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

Wolfgang Kerber and Severin Frank*

(draft version: May 14, 2015)

Abstract: Despite the "Actavis" decision of the U.S. Supreme Court and the "Lundbeck" decision of the EU Commission, both in EU competition law and US antitrust law it is still unclear how competition authorities should deal with patent settlements between originator and generic firms in the pharmaceutical industry. A crucial policy question is whether a per se prohibition (or at least a strong presumption of the illegality) of patent settlements with reverse payments should be recommended or whether a rule of reason approach should be applied. In this paper we critically analyze the contributions of economic papers (and explicit economic reasonings in law articles) for answering this question. This also includes the identification of the gaps in the current economic research. A crucial result of our analysis will be, on one hand, that not only the effects of antitrust rules about patent settlements on consumer welfare via prices are relevant but also the effects on consumer welfare via innovation incentives and incentives for challenging weak patents. On the other hand, we will show how deeply this problem of the antitrust assessment of patent settlements is linked to the general problems of the patent system (weak / probabilistic patent problem).

Keywords: competition law, patent settlements, reverse payments, pharmaceutical industry

* Wolfgang Kerber, Professor of Economics, School of Business and Economics, Philipps-University Marburg, kerber@wiwi.uni-marburg.de; Severin Frank, School of Business and Economics, Philipps-University Marburg, frank.severin@wiwi.uni-marburg.de. We would like to thank the participants of the Brown Bag Seminar at NYU Law School (April 1, 2015) and the Hohenheimer Oberseminar (Weimar, April 17, 2015) for their critical feedback on an earlier version of this paper.

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 "reverse payments" in combination with "agreed entry dates" of generic firms ("pay-for-delay") were challenged by antitrust authorities in the U.S. and the EU. In the U.S., the Supreme Court confirmed in the "Actavis" decision that these patent settlements can infringe U.S. antitrust rules under a rule of reason approach.[2] In the EU, the Commission decided in several cases that patent settlements with reverse payments can infringe European competition law, and dealt with this group of cases also in their new guidelines on technology transfer agreements.[3]

Since settlement outcomes with large reverse payments can only occur in cases of potentially invalid patents (so called "weak patents", i.e. patents with a low probability of surviving patent litigation), this question is deeply intertwined with the problem of fundamental defects in the patent system, leading to the claim that such patent settlements might harm consumers by protecting unjustified monopoly positions for originator firms with invalid patents. Whereas it is undisputed that patent settlement agreements that delay entry dates of generic firms beyond the duration of the respective patents are clearly anticompetitive and violate antitrust rules, the crucial question is, whether also patent settlements with "agreed entry dates" before the expiration dates of the patents, either with or without "reverse payments", can be anticompetitive, and, if so, under what specific circumstances. Most of the current controversies about the appropriate antitrust treatment refers to the role of "reverse payments", i.e. whether there should be a strong presumption of illegality of patent settlements with reverse payments (with possibilities of rebuttals) or whether, on the other hand, a rule of reason approach is more 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 this paper, we want to analyze what can be learned from the literature that explicitly has used economic models and economic reasonings for deriving policy conclusions for this problem. Beyond the many articles from a legal perspective, only a limited number of articles with an explicit economic analysis of this patent settlement problem can be found. A few articles directly address these patent settlements in the pharmaceutical industry, some with economic models,[4] others with at least explicit economic reasonings.[5] But we will see that also other economic contributions about the broader problem of antitrust scrutiny of patent settlements in the context of only a "probabilistic" validity of patents are very relevant for this problem.[6] Therefore, in this article, we will not present a new economic model about a certain aspect of the problem. Rather our objective is 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. A crucial claim of our paper is that the problem of patent settlements can only be understood, if we analyze it

---

[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] Important patent settlement cases In the US have been: FTC v. Cephalon, Inc., 061 0182, In Re: K-Dur Antitrust Litigation United States Court Of Appeals For The Third Circuit; In Re: Tamoxifen Citrate Antitrust Litigation United States Court Of Appeals For The Second Circuit, In Re Cardizem Cd Antitrust Litigation United States Court Of Appeals For The Sixth Circuit, 570 U. S. ____ (2013) FTC v. Actavis, Inc.

[3] Case At.39226 – Lundbeck, EC Guidelines on the Appl. Of Art 101 to Technology Transfer Agreements (TTA), pp.44, Antitrust: Commission sends Statement of Objections on Perindopril to Servier and others, IP/12/835, Antitrust: Commission opens investigation against pharmaceutical companies Cephalon and Teva, IP/11/511.

[4] Willig/Bigelow 2004, Elhauge/Krüger 2012, Gratz 2012, Addanki/Daskin 2009.

[5] Schildkraut 2004, Carrier 2009, Davis 2009, Yu/ Chatterji 2011.

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

not only from a narrow antitrust perspective but take into account its deep interrelationship with the (economics of the) patent system.[7]

Our paper is structured as follows: In section 2, a brief overview about the legal, economic, and policy discussions in regard to patent settlements in the pharmaceutical industry is given. Section 3 will present the general problem of "weak" / "probabilistic" patents as part of the discussion of fundamental defects in the design of the overall patent system and its implications for patent settlements in general. Section 4 about possible antitrust rules in regard to patent settlements and the relevant normative antitrust standard (consumer welfare) prepares for the following sections 5 to 7, in which step by step our economic knowledge in regard to three different effects of antitrust rules about patent settlements is critically analyzed and assessed. In section 5, we are dealing with the effects that have been mainly analyzed and discussed, i.e. whether patent settlements with or without reverse payments lead to a too long delay of generic entry harming consumers through a too late driving down of pharmaceutical prices through generic competition. However, for consumer welfare also the effects of patent settlements on innovation incentives (dynamic efficiency) is relevant (section 6), as well as the effects on the incentives for generic firms to challenge patents and therefore to contribute to the elimination of invalid patents (and unjustified monopoly positions) in the patent system (section 7). Our concluding section 8 will encompass an overall analysis of our knowledge in regard to all three effects, identify the gaps and the priorities for future economic research, and will discuss the implications of our results for the policy question how competition and antitrust law should deal with these patent settlements.

2. Patent Settlements in the Pharmaceutical Industry: Facts, Policies, and Discussions

Both in the U.S. as well as in the EU a considerable number of patent settlements between originator and generic firms could be observed, in which the originator firms made large payments to generic firms and/or agreed on specific future entry dates for generic firms. Empirically, it can be distinguished between settlements without a reverse payment and without agreed entry date, settlements without a reverse payment and with an agreed entry date and settlements with reverse payment and with agreed entry date.[8] A particular difficult problem can be that the value transfer need not be a direct "reverse payment" but might be hidden in a complex package deal between both parties (e.g., with additional licensing agreements or the supply of ingredients etc.).[9] The other important empirical fact is that on both sides of the Atlantic generic firms who are challenging patents of originators seem to

[7] 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 for the EU or the U.S., because this would require to include into this analysis also these specific institutional settings, which also differ between EU and U.S., and other countries.

[8] Between 2000 and 2008 the European Commission traced 207 patent settlements. Nearly half of them (99) included a generic entry restriction and of those nearly half included a direct reverse payment (45). Also other agreements where conducted between originators and generic between 2000 and 2007 including package deals or distribution agreements (EC Pharmaceutical Sector Inquiry Final Report 2009, pp. 271 and p. 310). Between 2004 and 2009 66 out of 218 settlement agreements in the US involved a restriction of entry as well as a reverse value transfer (FTC Staff Study 2010, p. 4). For an empirical analysis of patent settlements in the U.S., see also Hemphill (2009).

[9] E.g. Bulow 2004, pp. 169 makes the point that an originator could also pay the generic for later market entry while the generic in return offers a license to the originator so that the question whether the payment to the generic is really a “reverse payment” is not so clear. Such a value transfer could also consist of the commitment of the originator not to launch an own authorized generic after the generic has entered as compensation for the generic entry delay. This was observed in the US between 2004 and 2010 where 39 out of 157 settlements included such value transfers and also a generic delay of approx. 37.9 months (FTC Report Authorized Generics, p. vi).

have a high probability of winning in patent litigation, implying that often the patents of the originator are weak.[10]

In the U.S., the Federal Trade Commission (FTC) challenged such patent settlements with reverse payments in the pharmaceutical industry since 1999, because these settlements would impede and delay price reductions through the market entry of generics, and therefore harm consumers through too high drug prices.[11] 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) and that settlements without reverse payments can properly reflect patent strength.[12] This policy of the FTC ran into much resistance in the U.S. courts. One important opinion claimed that as long as the patents are not revoked through patent litigation, they should be presumed as valid, and therefore settlement about these patents cannot be an antitrust violation, as long as the settlement would not extend the protection beyond the duration of the patents (formal scope of patent).[13] However, other courts saw the problem of a potential violation of antitrust rules, but there were still different opinions about whether the problem should be solved by the application of a presumption of illegality along the policy of the FTC.[14] These contradictions were resolved by the "Actavis" decision of the Supreme Court. On one hand, the Supreme Court clarified that a large unexplained reverse payment can be a signal for the weakness of the patent and therefore these "pay-for-delay"-settlements can be anticompetitive and illegal. On the other hand, the Supreme Court did not agree with the FTC position that patent settlements with reverse payments should be seen as presumptively illegal. Rather a rule of reason approach should be applied, which also takes into account possible explanations for any value transfer (as, e.g., saved litigation costs of the originator firm).[15] Therefore, in the U.S., the Supreme Court asked the lower courts to develop suitable structured rule of reason-approaches for the antitrust assessment of patent settlements with reverse payments.[16]

The European Commission conducted a Pharmaceutical Sector Inquiry starting in 2008 and monitored patent settlement agreements. The inquiry classified patent settlements in four categories distinguishing between restriction of generic entry and a value transfer from the originator to the generic.[17] The Commission argued that patent settlements with a restriction of entry and with a reverse value transfer require closer competition policy scrutiny.[18] As a consequence, several patent settlements with reverse payments were challenged by the EU Commission. Whereas some of these cases are pending, a decision has been made in the case Lundbeck and others.[19] Newly adapted guidelines for the appli-

---

[10] There is strong empirical evidence in the US and the EU that patents are often found invalid or partially invalid by courts if litigated (figures indicate in 50% of the cases or more) (Lemley/Shapiro 2005, p. 76, Allison/Lemley 1998, p. 251, FTC Study 2002, p. vi, EC Pharmaceutical Sector Inquiry Final Report, p. 224).

[11] FTC Study 2002, p. vii. It is assessed that over 10 years consumers in the US could save 35 billion $ in the absence of pay-for-delay restrictions (Leibowitz 2009).

[12] 570 U. S. ____ (2013) FTC v. Actavis, Inc. p. 20, Brankin 2010, p. 24, FTC Staff Study 2010, p. 9.

[13] In re United States Court of Appeals for the Eleventh Circuit FTC v Watson Pharmaceuticals, Inc., Solvay Pharmaceuticals, Inc. the court argued that it would be “ill-equipped” to assess the outcome of patent litigation.

[14] E.g. in Re Cardizem Cd Antitrust Litigation United States Court Of Appeals For The Sixth Circuit, in Re: K-Dur Antitrust Litigation United States Court Of Appeals For The Third Circuit, see Carrier 2012, p.4.

[15] 570 U. S. ____ (2013) FTC v. Actavis

[16] Edlin et al (2013), Wang (2014).

[17] EC Pharmaceutical Sector Inquiry Final Report (2009), pp. 270.

[18] These settlements had a share of 22% of all settlements between 2000 and 2008 (5 on average per year); afterwards this share decreased to 8% (in total 11 settlements) in January-December 2013 (European Commission Competition DG 5th Report on the Monitoring of Patent Settlements, p. 16 at para 50).

[19] Case At.39226 – Lundbeck, Antitrust: Commission sends Statement of Objections on Perindopril to Servier and others, IP/12/835, Antitrust: Commission opens investigation against pharmaceutical companies Cephalon and Teva, IP/11/511. In Lundbeck the main arguments of the Commission were

cation of Article 101 (3) TFEU to Technology Transfer Agreements put patent settlements with reverse payments with a considerable value transfer from the originator to the generic under antitrust scrutiny, if both parties are actual or potential competitors. 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.[20]

Although in the application of both the US antitrust law and the EU competition law large reverse payments seem to be viewed as a strong signal for the anticompetitiveness of patent settlements, such patent settlements are not been assessed as being presumptively illegal. Rather in both competition law regimes a deeper investigation into the case seems necessary, and it is still an open question how a suitable structured rule of reason approach should look like. How does this fit to the general academic discussion among legal and economic scholars about these patent settlements? We will first briefly summarize the general discussion which will be followed by a more specific overview about the economic contributions, which will be in the main focus of this article.

