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-- Expert Paper by Romano Subiotto --

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*More documents related to this discussion can be found at
<http://www.oecd.org/daf/competition/generic-pharmaceuticals-competition.htm>.*

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THE IMPLICATIONS OF THE IMPERFECT EUROPEAN PATENT ENFORCEMENT SYSTEM ON THE ASSESSMENT OF REVERSE PAYMENT SETTLEMENTS*

1. Reverse payment patent settlements provide for a payment by the patent holder to the alleged patent infringer in connection with the settlement of disputes concerning patent validity or infringement. In July 2013, the U.S. Supreme Court and the European Commission issued two landmark decisions concerning the legal standard to assess reverse payment patent settlement under antitrust laws. In *Actavis*, the U.S. Supreme Court held that so-called pay-for-delay settlements should be subject to the rule of reason.¹ In *Lundbeck*, the European Commission found that the reverse payment settlements at issue were market sharing agreements which constituted restrictions of competition by object.²

2. *Lundbeck* and the Pharmaceutical Sector Inquiry show that the European Commission assesses patent settlement agreements under EU competition law in light of two principal criteria: whether the settlement restricts generic entry and whether it foresees a value transfer from the originator to the generic.³ Issues arising from the current patent enforcement system in Europe seem to play no role in this assessment.

3. This paper maintains that settlement agreements must be examined under the antitrust laws against the background of the applicable patent system. Section I illustrates the EU patent enforcement system and three key issues, namely: the limited availability of preliminary injunctions, insufficient compensation in case of infringement, and the absence of a unified patent judiciary. Section II explains how these issues may cause originator companies to enter into reverse payment settlements and the implications for the assessment of the restriction of competition. Section III looks briefly at the US regime and the recent *Actavis* judgment. Section IV sets forth the conclusion.

1. The Imperfect European Patent Enforcement System

4. In the EU, patents are enforced at national level. Patents are granted by either the competent national patent office or, centrally, by the European Patent Office. However, a European patent is a bundle of national patents, which have to be enforced separately in each Member State.⁴ Most national patent

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¹ *Federal Trade Commission v. Actavis*, judgment of June 17, 2013, 570 US 756 (2013).

² Case AT.39226 – *Lundbeck*, Commission decision of June 19, 2013.

³ See, e.g., European Commission, Fourth Report on the Monitoring of Patent Settlements, ¶8: “In its Final Report, the Commission proposed a categorisation of patent settlement agreements [...]. In a nutshell it is based on two main criteria, firstly, whether the agreement foresees a limitation on the generic company’s ability to market its own medicine and secondly, whether it foresees a value transfer from the originator to the generic company.”

⁴ In February 2013, 25 EU Member States signed the Agreement on a Unified Patent Court. The new system, which is expected to enter into force in 2015-2016, will introduce patents with unitary effect in all contracting Member States, and will establish a Unified Patent Court. The Unified Patent Court’s rulings

enforcement regimes do not ensure that the originator (i) obtains an effective preliminary injunction preventing the sale of infringing products (*ex ante* enforcement) or that (ii) it is fully compensated for the harm caused by an infringing entry if it ultimately wins in litigation against the generic on infringement or validity of its patents (*ex post* enforcement). In addition, (iii) the absence of a unified patent judiciary forces originators to file requests for an interim injunction, and the generics to defend themselves, in all countries where the originators' patent rights are infringed. These three factors create a *hold-up* problem that incentivizes originator companies, especially the most risk averse, to make reverse payments to generics even if their patent position is strong.

1.1 *Limited Availability Of Preliminary Injunctions*

5. Originator companies typically face substantial hurdles and delays in obtaining preliminary injunctions against infringing products. In several national regimes, preliminary injunctions are *de facto* not available if the patent infringement case is complex.⁵ Other countries, like Germany, have a strong policy interest in limiting the availability of preliminary injunctions, which are generally not granted if the infringed patent is being challenged in contradictory proceedings (oppositions or nullity actions), regardless of the fact that the challenge may eventually fail. In other cases, the grant of preliminary injunctions without hearing the other party may be prevented by filing protective letters, or preliminary injunction hearings can be otherwise postponed. Finally, until recently, certain national courts granted preliminary injunctions to prevent the continuation of infringing acts, but not to prevent imminent infringing entry.⁶

1.2 *Insufficient Compensation*

6. Even if originator companies have no effective means of preventing *ex ante* infringement of their IP rights, their interests could in principle be sufficiently protected through damages awards (*ex post* enforcement). Yet, an originator is rarely fully compensated in Europe for the harm caused by an infringing entry even if it is established in litigation that the generic infringed its patents, for the following reasons: (i) damages awards typically do not cover the full actual financial loss caused by infringing entry; (ii) courts do not factor in future or collateral damages caused by the drop in pharmaceutical product prices; (iii) the losing party is rarely liable for all litigation costs; and (iv) generic companies are more likely to be judgment-proof or unable to pay damages than originators.

