entry should be not later than in two years.

What are the results of a patent settlement between both firms? From the law and economics of settlements we know that the settlement range between both firms is determined by the outside options and these are the expected values of litigation of both parties. In this simple version of the model we assume that both firms know the true patent strength θ and have litigation costs c_A and c_B.[22] In the settlement the parties can agree on an entry date E and a reverse payment R that is paid by the patent holder to the generic firm. What settlement would be optimal for both firms, if there were no antitrust limits? It can easily be shown that joint profit maximization would lead to a settlement, in which both firms agree to delay market entry of the generic firm until the expiration of the patent (i.e. $E > E^* = \theta\ T$). The joint profits would be identical to the monopoly profits of an iron-clad patent with a patent strength θ = 1. The generic would need to get a reverse payment which is not lower than its expected value of litigation. The consumers would be worse off compared to litigation, and the loss of consumer

[19] See e.g. Dickey/Orszag/Tyson 2010, Elhauge/Krüger 2012, Yu/Chatterji 2011, Gratz 2012, Edlin et al. 2013.

[20] The sum of the two duopoly profits is smaller than the monopoly profit ($D_A + D_B < M_A$).

[21] Therefore the expected consumer welfare in case of litigation is: $W_L = \theta\ T\ W_M + (1 - \theta)\ T\ W_D$. Please note that the consumer welfare in the litigation solution depends on the true patent strength θ and not on the subjective estimations of the firms A and B about the strength of the patent, i.e. θ_A and θ_B. This is often overlooked in the literature.

[22] Then the expected value of litigation is for A: $V_{LA} = \theta\ T\ M_A + (1 - \theta)\ (T\ D_A) - c_A$; and for B: $V_{LB} = (1 - \theta)\ (T\ D_B) - c_B$.

welfare through such patent settlements increases with the weakness of the patents.[23] If the firms are not allowed to maximize their joint profits in the settlement due to antitrust limits, we can analyze the relation between the agreed entry date E and the reverse payment R. The earliest entry date that the originator would accept (E_{min}) as well as the latest entry date acceptable for the generic (E_{max}) depends on the expected monopoly and duopoly profits, the litigation costs, and the reverse payment. Most influential for the entire discussion is the result of the model that in the case of the absence of reverse payments (R = 0), an agreed entry date can be expected which is very close to the normatively correct entry date $E^* = \theta T$. And: The higher the reverse payment R, the later is the generic entry and therefore the welfare losses for consumers.[24]

From this basic model several conclusions can be derived that have been very influential in the policy discussion:

(1) The normative criterion that patent settlements should not harm consumers compared to patent litigation translates into the criterion that generic entry should not be later than $E^* = \theta T$, i.e. the agreed time of generic entry should be strictly proportional to patent strength.

(2) If there are no reverse payments, then the bargaining would lead to a settlement range around this optimal entry date $E^* = \theta T$. As soon as the reverse payment R is larger than the litigation costs of the originator (i.e., $R > c_A$), the agreed entry date E is later than the optimal entry date E^* and therefore anticompetitive.

(3) Reverse payments are a very effective instrument for restricting price competition through generic entry. Increasing reverse payments leads directly to later entry dates and higher joint profits and higher welfare losses for consumers compared to patent litigation.

(4) Without antitrust limits for patent settlements, the settling parties would agree on an entry date at the end of patent duration T, i.e. weak patents would lead to the same profits and consumer welfare as iron-clad patents with a patent strength $\theta = 1$.

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[23] The value of the settlement solution would be for firm A: $V_{SA} = E\ M_A + (T - E)\ D_A - R$; and for firm B: $V_{SB} = (T - E)\ D_B + R$. If both firms maximize their joint profits for finding the most profitable settlement solution, their joint profit would be: $V_{SAB} = V_{SA} + V_{SB} = E\ M_A + (T - E)\ (D_A + D_B)$. Since $D_A + D_B < M_A$, it is optimal for both of them to agree delaying the generic market entry until the expiration of the patent, i.e. $E = T$ (with $V_{SAB} = T\ M_A$). For agreeing to this settlement the generic firm would at least need a reverse payment that equals its value of litigation: $R_{min} = V_{LB} = (1 - \theta)\ (T\ D_B) - c_B$. Vice versa, the maximal reverse payment that the patent holder A would be willing to pay equals its monopoly profits minus its value of litigation: $R_{max} = T\ M_A - V_{LA} = (1 - \theta)\ T\ (M_A - D_A) + c_A$. Therefore the range for the reverse payment R would be: $(1 - \theta)\ (T\ D_B) - c_B \leq R \leq (1 - \theta)\ T\ (M_A - D_A) + c_A$. Economically, the benefits of such a settlement for both parties consist of the additional profits (because: $M_A > D_A + D_B$) plus the saved litigation costs c_A and c_B. The consumer welfare in this case, $W_S = T\ W_M$, is identical with the case that the patent holder can get monopoly profits for the entire duration of its patent. Therefore it is considerably smaller than under litigation: $W_S - W_L = T\ W_M - [\theta\ T\ W_M + (1 - \theta)\ T\ W_D] = (1 - \theta)\ T\ (W_M - W_D) < 0$.