How can the state of the academic discussion be summarized? Arguments can be found that defend the formal scope of the patent doctrine which can be substantiated on one hand by the general principle of the efficiency advantages of litigation settlements that should not be meddled with, and, on the other hand, with the principle that antitrust law should not interfere with patent law, either on the grounds of not endangering innovation incentives, or with the argument that problems of patent law should be solved within patent law and not by competition law.[21] The large majority of scholars, however, claim that patent settlements under certain circumstances can certainly be anticompetitive through delaying or impeding market entry and therefore restricting generic competition. From that perspective, the patent settlements with reverse payments are discussed as a collusive agreement, in which the generic firm is paid for not competing through challenging the patent.[22] There is a nearly unanimous consensus among these scholars that the size of reverse payments is an important criterion for its anticompetitive effects, and that, in the case of package deals, the net value transfer from originators to generics can be used as assessment criterion. However, there is also a broad consensus that there might be a number of efficiency advantages of the patent settlements, esp. saved litigation costs etc., and other specific conditions (e.g., risk aversion) which might influence the outcome of the settlement, and therefore should be taken into account in the competitive assessment of patent settlements.[23]

The main discussion refers to the question whether a presumption of the illegality of patent settlements with reverse payments should be used (with different degrees of rebuttability, or whether a full-blown rule of reason approach should be applied, with the consequence of a specific case-by-case analysis.[24] Although nobody denies the possibilities of efficiency advantages of patent settlements, there is a wide range of opinions about the number and size of these efficiencies. Depending on these opinions, it is seen as more or less important whether we should stick more directly to a simple rule of prohibiting patent settlements with reverse payments or analyze deeper the positive and negative

---

that the patent holder had a process patent where the base patent had expired which basically rendered the market open for generic entry with the possibility to invent around the process patent. However, potential competition was suppressed by the patent holder by the use of a reverse payment. The process patent was not granted to give the same level of exclusion than the (expired) base patent so restrictions through the patent settlements were out of the actual patent scope (Case At.39226 – Lundbeck, pp. 220).

[20] EC Guidelines on the Appl. Of Art 101 to TTA, pp. 44.

[21] E.g. in re United States Court of Appeals for the Eleventh Circuit FTC v Watson Pharmaceuticals, Inc., Solvay Pharmaceuticals, Inc., the court made the point that it sees itself “ill-equipped” to judge patent validity issues (p. 37).

[22] 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, Carrier 2009, Brankin 2010, Edlin et al. 2013, Piecht 2013, Carrier 2014b, Cotter 2014, Feldman 2014.

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

[24] See e.g. Crane 2002, McDonald 2003, Leffler/Leffler 2004, Davis 2009, Gratz 2012.

effects of these settlements for avoiding decision errors. Since many authors see the size of reverse payments as an important indicator for the anticompetitiveness of a settlement, a more or less formal presumption of illegality (with rebuttals) is recommended by many.[25] In that respect, there are also authors which much more explicitly analyze this problem from an error-cost approach, leading them, e.g., to the conclusion that we should stick to a simple rule of prohibiting settlement with reverse payments, because on average we cannot improve our decisions by making deeper analyses along a rule of reason approach.[26] However, 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 of the generic (before patent expiry) as long as there is no reverse net value transfer.[27] Most scholars also emphasize that courts should not assess the merits of the patents in the antitrust case, although a small minority disagrees.[28]

Since we will look in this paper especially on the contributions of the economic papers, a brief first overview about the main conclusions of these papers should be already given here. Generally, the economic papers are much more cautious about making specific policy conclusions limiting their focus instead on the analysis of specific aspects ot the problem. Shapiro (2003) proposed the normative standard (accepted by most of these other scholars) that a patent settlement should be assessed as anticompetitive, if it leads to less welfare for consumers than in the case of patent litigation. Willig/Bigelow (2004) and Dickey/ Orszag/ Tyson (2010) concluded from their analyses of the settlement bargaining processes between originator and generic firms that a per se prohibition of reverse payments is not a suitable rule, because under certain conditions reverse payments might be necessary for socially beneficial settlements. Similarly, Yu/ Chatterji (2011) try to show in their model that in the case of risk asymmetry reverse payments should be allowed, which leads them to the recommendation of a rule of reason and a case-by-case analysis of patent settlements. Vice versa, Davis (2009) uses economics of dispute resolution by carrying out an error costs analysis of different rules which leads him to the conclusion that a per se prohibition of reverse payments would be most appropriate.[29] An extensive model-theoretic analysis can be found in Elhauge/ Krüger (2012). They conclude from their model that a reverse payment that is larger than litigation costs will under standard assumptions always harm consumers and undermine innovation incentives. In addition to that, they also claim that patent settlements with agreed entry dates but without reverse payments larger than litigation costs are on average anticompetitive. Gratz (2012) analyzed patent settlements from a very different perspective, namely in regard to the incentives of generics for challenging patents. She claims to have shown in her model that a rule of reason approach would lead to larger incentives for challenging patents due to larger errors of the courts.[30]

3. The Background: The Problem of Weak / Probabilistic Patents, the Design of the Patent System, and General Patent Settlement Problems

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 economic assessment of these patent settlements therefore requires to analyze this problem

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

[26] See, e.g., Davis (2009).

[27] 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.

[28] A different view can be found in Shapiro (2003, p. 397), Janis/ Hovenkamp/ Lemley 2003 and Crane (2002).

[29] There is only one exception, i.e. if it can be shown that originator firms have a systematic disadvantage in their settlements negotiation process with generic firms, which he sees as unlikely (Davis 2009).

[30] Explicit economic reasonings which are partly based on the above mentioned articles and which take into account the complex bargaining between originators and generics in regard to patent settlements can also be found in Schildkraut (2004. pp. 1057), Hemphill (2006, pp. 1590) as well as Addanki/Daskin (2009), Kobayashi et al. (2015), and Edlin et al. (2015).

within the much larger context of the overall design of the patent system. In the following, we briefly analyze the economic rationale of "weak" or "probabilistic" patents as part of the patent system, the incentive problems through the "public good" problem of challenging potentially invalid patents, and the ensuing general patent settlement problems.

Empirically, there is a broad consensus that patent offices grant on average too many patents with the consequence that many of the granted patents would not survive a challenge in patent litigation. The extent of erroneously granted patents is unclear (and certainly also different between the U.S. and the EU) but empirical studies suggest that litigated patents are often found invalid with ranges from 50% to 60%.[31] In regard to the reasons, there is some consensus that the patent offices do not invest enough time and resources in patent examination (esp. in regard to "prior art"). This result could be interpreted as a defect of the patent system. However, from an economic perspective, e.g., Lemley (2001) argued that such a result might also be explained as efficient: It might not be worthwhile to make deep and costly examinations of all patent applications, because many of the granted patents do not prove to be valuable ("rationally ignorant patent offices").[32] But both interpretations lead to the conclusion that it is necessary that the patent system has effective legal instruments for challenging and weeding out economically valuable invalid patents. Therefore both, patent opposition as challenging directly the granting of the patent through the patent offices as well as patent litigation in courts, are crucial for ensuring that economically valuable invalid patents are weeded out for avoiding monopoly profits and impediments for further innovation through unjustified exclusivity rights through granted 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 their rules about granting, opposing, and challenging patents in courts) can be viewed as leading to efficient patent systems or - as many legal and economic scholars claim - that the existing patent systems are deeply flawed and suffer from serious problems.[33]

One critical issue are the incentives for firms to challenge potentially invalid patents. The fact that all patent systems rely on private litigation for challenging patents (either in patent opposition or in patent litigation) leads to a crucial free-rider problem: Since the granting of patent rights is an exclusive right against everybody, the private incentives for challenging patent rights 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.[34] This externality of challenging patents cannot only lead to too small incentives for challenging firms, but implies also 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 of patent settlements, the usual normative notion that private parties should be free how to settle their conflicts in private litigation is problematic in patent litigation. Therefore also from an economic perspective, rules for critically scrutinizing (and limiting the scope of) patent settlements might be justi-

---

[31] In the U.S., there exists evidence that approximately half of the litigated patents are found invalid (Lemley/Shapiro 2005, p. 76, Allison/Lemley 1998, p. 251) and that generics won in 73% of the patent infringement cases between 1992 and 2002 (FTC Study 2002, p. vi), In the EU, the pharmaceutical sector inquiry of the European Commission found that generics won more than 60% of all final judgment patent litigation between 2000 and 2007. Where there was the question of validity of the patent, the courts revoked them in 55% of the cases (in total 78) (EC Pharmaceutical Sector Inquiry Final Report, p. 224).

[32] Lemley 2001 argues that it is more efficient to accept the issuance of some potentially invalid patents by the patent office with the possibility to later have patent litigation regarding the valuable ones (which refers to just a smaller fraction of all patents), since deep ex ante examinations of every patent`s validity are too expensive (Lemley 2001, p. 34).

[33] See, e.g., Shapiro (2004, pp. 1018) and Hall/Harhoff (2004, pp.4).

[34] See Farrell/Merges (2004, pp. 952), Hemphill (2006, pp. 150). This is the reason why in the U.S. the Hatch-Waxman Act wanted 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).

fied.[35] As a consequence, the effects of patent settlements on the incentives for challenging potentially invalid patents and therefore on the overall effectiveness of the patent system are an important problem.

Another important issue is the concept of "probabilistic" patents which was developed in the context of the "weak" patent problem and has played a major role in the patent settlement discussion.[36] The basic idea is simple: Whereas from a legal perspective a patent right is either valid or not, the 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.[37] In the economic literature this probability θ is used for defining the strength of a patent ($0 \leq \theta \leq 1$). This "probabilistic" character of a patent can be used in two different ways: In regard to settlement negotiations the patent strength θ is used as an indicator for the winning probabilities of the settling parties in patent litigation, which influence crucially the ranges of the settlements (in regard to agreed entry dates and/or the size of reverse payments as we will see in section 4). 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.[38] We will see later that this might be much more difficult.

The probabilistic character of patents, however, can also be interpreted from an innovation incentive perspective. At first sight, it seems plausible that the rents from a patent for the patent owner are proportional to the patent strength θ, i.e. a patent with $\theta = 0.5$ has half of the value of an iron-clad patent and twice the value of a patent with $\theta = 0.25$. This is called in the literature the proportionality principle.[39] From an innovation economics perspective this also would imply that the innovation incentives for getting a patent with $\theta = 0.5$ are twice as large as being granted a patent with $\theta = 0.25$. In an important seminal paper with the title "How Strong are Weak Patents?" Farrell/Shapiro (2008) analyzed the welfare effects of probabilistic patents. With their economic model they tried to show that under certain market conditions this proportionality principle need not hold. Rather it might be possible that the profits from weak patents might be larger than they should be according to the proportionality principle, 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.[40] Their conclusion is that under certain conditions patent offices should invest more in ex ante-examination of patent applications in order to avoid the negative welfare effects through this effect. They wanted to contribute to the discussion about the optimal design of the patent system in regard to the optimal amount of ex ante examination of patents through patent offices. However, from an innovation economics perspective, it is not clear whether such an innovation-incentive interpretation of probabilistic patents was convincing, even if this proportionality principle would hold.[41]

---

[35] Both the problem of lacking private incentives and these third-party effects of patent settlements would not emerge, if the patent system did not rely on private litigation for weeding out invalid patents but would solve the problem, e.g., through a (tax-funded) public agency.

[36] See Ayres/Klemperer (1999), Shapiro (2003), Farrell/Shapiro (2008); for a fundamental critique of the concept of "probabilistic patents" see Mc Donald (2003).

[37] The term "probabilistic patent" might be somewhat misleading, because, e.g., a "25%-patent" does not exist legally. This is the reason why Shapiro (2003) first used the term "partial property rights", i.e. that patent holders only get an imperfect right with imperfect enforcement.

[38] E.g. Elhauge/Krüger 2012, Gratz 2012.

[39] Farrell/Shapiro 2008, p. 1348.

[40] A 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. Thus higher per-unit royalties could be possible for probabilistic patent owners (Farrell/Shapiro 2008, p. 1349). A follow-up paper of Encaoua/Lefouili (2009) confirms these effects but shows that the results might not be as robust as Farrell/Shapiro (2008) suggested.