- **Damage awards do not fully cover the actual financial loss caused by infringing entry.** In most European countries damages are determined based on a reasonable royalty rate – not at the level of actual harm. A recent Commission-sponsored study confirms that “*Member States generally provide for reasonable royalty damages*”⁷ as a yardstick for damage compensation in patent infringement litigation. But a “*reasonable royalty*” is much lower than the actual damage

will have effect in the territory of all Contracting Member States having ratified the Agreement on the Unified Patent Court.

⁵ E.g., the Netherlands.

⁶ The Enforcement Directive (Council Directive 2004/48/EC of April 29, 2004 on the Enforcement of Intellectual Property Rights OJ [2004] L195/16-25) seems to have addressed this discrepancy. Article 9(1)(a) provides that judicial authorities must be able to issue an injunction to prevent imminent infringement or to forbid the continuation of infringement. For example, in 2007 the French legislator adopted a law on “Fight against Infringement”, which introduced the possibility of obtaining preliminary measures to prevent an imminent infringement in France.

⁷ European Observatory on Counterfeiting and Piracy, Civil Damages in Intellectual Property Rights Cases, , available at: http://ec.europa.eu/internal_market/iprenforcement/docs/damages_en.pdf, p.4.

caused to the originator by infringing entry, which explains why originators are often undercompensated in case of infringement. Indeed, Article 13 of the Enforcement Directive provides that courts shall award damages based on the actual prejudice suffered by the patent holder, and only in “*appropriate cases*” will they award a lump sum based on a reasonable royalty rate if the infringer had requested authorization to use the IPR in question.⁸

- **Damage awards do not cover loss caused by regulatory price cuts.** In most European countries medicine prices are regulated by the state.⁹ Publicly set prices or reimbursement levels may be automatically cut once a generic enters in that country, regardless of whether the generic infringes valid patents.¹⁰ Moreover, other Member States that take account of the public prices in that country (so-called reference pricing) may lower their prices too. Even after generics are enjoined, the regulatory cuts are often irreversible and generics are generally not required to compensate for these cuts. As the Commission-sponsored study found, “[o]utside of lost profits, rightholders may not in practical terms be compensated for other negative economic consequences resulting from an infringement” and “[t]here are many types of consequential damage that can result from an infringement – [...] price declines [...], and the like – which are rarely taken into account or compensated.”¹¹
- **The losing party is not liable for litigation costs.** Patent litigation in Europe is complex and very costly. Average legal fees in the UK (not including man-hours and other litigation costs, such as costs of investigating and rectifying infringement) normally exceed EUR 1 million, and in several other European jurisdictions may well exceed EUR 400,000.¹² Significantly, the Commission has estimated that litigation costs in a unified patent jurisdiction, such as the US, are at least 10% to 45% lower than the combined litigation costs in the four Member States (Germany, France, UK, and the Netherlands) in which most patent litigation takes place.¹³ Yet, European courts sometimes do not award full reimbursement of legal costs and generally do not award full litigation costs.¹⁴

⁸ Council Directive 2004/48/EC of April 29, 2004 on the Enforcement of Intellectual Property Rights OJ [2004] L195/16-25. Article 13 of the Enforcement Directive reads: “*When the judicial authorities set the damages: (a) they shall take into account all appropriate aspects, such as the negative economic consequences, including lost profits, which the injured party has suffered, any unfair profits made by the infringer and, in appropriate cases, elements other than economic factors, such as the moral prejudice caused to the rightholder by the infringement; or (b) as an alternative to (a), they may, in appropriate cases, set the damages as a lump sum on the basis of elements such as at least the amount of royalties or fees which would have been due if the infringer had requested authorisation to use the intellectual property right in question.*”

⁹ See, e.g., Pharmaceutical Sector Inquiry (Executive Summary), p.8.

¹⁰ Figure 28 of the Commission’s Final Report in the Pharmaceutical Sector Inquiry indicates that originator’s price drops on average by more than 10% in the first year from loss of patent protection and by around 20% by the second year, as a result of generic entry and regulatory price cuts.

¹¹ European Observatory on Counterfeiting and Piracy, Civil Damages in Intellectual Property Rights Cases, , available at: http://ec.europa.eu/internal_market/iprenforcement/docs/damages_en.pdf, p.3.

¹² Pharmaceutical Sector Inquiry (Final Report), ¶659 and figure 88.