[24] The earliest entry date, E_{min}, that the patent holder would accept is $E_{min} = \theta\ T - c_A / (M_A - D_A) + R / (M_A - D_A)$, and the latest acceptable entry date for firm B is $E_{max} = \theta\ T + c_B / D_B + R / D_B$. We see that increasing the reverse payments R shifts the settlement range in the direction of later entry dates, which would increase profits and reduce consumer welfare. If, however, there are no reverse payments (R = 0), we get a settlement range $\theta\ T - c_A / (M_A - D_A) \leq E \leq \theta\ T + c_B / D_B$ around the optimal entry date $E^* = \theta\ T$, and the range on both sides depends only on the litigation costs of both parties (divided by the profit changes through the entry). If, in addition to that, there would be no litigation costs ($c_A = c_B = 0$), then the agreed entry date in the settlement would exactly equal the normatively correct one: $E = E^* = \theta\ T$.

(5) This model also suggests that patent settlements without reverse payments are not anticompetitive, because they usually lead to the correct entry date.[25]

From these results, it can easily be understood why antitrust scholars are so concerned about reverse payments, and why antitrust rules were proposed that prohibit reverse payments (beyond litigation costs) or recommend at least a strong presumption of their illegality. However, the decisive question from an economic perspective is whether these results still hold, if we take into account that the conditions on pharmaceutical markets and in settlement processes are in reality much more complex than represented by the very simple assumptions of this model. This is the starting-point of primarily economic papers that can show that under more realistic assumptions these simple conclusions do not hold and therefore also patent settlements with reverse payments (beyond litigation costs) can be efficiency-enhancing and do not harm consumers, supporting the calls for a rule of reason approach (esp. Willig/Bigelow 2004). In the following, we cannot discuss all these specific reasonings, but provide a broader assessment of the consequences of relaxing the strict assumptions of this model.[26]

Implications of more realistic assumptions

One example are knowledge assumptions about patent strength. Since nearly the entire literature assumes that the true patent strength θ is unknown, it cannot be assumed as in the basic model that the firms know the true patent strength or that they have the same subjective estimates about the patent strength. A number of papers have focussed on the analysis of settlement outcomes, if the patent holder and the entrant have different estimates about patent strength (optimistic/pessimistic).[27] Depending on the specific assumptions the settlement ranges in these cases can get broader (and making settlement easier) or smaller. It can even get negative, which despite the saving of litigation costs might make a settlement impossible without reverse payments.[28] The other possibility is that both parties might generally over - or underestimate the patent strength. If the parties overestimate the patent strength (i.e., $\theta_A = \theta_B > \theta$), then even without reverse payments the agreed entry date will be later than the normatively optimal one ($E > E^*$), rendering this patent settlement anticompetitive. Vice versa, in the case of an underestimation of the patent strength ($\theta_A = \theta_B < \theta$), the agreed entry date (with $R = 0$) will be earlier than the optimal one ($E < E^*$), which would allow positive reverse payments (beyond litigation costs) without making the patent settlement anticompetitive.

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[25] E.g. Shapiro 2003, Dickey/Orszag/Tyson 2010, pp. 379.

[26] For caveats in regard to the conclusions from the basic settlement model, if more realistic assumptions are considered, see already Shapiro (2003, 410). He mentioned explicitly multiple challengers, asymmetric information, signaling, risk aversion, and also the existence of a portfolio of patents as unresolved topics.

[27] Willig/Bigelow 2004, pp. 672, Davis 2009, p. 292, Schildkraut 2004, pp. 1064.