[41] The question can be put as follows: Is there a clear innovation economics rationale for incentivizing "innovative" activities, which allow only for a 10% or 20% probability of getting a valid patent, by granting them incentives that correspond to a patent duration of two or four years? The answer to this ques-

In the discussion about patent settlements with reverse payments in the pharmaceutical industry, it was argued that through the reverse payment the patent holder can protect his monopoly position against a challenging generic. However, Shapiro (2003) showed that a patent owner has also many other possibilities for achieving the same result. Instead of a settlement, a patent owner with weak patents can offer a licensing agreement with so small royalties to other firms that they accept the license and refrain from challenging the patent. The difference to the "normal" royalties in case of a fully defendible patent could also be interpreted as a "reverse payment". In a similar way also mergers and patent pools can be used for protecting weak patents and compensating potential challengers, e.g., through a lower price for buying the firm of the patent owner. Therefore it is consequent that Shapiro (2003) called for an antitrust scrutiny of all those transactions in that respect. This can be called the general patent settlement problem. Another recently much discussed problem in that respect is the antitrust assessment of "non-challenge clauses" in licensing agreements, which from an economic perspective raises very similar concerns to the patent settlement problem.[42]

4. Assessing Different Antitrust Rules for Patent Settlements: Normative and Methodological Questions and the Distinction Between Three Effects

4.1 The Normative Criterion and the Three Relevant 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 formulated in Shapiro (2003, p. 396): "A patent settlement cannot lead to lower expected consumer surplus than would have arisen from ongoing litigation". He continues: "Effectively, 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.).[43] Shapiro emphasizes that this normative criterion both respects intellectual property rights and is in line with other applications of antitrust law, in which, e.g., mergers are allowed, if they do not lead to harm for consumers in comparison to the absence of this merger (consumer welfare standard). From this perspective, the expected consumer welfare of the patent litigation solution is the relevant reference standard for assessing patent settlements from an antitrust perspective. 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.). Many other scholars, both lawyers and economists, use in the patent settlement discussion the same normative standard, although most of them have not explained its implications so clearly.[44]

---

tion would require a much deeper analysis in the economics of innovation and also in the reasons for the low probability of the survival of patents in patent litigation.

[42] Janis/Hovenkamp/Lemley 2003, pp. 1721. Roper (2014) points at cases which indicate that there is generally not much of a difference between a licensing contract with a no-challenge clause and a settlement agreement (p. 1670). Important rulings in the US (MedImmune v. Genentech 2007, Lear v. Adkins 1969) developed that licensees are not required to pay royalties for invalid patents and that they can challenge patents validity without first terminating or being in breach of the license (Server/Singeleton 2011, pp. 245). Also, according to Article 5 of the new European Commission Regulation on the Application of Art. 101 (3) to Technology Transfer Agreements direct or indirect no-challenge clauses in licensing agreements with a prejudice of a licensing termination in case of a challenge cannot be exempted according to Art. 101 (3).

[43] 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.

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

In the following, the question should be discussed how this Shapiro criterion can be applied. From the economic literature we can distinguish three different ways how patent settlements might affect consumer welfare.
(1) The discussion so far focussed mainly on the 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 for the consumers of future lower prices through generic competition are less than what could be expected in the case of patent litigation. This are the effects on consumer welfare via prices (static price effects).
(2) Patent settlements, however, can also have effects on consumer welfare in the long run through influencing the innovation incentives for originator firms. In the economic literature, especially Elhauge/Krüger (2012) emphasized the necessity to take into account also the effects of patent settlements on innovation incentives, i.e. that innovation incentives should not be too small or too large.
(3) The third effect on consumer welfare, analyzed explicitly by Gratz (2012) but mentioned also by other authors, stems from the effects of patent settlements on the incentives to challenge weak patents. If patent settlements, for example, 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.

An important fundamental question is whether the last two effects should be relevant at all 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.[45] However, the situation is more complicated: First, although the main discussion focusses on the first effect (static price effect), 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"[46] was explicitly mentioned as relevant for the assessment of patent settlements. 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 (by offering a 180 days market exclusivity for the first challenging generic firm). Therefore the second and third effect have always been present in this discussion. Secondly, from an economic perspective, the Shapiro criterion of using the consumer welfare in the case of litigation as normative standard can certainly encompass also the effects on innovation incentives and incentives to challenge invalid patents, because both can have effects on the welfare of consumers. And since innovation is also one of the objectives of competition law, such a consideration of innovation effects is also consistent with the general competition law practice.

However, it is also clear that 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. But some observations about the reasoning in the patent settlement discussion should already be made here. Using the patent litigation outcome as normative standard implies that competition law should accept the outcome of this solution for consumers, irrespective of the question whether this is the best solution from a consumer welfare perspective. This can be interpreted in two ways: (1) In a surprisingly large number of contributions, also from the economic side, an explicit assumption has been made that the existing system of patent law (including the probabilistic character of the patents and all rules for opposition, litigation and enforcement) is an efficient system, which would imply that also the outcome of the patent litigation solution and therefore the normative reference standard for assessing patent settlements is efficient.[47] (2) The other interpretation of this approach, which is more in line with our knowledge about the problems and inefficiencies of the patent system, is that we use the patent litigation solution as normative standard, although we know that this solution might not be optimal. Then the main argument for using the patent litigation solution as benchmark is an argument about a division of labor between both fields of law.[48] However,

[45] For a discussion about the intersection of competition law and IP law see e.g. Régibeau/Rockett 2004.
[46] EC Guidelines on the Appl. Of Art 101 to TTA, p. 44 at para. 235.
[47] E.g. very explicitly Elhauge/Krüger 2012 p. 295.
[48] Shapiro himself would tend to the second interpretation. See Farell/Shapiro 2008 about the problems of the patent system.

if we think that there are serious problems with the existing patent systems, then this second way of thinking leads back to the general discussion about the relationship between both fields of law, which already has been going on for at least a decade.[49]

4.2 Antitrust Rules for Patent Settlements

In the following sections, we will analyze what economic models and reasonings have contributed to the question what the effects of different antitrust rules for dealing with patent settlements in the pharmaceutical industry are. As the relevant normative criterion we will use the effects on consumer welfare (as discussed in the last section). We will analyze the effects of different antitrust rules on the three kinds of effects on consumer welfare (via prices, innovation incentives, and incentives for challenging potentially invalid patents) separately. Most important are the following antitrust rules: (1) Per se permission: The parties are free to make patent settlements with agreed entry dates (up to the patent expiration date) and reverse payments (formal scope of the patent). (2) Per se prohibition: The parties are allowed to make patent settlements only on agreed entry dates but no reverse patents are allowed (or the variant "no reverse payments beyond litigation costs"). (3) Full rule of reason: Such an antitrust assessment of patent settlements would require a case-by-case analysis of all positive and negative effects of the patent settlement. (4) Presumption of illegality: (High) reverse payments would lead to a presumption of illegality that could be rebutted by a number of efficiency effects.[50] Depending on the strength of the presumption, such a rule might be close to a rule of reason or close to a per se prohibition of reverse payments. It is also one example of a broader set of differently designed structured rule of reason approaches.

When we ask about appropriate antitrust rules for assessing patent settlements, we also have to take into account what kind of information competition authorities or courts can use and the probability and welfare costs of decision errors (false positive / false negatives). From an economic perspective, therefore not only the economics of litigation, settlements and bargaining as well as competition economics is relevant but also the error cost approach based upon decision theory.[51] In order to decide, which of the different rules is more appropriate it is also necessary to analyze the frequency and size of "false positives" (prohibiting patent settlements that are enhancing consumer welfare) and of "false negatives" (allowing patent settlements with negative effects of consumers). We will come back to this specific problem in section 8.

5. 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 which would increase consumer welfare. Most of the discussion revolved around the question whether patent settlements with reverse payments would delay generic entry and therefore harm consumers. Since there is a broad consensus that settlements should be preferred to litigation due to litigation costs, the crucial questions concerns the antitrust limits that should be set for settlements in order to avoid negative effects for consumers. But saving of litigation costs might not be the only efficiency argument for settlements and for the question, whether and to what extent reverse payments might be defended. In the following, we want to analyze this discussion from an economic perspective. It is surprising that - despite all the controversies - most of the contributions use roughly the same basic economic model, either explicitly or implicitly. In the following, we will explain the reasonings by presenting a simple version of this model.

---

[49] E.g. OECD 1997 and for the US discussion see FTC Report 2003.

[50] Although the recently discussed "Actavis inference" solution of Edlin et al (2015) is not seen by their authors as a presumption, the "inference" works very similar to a presumption.

[51] Crane 2002, Davis 2009, Edlin et al. 2014.

The basic model

An originator firm A has a patent which would allow for annual monopoly profits M_A for the remaining patent duration T. In this basic model it is also assumed that there is only one firm B that can challenge the patent. If this generic firm B would enter the market at entry date E,[52] both firms have annual duopoly profits D_A and D_B , and the sum of the two duopoly profits is smaller then the monopoly profit ($D_A + D_B < M_A$). Since it can safely be assumed that duopoly prices are lower than monopoly prices, the annual welfare of consumers under duopoly is larger than under monopoly ($W_D > W_M$). If we assume that the true patent strength (probability of defending the patent in litigation) is θ, then the expected consumer welfare after litigation is: $W_L = \theta\ T\ W_M + (1 - \theta)\ T\ W_D$. , i.e. The consumers can expect with the probability θ that they have to live with a low consumer welfare due to high monopoly prices, whereas with the probability of 1 - θ the patent is revoked leading to a higher consumer welfare due to lower duopoly prices. According to the Shapiro criterion that the settlement solution should not make consumers worse off than under litigation, this would be the relevant normative standard for assessing patent settlements, i.e., the consumer welfare in the settlement case should be not smaller than in the litigation case: $W_L \leq W_S$. 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.[53] 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. Therefore we can derive from the above inequality that under these assumptions the normative criterion of Shapiro is fulfilled, if the entry date of the generic $E \leq \theta\ T$ (for the following analysis, we define: $E^* = \theta\ T$). This shows that the correct entry date of the generic E is a direct function of the true patent strength θ. 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 (pay offs) of litigation. In this simple version of the model we assume that both firms know the true patent strength (i.e., $\theta_A = \theta_B = \theta$) and have litigation costs c_A and c_B. 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: $V_{LB} = (1 - \theta)\ (T\ D_B) - c_B$. 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 and what are the upper and lower bounds of the settlement range in regard to the entry date E and the reverse payment R?

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: $V_{SAB} = V_{SA} + V_{SB} = E\ M_A + (T - E)\ D_A - R + (T - E)\ D_B + R = E\ M_A + (T - E)\ (D_A + D_B)$. Since $D_A + D_B < M_A$, it is optimal for both of them to agree delaying the market entry of the generic until the expiration of the patent, i.e. E = T.[54] Then the joint profits would be identical to the profits of the patent holder with an ironclad patent θ = 1: $V_{SAB} = T\ M_A$. 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: $R_{max} = T\ M_A - V_{LA} = T\ M_A - [\theta\ (T\ M_A) + (1 - \theta)\ (T\ D_A) - c_A] = (1 - \theta)\ T\ (M_A - D_A) + c_A$. 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 settle-

---

[52] It is also assumed in this simple model that litigation does not need time. For a variant of this model that includes the time for litigation, see Elhauge/Krüger (2012). They also include in their model the two possibilities that the generic firm already enters the market before a decision of the court (at-risk entry) with the danger of having to pay damages (if they lose) or that the generic firm waits for the final decision about the validity of the patent before deciding about entry.

[53] This is often overlooked in the literature.

[54] This assumes that the parties are not allowed to make settlements for delaying entry after the expiration of the patent (formal scope of patent rule).

ment 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. This is the settlement solution under per se legality of reverse payments (formal scope of the patent rule). 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: $W_S - W_L = T\ W_M - [\theta\ T\ W_M + (1 - \theta)\ T\ W_D] = (1 - \theta)\ T\ (W_M - W_D) < 0$.[55] Or to put it otherwise: Here $E = T$ is larger than the correct entry date $E^* = \theta\ T$. We also can conclude that the loss of consumer welfare is the larger, the smaller the patent strength θ is, i.e. the weaker the patent is. Based upon these considerations nearly all contributors to this discussion see the anticompetitive effects of such a per se permission of reverse payments and agree on the need for antitrust limits for settlements.[56]

If the firms are not allowed to maximize their joint profits in the settlement, we can first analyze the relation between the agreed entry date E and the reverse payment R. It can be shown that 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 $E_{max} = \theta\ T + c_B / D_B + R / D_B$.[57] First, we see that by increasing the reverse payments R, both parties can shift the settlement range in the direction of later entry dates, which would increase profits and reduce consumer welfare.[58] 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 optimal one: $E = E^* = \theta\ T$.

