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Patent Settlements in the Pharmaceutical Industry: An Antitrust Perspective

1 Introduction

In the beginning of 2008 the European Commission (EC) started a sector inquiry in the pharmaceutical industry. The Commission states that particularly generic competition is a key factor in protecting consumer interests by allowing access to drugs and containing costs of public healthcare (EC 2009a, p.2). The pharma sector inquiry was conducted against the background of significant changes in the pharmaceutical sector where the rate of newly introduced drugs has declined and several blockbuster medicine patents, accounting for large total revenue shares, have expired or will soon (ibid., p.3). Originator firms try to countervail this trend by maintaining patent protection on drugs as long as possible and by diversifying their revenue streams (ibid.).

The strategic use of the patent system plays a crucial role since original manufacturers and patent owners try to shield themselves from generic competition. One option for original drug patent owners is the creation of "patent clusters" (including pending patent applications) around a base patent, providing a "multi-layered defence" which makes generic access more difficult after the base patent has expired (EC 2009b, pp. 184). Another possibility is "divisional patent application" where besides the "parent patent" smaller-scope patents are registered which however grant an exclusivity period of their own. Such patent application strategies can create higher uncertainty with respect to pending "divisional" patents (ibid., pp. 193). "Lifecycle strategies" refer to the registration of follow-on patents for already existing drugs. This is also referred to as "evergreening" of patents hindering or delaying generic competition for the original product by the patenting of small, incremental changes to it (e.g. different formulations or dosage forms of the same drug) (ibid. pp. 351). Originators can also try to send credible signals that they will fight patent infringement in courts, esp. with the help of injunctions, and create barriers against market entry for potential entrants (ibid., pp. 199).

Besides such practices, a particularly interesting strategy for impeding generic competition is the use of patent settlement agreements between originator and generic firms. Since the patents of the originator firms might be weak and perhaps found invalid if challenged by generic firms, the ensueing patent litigation can lead to settlements between the parties, in which the originator firms agree to pay the challenging generic firms a considerable amount of money for accepting their patents and therefore delaying their entry into the market (pay-for-delay

agreements; FTC 2010, p. 1, EC 2012b, p. 14 at para. (43)). Whereas settlements in expensive patent suits might generally be deemed as having positive welfare effects (due to the saving of litigation costs), the fact that in some of these patent settlements the patentholder pays large sums to the generic firm raises the suspicion that such "reverse payment" clauses (or other side-deals with similar intentions and effects) might only impede generic competition. The ensueing longer period of high drug prices would harm consumers, whereas the additional profits from this strategy accrue to both the originator and the generic firm.

Therefore, it is not surprising that the European Commission views such patent settlements, in which original manufacturers pay generic competitors for their acceptance of restricted market entry, as problematic from a competition law perspective (EC 2009b, p. 509). This critical stance on patent settlements is supported by findings of a large share of successful patent challenges of generic firms raising the question of the validity of many patents. In its examination of the pharmaceutical sector the EC found that generic manufacturers have won approximately 60% of the lawsuits in the period from 2000 to 2007 concerning secondary patent oppositions (Boards of Appeal decisions encompassed) on which generic firms nearly exclusively focused on.[1] In 15% of these cases the original patent scope was limited by courts (EC 2009a, p. 12), whereas litigation lasts over two years on average for approximately 80% of final decisions taking into account opposition and appeal (EC 2009b, p. 253). Although the EC does not refer to secondary patents as generally going along with lower patent quality, as the patentability criteria are the same (EC 2009a, p. 5), the high percentage of successful generic challenges hints at questionable patent validity in these cases.

The EC therefore conducted a patent settlements monitoring between generic and original manufacturers and released several reports (e.g. EC 2010, para. (1)). Restrictions for generic entry, which the parties agreed on, were found by the EC in nearly half of the settlement agreements between originator and generic firms between 2000 and 2008 while it was mentioned that a high share of those included reverse value transfers from the originators to the generic firms (EC 2009a, p. 13). The Commission estimates that 20% higher savings due to generic entry could have been achieved in contrast to the actual savings that have been generated (see EC 2009a, p. 9). So far the European Commission has not developed a clear policy in regard to patent settlement agreements between originator and generic firms with reverse payments. Currently several investigations take place

[1] Secondary patenting concerns follow-on products, different dosages or related processes of already patented products which can be seen as an attempt to extend the duration of protection of the product family involved (EC 2009a, p. 5, 9 and EC 2009b, p. 253).

with respect to settlement agreements between pharmaceutical firms possibly hindering generic access in cases including Johnson & Johnson and Novartis, Cephalon and Teva, Lundbeck, and Servier (EC 2011a, EC 2011b, EC 2012a). The current presumption in the EU being skeptical towards agreements which include a reverse payment and a restriction of generic entry might become clearer when upcoming final decisions on relevant cases are made.

In the U.S., this problem of patent settlements with reverse payments between originator and generic firms has been the object of intense scrutiny and discussion by antitrust authorities and courts for a much longer time. These agreements, in the U.S, are also strongly influenced by the Hatch-Waxman Act, which intended to provide an appropriate institutional framework for this relationship between originator and generic firms in the pharmaceutical industry and which should promote generic competition. The fact that the introduction of generic pharmaceuticals would lead to much lower prices and therefore increases consumer welfare has also been emphasized by the U.S. Federal Trade Commission (FTC) and the U.S. Department of Justice (DOJ) (FTC 2010, p. 1, U.S. DOJ, 2011, pp. 3). Therefore, in the U.S., patent settlements with restrictions of market entry and reverse payments are expected to considerably increase health care costs, which countervails the original aim of fostering generic entry by establishing their easier access to the market thus providing consumer benefits (Leibowitz 2009, p. 8 cited by Carrier 2009, p. 50 at supra note 82). Therefore, the FTC has used antitrust scrutiny to confront possibly anticompetitive patent settlements in the context of litigation in the Hatch-Waxman framework (FTC 2002a, p. i). However, the policy of the FTC to challenge patent settlements with reverse payments on grounds of their anticompetitive effects due to impeding generic competition has met some resistance in the U.S. courts, which partly upheld the patent settlements as a legitimate instrument for defending patents as long as they do not lead to an extension beyond the scope of the patents. In the U.S., there is an intense debate about the assessment of this kind of patent settlements whose result is still open. The current situation is characterized by a very controversial debate and inconsistent views of competition authorities and courts on this issue. This is highlighted by the fact that last year the Supreme Court has accepted a case of patent settlements with reverse payments[2], which might offer the perspective of a clear resolution how such patent settlements should be de-

[2] The U.S. Supreme Court decided to accept the reverse payment settlement case Federal Trade Commission, Petitioner V. Watson Pharmaceuticals, inc., et al. 2012 on 07.12.2012 (U.S. Chamber of Commerce, 2012) to make a decision as reaction to an FTC appeal to the Supreme Court.

cided from an antitrust perspective. In the recently published petition to the U.S. Supreme Court for a clarification on this matter, the FTC held that anticompetitive reverse payment agreements are “a recurring question of great economic importance that has divided the courts of appeals” (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., 2012, p. 2) and are estimated to “cost consumers billions of dollars annually” (ibid., p. 11).