[28] Willig/Bigelow (2004, pp. 672) analyzed such a case. They assume that the incumbent patent holder knows the true patent strength and the entrant is overoptimistic, i.e., assumes a too low patent strength ($\theta = \theta_A > \theta_B$). Willig/Bigelow are right that this is a case, in which the wrong estimate of the entrant makes a procompetitive settlement without a reverse payment impossible. However, if a competition authority or court does not know the true patent strength, then this case cannot be distinguished from another case, in which the entrant knows the true patent strength and the patent holder is over-optimistic ($\theta_A > \theta_B = \theta$), and in which a settlement with reverse payment would clearly lead to a too late entry and therefore would be anticompetitive.

Similar results can be derived, if one or both firms make wrong predictions about the future market conditions (market demand, new substitutes, market shares between brand name and generic products, co-payment rules of insurances etc.), and therefore their expected future monopoly and duopoly profits. For example, in the case of underestimation of the duopoly profits D_B and no reverse payments (R = 0), a generic firm would accept later entry, which might lead to an anticompetitive patent settlement (despite the absence of reverse payments).[29] Please note that in the basic model it was assumed that both firms A and B have the same and correct predictions about future market conditions, which are very unrealistic assumptions. Any kind of wrong and/or different predictions and other information asymmetries will lead to different settlement outcomes in respect to agreed entry, which might be far from the optimal entry date (as derived in the basic model). One of these cases was modelled by Willig/ Bigelow (2004, pp. 667). They can show that in a case of asymmetric information about the value of a patent a procompetitive settlement is only possible with a reverse payment.

Settlement outcomes can also change due to other factors. In the basic model it was assumed that both parties are risk-neutral. In the case of risk-averse originators or entrants settlement economics shows that the settlement ranges and therefore also the agreed entry dates and/or reverse payments change (Willig/Bigelow 2004, p. 666). There is a discussion in the literature that originator firms might be particularly risk-averse in respect to their probabilistic patents, implying that they would accept early generic entry despite making reverse payments.[30] So far not analyzed in economic models about patent settlements are strategic considerations of originator or generic firms. Since both the originator and often also the generic firms are usually large firms which are active in many markets and producing and selling a number of products and have a portfolio of patents, there might be other relevant strategic considerations for the decision about litigation or settlement in regard to a specific patent than only the future monopoly or duopoly profits of this one product. This also can change settlement ranges and therefore influence agreed entry dates and reverse payments.[31] Analyzing the effects of strategic considerations, especially in multi-product and/or multi-market contexts, would be an interesting field of further research.

The multiple challenger/entrant problem

A particular problem of all economic models about the patent settlement outcomes is that - contrary to the assumption in the basic model - more than one generic firms can challenge and enter the market. If originator firms are aware of multiple potential generic entrants, then they have to consider in their settlements with the first challenger that they might have to make several settlements for defending their weak patents, as well as the generic has to take into account the expected entry of more generic firms. This will change both the upper and lower limits of the settlement ranges, and also leads to the consequence that the patent settlements with several generics are not independent from each other anymore. This multiple challenger/ entrant problem, which is also directly linked to the public good

[29] For R = 0: $E_{max} = \theta\ T + c_B / D_B$; therefore an underestimation of the profits D_B leads to a higher upper bound of the settlement range E_{max}.
[30] Schildkraut (2004, pp. 1061); for explaining risk aversion of firms through risk aversion of managers see Willig/Bigelow (2004, p. 666, fn. 10) and the critique in Elhauge/Krüger (2012, p. 312).
[31] Strategic considerations and patent portfolios are mentioned in Shapiro (2003, 410) and Davis (2009, p. 292).

problem of challenging weak patents, has not been analyzed so far. It is also linked to the problem that generally competition among generic firms in regard to challenging and market entry has not been analyzed sufficiently.[32] [33] Therefore the implications of the existence of multiple challengers on the assessment of patent settlements are unclear, although such a situation seems to be empirically more relevant than assuming only one potential entrant (Grabowski/Kyle 2007, pp. 500).

Conclusions

If we take into account that in reality the assumptions of the basic model are not fulfilled (due to information problems about patent strength and future market conditions, risk aversion, strategic considerations, and the existence of multiple potential entrants), then we can expect that in most cases the patent settlement outcome will not correspond to the outcome of patent litigation (even in the case of no reverse payments).[34] Depending on the specific conditions the agreed entry dates might be earlier or later, and therefore also consumer welfare might be higher or lower.[35] Especially problematic is that in regard to important aspects we so far do not have enough economic research.