Important conclusions from the basic model

From this basic model several important conclusions can be derived that have been very influential in the policy discussion:
(1) From the model the normative benchmark (according to the Shapiro criterion) for patent settlements can be derived. It is the consumer welfare that can be expected under patent litigation ($W_L = \theta\ T\ W_M + (1 - \theta)\ T\ W_D$), and under the assumptions of the model this criterion is fulfilled if the generic would enter the market at $E^* = \theta\ T$, i.e. the duration until generic entry is exactly proportional to the patent strength.
(2) If there are no reverse payments, then the bargaining would lead to a settlement range around this optimal entry date $E^* = \theta\ T$, i.e. under the assumptions of this simple model patent settlements without reverse payments would lead to roughly the same consumer welfare than under litigation.[59]
(3) The model can show clearly that by increasing the reverse payments R the parties can shift the settlement range to later agreed entry dates with the consequence of delaying generic competition (pay-for-delay settlements). This increases the joint profits of the firms and decreases consumer welfare. Therefore reverse payments are a very effective instrument for restricting competition.
(4) If there are no limitations in regard to the reverse payments (per se permission of reverse payment within the formal scope of the patent), both firms would agree to an entry date at the end of patent duration ($E = T$), eliminating any price competition until the expiration of the patent. The consumers would have the same welfare $T\ W_M$ as if it would be an ironclad patent, and the patent strength θ

---

[55] Please remember: $W_M < W_D$. Since prices after the entry of generics are usually much lower than before, this difference is also a significant one.

[56] E.g. Shapiro 2003, Elhauge/Krüger 2012, Gratz 2012.

[57] For firm A: $V_{SA} = V_{LA}$; this leads to: $E_{min}\ M_A + (T - E_{min})\ D_A - R = \theta\ (T\ M_A) + (1 - \theta)\ (T\ D_A) - c_A$, from which follows the above result: $E_{min} = \theta\ T - c_A / (M_A - D_A) + R / (M_A - D_A)$. Similarly for firm B: $V_{SB} = V_{LB}$; this leads to: $(T - E_{max})\ D_B + R = (1 - \theta)\ (T\ D_B) - c_B$, from which follows the above result: $E_{max} = \theta\ T + c_B / D_B + R / D_B$.

[58] The consumer welfare of a settlement is: $W_S = E\ W_M + (T - E)\ W_D = T\ W_D - E\ (W_D - W_M)$. If we look for the lower and upper limits of E, then it follows: $CW_S(E_{min}) = T\ W_D - [\theta\ T - c_A / (M_A - D_A) + R / (M_A - D_A)]\ (W_D - W_M)$, and $CW_S(E_{max}) = T\ W_D - [\theta\ T + c_B / D_B + R / D_B]\ (W_D - W_M)$; since $W_D - W_M > 0$, $W_M > 0$, and $M_A - D_A > 0$, any increase of R leads to a decrease of consumer welfare in patent settlements.

[59] There is, however, an additional small settlement range to both sides of $E = \theta\ T$ due to the litigations costs of both parties.

would only influence the sharing of the monopoly profits between the patent holder and the challenging generic firm.
(5) This model also suggests, although it is rarely discussed explicitly, that patent settlements without reverse payments are not anticompetitive, because they usually lead to the correct entry date.

The basic structure of this model of patent settlements is generally accepted, and therefore these conclusions constitute the crucial starting-point for the more concrete policy discussion about the appropriate antitrust rules for dealing with patent settlements. From these results, it can easily be understood why antitrust scholars are so concerned about reverse payments, and why antitrust rules are proposed that prohibit reverse payments or use a presumption of their illegality or at least use the size of reverse payments as a fact that has to be explained by other reasons. However, in the discussion, esp. also through economic contributions (as, e.g, Willig/Bigelow 2004), also a number of economic reasonings have been developed, which claim to show that patent settlements can also lead to efficiencies, and that under certain conditions also reverse payments might be needed for enabling efficiency-enhancing patent settlements. Therefore a number of scholars have argued against a per se prohibition or a presumption of the illegality of reverse payments. In the following, we will summarize and extend this discussion. However, we will not focus - as much of the literature has done - only on the question whether there might be settlements with reverse payments that are procompetitive. Rather we will analyze much more generally the possible outcome of such negotiation processes and whether the above conclusions from the basic model also hold under more realistic assumptions about the bargaining processes between originator and generic firms.

The basic model as presented above (and used similarly in the literature) uses a number of very unrealistic assumptions about the bargaining situation: First, on real markets, the firms A and B can only make estimates about the future market conditions (market demand, new substitutes, market shares between brand name and generic products, co-payment rules of insurances etc.), which are important for estimating the future profits M_A, D_A and D_B until patent expiration. Since the market can grow or shrink over time, it can also be expected that M_A, D_A and D_B are not constant over time but might be changing and fluctuating to some extent (independent from any discounting factor).[60] This implies that both firms will most certainly (1) have different expectations about the future profits M_A, D_A and D_B, and (2) make prediction errors, i.e. their expected market conditions will often prove wrong.[61] The same problem emerges for the estimates of the parties about the strength of the disputed patent. Since nearly the entire discussion assumes that the true patent strength θ is unknown, it cannot really be assumed that both firms will have the same estimates, θ_A and θ_B, or that any of these estimates are equal with the true patent strength θ. Other critical assumptions refer to the problem of risk aversion, unequal bargaining power, strategic considerations of the parties, and the number of generic challengers and entrants. We will look at deviations from these assumptions separately and step-by-step.[62]

Wrong and different estimations of patent strength

Very important and analyzed in several economic papers are the consequences of different estimations about the patent strength θ (e.g., Willig/Bigelow 2004, pp. 672, Gratz 2012, pp. 26). Also here two groups of problems can be distinguished, (1) whether the parties make mistakes in their estimations of the true patent strength, and (2) the effects of different estimations of the patent strength by both parties. An important result of the model, which has not been emphasized in the literature, is that an over- or underestimation of the patent strength by the parties leads to distorted settlement results.

---

[60] If these profits are not constant over time, then the optimal entry date E* which just fulfills the normative criterion of Shapiro is not any more proportional to the patent strength θ, i.e. $E^* \neq \theta T$, as in the basic model.

[61] This is partly analyzed as asymmetric information about market conditions in Willig/Bigelow 2004, pp. 667.

[62] For the 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.

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 larger than the optimal one according to the Shapiro criterion ($E > E^*$), rendering this patent settlement anticompetitive. Vice versa, if both firms underestimate the patent strength $\theta_A = \theta_B < \theta$, then the agreed entry date (with $R = 0$) will be earlier than optimal one ($E < E^*$), which leads to a higher consumer welfare compared to the litigation outcome. However, this also would allow some positive reverse payments without making the patent settlement anticompetitive. Most papers instead have focussed on the consequences of differing estimates about the patent strength θ. If both parties have different estimates of the patent strength (optimistic/pessimistic), the settlement range can get broader or smaller, and can even get negative, making a settlement despite the saving of litigation costs impossible without reverse payments.[63]

Willig/Bigelow (2004) analyzed such a case (pp. 672): They assume that the incumbent knows the true patent strength and the entrant is overoptimistic, i.e., assumes a too low patent strength ($\theta = \theta_A > \theta_B$). The difference is assumed to be so large that even with saved litigation costs the settlement range is negative, and therefore this litigation cost-saving settlement is only possible, if the incumbent offers a reverse payment to the entrant. 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, this conclusion can only be made, because Willig/ Bigelow (2004) assume that the incumbent knows the true patent strength, i.e. $\theta = \theta_A$. However, if we accept that the true patent strength is unknown, then we can only observe that the estimated patent strength of the patent holder is larger than the one of the entrant ($\theta_A > \theta_B$) without knowing the true θ. The problem is that we cannot distinguish this procompetitive case from another case, in which the patent holder is overoptimistic and the entrant makes the correct estimation about the patent strength ($\theta_A > \theta_B = \theta$). Also here a settlement is only possible, if a reverse payment is made. However, in this second case, such a reverse payment would lead to a too late entry date and therefore would be clearly anticompetitive. Although Willig/Bigelow (2004) are right in describing a case in which a prohibition of reverse payments would make a procompetitive settlement impossible, without knowledge of the true patent strength it is impossible to distinguish this case from others where the same patent settlements with reverse payments are anticompetitive and harm consumers.

Wrong and different expectations about future market conditions

What are the consequences of wrong and/or asymmetric predictions about future market conditions and therefore future profits of both firms? For example in the case of underestimation of D_B and no reverse payments ($R = 0$), generics would accept later entry (larger E_{max}), which might lead to an anticompetitive patent settlement (despite $R = 0$).[64] In the case the originator overestimates M_A and/or underestimates D_A, the earliest entry date which is acceptable is delayed without a reverse payment with similar results.[65] The reverse cases then lead to the opposite results leading to possible earlier entry dates, which even would allow a certain reverse payment without rendering the patent settlement anticompetitive. If the estimations of both firms about future market conditions are different (or only one firm has knowledge about these market conditions), then there might be cases where a reverse payment is necessary to establish the settlement.[66] Willig/Bigelow (2004) succeed in proving that there is a case of asymmetric information about the value of a patent, in which only a reverse payment can make a settlement possible. Therefore a prohibition of reverse payments would not allow

---

[63] From the economics of settlements it can be derived that if both parties have the same estimates of the patent strength ($\theta_A = \theta_B$), then this also implies that the estimated winning probability of B in litigation is $1 - \theta_A$, i.e., the sum of estimated winning probabilities in litigation equals 1. If, however, $\theta_A > \theta_B$, then the sum of estimated winning probabilities is larger than 1 ($\theta_A + (1 - \theta_B) > 1$), which might lead to a negative settlement range, and therefore might render settlements, at least without reverse payments, impossible. Vice versa, if $\theta_A < \theta_B$, then the sum of winning probabilities is smaller than 1 ($\theta_A + (1 - \theta_B) < 1$), broadening the settlement range (Willig/Bigelow 2004, p. 673).

[64] 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}.

[65] For $R = 0$: $E_{min} = \theta\, T - c_A / (M_A - D_A)$; therefore an overestimation of the profits M_A or an underestimation of D_A leads to a higher lower bound of the settlement range E_{min}.

[66] Willig/Bigelow (2004, pp. 667).

such procompetitive settlements.[67] However, we have to understand that these are very specific examples among many different situations, in which there might be differences in regard to the information and predictions of future market conditions. Depending on the specific assumptions about these differences, it can be expected that a number of different groups of cases could be distinguished, each with different effects on agreed entry dates in settlements (with R = 0), and therefore different positive and negative effects on consumer welfare.

Risk aversion

Another problem that has been raised in the discussion both by legal and economic scholars is the problem that one or both parties might not be risk-neutral (as assumed in the basic model) but risk-averse. From an economic perspective, it is true that risk aversion of one party has the same effect as an increase of its litigation costs, leading to a lower value of litigation and therefore to a larger willingness for accepting less favourable terms of settlements.[68] If the originator is more risk averse, he would be willing to accept earlier generic entry, as well as a risk-averse generic firm might accept later entry. Thus risk aversion on one or both sides changes the settlement ranges and therefore also the agreed entry dates and/or reverse payments.[69] From an economic perspective the argument can be made that a high risk aversion of an originator firm might justify a certain amount of reverse payment for insuring against the risk of litigation, because this would be efficiency-enhancing. If the delay through this reverse payment would only compensate for the acceptance of an earlier entry due to the risk aversion of the originator, then such a patent settlement need not harm consumers compared with the litigation solution.[70] However, whether there exists risk aversion and how significant it is, is an open empirical question. It is also unclear how the risk neutrality or risk aversion of the parties should be assessed in an antitrust case. If we take into account more precisely whether the managers or the shareholders of an originator or a generic firm have risk aversion, then also important new normative questions have to be raised whether risk aversion should be taken into account at all in such antitrust cases.[71] It is therefore not clear if and how risk aversion can be taken into account as efficiency defence for reverse payments. However, it is clear that any deviations of risk neutrality of both parties will influence both the bargaining positions, the settlement range, and the ultimate settlement terms. Any asymmetry of risk preferences between the originator and the generic firm tends to shift the agreed entry date in one or the other direction.

Strategic considerations

What so far has not been discussed in the economic contributions about the determinants of the entry dates and reverse payments in patent settlements are strategic considerations of the originator and

---

[67] In Willig/Bigelow (2004, pp. 667) a very specific situation of asymmetric information about the value of the patent was analyzed. Here it was assumed that the originator firm knows better than the entrant the economic life and therefore the value of the patent. In this situation they show that reverse payments might be required to find a settlement solution since for the generic the high- and low value patent holder type look the same. In this signalling game, the reverse payment of the patent holder is necessary to signal credibly that he has a patent with high value.

[68] E.g. Gratz 2012, pp. 48, Willig/Bigelow 2004, pp. 682.

[69] Willig/Bigelow 2004, p. 666. Independent from the problem of risk aversion there might also be a different distribution of risks between incumbents and entrants. An originator might have more to lose in litigation (loss of monopoly profits) compared to a generic firm. Also this would change the settlement ranges. See ibid., and also in much more detail Yu/Chatterji (2011).

[70] Schildkraut 2004, pp. 1061.