Since the experiences and debates in the U.S. might be very helpful for the discussion of patent settlement agreements in Europe, this article will give first an overview about the legal rules in regard to the relationship between originator and generic firms in the U.S. (including the Hatch-Waxman Act) and about the different positions of the competition authorities and courts in regard to patent settlements with reverse payments and restrictions to generic entry. In a second step, the most important arguments in this debate are analyzed from an economic perspective. A crucial insight will be that the effects of patent settlements have to be analyzed under consideration of the interplay of the regulations of the patent law, the Hatch-Waxman Act, the U.S. Food and Drug Administration, and antitrust rules. Finally, some conclusions are drawn in regard to policy implications and further need of research.

2 Pay-for-delay Settlements in U.S. Antitrust Policy

2.1 The Role of the Hatch-Waxman Act

The Drug Price Competition and Patent Term Restoration Act of 1984, also known as Hatch-Waxman Act, created a framework for balancing the tradeoff between maintaining sufficient innovation incentives for originator firms on one hand and enabling generic competition on the other hand (FTC 2002a, p. i; Hemphill & Sampat 2012, p. 327). Its original purpose was to foster generic competition by ensuring an easier market access while at the same time providing incentives for faster generic entry and patent exemptions for research and development. Due to previously existing patent law and regulation under the U.S. Federal Food, Drug, and Cosmetic Act it was difficult for a generic competitor to enter the market. Since 1962, these regulations required brand pharmaceutical companies to show to the U.S. Food and Drug Administration (FDA) additionally to the safety also the effectiveness of the respective drug. The result of this amendment was the necessity of high investments by pharmaceutical companies to get approval for the marketing of a drug. Since also generic suppliers had to comply with these safety and efficiency standards, generic firms had to spend large costs on tests, which were largely redundant due to the fact that the safety and efficiency of the original drug was already shown before (FTC 2002a,

pp. 3). Due to this regulation the market entry of generic suppliers was possibly delayed for years (Carrier 2009, pp. 41, Robinson 2003, pp. 833). Moreover, for potential generic competitors it was not possible to conduct clinical tests until the relevant patents had expired. Thus, the combination of approval procedures of the FDA and patent law led to a dominant role of brand pharmaceuticals in the market and difficult generic entry. However, also the original suppliers had difficulties to recoup their enormous investments as patent protection was de facto shortened due to FDA approval procedures (FTC 2002a, pp. 3). The Hatch-Waxman Act sought to change this situation by putting a bundle of provisions into force.

Concerning the aim to foster generic competition, especially three elements of the Hatch-Waxman Act are relevant: Firstly, under Hatch-Waxman a research exemption was introduced under which it became possible to conduct certain proceedings necessary for an FDA approval of the respective drug without infringement of existing patents. Secondly, for this purpose generic firms got access to trade-secret data of original manufacturers to prove safety and effectiveness of their generic drugs. Thirdly, to maintain innovation incentives for original manufacturers under Hatch-Waxman it became possible to apply for a special exclusivity period compensating for lost time due to regulatory approval for marketing their products (United States Patent and Trademark Office, FTC 2002a, p. 4). These changes to regulatory proceedings clearly indicate that the U.S. Congress sought to balance incentives for research and development for original manufacturers by giving them a powerful patent claim with a chance for compensation for FDA approval time and the promotion of generic access, mainly by enabling competitors to start FDA approval tests already under patent protection and by giving them access to relevant information by original manufacturers.

For a generic competitor to enter the market for a drug several steps can be distinguished. At first the generic company has to file an Abbreviated New Drug Application (ANDA) at the FDA on the basis of the New Drug Application (NDA) of the originator product. As mentioned above the generic firm can use data of the originator to show that the generic drug is safe and effective by attesting it as “bioequivalent” (U.S.C. Title 21 at § 355(j)(2)(A)(iv)). For the question of patent infringement the generic company has to certify one out of four possible paragraphs referring to patent listings in the “Approved Drug Products with Therapeutic Equivalence Evaluations” also called “Orange Book”. These listings are part of the filing of the NDA under the Federal Food, Drug, and Cosmetic Act, where the originator company inter alia has to provide information to the FDA about patents covering the original drug (U.S. FDA 2012). On the basis of these “Orange Book” – patents the generic competitor has to certify that (i) the required intellectual property is not filed as patents in the “Orange Book” or (ii)

the required patents in the “Orange Book” have expired or (iii) the approval of the generic will be sought at the date when the required patents in the “Orange Book” have expired or (iv) the required patents in the “Orange Book” are invalid or the ANDA does not infringe them. This statement of the generic company now may trigger certain effects dependent on the respective statement. Paragraph (i) and (ii) statements are not problematic since immediate approval by the FDA is possible. A paragraph (iii) approval is possible after the expiry of the respective “Orange Book” – patents.

However, a certification under paragraph (iv) involves the duty of the generic company to send a notice to the patent holder and NDA-filer showing the grounds why patents listed in the “Orange Book” are invalid or not infringed by the ANDA (U.S.C. Title 21 at § 355(j)(2)(A)(vii)). Subsequently, the originator brand company (patent holder and NDA-filer) has 45 days to file an infringement suit against the generic company. If this suit is not filed in this time, the approval procedure by the FDA continues. In case the suit is filed, this triggers an automatic 30-month stay with respect to the approval of the generic drug by the FDA. The approval process can only be conducted by the FDA, if the 30 month period is over or the invalidity or no infringement of originator patents is determined by a court or the patent has expired before the end of the 30-month stay (FTC 2002a, pp. 5). A second implication of Hatch-Waxman regulation is a 180-day exclusivity period for the generic firm who first files the ANDA based on a certification under paragraph (iv) (FTC 2002a, pp. iv). By giving this exclusive marketing right, generic firms should get a higher incentive to enter the market or to challenge the patent in the first place which is aligned with the original aims of Hatch-Waxman.