This leads to the following preliminary conclusions:

(1) There will be a number of patent settlements without reverse payments, which harm consumers in comparison to litigation and are therefore anticompetitive, because the agreed entry date is later than the optimal one ($E > E^*$). Therefore the prohibition of reverse payments does not ensure that patent settlements are not anticompetitive.[36]

(2) There will also be a number of patent settlements with a certain amount of reverse payments (even beyond litigation costs), which will not harm the consumers, i.e. the entry date will be not later than the optimal one ($E \leq E^*$). In a part of these cases, these reverse payments might be necessary for achieving litigation cost-saving settlements.

(3) Although both results imply that the observed size (or absence) of reverse payments is not a very reliable indicator for assessing the (il)legality of the patent settlements, economists would agree that even under more realistic conditions than in the basic model reverse payments can be a very effective and easily applicable instrument for restricting competition between originators and generic firms. Therefore it is justified that (high) reverse payments should raise (serious) antitrust concerns.

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[32] Willig/Bigelow's (2004, pp. 673) analysis of an additional entrant is not a case of an additional challenger, because the entrant offers a substitute product (which does not infringe the patent). Also Edlin et al. (2015, pp. 19-28) do not analyze the multiple challenger problem. Their analysis refers to the consequences of more price competition, if after the 180 days exclusivity period for the first generic entry (in the U.S. Hatch-Waxman framework) several additional entrants instead of only one enter. Only in the model of Gratz (2012) a second generic entrant with a second settlement is included but without addressing directly the multiple challenger problem.

[33] In the U.S., this problem is deeply influenced by the Hatch-Waxman Act due to the 180 days market exclusivity for the first entrant, which both protects the first generic against the competition of other generics but also protects the originator against more challenges from other generics (FTC Study 2002, p. vi).

[34] Especially Davis (2009) also emphasized the range of possible outcomes in settlement processes due to a number of "imperfections" of the settlement process.

[35] This also implies that the settlement results (e.g., the agreed entry dates) do not allow to make reliable conclusions about the true patent strength as it is suggested by the basic model.

[36] See also Elhauge/Krüger (2012) who even try to show that on average patent settlements without reverse payments are anticompetitive.

(4) Another additional problem of using the size of reverse payments as important criterion is that originator and generic firms can hide the (size of) reverse payments through complex package deals (e.g., licensing agreements, deliveries of ingredients), which require difficult and error-prone evaluations for determining the correct net value transfer.[37]

5. Effects on Consumer Welfare via Innovation Incentives

In the patent settlement discussion the question was asked whether restrictive antitrust rules on patent settlements with reverse payments might have negative effects on innovation incentives for the originators and therefore also harm consumers in the long run through fewer development of new drugs.[38] Since it is a well-established insight in the economics of patents that innovation incentives through patents should not be too small but also not too large (leading to the notion of optimal length and breadth of patents),[39] it is clear that it cannot simply be argued that the fact that the prohibition of reverse payments would lead to lower profits for the originator firms would lead to the consequence that the innovation incentives are smaller than optimal. Since innovation incentives can also be too large, a much deeper economic analysis is necessary.

In regard to the economic contributions to the patent settlement problem in the pharmaceutical industry, so far only Elhauge/Krüger (2012) explicitly presented a model, in which they analyze both static price effects and innovation incentive effects. In regard to patent settlements they prefer a strong presumption against patent settlements with reverse payments (that are larger than litigation costs of the originator) with only a few possibilities of rebuttals. They want to show that such a rule would not lead to a trade off between static price effects on consumers and effects on innovation incentives. Whereas their analysis of price effects uses (a variant of) the basic model (as presented in section 4), it is their analysis of the effects of patent settlements on innovation incentives which is relevant here. Starting from the above-mentioned insight that both a too long and a too short exclusion period through patents is not optimal from an innovation economics perspective (ibid, pp. 293), they apply an innovation-incentive perspective on the concept of probabilistic patents. They explicitly assume that a patent with a patent strength of $\theta = 0.25$ should from an innovation incentive perspective be equal to an ironclad patent of 5 years (25% of the patent duration of 20 years), i.e. the innovation incentives that should be granted to an innovation by a probabilistic patent should be proportional to the patent strength (proportionality principle, Farrell/Shapiro 2008) and can be translated into a proportion of the patent duration. Although a lot of assumptions have to be made for defending such a linear transformation in years of patent duration,[40] the basic idea is in line with such an innovation incentive interpretation of probabilistic patents.