[71] Although shareholders of large companies are likely to be risk-neutral (due to large product portfolios of these firms and diversified portfolios of shareholders), the managers of these companies might be more risk-averse (Willig/Bigelow 2004, p. 666, fn.10). If, however, managers and shareholders have different risk preferences, then the preferences of the managers for a patent settlement with reverse payments for reducing their risk would not reflect the interests of their shareholders (principal agent problem). In that case it would not be an efficiency effect which would justify a reverse payment. See for such a critique Elhauge/Krüger 2012, p. 312.

generic firm.[72] All economic models and reasonings analyze the litigation/settlement-problem between the two parties only in regard to this one patent dispute and only in regard to the future profits of this one product. 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 and products, 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. There might be synergies in producing and selling other pharmaceuticals in the same markets, which would change the relative advantage of litigation and settlements for either the originator or the generic firms. This also can change settlement ranges and therefore influence agreed entry dates and reverse payments.[73] Another possibility for strategic effects can be based upon well-established models on strategic entry barriers. For example, originator firms might embark on a strategy of deterring future challenges of patents by building up a reputation for defending their patents rigorously and reject settlements.[74] 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

In addition to these problems, there is one very important issue that so far has not been analyzed sufficiently in regard to its implications for settlements. Nearly all economic models and reasonings about the litigation and settlement process have not taken into account that there might be more than one generic firm that can challenge and enter the market. In section 3, we already discussed the public good problem in regard to the challenging of patents as an exclusive right, i.e. that the first challenging firm takes the risk but in case of nullifying the patent, all firms can profit from this litigation. One side of this problem are the incentives for challenging patents, to which we will come back in section 6. But the other part of this problem is that the originator firms in their settlement calculus have to take into account that after the settlement with firm B, other generic firms might also challenge the same patent, which might require additional settlements. If after litigation with firm B, the validity of the patent is clarified, this problem of additional challenges might not be relevant anymore. But a patent settlement with firm B does not preclude the need of additional settlements with firms C and D etc. Theoretically, firm A has to compare the value of litigation with the value of all settlements that are necessary if litigation should be avoided. This changes the upper limits of the settlement range in the first patent settlement, i.e. the patent settlements with different generic firms are not independent from each other.[75]

So far only very few papers have analyzed certain aspects of this problem. For example, the article of Elhauge/Krüger (2012) has not addressed this problem at all. Although Willig/Bigelow (2004) have analyzed the implications of an additional entrant, the product that this entrant will offer at a certain

---

[72] Davis (2009, p.292) mentions that also strategic considerations can influence settlement ranges; see also Shapiro (2003, 410) for considering the existence of entire patent portfolios.

[73] For example, an originator firm might want to defend its strong market position in certain markets and therefore would attribute a higher value on the difference between keeping the monopoly and accepting a new entrant than the difference between M_A and D_A would suggest. The decisive point is that strategic considerations might change the values of the litigation solution, and hence influence settlement ranges.

[74] In regard to the basic model this would imply that the value of litigation in regard to a specific patent is not more the relevant benchmark for a settlement solution. Rather firm A would be willing to make short-term losses by not accepting an easy settlement (i.e. they would accept only a later entry or no entry), because this might lead to a deterrence of future challenges. This is to some extent the opposite of the strategy to defend weak patents by reverse payment. However, if such a strategy is working, it also would lead to less consumer welfare through later entry or fewer challenged patents.

[75] In the U.S. context, this problem is also influenced much 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). However, this also can lead to complex incentive problems. See, e.g., (lit), as well as In re United States Court of Appeals for the Eleventh Circuit FTC v Watson Pharmaceuticals, Inc., Solvay Pharmaceuticals, Inc., p. 38, in which the possibility of multiple challengers was addressed.

date in the future is a substitute product, which does not infringe the patent, but only limits the economic life of the patent (pp. 673). Therefore this is not a case of multiple challengers and therefore the question of an additional settlement is not relevant. In a very recent paper Edlin et al (2015, pp.19-28) analyzed with a theoretical model the consequences of multiple generic entrants in regard to the inference that can be drawn from the existence of reverse payments. Crucial for their analysis is that it takes place in the context of the rules of the Hatch-Waxman Act which gives the first generic challenger a 180 days exclusivity before other generic firms can enter the market. In their analysis they can show that if there are multiple generic firms which would enter the market after the 180 days exclusivity period, then there is an even larger incentive for a pay-for-delay settlement between the originator and the first challenging generic firm, because the price decrease would be larger after the 180 days exclusivity period.[76] This is a very important insight, which due to the very specific US rules in the Hatch-Waxman Act does not address the problem of the existence of multiple challengers. The only paper which considers the effects of an additional challenging entrant is Gratz (2012). In her paper she assumes that at a specific date a first generic can challenge and enter the market (leading to a duopoly) and then after an additional period a second generic can challenge and enter (leading to triopoly prices). However, due to specific assumptions her model does not analyze this problem directly. Overall, the problem of the impact of the possibility of multiple challengers has not been analyzed so far systematically, although all scholars would admit that usually more than one generic can challenge and enter, and that therefore one settlement with one generic might not be enough for protecting a weak patent. From an empirical perspective, it is interesting that usually only a very limited number of generic firms exist that could challenge and enter a specific pharmaceutical market.[77]

Conclusions

What can we learn from these results by considering more realistic assumptions for the negotiating process? If we take into account all these information (asymmetry) problems about future market conditions, patent strength, risk aversion, and strategic considerations, then it can be expected that in most cases the settlement solution (even in the case of no reverse payments, i.e., R = 0) will not correspond to the normative benchmark of the outcome that can be expected through litigation.[78] Depending on the specific conditions the agreed entry dates might be earlier or later than it would correspond to the outcome of litigation, and therefore also consumer welfare might be higher or lower. We have already seen this in the simplest case of an over- or underestimation of the patent strength by the settlement parties.[79] Especially problematic is that in regard to important aspects, we so far do not have sufficient economic research, as, e.g. in regard to the problem of multiple challenging entrants.

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 criterion of Shapiro would allow ($E > E^*$). Therefore the prohibition of reverse payments does not ensure that the patent settlements are not anticompetitive.
(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 criterion of Shapiro would suggest ($E \leq E^*$). In a part of these cases these reverse payments might be necessary for achieving litigation cost-saving settlements or other efficiencies.

---

[76] The decisive point is that with a patent settlement they can delay the entire 180 days exclusivity period.

[77] Grabowski/Kyle 2007, pp. 500.

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

[79] This also implies that the possibilities to make reliable conclusions from the settlement results (e.g., the agreed entry dates) on the true strength of the patent, as this was suggested in the basic model, are very much limited. Therefore we cannot conclude from an agreed entry date in three years (with a remaining patent duration of 10 years) that the true patent strength is 30%. It might be much higher or much lower, depending on the specific conditions of the real-life bargaining situation with all its imperfections in terms of information and unpredictability.

(3) A consequence of these results is that it can be questioned whether the observed size (and also the absence) of reverse payments is a very reliable indicator for the anticompetitiveness of the patent settlements. However, the "imperfections" of the bargaining process do not seem to endanger the effectiveness of reverse payments as a very suitable and easy applicable instrument for restricting competition between originators and generic firms and harming consumers. Therefore the necessity to eliminate the possibility that the settlement parties can use this instrument for restricting competition is also relevant in more complex real-life bargaining situations.
(4) Since also patent settlements without reverse payments can be anticompetitive, it might be necessary that also this group of settlements should be analyzed more critically in regard to its compatibility with competition law rules. Therefore the application of competition law should not only focus on reverse payments.
However, before we can discuss the consequences for the suitable antitrust rules for dealing with patent settlements with or without reverse payments, we have to look at the other two effects in the next sections.

6. Effects on Consumer Welfare via Innovation Incentives

Have antitrust rules on patent settlements effects on innovation incentives for the originators and therefore on the development of new drugs, which in the long-term would also affect the welfare of consumers? In the economic analysis of patents it is a well-established insight that the duration of the exclusivity right for protecting the innovation should not be too short but also not too long, leading to the notion of optimal length and breadth of patents. This is the result of an economic rationale that takes into account the necessity of innovation incentives but also the costs in terms of dead weight losses through monopoly prices and the potential impediments of further innovation.[80] From that perspective, it is clear that it cannot be simply argued that the fact that the prohibition of reverse payments would lead to lower profits for the originator firms would lead to less innovation incentives. This is a wrong conclusion from an innovation economics perspective; because (1) there also should not be too large innovation incentives through patent protection and (2) such an argument could justify all kinds of anticompetitive behaviours leading to higher profits.[81] On the contrary, the question emerges whether the possibility of protecting innovations, which only lead to weak patents, with reverse payments would not distort innovation incentives into the direction of "pseudo" or "trivial" innovations which have a lesser benefit for society than "regular" innovations. This is directly linked to the discussion in Farrell/Shapiro (2008) about the proportionality principle, i.e. that the rents (innovation incentives) from the patents should be proportional to the patent strength. 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.

Elhauge/Krüger (2012) emphasized that both the static price effects and the innovation incentive effects for the originator are important, which also might lead to difficult trade off problems. However, they wanted to show that in regard to their preferred rule of a strong presumption against patent settlements with reverse payments no such trade off exists. Rather reverse payments (that are larger than litigation costs of the originator) would lead to a too late agreed entry date in the settlement which would harm consumers via too high prices and also lead to too large innovation incentives. Therefore such a rule would also be supported by their innovation incentives analysis. How do Elhauge/Krüger (2012) come to this result and have they used an appropriate approach for their analysis? In a first step, Elhauge/ Krüger are entirely in line with the law and economics literature on patents by emphasizing that an optimal duration of patent exclusivity exists, i.e. that both a too long and a too short exclusion period through patents is not optimal from an innovation economics perspective (ibid, pp. 293). In a second step, they use the concept of probabilistic patents (as presented in section 3) and interpret this concept not only from a litigation perspective (as in their analysis about the price effects of settlements) but also from an innovation incentive perspective. They explicitly assume that a patent with a patent strength of $\theta = 0.25$ is from an innovation incentive perspective equal to an ironclad patent of 5

[80] See e.g. Gilbert/Shapiro 1990 or Klemperer 1990.

[81] Regarding the problem of the design of patent protection especially in the context of cumulative innovation see Scotchmer 1991, Gallini/Scotchmer 2002 or Bessen 2004.

years (25% of the patent duration of 20 years), i.e. they translate the probabilistic character of a patent into an ironclad patent with T = θ 20. Although a lot of assumptions have to be made for defending such a linear transformation,[82] the basic idea is in line with an innovation incentive interpretation of probabilistic patents. A different question is whether their claim is correct that also the U.S. patent law can be interpreted in that way from a legal perspective, i.e. that a patent holder whose patent has a patent strength of θ should also get innovation incentives in the size of a proportionally shorter patent duration (ibid, pp.295).

The main problem in the analysis of Elhauge/Krüger (2012) emerges in their next step. They define a proportional share of the usual patent duration of 20 years (based on the patent strength) as the optimal patent exclusion period and use this as their second normative benchmark for assessing patent settlements. In the following, they analyze whether the expected settlement exclusion period (derived from the agreed entry dates) is larger than their two normative benchmarks, (1) the expected litigation exclusion period (in regard to price effects), and (2) this optimal patent exclusion period. The problem with this second benchmark now is that they do not define the optimal patent exclusion period as a percentage share of the entire patent duration from the date of granting the patent (i.e., the optimal entry date $E_{inno}^* = \theta\ 20$). Rather they define it as a percentage share of the remaining (!) patent duration from the date of the settlement ($E_{inno}^* = \theta\ T$). From an innovation economics perspective, this is a serious mistake, because it ignores the entire period of unchallenged monopoly prices for the originator before the settlement. This leads to a wrong benchmark from an innovation economics perspective. 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. If the optimal patent exclusion period is calculated from the remaining patent duration, then the innovation incentives are always too large except the extreme case that the challenge and settlement is made directly at the beginning of the life of the patent.[83] As a consequence of this problem at the beginning of the analysis of Elhauge/Krüger (2012), their conclusions about the innovation incentive effects of a rule prohibiting patent settlements with reverse payments do not hold.

Overall, in regard to innovation incentive effects the following conclusions can be drawn:
(1) Since this error in Elhauge/Krüger (2012) leads to a systematic bias of their results in one direction, we can still conclude from their results that if the date of the settlement is later than the date of the granting of the patent, then the agreed entry dates in patent settlements without reverse payments (that are larger than litigation costs) are leading systematically to too large innovation incentives for the originator firms. This also implies that patent settlements with larger reverse payments even aggravate this problem of too large innovation incentives, which supports Elhauge/Krüger's suspicion against these patent settlements. This result also is another argument why also patent settlements without reverse payments might have anticompetitive effects, now from an innovation incentive effects perspective.
(2) This analysis shows that from an innovation economics perspective the date of the challenge and settlement within the lifetime of the patent is getting important. It is interesting that the question whether the patent is challenged at the beginning or the end of the patent duration has not played any major role in the antitrust discussion about patent settlements.
(3) Another conclusion is that there might be a trade-off between the benchmark of the litigation solution and the optimal innovation incentives. This trade-off might be much more severe for patents that

[82] This would assume constant rents from the innovation over time and the absence of the need of discounting future revenues. For the problem of linearity of patent rewards, see also more generally Ayres/Klemperer 1999.