2.2 The Positions of Antitrust Authorities and Courts

Although the Hatch-Waxman Act led to a promotion of generic entry, a growing number of settlements in regard to patent infringement suits between originator firms and generic firms emerged.[3] In these settlements, reverse payments from originator to generic firms and agreements about a delay of the entry of ge-

[3] Despite existing antitrust scrutiny in the U.S., a recently published report by the FTC indicates that in the fiscal year 2012 40 settlements of a total of 140 final resolutions of patent disputes “may involve pay-for-delay payments” from the original to the generic manufacturer. Moreover it is shown that, on overall, the numbers of such settlements have increased in recent years (FTC 2013, pp. 1).

nerics could be observed, raising the concerns of U.S. antitrust authorities. Those "Pay for delay" agreements could be interpreted as a sharing of monopoly profits and a "win-win" between originator and generic companies to the detriment of consumers (FTC 2010, p. 1). The FTC estimated that these agreements between original and generic manufacturers have delayed generic market entry by 17 month on average compared to agreements where no reverse payment takes place (FTC 2010, p. 2). As a result costs are estimated to increase for consumers by 35 billion $ over ten years while for the same period their elimination would result in federal savings of 12 billion $. Lesser conservative assumptions, taking into account the expected increase of the governments share of drug costs, led to estimated costs for consumers of 75 billion $ and potential federal savings of 25 billion $ over ten years (Leibowitz 2009, p. 8 cited by Carrier 2009, p. 50 at supra note 82, FTC 2010, p. 6). Due to these effects the FTC began to challenge settlement agreements within the Hatch-Waxman framework since March 2000 (Bulow 2004, p. 145). The FTC regards such settlement agreements with substantial reverse payments, which clearly delay generic entry without a different motive (Brankin 2010, p. 24), as unlawful. However, the U.S. courts were in parts very critical to these challenges of the FTC, and also upheld these patent settlements. All in all it becomes apparent that there exist different opinions of competition authorities and courts but also ambiguity with respect to decisions of different courts at different levels of jurisdiction about the topic.

The case Schering-Plough, involving a settlement between original manufacturer Schering and generic supplier Upsher-Smith of June 1997, shows these difficulties regarding challenges of the FTC with respect to reverse payment agreements. The parties entered into a settlement after Upsher-Smith was first to file an ANDA under paragraph (iv) certification. Subsequently, Schering sued for infringement of its patent for the original drug version K Dur 20 expiring in 2006.[4] The settlement shortly before the start of the trial involved a commitment by Upsher-Smith not to market the generic version until September 2001 and to grant Schering several unrelated licenses, whereas Schering agreed to pay Upsher-Smith an amount of 60 million $. Similarly, Schering settled with generic manufacturer ESI Lederle which also filed an ANDA under paragraph (iv) certification.[5] The agreements were challenged under Section 5 of the FTC Act, while there was a settlement between ESI Lederle and the FTC (Bulow 2004, pp.

[4] The litigation is also referred to as "K Dur Antitrust Litigation" (U.S. DOJ 2011).
[5] The settlement involved ESI Lederle`s commitment to not market their generic until January 2004 for a payment of 15 million $ from Schering. Additionally, a grant of unrelated licenses by ESI Lederle was included for another 15 million $. (Bulow 2003, pp. 153).

153).[6] The Administrative Law Judge found the agreement between Schering and Upsher-Smith lawful under the rule of reason, because there were pro-competitive elements, especially the earlier generic market entry and a resolution of patent litigation. The payment of Schering was accounted to the unrelated license granted by Upsher-Smith. The FTC`s appeal, inter alia including the argument that the reverse payment was too large for only accounting for the unrelated license grant by Upsher-Smith, was turned down by the 11th Circuit court decision, mostly arguing in a similar way like the Administrative Law Judge. The court argued that the valid patent was a right to exclude, that the patent scope was not extended while the settlement terms were a result of the patent claim and that any impediments of competition subject to the agreement were a necessary element of the settlement itself (Carrier 2009, p. 54). The FTC subsequently sought review of the Supreme Court on the subject who refused to make a decision (ibid, pp. 55).

This case shows the importance of the presumption of patent validity which was crucial for the conclusion of the court in not finding an anticompetitive agreement: An original manufacturer should not be subject to antitrust liability while having a valid patent (35 U.S.C. § 282 2006 cited by Carrier 2009, p. 62 at supra note 173.). It is a general tendency that courts in the U.S. have focused on the social and private gains of patent settlements like reduction of uncertainty or litigation costs (Holman 2007, pp. 499, FTC 2002a, p. 25). The contrary argument of the FTC is rather in favor of consumers having a right of protection against settlements diametric to their interests (Carrier 2009, p. 63). The U.S. Courts of Appeal held that reverse payment settlements are accepted, if they delay generic entry within the scope of the actual patent grant and only with regard to possibly infringing products.[7] However, patent settlements resulting in a prevention of generic entry beyond the patent scope, e.g. by preventing the entry of non-infringing products, are treated as illegal per se.[8]

While the FTC regards substantial reverse payments with the motive to delay generic entry as being a critical issue because the original manufacturer buys

[6] Section 5 of the FTC Act declares as unlawful: "Unfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce (…)" (United States Code U.S.C. Title 15 at § 45, (a) (1)).

[7] See Schering-Plough Corp. v FTC, 402 F.3d 1056 11th Cir. 2005 cert. denied, 126 S. Ct. 2929 2006; In re Tamoxifen Citrate Antitrust Litig., 466 F.3d187 2nd Cir. 2006 and In re Cardizem CD Antitrust Litig., 332 f.3d 896 6th Cir. 2003, cert. denied, 543 US 939 2004 cited by Brankin 2010, p. 24 at supra note 9.