However, in our view, in their next step Elhauge/Krüger (2012) make a serious mistake. From an innovation economics perspective, the optimal entry date in a patent settlement needs to be calculated in

[37] In regard to the problem of side deals, see Hemphill (2009). Very interesting is his proposal of a presumption of the problematic character of a patent settlement, if it is embedded into a package of side-deals, whose existence is unusual in the absence of a patent settlement.
[38] Crane 2002, pp. 760, Shapiro 2003, p. 396, Willig/Bigelow 2004, pp. 656, fn. 3.
[39] See e.g. Gilbert/Shapiro 1990.
[40] This would assume constant rents from the innovation over time and the absence of the need of discounting future revenues.

regard to the entire patent duration of 20 years, i.e. a patent with a patent strength of 25% should lead to a generic entry after 5 years of the entire patent duration. Instead Elhauge/Krüger (2012) erroneously define their normative benchmark for the optimal innovation incentives perspective as a percentage of the remaining (!) patent duration at the time of the settlement. This, however, ignores that the originator already earned monopoly profits from the date of granting the patent until the date of the patent challenge and settlement. If, for example, a patent with a patent strength of 25% is challenged after five years of its patent duration, then the originator firm has already reaped all the necessary rewards for its innovation (according to the innovation incentive interpretation of probabilistic patents) and any more delay of generic entry would lead to too high innovation incentives. Therefore their normative benchmark about optimal innovation incentives for patent settlements is flawed, because it would allow for too large innovation incentives (except the extreme case that a patent is challenged right at the beginning of the patent duration).[41] Due to this mistake at the beginning of their otherwise convincing analysis, the conclusions of Elhauge/Krüger (2012) do not hold that there might be no conflict between dynamic and static effects on consumers under their proposed rule of presumptive illegality of patent settlements.

How can the economic knowledge about the innovation incentive effects of patent settlements be summarized?

(1) Most important is that much more research is needed, before reliable answers can be given. Except Elhauge/Krüger (2012) all other contributions from an economic perspective did not analyze and take into account the innovation incentive effects at all.

(2) From the analysis of Elhauge/Krüger (2012) one specific thesis can be suggested. Since their results are systematically biased into one direction, it might be suggested from our critique above, that the agreed entry dates in patent settlements without reverse payments might be leading to too large innovation incentives for the originator firms. This analysis also shows that from an innovation economics perspective the date of the challenge and settlement within the lifetime of the patent is getting important, which so far has not played a major role in the antitrust discussion about patent settlements. This would imply that also patent settlements without reverse payments might be anticompetitive due to too large innovation incentives. Therefore trade offs between the static price effects and the dynamic innovation incentive effects cannot be excluded, and they might be much more severe for patents that are challenged late in their patent life and for weaker patents.

(3) This last point is directly linked to the important general analysis of Farrell/Shapiro (2008). In their model they show that under certain conditions weak patents might lead to disproportionately too high innovation incentives compared to innovations that allow for patents with a higher patent strength.[42] This might lead to too large incentives for investing in pseudo or trivial innovation activi-

[41] If D is the number of years the patent holder could reap monopoly profits before the settlement (with D + T = 20), then the optimal entry date from an innovation incentive perspective under the proportionality principle would be E* = θ 20 - D, which is always smaller than the agreed entry date in a settlement, E = D + θ T (as long as D > 0) and can also be negative (if D > θ 20). However, there is one specific effect, especially in regard to pharmaceutical products, that has to be considered additionally: If the originator firms can sell their products only after a certain period of time (due to clinical tests and getting the market approval), then this period would also have to be considered.

[42] The reason is that downstream firm's incentives to challenge probabilistic patents could be smaller than optimal since other downstream firms as well as consumers could free-ride on a challenge (Farrell/Shapiro 2008, p. 1349). A follow-up paper of Encaoua/Lefouili (2009) confirmed these results but questioned their robustness under different settings.

ties and therefore discourage the search for true innovations. Also in regard to this problem much more research is needed.