¹³ Enhancing the Patent System in Europe, Communication from the Commission to the European Parliament and the Council, COM(2007) 165, pp.7-8. See also Pharmaceutical Sector Inquiry (Final Report), ¶661, founding that “*legal fees incurred in multiple patent litigations [...] are very substantial.*”

¹⁴ European Observatory on Counterfeiting and Piracy, Civil Damages in Intellectual Property Rights Cases, p.4, available at: http://ec.europa.eu/internal_market/iprenforcement/docs/damages_en.pdf, p.3: “*costs of*

- **Generic companies may avoid payments of awarded damages.** In the case of thinly capitalized generic firms, it might be more difficult for an originator to collect a judgment award than it would be for the generic firm in the opposite case. Nor it can be excluded that a generic undertaking (as any other debtor) avoid paying compensation, e.g., by entering into administration or by liquidating itself and reappearing as a different corporate entity.

1.3 *No Unified Patent Judiciary*

7. In addition to the substantial litigation costs mentioned above, the absence of a unified patent judiciary in the EU exposes originators to the risk of obtaining conflicting interim or final judgments, with the result that a generic product is considered infringing in some countries but not in others. This does not only artificially partition the EU single market, but it also jeopardizes the originator's commercial strategy and business plan, which are often conceived on a EU-wide basis. In this regard, the Final Report in the Pharmaceutical Sector Inquiry finds that the lack of a unified patent judiciary results in a "*substantial burden for originator companies which need to file requests for interim injunctions in all the Member States where their patent rights are (about to be) infringed, without having any certainty as to the outcome of the request.*"¹⁵

8. Against this background, an originator may opt to avoid multiple litigation proceedings by pursuing one "*key case*" (on validity or infringement), while staying all other actions and tying them to the key case through settlements. The tied litigation proceedings may be pending in other countries against the generic, which is a defendant in the key litigation, or in the same or other countries against other generics who use the same API as that of the key defendant. Where the validity of the originator's patent is at stake in the key litigation, the tied litigation proceedings may also be actions initiated against generics using a different API.

2. **Implications for the Competitive Assessment**

9. The incomplete compensation for damages or legal costs resulting from the the European patent enforcement system, creates an asymmetric situation between the originator and the generic, which allows the generic to hold up the originator regardless of the patent strength. This asymmetry renders it rational for a patent owner to make payments to the generic for settling the dispute, even if the patent is objectively strong.

10. The difference between the originator's actual losses and the lower compensation it will obtain in litigation constitutes a seemingly "*invisible*" value transfer from the originator to the infringing generic company. In order to prevent such value transfer, the originator may be forced to make a "*visible*" value

investigating, taking legal action against, and rectifying an infringement are often not compensated in full." Article 14 of the Enforcement Directive simply provides that "Member States shall ensure that reasonable and proportionate legal costs and other expenses incurred by the successful party shall, as a general rule, be borne by the unsuccessful party, unless equity does not allow this" (emphasis added).

¹⁵ Para. 683. See also European Commission, Commission proposes unitary patent protection in 25 member states – frequently asked questions, Press release of April 13, 2011. "*Another important element in the overall reform of the patent system in Europe is the development of a unified litigation system. The current system entails multi-forum litigation since companies may have to litigate in parallel in all countries where the European patent is validated. This results in considerable costs, complexity and legal insecurity. A European Patent Court would facilitate the development of a consistent jurisprudence and increase legal certainty.*" Note that Dutch Courts have to some extent started to grant cross-border injunctions. See e.g., Thomas F. Cotter, *Comparative Patent Remedies: A Legal and Economic Analysis*, OUP, 2013, p.250 *et seq.*

transfer to the generic company in the form of a settlement payment. Suppose that the originator expects actual losses from infringing generic entry (including litigation costs, *etc.*) of \$100; and that, although being sure (100%) of winning in litigation, the originator expects to be able to recoup from the generic only \$60, because of the defects in the patent enforcement system. The difference (\$40) represents the “invisible” value transfer. To avoid bearing the consequences of the imperfect enforcement system, the originator is forced to make a “visible” payment of \$0-39 to the generic as a settlement reverse payment.

11. The actual “size” of the reverse payment depends on the magnitude of the losses with which the originator would be left stranded after successful litigation, which is determined by the factors set forth in Section I (*i.e.*, incomplete damage compensation, financial losses due to regulatory price-cut, costs of litigation in multiple jurisdictions, and incomplete compensation of litigation costs) times the likelihood of the originator winning the patent infringement suit.