[8] See In re Cardizem CD Antitrust Litig., 332 f.3d 896 6th Cir. 2003, cert. denied, 543 US 939 2004 cited by Brankin 2010, p. 25 at supra note 12.

time for monopoly profits diametric to consumer interests, some courts rather apply a presumption of patent validity with the consequence that reverse payment settlements are assessed positively if there is earlier generic entry and resolution of litigation. Thus, the main difference between these two lines of arguments lays in the presumption of validity. If a patent is assumed to be valid, then every agreement, even if it includes some restrictions to competition, is positive, if it leads to earlier generic entry. However, if patent validity is assumed to be questionable, every agreement including a substantial and not justified reverse payment for restricting generic entry might be anticompetitive, because only a settlement without such payment and earlier generic entry correctly accounts for this questionable nature of patent validity. Following this line of argument, the outcome of the settlement agreement for consumers should account for the possibility of the patent not being found valid (Shapiro 2003b, p. 395). As consumers can expect the chance of patent invalidity in a paragraph (iv) litigation, the result of a (reverse payment) settlement is a signal for the perceived patent strength of the parties and should correctly take into account the likelihood of the patent`s invalidty.[9] This means that a substantial reverse payment indicates high doubts about the validity of the patent and should not go along with substantial entry restrictions (Dolin 2011, pp. 322).

The U.S. Department of Justice (DOJ). which also can enforce antitrust rules, was involved in the K-Dur Antitrust litigation (in the role of Amicus Curiae as an expert counsel in court). Also the DOJ cares about challenges of patent settlements in the pharmaceutical sector as they strongly affect consumer welfare (U.S. DOJ 2011, p. 1). The DOJ has had a standpoint in between the arguments of the FTC and decisions which have been made by U.S. courts (Brankin 2010, p. 26). In the K-Dur statement, the DOJ held that (A) private patent settlements should be subject to antitrust scrutiny, (B) they should not be held per se illegal while the rule of reason is the appropriate approach to assess reverse payment settlements in balancing efficiencies and anticompetitive effects, (C) settlements involving a payment which leads to a withdrawal of a challenge of patent validity or infringement “are presumptively unlawful” and that (D) defendants can show that a settlement does not aim at the exchange of money for a reduction of competition (U.S. DOJ 2011, pp. 10).

The DOJ makes clear that settlements which restrict generic entry by ending patent challenges prevent the risks of litigation for the patent holder to the detriment of price competition in markets where the patent holder has market power

[9] FTC Petition for a Writ of Certiorari in Schering-Plough Corporation, et al. 2005, supra note 244, at 17-19 cited by Holman 2007, p. 533 at supra note 251, 252.

which may strongly be reflected by a large reverse payment. A clear distinction is made between restrictions stemming from litigation and such restrictions stemming from settlements (ibid., pp. 17 f.). Also mentioning the position of the FTC, the DOJ notes that the amount of the reverse payment in question has to be assessed. If this amount accounts for avoided litigation costs or for different expectations of the parties of winning at trial, such a payment should be seen as rather unproblematic (Janis/Hovenkamp/Lemley 2003, Crane 2002). On the other hand, larger payments reveal the perception of the patent holder that the patent could be found invalid or not infringed and therefore suggests the intention to avoid competition. As an example, the DOJ holds an agreement as anticompetitive where parties ex ante assess the probability that a patent is valid above 50 percent while agreeing on a settlement not allowing for generic entry until the expiry of the patent. Even a reverse payment with earlier generic entry than actual patent expiry is not necessarily seen as adequate defense by the DOJ as long as the earlier entry date and other parts of the deal do not reflect the parties' assessment of the probability that generic entry could have been allowed earlier, if the patent was litigated (U.S. DOJ 2011, pp. 27). For the DOJ, it is therefore in society's interest that the agreement reflects the parties' respective perception of patent invalidity or non-infringement, which is also described as bargaining power, in the form of the agreed-on entry date to prevent "undeserved monopolies" (ibid, pp. 22 f.). Reverse payments, if part of such agreements, should be assessed in connection with the agreed entry date or other restrictions.

During the Obama presidency a change in the leading position of DOJ`s antitrust division led to a convergence of the positions with the FTC (U.S. DOJ 2010 cited by Brankin 2010, p. 26 at supra note 23). Accordingly, the DOJ supported the position of the FTC in an appeal to the U.S. Supreme Court concerning a reverse payment settlement case (see below).[10] The DOJ looks at the anticompetitive potential of settlement agreements exchanging money for not challenging patents and delaying generic entry, while holding that a shielding rule for such agreements would not be positive for competition and innovation.[11] The DOJ argues that such a presumption of patent validity should not be the legitimation for a restrictive application of antitrust rules of the Sherman Act (U.S. DOJ 2010, p. 7).

[10] See 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. 2012 henceforth referred to as FTC Petition for Certiorari 2012.

[11] See U.S. DOJ in its Brief Amicus Curiae of The United States in Support Of Rehearing In Banc, Arkansas Carpenters Health and Welfare Fund et al v Bayer et al.

The U.S. Supreme Court has recently decided to make a decision concerning a reverse payment settlement case (Watson Pharmaceuticals) which can be expected to result in more distinctiveness on this topic.[12] In its appeal to the Supreme Court, the FTC rejects the opinion of the Courts of Appeals For the Eleventh Circuit who denies antitrust scrutiny as long as the competition constraints fall within the patent scope and no other violations take place.[13] The FTC views the argument that reverse payments are lawful as long as they are not resulting in a larger restrictive power than granted due to the patent scope as erroneous since this would forestall the actual validity of the patent, yet to be decided. The FTC instead states that "the Third Circuit's approach, which treats reverse payment agreements as presumptively anticompetitive, reflects the appropriate balance between the competing interests implicated by such agreements" (FTC Petition for Certiorari 2012, p. 21). The FTC emphasizes that defendants often win in patent litigation and a victory of the patent holder should not be a general presumption in the Hatch-Waxman framework (FTC Petition for Certiorari 2012, p. 11). On the other hand, the FTC makes clear that not every reverse payment agreement should be seen anticompetitive per se as efficiency effects have to be acknowledged.[14] It seems that the decision of the Supreme Court in this matter could be a landmark for the future assessment of reverse payment settlements in the U.S. The split positions of different lower courts ranging from an assessment of such agreements of per se illegality close to per se legality (Leibowitz 2009, p. 9) in combination with the opinions of the FTC and the DOJ seems to be a call for more clarity which can possibly be restored by the Supreme Court. The fact that the Supreme court did accept the FTC`s appeal clearly indicates that the matter is important and that the court wants to decide on this subject.