[83] 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 would be $E^* = \theta\ (D+T) = \theta\ 20$, which is always smaller than the agreed entry date in a settlement, $E = D + \theta\ T$, as long as D > 0. 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.

are challenged late in their patent life and for more weak patents.[84] From this perspective, it can be suggested that the optimal entry date according to the criterion of Shapiro might lead itself to too large innovation incentives, at least for patents which are not challenged at once. But these conclusions should be seen as tentative and preliminary, because they need a far more thorough analysis.
(4) Overall, these considerations lead more to the conclusion that antitrust authorities and courts should not be too worried about curbing too much innovation incentives, if they want to pursue a restrictive approach to reverse payments and patent settlements in general.
(5) However, the biggest problem is that much more research is needed for analyzing this problem of effects on innovation incentives. A particular problem is that we do not even know whether from an innovation economics perspective such an innovation incentive interpretation of probabilistic patents, which has been used so far in the few studies, is a convincing basis at all for such an analysis.[85]

7. Effects on Consumer Welfare via Incentives for Challenging Patents

The last group of effects of antitrust rules for patent settlements on consumer welfare refer to the incentives for challenging potentially invalid patents of pharmaceutical firms. These effects would not be relevant, if there were no weak patent problem or the patent law regimes did not rely on private litigation for weeding out valuable invalid patents. This effect is important for the welfare of consumers of pharmaceuticals, because if more potentially invalid patents are challenged, then in regard to more pharmaceutical products a market entry before the expiration of patents takes place, which drives prices down earlier for more pharmaceuticals benefitting the consumers. In section 3, we already described the public good problem of challenging potentially invalid patents. In the U.S., this incentive problem was attempted to be solved by the Hatch-Waxman Act[86] by granting the first challenging entrant a 180 days exclusivity period before other generics are allowed to enter the market. In that respect, the first challenger can reap higher profits than the other generics which would reduce the free-riding problem from the patent challenge. In this paper, we want to analyze the problem of challenging incentives more generally and not in regard to the specific institutional setting in the U.S., which has also changed over time.[87] However, the problem is that so far nearly no economic analysis can be found that addresses this problem how antitrust rules about patent settlements influence the incentives for challenge, although a number of authors mentioned this problem and partly were concerned that a prohibition of reverse payments would reduce the incentives of generics for challenging potentially invalid patents.[88] The only paper we found is Gratz (2012), who presents a model with an integrated analysis of both the price effects and the challenging incentive effects through different antitrust rules for patent settlements.

Gratz (2012) analyzed the problem how different antitrust rules about patent settlements in the pharmaceutical industry affect the extent that patents are challenged by generics and the effects of these antitrust rules on consumer welfare. In her model there are originator firms with patents with different

---

[84] The latter is again directly linked to Farrell/Shapiro's problem with the proportionality principle.

[85] The question can be put as follows: Do we really want to incentivize "innovative" activities, which lead to a 10% or 20% probability of a valid patent? The answer to this question would require a deeper analysis also in the reasons for the low validity of many patents as well as a deep innovation economics discussion.

[86] The Hatch-Waxman Act had the explicit objective of optimizing the trade off between offering the originator firms sufficient innovation incentives and simultaneously alleviating price competition through generic entry. This has led to a very complex institutional setting, which is also directly intertwined with the market approval of new drugs by the FDA. See more generally United States Code U.S.C. Title 21 at § 355(j), Hemphill 2006.

[87] Due to the problem of patent settlement with reverse payments, the U.S. has changed the Hatch-Waxman Act in such a way that it does not allow any more that the first entrant can make a patent settlement with the patent holder, which violates antitrust rules, and at the same time retain its 180 days market exclusivity period, which blocks other entrants. See United States Code U.S.C. Title 21 at § 355(j), Medicare Prescription Drug, Improvement, And Modernization Act Of 2003, Subtitle A—Access to Affordable Pharmaceuticals, Kelly 2011, pp. 439.

[88] See, e.g. Dickey et al. 2010, p. 399, Gratz 2012, p.15.

strengths ($0 \leq \theta \leq 1$). In addition, two generic firms can challenge patents and enter the market at different future dates. As in the basic model, it is assumed that until the first entry date, there are monopoly profits, after the entry of the first entrant duopoly profits, and after the entry of the second entrant triopoly profits. The decreasing prices of this increasing number of firms in the market lead to higher welfare for the consumers. The originator firms can make patent settlements with the first - and afterwards with the second entrant with agreed entry dates and reverse payments. The decisive additional element is now that the decision whether the first and the second generic firm will challenge the patent is made endogenously in this model. The firms have to decide whether the profits from the challenge, which consist of the profits they can make through being able to enter the market before the expiration of the patent plus any reverse payments that the originator firms pays them in a settlement, are worthwhile in respect to the fixed costs they have to spend for challenging the patent (ibid., pp.6). After they have challenged the patent, they can decide - as in the basic model - to either carry out the litigation or accept a settlement offer by the originator. Now possible terms of the patent settlements (regulated by the antitrust rules) have an effect on the incentives of the generics to challenge patents, i.e. whether it is only worthwhile to challenge very weak patents (with therefore earlier entry dates and/or higher reverse payments) or whether it is worthwhile to challenge also less weak patents. For example, the result might be that only patents with $\theta \leq 0.2$ are challenged or perhaps a larger number of patents up to $\theta \leq 0.4$. If the settlements lead to larger profits for generic challengers of patents, then the model predicts that the generic firms would challenge more patents.

With this model Gratz (2012) wants to compare the effects on consumer welfare of different antitrust rules. She particularly compares the consumer welfare effects of a per se prohibition of reverse payments with a rule of reason approach. However, she does not analyze - as we have seen in section 5 - situations and efficiency arguments, why reverse payments might be needed for procompetitive settlements, which might be an argument for rule of reason. Instead, her argument is a very different one: She argues that due to the information problems courts have in order to make a correct decision under rule of reason, the courts make errors in the estimation of the correct future entry date. Although she assumes that the errors can be both ways, her way of modelling this effect leads to asymmetric effects of these errors in that way that the courts would accept erroneously a number of anticompetitive patent settlements (with reverse payments). This effect implies that the agreed entry dates of the patent settlements are later than without this error-making of the courts. Now the basic result of her entire model is that this collusive effect of later entry (compensated by reverse payments) leads on one hand to lower consumer welfare (through a later decrease of prices), but on the other hand also to larger profits of generics, which induces them to challenge more patents with the already described positive effects on consumer welfare. In that respect, she has modelled successfully the trade-off between the negative effects on consumer welfare through later entry and the positive effects through more challenging of weak patents. Based upon these effects, she concludes that a rule of reason approach is better for consumer welfare than a per se prohibition of reverse payments.[89]

The problem with the model of Gratz (2012) is not this specific positive effect of later entry through patent settlements with reverse payments on the challenging incentives of generics. This is the result of a solid economic analysis. Rather the problem consists in her reasoning why (!) these effects emerge and whether the rule of reason approach is responsible for that. That these effects emerge through more errors of courts is not convincing due to two reasons: (1) A rule of reason usually reduces decision errors and therefore should lead to lower welfare losses due to decision errors.[90] (2) It remains unclear why the errors of the courts have only a one-sided effect, i.e. that only more anticompetitive settlements (with too late entry dates) are erroneously accepted but not also more procompetitive settlements are erroneously rejected by the courts, which would reduce the profits of originators and generics, and therefore also reduce the incentives for challenging patents.[91] Using this reasoning

[89] She also analyzes in her model the effects of litigation- and settlement costs, risk aversion as well as asymmetries regarding expected litigation outcomes (Gratz 2012, pp. 26).

[90] From the perspective of the error-cost approach the rule of reason was seen as superior to more simple rules because of its potential to reduce the sum of decision errors by using more specific information. Such reasonings are not included in the model of Gratz (2012).

[91] Under the assumption of symmetric errors (as in Gratz 2012), it can be presumed that these effects would level each other out, and then, on average, there would be no positive effect on challenging incentives of generics.

with errors of courts also leads to the problematic conclusion that the positive incentive effects for challenging weak patents are the larger, the more errors courts make.[92] We think that this reasoning of the cause of this challenging incentive-increasing effect in Gratz (2012) is not convincing, and that therefore we also should not accept her conclusion about the superiority of rule of reason in comparison to a per se prohibition of reverse payments. However, her model with its first integrated analysis of price and challenging incentive effects is an important contribution to our understanding of the important trade-off between insisting on early entry dates due to the direct price effect on consumer welfare and the incentives for challenging invalid patents.

This trade-off can also be explained from a very different perspective. In section 3 about the patent system, we have seen that the patent system leaves it to private litigation to weed out valuable invalid patents through patent opposition and patent litigation. Since this process of weeding out invalid patents requires resources, the question arises who bears the challenging costs. Since the state that is granting too many exclusivity rights through its patent offices (and saves money by not examining them thoroughly) does not bear these costs, private parties have to bear them. In the case of the pharmaceutical industry, we can see the generic firms as the agents of society that also should fulfil the task of challenging invalid patents in order to remedy the mistakes of the patent offices. In the U.S., the solution of the Hatch-Waxman Act of granting the first entrant a 180 days exclusivity period, can be interpreted from the same trade off perspective: It leads on one hand to a later entry of other generics and therefore to higher prices for consumers (during the exclusivity period), however, on the other hand, it also offers larger incentives for generics for challenging patents, which would increase consumer welfare. As in the model of Gratz, also in the case of the Hatch-Waxman Act, it is the consumers who ultimately have to bear the costs of increasing the incentives to challenge weak patents, but they also benefit from more challenges.

A consequence from this economic reasoning is that scholars who were concerned that a prohibition of reverse payments might lead to fewer incentives for challenges by generics might find some support in economic analysis.[93] However, primarily we have to consider that this model of Gratz only analyzes a certain aspect of this problem of the incentives to challenge patents under specific assumptions. She particularly did not include the analysis of the public good problem in her model.[94] Therefore a lot of more research has to be done for clarifying the link between the antitrust rules about patent settlements (with or without reverse payments) and the incentives for challenging patents further. Another so far neglected question refers to the problem of competition between generic firms in regard to the challenge of weak patents.

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

In the sections 5 to 7 we have analyzed what we know from economics how antitrust rules about patent settlements might influence the welfare of consumers of pharmaceuticals. We can summarize our results in the following way:

First, from an economic perspective all three effects of antitrust rules about patent settlements in the pharmaceutical industry are relevant for the welfare of consumers, and should therefore be considered, if we apply the normative criterion of Shapiro that patent settlements should not lead to worse effects for the consumers than in the case of litigation.[95]

---

[92] It also leads Gratz (2012) to the result that there might be an optimal error interval of courts, which would optimize the trade-off between the negative effect (via prices) and the positive effect (via challenging more patents) on consumer welfare (p. 25).

[93] See, e.g., Dickey et al. 2010, p. 399.

[94] Therefore her critique of the 180 days exclusivity period is not convincing, because the Hatch-Waxman Act wants to solve this public good problem, which does not emerge under the specific assumptions of her model.

[95] However, it has to be seen that the effects on prices are usually short- and medium-term effects, whereas the effects via innovation incentives and challenging incentives are primarily medium- and long-term effects on consumer welfare.

Secondly, in regard to the effects via prices, i.e. the date of generic entry, economic analysis can show in a basic settlement model that patent settlements without reverse payments would lead to settlement outcomes whose consumer welfare implications are close to those of the outcome of litigation. From this model it can also clearly be derived that reverse payments are a very effective, simple instrument for restricting competition through delaying generic entry leading to larger joint profits of the settlement parties and to less consumer welfare. As all economists would agree on these conclusions, they 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, esp. in regard to (asymmetric) information, that are not reflected in the assumptions of the basic model. Wrong and different subjective estimations about the patent strength, the current or future market conditions, risk aversion, as well as strategic considerations and the (so far not sufficiently analyzed) implications of multiple generic challengers and entrants might lead to settlement outcomes which are far away from the optimal entry dates according to the normative criterion, even if there are no reverse payments in patent settlements. These deviations can lead into both directions, i.e. they can render patent settlements without reverse payments anticompetitive as well as allow for some extent of reverse payments (even beyond litigation costs) 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, and in which settlements would fail without the possibility of reverse payments.