(4) Although the results of these analyses are very preliminary and should be viewed with cautiousness, it is remarkable that all of them tend to lead to the conclusion that antitrust authorities and courts perhaps should not be too worried about curbing too much innovation incentives, if they pursue a restrictive approach to reverse payments and patent settlements in general.

6. Effects on Consumer Welfare via Incentives for Challenging Patents

In the patent settlement discussion a number of authors raised the question whether prohibiting or limiting reverse payments would reduce the incentives of generics for challenging potentially invalid patents, e.g. Chief Justice Roberts in his dissenting opinion in the Actavis Supreme Court decision.[43] Since in the EU guidelines for licensing agreements also the relevance of removing invalid patents is mentioned in regard to the assessment of patent settlements, the incentives for challenging weak patents is also important for the EU Commission. In section 2 we saw that these challenging incentives would not be so important, if the patent offices would not grant so many weak patents and if the patent system would not rely so much on private litigation for weeding out invalid patents. So far most of the economic contributions dealing with patent settlements did not take into account the effects on the incentives to challenge weak patents. Only the models of Gratz (2012) and Böhme/ Frank/ Kerber (2015) offer integrated analyses of the static price and challenging incentive effects of patent settlements.

Challenging weak patents and weeding out potentially invalid patents through patent opposition and patent litigation requires resources that in a system of private litigation have to be borne by private parties. Since the consumers are the victims of unjustified monopoly positions of originator firms in the case of invalid but unchallenged patents, the generic firms can be viewed as agents of the consumers who challenge these patents and drive down prices through generic entry. Since generics need profits that also cover the challenging costs, it is the consumers who ultimately have to bear the costs of incentivizing generics for challenging patents. In the U.S., the solution of the Hatch-Waxman Act of granting the first entrant a 180 days exclusivity period for solving the public good problem, can be interpreted in that way: Consumers pay with higher prices due to less generic competition during the 180 days exclusivity period for the challenging incentives for generics. This idea of a trade off for the consumers between lower prices through earlier generic entry and higher challenging incentives for generics can also be applied directly to the antitrust treatment of patent settlements. The basic idea is that it might be worthwhile for the consumers if competition law would allow patent settlements with a later generic entry date than the optimal entry date E* (derived in section 4 when only price effects were considered). Since the generics would participate in the higher joint profits through the delay of generic entry (which might require reverse payments), their incentives for challenging more weak patents increase. This would lead to more generic entry and lower prices for the consumers in regard to other pharmaceuticals whose protection through weak patents would otherwise remain unchallenged. From that perspective the question can be raised whether and to what extent competition authorities

[43] Case 570 U. S. ____ (2013) FTC v. Actavis, Roberts, C.J. dissenting pp.17; see also Dickey et al. 2010, p. 399, Gratz 2012, p.15.

and courts should perhaps be more lenient with pay-for-delay settlements and ensuing reverse payments and allow for an additional period of delay.

In their model Böhme/Frank/Kerber (2015) analyze this question directly by asking for the optimal additional delay that would maximize consumer welfare through taking into account both the negative effects through the additional delay and the positive effects on consumer welfare through challenging more patents. The structure of their model is partly based upon the model of Gratz (2012), who was the first to offer an integrated analysis of price and challenging incentive effects. In both models there are originator firms with patents of different strengths ($0 \leq \theta \leq 1$) and two generic firms that can challenge patents (with fixed challenging costs) and enter sequentially the market at different future dates. A later agreed entry date in the ensuing settlements leads to larger joint profits and therefore to more challenging incentives for generics in both papers. However, Gratz (2012) assumes that the courts unintendedly accept patent settlements with later generic entry, because under a rule of reason approach she assumes that the court would make errors due to information problems. Therefore her positive effect on challenging incentives is caused by judicial errors due to the application of a rule of reason approach.[44] Instead Böhme/Frank/Kerber (2015) treat the additional delay in their model as a policy parameter, which competition authorities and courts can intentionally take into account in their antitrust assessment of patent settlements (with agreed entry dates and reverse payments). They can show that if the challenging costs are not too low, such a delay would increase under relatively general conditions the welfare of consumers. The optimal additional delay of entry increases with the size of challenging costs, the intensity of competition (after generic market entry), and the length of the time between the first and second generic entry.