[12] The U.S. Supreme Court decided to accept the case Federal Trade Commission, Petitioner V. Watson Pharmaceuticals, inc., et al. 2012 on 07.12.2012 (U.S. Chamber of Commerce, 2012) as reaction to the FTC Petition for a Writ of Certiorari 2012.

[13] The Court Of Appeals For The Eleventh Circuit argued in related cases that "absent sham (patent) litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack as long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent" (The United States Court Of Appeals For The Eleventh Circuit cited by FTC Petition for Certiorari 2012, p. 2).

[14] In this context the FTC holds "a so called 'Quick Look' or 'truncated rule of reason' analysis" as appropriate where compensating efficiency advantages in a presumably anticompetitive reverse payment-settlement have to be created by the settling parties (Blair/Cotter 2002, pp. 534, FTC Petition for Certiorari 2012, pp. 23 citing K-dUR, 686 F.3D AT 209 and FTC V. Indiana Fed'n of Dentists, 476 U.S. 447, 459 (1986)).

3 Patent Validity, Patent Settlements, Reverse Payments, and the Regulatory Framework: An Analysis

3.1 Patent Validity and Patent Challenge within the Regulatory Regime of the Pharmaceutical Industry

From an economic perspective, it is clear that in the pharmaceutical industry originator firms need patent protection for ensuring sufficient incentives for carrying out their cost-intensive and risky R&D. After the expiry of patent protection, other competitors (generic firms) should be able to enter the market immediately, leading to lower prices (at the level of average production costs) and an increase of consumer welfare. Any kind of agreements between originator and generic firms, which through a payment to the generic firms would lead to a de facto prolonging of the monopoly of the originator firms beyond the duration of the patent, would be an anticompetitive (cartel) agreement and therefore prohibited both under EU and U.S. antitrust rules. This is not controversial. The current controversy, esp. in the U.S., refers to the very different problem that the patent in question might not be valid in the first place. If the originator firm has gotten a patent, which never should have been granted by the patent office, then the originator firm is not entitled to its exclusive rights and enforcing it against other pharmaceutical firms restricts competition and harms consumers (as any other kind of monopoly). Therefore, the position of some U.S. courts that such patent settlements are no problem as long as they remain within the scope of the patent is not relevant, because the validity of the patent itself is disputed.

In the last decade, the insight has increased that the patent law regime (both in the U.S. and the EU) suffers from serious defects.[15] In the meantime, there is a broad consensus that often patent claims are not precisely defined, leading to the problem of overlapping patents and patent thickets (Shapiro 2001, Gilbert 2009, p. 2). In addition to that, experience shows that the requirements, e.g., in regard to the necessary "inventive step", have been lowered (Harhoff et al. 2007, p. 250). Therefore, too many patents for often only minor inventions have been granted, which endangers competition and stifles innovation. Part of the problem is that the patent offices lack sufficient resources to carry out solid and well-

[15] This argument is referred to in a body of literature e.g. in Shapiro 2001, p. 121, Gilbert/Weinschel 2005, pp. 1, Leaffer 2010, p. 143 at supra note 9, 10 citing Bessen/Meurer: Patent Failure: How Judges, Bureaucrats And Lawyers Put Innovation At Risk, 1-25, 2008 and Jaffe/Lerner: Innovation And Its Discontents: How Our Broken Patent System Is Endangering Innovation And Progress, And What To Do About It 6, 50, 2004.

researched examinations of patent applications (Gallini 2002, p. 150, Shapiro 2003b, p. 392, Farrel/Merges, 2004, pp. 944). In the meantime, both economic and legal scholars of patent issues are well aware of these problems. Therefore, the assumption that all patents granted by the patent offices are justified and should be deemed as unquestionably valid, cannot be upheld any more.

One important response within the patent law regimes itself is to strengthen the internal mechanisms for screening and sorting out weak and non-defendible patent rights granted by patent offices by challenging them legally (e.g., through opposition procedures). The patent law regime relies in this respect on a private enforcement mechanism for challenging unjustified patent rights. Therefore, the patent law regime itself has a built-in mechanism for correcting erroneous grants of patents, whose effectiveness is however questioned by many scholars, leading to wide-spread claims for strengthening it. Consequently, also the patent laws do not and should not assume that all patents granted by patent offices are justified (Harhoff et al. 2007, pp. 276). In regard to the relation between originator and generic firms in the pharmaceutical industry, the problem that there might be unjustified (and therefore invalid) patents has been explicitly addressed both in the Hatch-Waxman Act as well as the regulations in regard to the FDA. It is very important to understand that the rules for granting, defending and challenging patents as well as using them in the pharmaceutical industry are the result of a comprehensive legal framework consisting of patent law, the Hatch-Waxman Act, the rules for the approval of new drugs by the FDA as well as other laws, as, e.g., antitrust rules (see also Hovenkamp 2004, pp. 14).

In the following, it is analyzed how the Hatch-Waxman Act in combination with FDA rules intentionally influences the incentives for originator and generic firms. This should simultaneously increase incentives for (true) pharmaceutical innovations and protect (generic) competition by providing additional explicit incentives for challenging weak patent rights, which should improve the effectiveness of the private enforcement system in regard to the invalidation of unjustified patent rights. Our main argument will be that patent settlements with reverse payments between originator and generic firms can weaken the effectiveness of this private enforcement system leading to anticompetitive effects by restricting the market entry of generic firms.

The Hatch-Waxman Act and its reform aimed at creating a framework to facilitate generic entry in the pharmaceutical industry (FTC 2002a, Executive Summary and Legislative Recommendations). Under the act generic competitors can enter the market without the need to reproduce clinical safety studies in case of “bioequivalence” of the drugs concerned and by challenging existing patents, which beforehand was difficult due to previously existing patent law and regulation (U.S.C. Title 21 at § 355(j)(2)(A)(vii) and FTC 2002a, pp. 3). So this act tried to balance innovation incentives of original manufacturers with promoting

easier access to the market (Carrier 2009, pp. 41, Robinson 2003, pp. 833). What are the rationales and problems of the 30-month stay period for generic entry and the 180-day exclusivity period for generic drugs as the most important elements of the Hatch-Waxman framework?