12. Three key considerations flow from the above:

1. Depending on the circumstances of the case, reverse payments may be made not in order to share the originator’s monopoly profit, but rather to avert the high losses with which the originator would be left stranded after successful litigation. This is not the result of any competitive process, but of the flawed patent enforcement system. No presumption of a restriction of competition can be attached to the existence of a reverse payment.
2. Because the “invisible” value transfer (*i.e.*, the originator’s under-compensation) and the “visible” reverse payment are strongly correlated, and both flow in the same direction (*i.e.*, from the originator to the generic), the direction of the payment is neither conclusive nor indicative as to the existence of a restriction of competition.
3. Since the generic company may retain some of its profits even if a court finds that it infringes,¹⁶ reverse payments may aim at rectifying the generic company’s skewed incentive to infringe the originator company’s patents (*i.e.*, the originator pays not to be unlawfully harmed). Reverse payments have no general probative value as regard the strength or weakness of the originator’s patent.

13. Legal standards that are exclusively or mainly based on the existence or the size of a reverse payment are not appropriate to determine whether the settlement is pro- or anticompetitive. First, they do not take into consideration the shortcomings of the patent enforcement system. Second, they tend to identify the restriction of competition with the reverse payment itself, which should instead be neutral from an antitrust perspective. Third, they create legal uncertainty: it is difficult to draw the line between allegedly anti-competitive reverse payments and other lawful payments (*e.g.*, compensation of legal costs or grant of an early entry).

14. The key question to assess a restriction of competition and consumer harm is whether the settlement is connected to a genuine dispute between the originator and the generic and enables the originator to obtain the same results that it could have obtained through enforcement of the patent in court.

¹⁶ See also Damages in IPR Cases, p.2 (“*comprehensive review of the law and practice in the EU Member States shows that [...] national IPR damages regimes often do not effectively achieve the twin objectives of compensation and deterrence*”); pp.3-4 (“*[i]nfringers may retain some of their profits, or otherwise have an economic incentive to engage in infringement*” and the damages rules in the Member States “*encourage infringers to take the risk of infringement, with little greater “downside” than the normal license fee even if the infringement is detected and proven*”; “*In a number of Member States, the current provisions and practices on damages not only fail to compensate rightholders and relieve infringers of their gains, but in fact may provide financial incentives for counterfeiting and piracy.*”)

3. Comparison with the US

15. In the US, damages for the harm caused by infringing generic entry are generally higher than in Europe.¹⁷ As a result, in the US an originator does not bear as high the risk of irreparable harm and may therefore more effectively rely on the patent court system to enforce its patent rights.

16. Although the hold-up described in the Sections above seems to be less of a problem in the US, the US Supreme Court's *Actavis* judgment has recently confirmed that lack of full compensation is a relevant factor that must be taken into account in the assessment of patent settlement agreements. The judgment rests on the proposition that “*the size of the unexplained reverse payment can provide a workable surrogate for a patent's weakness,*” but “*where a reverse payment reflects traditional settlement considerations, such as avoided litigation costs [...] there is not the same concern.*”¹⁸ The “*avoided litigation costs*” must include all irreversible, financial losses with which a patent owner would have to bear, even in case of litigation victory.

4. Conclusion

17. This paper is not intended to identify the appropriate legal standard for assessing reverse payment settlements. Rather, it maintains (i) that any legal standard for the assessment of patent settlements must take into consideration the shortcomings of the European patent enforcement system and (ii) that legal standards that are exclusively or mainly based on the existence or the size of reverse payments are not appropriate and create legal uncertainty.

18. The European Commission conducted a remarkable analysis of patent litigation in its Pharmaceutical Sector Inquiry and recently investigated various patent settlement agreements.¹⁹ Nowhere, however, does it take into consideration the shortcomings of the European patent system in its assessment of patent settlements.

19. Yet, reverse payment settlements may be concluded to mitigate or remedy these very shortcomings, and should not be assumed to be driven by a desire to share a monopoly or by the originator's fear that its patents could be held invalid or not infringed.

¹⁷ For example, under Section 284 of US Patent Act (35 U.S.C. 2006), US courts may award treble damages if the generic company has “willfully” infringed the patent. In the US, the courts must use the patentee's lost profit as the as the relevant damages standard unless an “established” royalty exists, which accurately reflects the patentee's actual loss from the infringement, *see* Thomas F. Cotter, *Comparative Patent Remedies: A Legal and Economic Analysis*, OUP, 2013, p.106. Also, empirical research has shown that patent damages are higher in jury trials, which are rather commonly used in patent lawsuits in the U.S., than in bench trials, *see* Kimberly A. Moore, *Judges, Juries, and Patent Cases – An Empirical Peek Inside the Black Box*, 99 Michigan Law Review (2000) 365, pp.386-95.

¹⁸ *Federal Trade Commission v. Actavis*, judgment of June 17, 2013, 570 US 756 (2013), p.10.

¹⁹ *See* Case AT.39226 – *Lundbeck*. Case AT.39612 – *Servier* and Case AT.39686 – *Cephalon* are pending.