The policy conclusions that can be drawn from a specific economic model are always limited. We would not recommend that based upon the results of such a model competition authorities or the courts should allow for a specific additional period of collusion between originators and generics (and accept also the additional reverse payments). However, we would claim that the models show the existence of such a trade off, and that scholars who were concerned that a prohibition of reverse payments might lead to fewer incentives for challenges by generics might have some support in economic analysis.[45] However, much more research is necessary for clarifying further the link between the antitrust rules about patent settlements (with or without reverse payments) and the incentives for challenging patents. What is missing in the analysis of these models is the integration of the public good problem. Another so far neglected question refers to the problem of competition between generic firms in regard to the challenge of weak patents.

[44] The analysis of Gratz (2012) about the superiority of a rule of reason is not convincing, because (1) it is unclear why the effects from judicial errors in her model only lead to the acceptance of more anticompetitive patent settlements and not also to the rejection of more procompetitive patent settlements, and (2) usually a rule of reason leads to less error costs and not more as in her model.
[45] See e.g. Dickey/Orszag/Tyson 2010, p. 399.

7. What Can We Learn From Economics? Insights, Open Questions, and Policy Conclusions

In the sections 4 to 6 we have analyzed what we know from economics how antitrust rules about patent settlements might influence the welfare of consumers of pharmaceuticals and where there are still significant gaps in research. In regard to the effects via prices, a basic settlement model with simplified assumptions can show that the agreed date of generic entry in patent settlements without reverse payments would lead to settlement outcomes whose consumer welfare implications are close to those of the outcome of litigation. However, economists also would agree that in reality the bargaining situations between originator and generic firms are much more complex and might suffer from a number of imperfections not considered in this basic model. Particularly information problems in regard to patent strength and future market conditions as well as risk aversion, strategic considerations and the implications of multiple generic challengers and competition among generic entrants will lead to settlement outcomes which can be far away from the normatively optimal entry dates. Only a small part of these problems have been analyzed so far (e.g. Willig/Bigelow 2004, Elhauge/Krüger 2012). However, it seems clear that these deviations can lead into both directions, i.e. they can render patent settlements without reverse payments anticompetitive as well as allow to some extent reverse payments without harming consumers. The latter can be the result of explicit efficiencies (as, e.g., saving litigation costs) but can also be the result of the "imperfections" of the bargaining situations in which efficiency-enhancing settlements would fail without the possibility of reverse payments.

The gaps in research are even larger in regard to the other two channels of effects, i.e. innovation incentives and incentives to challenge patents. Particularly problematic is the lacking research about innovation incentives. Although the only existing analysis of innovation incentives in Elhauge/ Krüger (2012) suffers from a serious flaw, a further analysis based on their results provides preliminary hints that patent settlements without reverse payments might lead to too large innovation incentives, esp. in the case of weak patents and in case of settlements in the later stages of the life of patents. More research about this problem might also be linked to the contribution of Farrell/Shapiro (2008) with their analysis whether weak patents might lead to disproportionately large innovation incentives. Also the problem of challenging incentives still lacks a lot of research. Gratz (2012) and Böhme/Frank/Kerber (2015) can show that there might be a trade off between promoting a faster generic entry by prohibiting pay-for-delay patent settlements and increasing the incentives for challenging patents through generics. This leads Böhme/Frank/Kerber (2015) to analyze this trade off and ask for the determinants of an optimal additional delay of generic entry for increasing challenging incentives. However, many other aspects of the challenging incentive problem have not been taken into account in patent settlement models.

What can we learn from these economic insights in regard to the antitrust rules for patent settlements in the pharmaceutical industry? First, we have to consider that there might be trade offs between all three groups of effects (price, innovation, and challenging effects) on consumer welfare. Whereas the first preliminary results of the analysis of challenging incentives might give some support for allowing longer delays, the effects on innovation incentives might lead to the opposite result. These results lead to a further relativization of the results of the basic model in section 4 and its main conclusion that patent settlements without reverse payments would lead to an optimal agreed generic entry.