The automatic 30-month prevention of market entry by the generic competitor is triggered in the case of a challenge of an existing patent (paragraph (IV) certification) followed by a subsequent infringement suit of the original patent owner. In this period, entry is only possible, with respect to an approval by the U.S. Food and Drug Administration, if the relevant patents expire during the time or a court decides that the respective patents are invalid (FTC 2002a, pp. 5). On one hand, this regulation acknowledges the position of the patent holder, because irrespective of the patent strength there exists protection against market entry of the generic firm for the length of patent litigation but for a maximum of 30 months. On the other hand, it also leads to a stronger position of generic competitors as they have the chance to enter the market under these provisions after 30 months irrespective of active patents. This could be interpreted as an attempt to mitigate the problem that litigation can last much longer than 30 months. In that respect this 30-month rule leads to a new balance between originator and generic firms in regard to the problem of legal uncertainty in respect to the validity of the patents but also the interests of the generic firms and the public for generic competition. What is particularly interesting is the fact that this rule does only apply to those patents which have been registered as relevant for the drugs by the originator firms in the "Orange Book" of the FDA. This confirms our argument that Hatch-Waxman rules, FDA rules, and patent law rules constitute an integrated institutional framework for the relation of originator and generic firms in the pharmaceutical industry.

A very interesting but also to some extent problematic rule is the 180-day exclusivity period in regard to an approval for market entry by the FDA for the generic firm that - under paragraph (IV) certification - challenges the patents of the originator firm first. It is clear that such a competitive advantage should give generic firms larger incentives for challenging the existing patents in order to avoid an underprovision of patent challenges (McDonald 2003, pp. 69, 72, and Shapiro 2003a, pp. 70). From an economic perspective the problem can be described as a public good problem with its ensueing free-rider problems (Farrell/Merges, 2004, pp. 952). Without the exclusivity period, all generic firms could enter the market after a court decision declared the patents invalid, which would make it hard for the challenging generic firm to recoup its litigation costs and risks, and therefore reduce considerably their incentives for challenging the patents in the first place. It is important to understand that the weeding out of unjustified patents by challenging them is a public good, which benefits all generic firms and all consumers of these drugs. Since this task is not fulfilled by a public agency

(paid by the tax payer) but left to a private enforcement system, its effective implementation requires appropriate incentives for private actors, i.e., here generic firms. Therefore, this 180-days limit to competition among generic firms can be seen as necessary for incentivizing patent challenges by generic firms (similar to the acceptance of patent monopolies over a certain time for the prospect of the development of new products and innovation).

If we see the Hatch-Waxman Act as an instrument for strenghtening the incentives for challenging unjustified patents through generic firms, then ensueing patent settlements between the patent holders and generic firms might not only lead to efficiency advantages through saving of litigation costs and reducing legal uncertainty (FTC 2002a, p. 25), but might also undermine the entire effectiveness of the private enforcement system in regard to challenging weak and unjustified patents. Patent settlements with large payments from originator to generic firms can be interpreted as the buying off of the challenges to unjustified patents, which would endanger the generation of the public good of weeding out weak patents. As a consequence, the public and private benefits of the parties to such a patent settlement can diverge dramatically (FTC 2010, p. 1). Therefore, it is justified to ask to what extent and under what conditions patent settlements should be allowed in the comprehensive legal framework consisting of the Hatch-Waxman Act, the FDA regulations, the patent law, and antitrust rules.

Independent from this crucial question, which will be discussed deeper in the next section, the specific rules of the Hatch-Waxman Act influence not only the incentives of originator and generic firms but also the allocation of bargaining power between both: Since a patent holder faces the risk that the patent is invalidated in court and that litigation lasts longer than 30 months allowing for generic entry, the scope for settlements is significantly larger. Thus, Hatch-Waxman provisions foster generic challenges and settlements by re-allocating the bargaining positions of the parties, which also has an impact on the chances of the originator firms to enforce their patents as an exclusivity right over the entire patent duration. A specific problem with the provisions of the Hatch-Waxman Act is that the 180-days exclusivity period for the first generic firm which has filed the ANDA aligns the incentives of the patent holder and the challenger in regard to upholding the validity of the patent in a collusive settlement (with reverse payment), because this will give the generic firm a competitive advantage in comparison to other generic firms (Bulow 2004, p. 164, Dolin 2011, p. 283).

Settlement agreements with generic firms are generally possible if the patent holders can win more in paying the generic firms for their lost earning from delayed entry. Or, in other words, if the generic firm`s potential profits from entry are less than the actual monopoly profits of the patent holder, which should normally be the case if lesser profits result after generic entry (Brankin 2010, p. 25.). If such practices restrict entry to a larger extent than the actual patent scope,

then these settlement agreements clearly have anticompetitive effects (but this is not controversial). If, however, patent validity is questionable, patent settlements can be regarded as anticompetitive even if they lead to an earlier entry than original patent expiry date. This is the case if the parties share higher revenues in comparison to profits which would occur in a state of ongoing litigation with courts deciding to restrict the exclusionary power of the patent conditional on the probability that this actually happens (Shapiro 2003b, p. 395). Therefore a part of the literature claims that a questionable patent validity should lead to earlier or extended competition on behalf of consumers based on the probability that the patent is invalid (McDonald 2003, pp. 69, 72 citing Shapiro 2001 at supra note 7) where the updated version is Shapiro 2003b; Shapiro 2003a, pp. 70). In the literature this is referred to as the probabilistic character of patent rights.[16]

The combination of the patent law regime, antitrust rules, the FDA as drug authorization agency, and the Hatch-Waxman legislation has the function to establish a framework where patent challenges are an inherent part of the system itself and which offers the right incentives for the challenging of weak patents. The Hatch-Waxman framework with its original aim to foster generic entry has however led to an environment where patent settlements can stifle the benefits of patent challenges in earlier generic entry. This is especially the case if originators and generics agree on delaying or restricting market entry while at the same time the quality of patents is low or their validity is questionable. In this respect, pay-for-delay patent settlements can make the private enforcement system of challenging unjustified patents ineffective. Since the incentives to challenge patents or to engage in settlements is determined by the overall design of the patent regime, Hatch-Waxman Act, antitrust rules and the role of drug authorization agencies, it is necessary to understand sufficiently the interplay between these different sets of regulations for the correct assessment of patent settlement agreements. At the same time, this also suggests that solutions for these problems can be sought in all these different sets of rules (Janis/Hovenkamp/Lemley 2003, pp.1756). Therefore, in the U.S., it can be thought about introducing limitations to patent settlements through a modification of the Hatch-Waxman Act and/or FDA regulations, through different decisions of the courts within patent law, and also - and this has been done by the FTC - through application of the antitrust rules. In the following section, we will focus only on the last approach for solving this problem. It should be remarked that it is not the first time that competition law has to step in, because the patent law regime does not seem ca-

[16] Probabilistic patent rights are e.g. discussed in Ayres/Klemperer 1999, Leffler/Leffler 2003, McDonald 2003, Shapiro 2003a, Lemley/Shapiro 2005.

pable of solving its own inherent problems, here in regard to the huge problems of legal uncertainty in regard to the validity of patents due to low quality of the assessment of patent applications.