Although only a very limited number of those specific bargaining problems have been modelled so far, economists would agree that such a wide range of settlement outcomes (and their effects on consumer welfare) is possible and can be expected under the complex conditions of the real world. A huge gap in economic research refers to the analysis of the implications of the existence of several generic firms that can challenge and enter the market. This is connected both with the public good problem of challenging patents and the so far not analyzed problem of competition between generic firms. Due to these very differentiated results and the gaps in research, it is not surprising that many economists are reluctant about per se rules against patent settlements with reverse payments (as, e.g. Willig / Bigelow 2004) and suggest a more cautious rule of reason approach. However, another (so far much less emphasized) conclusion from these insights is that also within the group of patent settlements without reverse payments a considerable number of settlements might lead to lower consumer welfare than under the litigation solution, rendering them anticompetitive. Only Elhauge/Krüger (2012) have been critical to patent settlements with agreed entry dates and without reverse payments (beyond litigation costs). However, so far no further studies exist about the possible anticompetitive effects of patent settlements in which the parties only agree on future entry dates.

Thirdly, the gaps in research are even larger about the effects of different antitrust rules about patent settlements on innovation incentives and incentives to challenge patents. In regard to challenging incentives so far only Gratz (2012) has developed a model that integrates price effects and challenging effects. Although her specific conclusion about the superiority of rule of reason is not convincing, she can show in her model that there might indeed be a trade off between increasing the incentives for challenging patents through generics and promoting a fast generic price competition through fighting against the collusive (pay-for-delay) effects of patent settlements. However, since her model does not include the public good effect of challenging patents (and the multiple challenger problem), so far it is unclear what kind of policy conclusions can be drawn from this insight. A similar problem does exist in regard to the effects on innovation incentives. We have seen that the analysis of the innovation incentive effects in Elhauge / Krüger (2012) suffers from the problem that the innovation incentives of probabilistic patents have to be analyzed from the beginning of patent duration and not from the date of settlement. Although their conclusions about these effects cannot be followed, a further analysis provides preliminary hints that even 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. But also in regard to innovation incentives much more economic analyses are necessary. It might be especially promising to make follow up-studies to the contributions of Farrell/Shapiro (2008) and Encaoua/Lefouili (2009), who have asked the question whether weak patents with a low patent strength might lead to disproportionately large innovation incentives in comparison to

patents with a larger patent strength (proportionality principle).[96] However such an analysis should also include scrutinizing very critically and carefully, whether the concept of probabilistic patents itself can be defended from an innovation economics perspective.

What can we learn from these economic insights in regard to the antitrust rules for patent settlements in the pharmaceutical industry? At first sight, it seems that the specific bargaining conditions that influence the settlement outcomes and the manifold effects of patent settlements suggests the recommendation of a rule of reason approach, because - theoretically - this would allow the consideration and analysis of all anticompetitive- and efficiency effects. However, from a law and economics perspective, such a question should be analyzed by using an error-cost framework, 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.[97] 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 to a minimization of the sum of regulatory costs and welfare costs of decision errors?

Although a number of authors have mentioned and partly used arguments from an error-cost perspective[98], so far mainly Davis (2009) tried to analyze the problem of patent settlements in a systematic way from an error-cost framework. He analyzes the error- and transaction costs of three different rules, (1) per-se legality of patent settlements, (2) rule of reason, and (3) prohibition of patent settlements with reverse payments. Whereas he assesses per-se legality as not suitable (due to too high error costs through false negatives), it is surprising that he comes to the very clear conclusion that a general ban of reverse payments (even without the possibilities for rebuttals) should be preferred to a rule of reason approach, which would lead to too high transaction costs. His results are also driven much by his scepticism that courts are able to improve their decisions by taking into account more reasonings for the justification of reverse payments. A number of critical questions can be raised in regard to the specific assessments of Davis (2009) about the size of the error- and transaction costs, which might also lead to different policy conclusions. However, more such kinds of analyses are necessary for better answering the question for the appropriately structured antitrust rule.[99] The question that ultimately has to be answered in this search for a properly structured rule of reason 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 has to be seen as an entirely open question. In this paper we cannot carry out a deeper analysis from such an error-cost perspective or sketch in more detail how it should be done (beyond the analysis of Davis). However, from our perspective of our three different effects we suggest that a more comprehensive error cost analysis would also include the error costs of different antitrust rules in regard to effects on innovation incentives and the incentives to challenging weak patents.

Without more research from such an error cost perspective, it is hard to derive clear policy conclusions about the most appropriate rule, if they should be based upon a sound economic reasoning. However, based upon our current knowledge about the effects of patent settlements in the pharmaceutical industry the current competition policy in the U.S. (after Actavis) and the EU can be defended to some extent, although overall we think that it might be 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 (very) limited number of (efficiency) arguments, can be defended. In that respect, it has to be seen that such a presumption need not be too far away from

---

[96] Another interesting path for further research could build upon Ayres/ Klemperer (1999) who generally discussed possible advantages of introducing probabilistic patents with potentially longer duration in balancing innovation incentives and dead-weight loss for consumers.

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

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

[99] 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 can offer important contributions for such an analysis. See, e.g., the proposal of an "aggregate approach" in Hemphill (2009).

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.[100] However, from our current knowledge we would not recommend that all patent settlements without reverse payments should be deemed as not violating competition law rules. This is in line with the U.S. Supreme Court in Actavis, not explicitly constituting a safe harbour rule for patent settlements without reverse payments.[101]

However, any antitrust rule which views the size of reverse payments as crucial for assessing its compatibility with competition law has to deal with the specific problem that, especially in recent cases of patent settlements, the originator and generic firms have embedded their patent settlements in a complex package of side-deals (licensing of other patents, buying of ingredients etc.), which allows the hiding of (the size of) reverse payments. This might lead to the problem that antitrust authorities anyway have to look deeply into the economic rationale of a patent settlement case for determining whether there is a reverse payment, and, if so, whether it is a large one or not.[102] In that respect, the attempt to look for a rather simple rule, e.g. by using only the criterion of the size of reverse payments, in order to avoid a deeper economic analysis of the (context of the) patent settlements might be futile. If we have to accept that even a presumption of the illegality of reverse payments might not provide an easy solution for the assessment of patent settlement that avoids a deeper case analysis, then also the question can be raised again whether competition authorities and courts should not try to assess the merits of the disputed patents. In the antitrust discussion about patent settlements there was always a minority of important scholars that have made this claim.[103] The argument against this approach was that the competition authorities and courts in antitrust cases are not qualified for that, but from an economic perspective it is not clear whether this would be more difficult and cost- and time-consuming than all the economic analyses that might seem necessary in complex antitrust cases about patent settlements.

This last approach to look more directly into the merits of the disputed patents themselves also leads back to the starting-point of the entire problem of patent settlements, which is the "weak" patent problem and the question of fundamental defects in the overall patent system (section 3). Therefore the solution of the patent settlement problem in the pharmaceutical industry can also be sought more directly in patent law itself. This is also 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.[104] This can encompass the strengthening of patent examination in patent offices (as Farrell/Shapiro 2008 suggest for certain groups of patents), the strengthening of patent opposition procedures, or also ideas about subsidizing patent challenges or allowing more easily joint challenges by several generic entrants (Encaoua/Lefouili 2009, pp. 21).

This leads to the already (in section 4) briefly mentioned discussion about the proper delineation between the fields of competition- and patent law. From an economic perspective, the strategy to assume for the antitrust analysis automatically the efficiency of patent law and ignore the defects of patent law is a problematic and dangerous strategy, which should not be pursued without having looked deeper into the deep relationships of both fields of law. Since competition law also protects competition for innovation, and patent law also takes into account competition between innovators, both fields of law are economically deeply intertwined with each other. Therefore from an economic perspective, policy solutions for the weak patent problem in competition law and in patent law are alternative options, and it is an open question whether it is easier to achieve good results through policy changes in

---

[100] See in that respect e.g. 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).

[101] See Wright 2013, p. 15.

[102] 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.

[103] See, in particular, Crane 2002, and Shapiro 2003.

[104] Gallini 2002, Shapiro 2004, Bessen/Meurer 2005, Shapiro 2008.

patent- or competition law.[105] Theoretically, it also might well be that a sophisticated combination of specific reforms in patent law and a specific antitrust solution for patent settlements will be the best solution. Therefore one of our claims is that it is necessary to link these two discussions in competition- and patent law and ask for an integrated analysis of the weak patent problem and the possible policy solutions. With the consideration of the effects of antitrust rules for patent settlements on innovation incentives and the incentives for challenging patents the first steps to such a more integrated analysis have already been made. With our framework of the three different mechanisms, how antitrust rules about patent settlements can have effects on consumer welfare, we also want to contribute to such an integrated discussion.

References

Addanki, Sumanth/Butler, Henry N. (2014): Activating Actavis: Economic Issues in Applying the Rule of Reason to Reverse Payment Settlements, in: Minnesota Journal of Law, Science & Technology, Vol. 15, No.1, pp. 13-49.

Addanki, Sumanth/ Daskin, Alan J (2009): Patent Settlement Agreements, in: Issues In Competition Law And Policy, Vol 3, Chapter 85, pp. 2127-2153.

Allison, John R./Lemley, Mark A. (1998): Empirical Evidence On The Validity Of Litigated Patents, in: American Intellectual Property Law Association Quarterly Journal, Vol. 26, No. 3, pp. 185-277.

Ayres, Ian/Klemperer, Paul (1999): Limiting Patentees' Market Power Without Reducing Innovation Incentives: The Perverse Benefit s of Uncertainty and Non-Injunctive Remedies, in: Michigan Law Review, Vol. 97, pp. 985-1033.

Balto, David A. (2000): Pharmaceutical Patent Settlements: The Antitrust Risk, in: Food and Drug Law Journal, Vol. 55, pp. 321-341.

Bessen, James, Meurer, Michael J. (2005): Lessons For Patent Policy From Empirical Research On Patent Litigation, in: Lewis And Clark Law Review, Vol. 9, No.1, pp. 1-27.

Bessen, James (2004): Holdup and licensing of cumulative innovations with private information, in: Economic Letters, Vol. 82, Issue 3, March 2004, pp. 321–326.

Blair, Roger D./Cotter, Thomas F. (2002): Are settlements of patent disputes illegal per se?, in: Antitrust Bulletin. Vol. 47, Issue 2/3, pp. 491-539.

Brankin, Sean-Paul (2010): Patent settlements and competition law: where is the European Commission going?, in: Journal of Intellectual Property Law & Practice, 2010, Vol. 5, No. 1, pp. 23-28.

Bulow; Jeremy (2004): The Gaming of Pharmaceutical Patents, in: Adam B. Jaffe, Josh Lerner and Scott Stern (eds.): Innovation Policy and the Economy, The MIT Press, Vol.4, February 2004, pp. 145-187.

Carrier, Michael A. (2014a): Payment after Actavis, in: Iowa Law Review, Vol. 100:7, 2014, pp. 7-49.

Carrier, Michael A. (2014b): A Response to Chief Justice Roberts: Why Antitrust Must Play a Role in the Analysis of Drug Patent Settlements, in: Minnesota Journal of Law, Science & Technology, Vol. 15, No.1, pp. 31-40.

Carrier, Michael (2012): Why The “Scope Of The Patent” Test Cannot Solve The Drug Patent Settlement Problem, in: Stanford Technology Law Review Vol. 16, No. 1, pp. 1-8.

Carrier, Michael (2009): Unsettling Drug Patent Settlements: A Framework For Presumptive Illegality, in: Michigan Law Review, Vol. 108, No. 1, pp. 37-80.

[105] One important argument in this regard is that from an institutional perspective the patent law system lacks such regulatory agencies as competition authorities, which are capable of developing and implementing policies for solving specific problems in patent law.

Christiansen, Arndt/Kerber, Wolfgang (2006): Competition Policy with Optimally Differentiated Rules Instead of "Per se Rules vs. Rule of Reason", in: Journal of Competition Law and Economics, Vol. 2, No. 2, pp. 215-244.

Consolidated Version Of The Treaty On The Functioning Of The European Union - Part Three: Union Policies And Internal Actions - Title Vii: Common Rules On Competition, Taxation And Approximation Of Laws - Chapter 1: Rules On Competition - Section 1: Rules Applying To Undertakings - Article 101 (Ex Article 81 Tec), Official Journal 115, 09/05/2008, pp. 88–89.

Cotter, Thomas F. (2014): FTC v. Actavis, Inc.: When Is the Rule of Reason Not the Rule of Reason?, in: Minnesota Journal of Law, Science & Technology, Vol. 15, No.1, pp. 41-49.

Court of Appeals for the Eleventh Circuit FTC v Watson Pharmaceuticals, Inc., Solvay Pharmaceuticals, Inc., No. 10-12729.

Crane, Daniel A. (2002): Exit Payments In Settlement Of Patent Infringement Lawsuits: Antitrust Rules And Economic Implications, in: Florida Law Review, Vol. 54, No. 4, pp. 747-797.