Does this result lead to the recommendation of a rule of reason approach instead of a presumption of illegality of patent settlements with reverse payments, because it would allow the analysis and consideration of all anticompetitive and efficiency effects under the circumstances of the specific case? From a law and economics perspective, this is not clear at all, because such a claim would require an error-cost analysis, which would make a comparative analysis of the different regulatory options in regard to the size of decision errors (false positives, false negatives) and direct and indirect regulation costs:[46] Would a full-blown rule of reason, a per se prohibition of patent settlements with reverse payments, a presumption of illegality (with a limited number of options for rebuttals), or another form of structured rule of reason lead on average to a minimization of the sum of regulatory costs and welfare costs of decision errors and therefore to higher welfare for the consumers? Although a number of authors have mentioned and partly used arguments from an error-cost perspective,[47] so far only Davis (2009) tried to analyze the problem of patent settlements in a systematic way from an error-cost framework by assessing error and transaction costs. In regard to his analysis, which leads him to the recommendation of a general ban of reverse payments (even without the possibilities for rebuttals), a number of critical questions can be raised, which cannot be discussed here. However, much more research from such a perspective is necessary before an economically well-substantiated answer can be offered how an appropriately structured antitrust rule should look like.[48] The question that ultimately has to be answered is to what extent a further differentiation in more case groups beyond the distinction between patent settlements with or without reverse payments is worthwhile for better assessing patent settlements. So far this question has not been answered.

This contribution cannot give a detailed assessment of the current policy in regard to patent settlements. However, based upon the so far existing economic knowledge the current competition policy in the U.S. (after the Actavis decision of the U.S. Supreme Court) and the EU can be defended to some extent, although we think that it still might be a bit too cautious in regard to patent settlements. Since it is undisputed that reverse payments are a very effective instrument for delaying generic entry (also in more realistic and complex bargaining contexts), the strategy to focus the analysis primarily on (the size of) reverse payments is a correct one. From this perspective also a presumption of the illegality of reverse payments, which can be rebutted with a limited number of reasonings, can be defended. In that respect, it has to be seen that such a presumption need not be too far away from the approach of the U.S. Supreme court, which sees the necessity that a large reverse payment has to be explained for viewing such patent settlements as complying with antitrust rules.[49] However, this need not mean that these assessments are getting easy and simple. Since reverse payments in settlement cases can be hidden in complex package of side-deals (e.g., licensing agreements and supply of ingredients), even proving the existence and size of reverse payments might need a deep case analysis. However,

[46] For the error-cost approach in law and economics, see Easterbrook (1992) and Christiansen/Kerber (2006) with many references.

[47] E.g. Crane 2002, McDonald 2003, and Edlin et al. 2014.

[48] Since such an analysis of decision errors also needs information about the frequency of certain types of patent settlements, also empirical studies about patent settlements (as Hemphill 2009) are important.

[49] See the recent proposal of an "Actavis inference" by Edlin et al. (2015), a proposed framework in light of the Actavis ruling by Carrier (2014a) as well as a critical analysis by Kobayashi et al. (2015).

vice versa, we also would not recommend that the lack of reverse payments in patent settlements should be viewed as a strong indicator for their compatibility with competition law.[50]

The complexity of a correct antitrust assessment of patent settlements which might protect unjustified monopoly positions through potentially invalid patents raises the question whether more suitable policy solutions could be found by directly addressing the underlying problem of the fundamental defects of the patent system that produces too many weak patents. This is in line with Farrell/Shapiro (2008) and Encaoua/Lefouili (2009) who discuss the weak patent problem in the context of the optimal design of the patent system. From that perspective the entire discussion about patent reform for dealing with the many problems and defects of the current patent system is relevant.[51] This can encompass the strengthening of patent examination in patent offices (as Farrell/Shapiro 2008 suggest for certain groups of patents) with the objective of directly reducing the number of weak valuable patents, e.g. also by including competitors and other interested firms already in the process of granting patents (ibid. p. 1361). Other possibilities are the facilitating and strengthening of the possibilities of weeding out invalid patents through patent opposition and patent litigation (ibid., Fischmann 2014, pp. 431). Other proposals refer to the idea of solving the challenging incentive problem by subsidizing patent challenges, e.g. through a cashbounty program, or allowing more easily joint challenges by several generic entrants (Miller 2004, Encaoua/Lefouili 2009, pp. 21). As our analysis of the three channels of effects (price, innovation, and challenging incentive effects) of patent settlements already showed, from an economic perspective an integrated view of competition and patent law is necessary. Therefore we should search for the best combination of policy solutions in competition and patent law for solving the competition and innovation problems through weak patents.

[50] Also this is in line with the Actavis decisions of the U.S. Supreme Court, which did not explicitly constitute a safe harbour rule for patent settlements without reverse payments (Wright 2013, p.15).
[51] Gallini 2002, Shapiro 2004, Bessen/Meurer 2005, Shapiro 2008.

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