3.2 The Assessment of Patent Settlements from an Antitrust Perspective

In the last section, it was clarified that patent settlements between originator and generic firms in the pharmaceutical industry can lead to anticompetitive effects, because they can be used for protecting unjustified patent rights, leading to illegitimate monopoly positions. There is also consensus that settlements can have considerable efficiency advantages due to saving of litigations costs and the benefits of legal certainty. However, this general benefit of settlements cannot immunize them from antitrust scrutiny, if these settlement agreements lead to considerable negative effects on third-parties, as, e.g., consumers of drugs and health care providers. The difficult problem is under what conditions these patent settlement agreements have to be viewed as anticompetitive and therefore violate antitrust rules. The discussion has mostly focussed on patent settlement agreements with large reverse payments and restrictions of generic entry. Both the U.S. and European competition authorities and many scholars suggest that these settlements are the most problematic. But it is an open question whether a rule of per se illegality, a rebuttable presumption of illegality or a rule of reason approach, which would analyze the settlements on a case-by-case approach, should be applied (see also Janis/Hovenkamp/Lemley 2003, pp. 1728). Beyond that, also other patent settlement agreements might be problematic under certain circumstances.

In its pharma sector inquiry the European Commission distinguished between different groups of patent settlements between original and generic manufacturers. The first category contained agreements with no restrictions on generic entry (A-type agreements), whereas in the second category such restrictions were present (B-type agreements). The EC distinguished such generic entry restricting agreements further into those including a value transfer (type B 2), meaning a reverse transfer from original to generic firm, and those where this is not the case (type B 1) (EC 2010, paras. (11), (15)). For the Commission type A-agreements, which are not restricting generic entry, are per se unproblematic from a competition law perspective. Type B 1-agreements, i.e., those restricting entry without a value transfer, are normally regarded unproblematic except specific conditions as e.g., settlements which restrict generic entry beyond the patent scope. For B 2-settlements, restricting generic entry and including a value transfer from original to generic firms, the highest antitrust scrutiny is demanded. However, the Commission states that not all of these B 2-type agreements are incompatible with EU Competition Law but should be assessed on a case by case basis taking into ac-

count market characteristics or the value transfer itself (ibid., paras. (12)-(14)). The Commission in its 3rd Settlement Report, covering all patent settlements in 2011, concludes that the monitoring itself has not hindered the occurrence of settlements as there is an increasing trend of such agreements in the EU, similarly to the U.S. (FTC 2013, pp. 1). Moreover it is stated that most of them, 89%, are typically not problematic from a competition law perspective, but that ongoing scrutiny is needed since the number of type B 2-settlements have increased (EC 2012b, pp. 15). There can be no doubt that the distinctions of the European Commission in these different types are helpful, although it might be worthwhile to ask whether type A-agreements can never be anticompetitive or to discuss in more detail, under what conditions patent settlement agreements with restrictions to generic entry but without value transfer might be really unproblematic. However, in the following we will focus primarily on the most critical category of patent settlement agreements with restrictions to generic entry and reverse payments.

From a competition policy perspective, patent settlements between originator and generic firms might have both welfare-enhancing efficiency advantages and welfare-reducing anticompetitive effects. The most important efficiency advantages are (1) the saving of (potentially very high) litigation costs due to long and expensive patent litigation, and (2) the benefits of reducing the (often large) legal uncertainty in regard to the validity of patents, which might accrue not only to the patent holder, but also to the challenging generic firms and even to other firms (FTC 2002a, p. 25, Leffler/Leffler 2004, pp. 38). Both of these efficiency advantages might be large and this is also the reason why courts usually support settlements. The most important anticompetitive effects have already been discussed sufficiently in previous sections: Patent settlements with reverse payments might allow the holders of weak and unjustified patents to defend their unjustified monopoly positions, either for the entire patent duration or at least for a certain period until the generic firm is allowed under the agreement to enter the market. In both cases the pharmaceutical firm with the patent reaped unjustified monopoly profits and generic competition was restricted, leading to huge losses for consumers and the public due to too high prices. It should also be kept in mind that these patent settlement agreements are horizontal agreements between direct competitors which can often only be justified by the existence of valid patents (Janis/Hovenkamp/Lemley 2003, pp. 1721). What about the argument that these patent settlements might lead to more innovation, because they might allow pharmaceutical firms to better defend their patents? On first sight, this looks like an argument that would end up on the efficiency side in this discussion (Hemphill 2006, p. 152). However, this is not at all clear: From an economic perspective, we only want to give incentives in regard to R&D in regard to true innovations. Therefore, increasing the incentives for getting weak and unjustified

patents by improving the chances for defending those patents, provides wrong incentives and has welfare-decreasing and therefore anticompetitive effects. If the patents are justified, then the shielding of patents through patent settlements might have positive efficiency effects. The crucial main reason for all these problems is the legal uncertainty, which follows from the low quality of the patent system, which is not capable to distinguish in a clear and fast way between justified and unjustified patent rights (either through the patent office or through courts).

It is not possible here to present a comprehensive discussion of all the relevant arguments and assessment criteria of this kind of patent settlement agreements. Our main claim is that there are many open questions and therefore also a lot of need for further research in order to derive well-informed and solid policy recommendations. In the following, we want to hint to some of these questions.