Davis, Joshua P. (2009): Applying Litigation Economics To Patent Settlements: Why Reverse Payments Should Be Per Se Illegal, in: Rutgers Law Journal, Vol. 41, Issue 1/2, pp. 255-307.

Dickey, Bret/ Orszag, Jonathan/Tyson, Laura (2010): An Economic Assessment of Patent Settlements in the Pharmaceutical Industry, in: Annals of Health Law, Volume 19, Issue 2 Winter 2010, Article 5, pp. 367-400.

Commission Regulation(Eu) No 316/2014 Of 21 March 2014 On The Application Of Article 101(3) Of The Treaty On The Functioning Of The European Union To Categories Of Technology Transfer Agreements.

Easterbrook, Frank H. (1992): Ignorance and Antitrust, in: Thomas M. Jorde and David j. Teece (eds.): Antitrust, Innovation and Competitiveness, New York: Oxford University Press, pp. 119-136.

Edlin, Aaron/Hemphill, Scott/ Hovenkamp, Herbert, Shapiro, Carl (2015): The Actavis Inference: Theory And Practice, in: Rutgers University Law Review, Vol. 67, No.3, pp. 1-51.

Edlin, Aaron/Hemphill, Scott/ Hovenkamp, Herbert, Shapiro, Carl (2014): Actavis and Error Costs: A Reply to Critics, in: The Antitrust Source, October 2014, pp. 1-8.

Edlin, Aaron/Hemphill, Scott/ Hovenkamp, Herbert, Shapiro, Carl (2013): Activating Actavis, in: Antitrust, Vol. 28, No. 1, Fall 2013, pp. 16-23.

Elhauge, Einer/Krüger, Alex (2012): Solving the Patent Settlement Puzzle, in: Texas Law Review, Vol. 91, pp. 283-330.

Encaoua, David/Lefouili, Yassine (2009): Licensing weak patents, in: Journal of Industrial Economics, Wiley-Blackwell, 2009, Vol. 57, No. 3, pp. 492-525.

European Commission Competition DG: Case At.39226 – Lundbeck.

European Commission Competition DG: Pharmaceutical Sector Inquiry Final Report 8 July 2009.

European Commission Competition DG: 5th Report on the Monitoring of Patent Settlements, period: January-December 2013, Published on 5 December 2014.

European Commission Press Release (2012): Antitrust: Commission sends Statement of Objections on Perindopril to Servier and others, IP/12/835.

European Commission Press Release (2011): Antitrust: Commission opens investigation against pharmaceutical companies Cephalon and Teva, IP/11/511.

Farrell, Joseph/Shapiro, Carl (2008): How Strong Are Weak Patents?, in: American Economic Review 2008, Vol. 98, No. 4, pp. 1347–1369.

Farrell, Joseph/Merges, Robert P. (2004): Incentives To Challenge And Defend Patents: Why Litigation Won't Reliably Fix Patent Office Errors And Why Administrative Patent Review Might Help, in: Berkeley Technology Law Journal, Vol. 19, pp. 943-970.

Feldman, Robin (2014): Ending Patent Exceptionalism and Structuring the Rule of Reason: The Supreme Court Opens the Door for Both, in: Minnesota Journal of Law, Science & Technology, Vol. 15, No. 1, pp. 61-76.

Frank, Severin/Kerber, Wolfgang (2013): Patent Settlements in the Pharmaceutical Industry: An Antitrust Perspective, in: Dewenter, Ralf, Haucap, Justus, and Christiane Kehder (eds.), Wettbewerb und Regulierung in Medien, Politik und Märkten, Festschrift für Jörn Kruse zum 65. Geburtstag, pp. 385-413.

FTC (2012): FTC Petition for a Writ of Certiorari to the U.S. Supreme Court in the case Federal Trade Commission, Petitioner V. Watson Pharmaceuticals, inc., et al.

FTC (2011): FTC Report: Authorized Generic Drugs: Short-Term Effects and Long-Term Impact, August 2011.

FTC (2010): Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions, An FTC Staff Study January 2010.

FTC (2003): To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy – A Report by the Federal Trade Commission, October 2003.

FTC (2002): Generic Drug Entry Prior to Patent Expiration: An FTC Study, July 2002.

FTC v. Cephalon, Inc., 061 0182

Gallini, Nancy (2002): The Economics of Patents: Lessons from Recent U.S. Patent Reform, Journal of Economic Perspectives, Vol. 16, No. 2, Spring 2002, pp.131–154.

Gallini, Nancy/Scotchmer, Suzanne (2002): Intellectual Property: When Is It the Best Incentive System?, in: Adam B. Jaffe & Josh Lerner & Scott Stern (eds.): Innovation Policy and the Economy, Volume 2, 2002, NBER Book series, pp. 51-77.

Gilbert, Richard/Shapiro, Carl (1990): Optimal Patent Length and Breadth, in: The RAND Journal of Economics, Vol 21, No.1, Spring 1990, pp. 106-112.

Grabowski, Henry G./Kyle, Margaret (2007): Generic Competition and Market Exclusivity Periods in Pharmaceuticals, in: Managerial Decisision Economics, Vol. 28, pp. 491-502.

Gratz, Linda (2012): Economic Analysis of Pay-for-delay Settlements and Their Legal Ruling, Munich Discussion Paper No. 2012-6.

Guidelines on the application of Article 101 of the Treaty on the Functioning of the European Union to technology transfer agreements (2014/C 89/03), 28.3.2014 Official Journal of the European Union C 89/3.

Hall, Bronwyn. H./Harhoff, Dietmar (2004): Post-Grant Reviews in the U.S. Patent System-Design Choices and Expected Impact. In: Berkeley Technology Law Journal, 2004, Vol. 19, No. 3, pp. 989-1015.

Hemphill, C. Scott (2009): An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition, in: Columbia Law Review, Vol. 109(4), pp. 629-688.

Hemphill, C. Scott (2006): Paying For Delay: Pharmaceutical Patent Settlement As A Regulatory Design Problem, in: New York University Law Review, Vol. 81, pp. 1553-1623.

Holman, Christopher M. (2007): Do Reverse Payment Settlements Violate The Antitrust Laws?, in: Santa Clara Computer & High Technology Law Journal, Vol. 23, pp. 489-587.

In Re: K-Dur Antitrust Litigation United States Court Of Appeals For The Third Circuit, 10-2077, No. 10-2078, No. 10-2079, No. 10-4571.

In Re: Tamoxifen Citrate Antitrust Litigation United States Court Of Appeals For The Second Circuit, 03-7641.

In Re Cardizem Cd Antitrust Litigation United States Court Of Appeals For The Sixth Circuit, CASE NO. 00-2483.

Janis, Mark D./Hovenkamp, Herbert/Lemley, Mark A. (2003): Anticompetitive Settlement of Intellectual Property Disputes, in: Minnesota Law Review, Vol 87, pp. 1719-1766.

Kelly, Colleen (2011): The Balance Between Innovation and Competition: The Hatch-Waxman Act, the 2003 Amendments, and Beyond, in: Food And Drug Law Journal, Vol.66, No.3, pp. 417-478.

Klemperer, Paul (1990): How broad should the scope of patent protection be?, in: The RAND Journal of Economics, Vol 21, No.1, Spring 1990, pp. 113-130.

Kobayashi, Bruce H./Wright, Joshua D./Ginsburg, Douglas H./Tsai, Joanna (2015): Actavis And Multiple Anda Entrants: Beyond The Temporary Duopoly, in: Antitrust, Vol. 29, No. 2, pp. 89-97.

Lear, Inc. v. Adkins, 395 U.S. 653 (1969).

Leary, Thomas B. (2007): Antitrust Issues in the Settlement of Pharmaceutical Patent Disputes, Part III, in: Seattle University Law Review, Vol. 30, pp. 377-393.

Leffler, Keith/Leffler, Christopher (2004): Efficiency Trade-Offs in Patent Litigation Settlements: Analysis Gone Astray?, in: University of San Francisco Law Review, Vol. 39, pp. 33-56.

Leibowitz, Jon (2009): Speech: „Pay-for-Delay“ Settlements in the Pharmaceutical Industry: How Congress Can Stop Anticompetitive Conduct, Protect Consumers´ Wallets, and Help Pay for Health Care Reform (The $35 Billion Solution) as Chairman Federal Trade Commission At the Center for American Progress June 23, 2009.

Lemley, Mark A /Shapiro, Carl (2005): Probabilistic Patents, in: Journal of Economic Perspectives, Vol. 19, No. 2, Spring 2005, pp. 75-98.

Lemley, Mark A. (2001): Rational Ignorance At The Patent Office, in: Northwestern University Law Review, Vol. 95, No. 4, pp. 1497-1532.

McDonald, Kevin D. (2003): Hatch-Waxman Patent Settlements and Antitrust: On “Probabilistic” Patent Rights and False Positives, in: Antitrust, Spring 2003, pp. 68-76.

Medicare Prescription Drug, Improvement, And Modernization Act Of 2003, Subtitle A—Access to Affordable Pharmaceuticals, Public Law 108–173—Dec. 8, 2003.

MedImmune, Inc. v. Genentech, Inc., 549 U.S. 118 (2007).

Morse, Howard M. (2002): Settlement of Intellectual Property Disputes In The Pharmaceutical And Medical Device Industries: Antitrust Rules, In: George Mason Law Review, Vol. 10, No. 3, pp. 359-401.

OECD (2007): Policy Roundtables: Competition Policy and Intellectual Property Rights, 1997.

Piecht, Peter (2013): New Law on Reverse Payment Settlements-The Agenda for Courts and the Legislature After the Supreme Court's Actavis Ruling, in: Tulane Journal of Technology & Intellectual Property, Vol. 16, pp. 1-36.

Ponsoldt, James F./Ehrenclou, W. Hennen (2006): The Antitrust Legality Of Pharmaceutical Patent Litigation Settlements, in: Journal Of Law, Technology & Policy, Vol. 2006, No.1, pp. 37-61.

Régibeau, Pierre/ Rockett, Katharine (2004): The Relationship Between Intellectual Property Law and Competition Law: An Economic Approach, University of Essex and CEPR, June 2004.

Roper, Nicholas (2014): Limiting Unfettered Challenges To Patent Validity: Upholding No-Challenge Clauses In Pre-Litigation Patent Settlements Between Preexisting Parties To A License, in: Cardozo Law Review, Vol. 35, pp. 1649-1686.

Schildkraut, Marc G (2004): Patent-Splitting Settlements And The Reverse Payment Fallacy, in: Antitrust Law Journal, Vol. 71, No.3, pp. 1033-1068.

Scotchmer, Suzanne (1991): Standing on the Shoulders of Giants: Cumulative Research and the Patent Law, in: The Journal of Economic Perspectives, Vol. 5, No. 1, Winter, 1991, pp. 29-41.

Server, Alfred C./Singleton, Peter (2011): Licensee Patent Validity Challenges Following Medimmune: Implications For Patent Licensing, in: Hastings Science & Technology Law Journal, Vol. 3, No. 2, Summer 2011, pp. 243-440.

Shapiro, Carl (2008): Patent Reform: Aligning Reward and Contribution, in: Adam B. Jaffe, Josh Lerner and Scott Stern (eds.): Innovation Policy and the Economy, Vol. 8, NBER Book series, April 2008, pp. 111-156.

Shapiro, Carl (2004): Patent System Reform: Economic Analysis and Critique, in: Berkeley Technology Law Journal, Vol. 19, No. 3, pp. 1017-1047.

Shapiro, Carl (2003): Antitrust limits to patent settlements, in: RAND Journal of Economics, Vol. 34, No. 2, Summer 2003, pp. 391–411.

United States Code U.S.C. Title 21 § 355 (j).

Wang, Zhenghui (2014): Reanalyzing Reverse-Payment Settlements: A Solution To The Patentee's Dilemma, in: Cornell Law Review, Vol. 99, pp. 1227-1258.

Willig, Robert D./Bigelow, John P. (2004): Antitrust policy toward agreements that settle patent litigation, in: The Antitrust Bulletin, Vol. 49, Fall 2004, pp. 655-698.

Wright, Joshua D. (2013): FTC v. Actavis and the Future of Reverse Payment Cases, Remarks at the Concurrences Journal Annual Dinner, New York, NY, September 26, 2013, in: https://www.ftc.gov/sites/default/files/documents/public_statements/ftc-v.actavis-future-reverse-payment-cases/130926actavis.pdf (11.05.2015).

Yu, Xiang/Chatterji, Anjan (2011): Why Brand Pharmaceutical Companies Choose to Pay Generics in Settling Patent Disputes: A Systematic Evaluation of the Asymmetric Risks in Litigation, in: Northwestern Journal of Technology and Intellectual Property, Vol. 10, No. 2, pp. 18-36.

570 U. S. ____ (2013) FTC v. Actavis, Inc.