From a law and economics perspective, the efficiency arguments of settlements with reverse payments depend crucially on information about the assessment of winning probabilities of the patent holder and their generic challenger. Since such information is hard to ascertain, it might be difficult to assess whether the reverse payment might be considerably higher than what could be expected from a simple settlement agreement for saving litigation costs. The assessment of patent settlements and the design of regulations in the U.S. can also be interpreted as an attempt to use the parties' assessment of patent validity as a proxy for the factual validity probability (O'Rourke/Brodley 2008, p. 19). The parties' behavior concerning the decision to challenge or not and to agree on certain terms might be interpreted as a signal reflecting their own perceptions of patent validity. This problem can lead to a discussion about mechanisms for revealing this private information or to attempts of competition authorities and/or courts to assess directly the probability of the validity of patents. All of this needs much more analysis and discussion. Beyond that, it can also be asked whether there are more kinds of important efficiency arguments which would support the legality of these patent settlements with reverse payments and/or restrictions to generic entry.

Another broad field of questions refers to the problem that the assessment of these patent settlements as well as the rules for allowing or prohibiting them under certain conditions have to take into account the interplay between the different sets of rules (as specific rules as the Hatch-Waxman Act, patent law rules, FDA regulations etc.), which constitute the comprehensive institutional framework for innovation and generic competition in the pharmaceutical industry and have an impact on its overall effectiveness and welfare implications. One example might be the interplay between rules for the (il)legality of patent settlements and rules ensuring a competitive advantage for the first challenging generic firm (as the 180-day exclusivity period in the Hatch-Waxman Act). A prohibition of

patent settlements with reverse payments (which exceed the expected litigation costs) might lead to the problem that generic firms might have fewer incentives for challenging weak patents, because profitable patent settlements with the patent holder are not possible. Therefore, prohibiting settlements with reverse payments might also weaken the effectiveness of the private litigation system for weeding out weak patents through challenging patents (Dolin 2011, p. 319). But this also depends crucially on the fact, whether only one or many generic firms could enter the respective market. If there are multiple generic firms, then patent settlements with reverse payments with anticompetitive effects might be difficult, because the patent holder would have to pay all potential challengers.[17] Therefore, the public good problem for the incentives to challenge weak patents turns up again for the patent holder, if the patent shall be defended against all challengers. This implies that the exclusivity rule for the first challenging firm, which should help to incentivize patent challenges, leads at the same time to larger incentives for anticompetitive patent settlements with reverse payments. Therefore, the probability and effects of patent settlements might depend much on the existence of other rules within this comprehensive institutional framework. This implies that much more research is necessary to understand the interplay between these different sets of rules.

However, this also means that in the European Union with its (to some extent) different patent law systems and different procedures for the approval of drugs, the effects of patent settlement agreements might differ from the U.S. system (with the specific rules of the Hatch-Waxman Act). Therefore, we should be cautious about a direct transfer of the results of the U.S. discussion to the European Union. Rather it is necessary to study the effects of different types of patent settlements and the impact of their prohibition or clearance in the context of the specific European institutional framework in respect to the rules for granting and challenging patents and the rules for the approval of new drugs in Europe. It can be expected that the competition policy conclusions in respect to patent settlements agreements in the pharmaceutical industry might be different to a certain extent.

There might also be differences between the U.S. antitrust law and European competition law in regard to the question of the recommendability of using a per se illegality rule for certain kinds of patent settlements, or presumptions about legality or illegality, which might be rebuttable or not. For the most likely anti-

[17] See Hemphill 2006, pp. 126, Hovenkamp 2004, p. 25 cited by United States Court of Appeals for the Eleventh Circuit in the case Federal Trade Commission, Petitioner V. Watson Pharmaceuticals, inc., et al., no. 10-12729, Apr. 25, 2012, pp. 35a.

competitive type of patent settlements with large reverse payments and restrictions to generic entry, the debate focusses on the question whether there should be a presumption of illegality, which, however, might be rebuttable by proving efficiency advantages. Despite all the above-mentioned need for more research, such an approach might be recommended given our current knowledge (see also Janis/Hovenkamp/Lemley 2003, pp. 1759, Ponsoldt/Ehrenclou 2006, pp. 57). However, it is not clear whether the difference to a cautious case-by-case approach might be large. The problem is that the parties of the patent settlement agreements, as also the case Schering-Plough has shown, have ample opportunities to make a variety of complex side-deals (e.g., through lower fees of licensing other patents or allowing earlier generic entry for other drugs) in order to conceal the reverse payment or at least its size. Therefore, it might be difficult for competition authorities and courts to identify such types of agreements (Brankin 2010, p. 27, Hemphill 2009, pp. 663 cited by U.S. DOJ 2011, pp. 24 at supra note 10). Thus, even if specific rules are found and possibly boundaries for the amount of value transfers in combination with different entry dates are established, it might be necessary to analyze these settlements on a case-by-case basis to identify the problematic ones.

4. Conclusions

The question how to assess patent settlements between originator and generic firms in the pharmaceutical sector has raised much attention in the EU and the U.S. The competition authorities and many legal and economic scholars are right to claim that especially a certain type of patent settlements, i.e. those with large reverse payments and restrictions to generic entry, might have large negative effects on consumers and public health care, and therefore raises strong antitrust concerns. The main problem is that originator firms might have weak patents, whose challenging by generic firms might be bought off by patent settlements with large payments to the challenging generic firms. Therefore, firms with weak (and ultimately invalid) patents might be able to defend unjustified monopoly positions through patents, which should not have been granted in the first place, by sharing these monopoly profits with the settling generic firms. Large and otherwise unjustified reverse payments in patent settlements can be seen as a strong sign for the parties' doubts concerning the validity of patents. In this article, we used the U.S. example to show that the entire regulatory framework, consisting of the Hatch-Waxman Act, patent law, drug approval proceedings and antitrust rules, and the interplay between these rules, are crucial both for the correct incentives for challenging and weeding out unjustified patents and for assessing properly, under what conditions patent settlements between originator and gener-

ic firms are anticompetitive, and therefore violate antitrust rules. However, the academic discussion as well as the U.S. experience show that there are many open questions which require much more research. This refers especially to the interplay between the different sets of rules within the entire regulatory framework and to the assessment criteria for distinguishing efficiency-enhancing and anticompetitive patent settlements. Therefore, it is not surprising that so far both in the EU and the U.S. no clear and well-established policy exists how these patent settlements in the pharmaceutical industry should be dealt with.

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