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Abstract

*In its inquiry, the European Commission laid bare manifold practices usually carried out by originator companies hindering the entrance of generics.**

In this context, this article aims to discuss the scope for applying EU Competition Law, by critically analyzing both the recent European Commission's policy and the views taken by the Court of Justice of the European Union (CJ) and by the General Court (GC), with regard to i) the misuse of Intellectual Property Rights (IPRs) related procedures and ii) reverse payments. Accordingly, this article claims that the game rules are a hurdle to certainty and provides hints as to further developments.

Au cours de son enquête, la Commission Européenne a exposé au grand jour nombreuses pratiques, généralement effectuées par les laboratoires de princeps, visant à entraver l'entrée des génériques sur le marché. Cet article vise, au travers d'une analyse critique de la politique récente de la Commission Européenne, ainsi que de la jurisprudence de la Cour de Justice de l'Union Européenne et du Tribunal, à discuter de la possibilité d'appliquer le Droit Européen de la Concurrence i) à l'usage abusif des procédures relatives aux droits de propriété intellectuelle et ii) aux paiements inversés. Cet article affirme que les règles du jeu constituent un obstacle à la sécurité juridique et envisage des pistes de développements futurs.

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I. General overview

1. Competition Law aims to control restrictive trade practices, enhancing competition in the markets. Its policies struggle to promote efficiency and to maximize welfare. IPRs reward originator companies by granting them a period of exclusivity, which is likely to increase market power. Competition policy aims to regulate the use of IPRs based market power. Although at first glance IPRs and Competition Law might be deemed to be areas of law having contradictory aims, one should bear in mind that they share the same objective of promoting consumer welfare: IPRs provide originator companies the opportunity to recoup investment costs and provide incentives to continue innovating, which consequently might also raise consumer welfare. Other than consumer welfare, both should foster economic growth, innovation and efficiency. Be that as it may, conflicts might arise between them.

2. On 8 July 2009 the European Commission adopted the Final Report on its competition inquiry into the pharmaceutical sector. As the former Competition Commissioner Neelie Kroes underlined¹: “(...) the sector is too important to the health and finances of Europe's citizens and governments to accept anything less than the best. The inquiry has told us what is wrong with the sector, and now it is time to act. When it comes to generic entry, every week and month of delay costs money to patients and taxpayers. We will not hesitate to apply the antitrust rules where such delays result from anticompetitive practices (...)”

3. Accordingly, the European Commission has been shifting its competition enforcement policy priorities in the pharmaceutical sector from parallel trade to generic entry.² “The entry of a competing generic product on the market inevitably results in a significant decline in the price and market share of the corresponding originator product. Therefore, originator companies may seek to protect their market position using various means ranging from strategic patenting around the product to patent litigation and interventions before national regulatory authorities.”³

* Pharmaceutical Sector Inquiry, part 1, final report, available at http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf (5 November 2012).

1 Antitrust: shortcomings in pharmaceutical sector require further action, available at: http://europa.eu/rapid/press-release_IP-09-1098_en.htm?locale=en (5 November 2012).

2 D.W. Hull, The application of EU Competition Law in the Pharmaceutical Sector, *Journal of European Competition Law & Practice* 2011, Vol. 2, n° 5, p. 480.

3 Pharmaceutical Sector Inquiry, part 1 (...), p. 181.

4. In its inquiry, the European Commission laid bare manifold practices usually carried out by originator companies hindering the entrance of generics. This set of strategies, named by the industry as “Tool-box”, encompasses a wide range of practices such as: “*patenting activities of originators, contacts, disputes and litigations between originator and generic companies; opposition procedures and appeals before patent offices; patent settlements and other agreements between originator and generic companies; interventions of originator companies before national authorities deciding on marketing authorization, pricing and reimbursement of generic products; promotional activities; and second generation products.*”⁴

5. Within this frame, one should seek to find out among these practices, which ones and in which circumstances might have anticompetitive effects. It might not be very straightforward to determine their (un)lawfulness. Accordingly, the European Federation of Pharmaceutical Industries and Associations (EFPIA), for instance, in the response to the preliminary report in the pharmaceutical sector inquiry, pointed out that “*the so-called ‘toolbox’ of originator strategies alleged to delay generic entry is simply a description of lawful commercial activities common to all innovative industries.*” The EFPIA also noted its sharp disagreement with “*any suggestion that these practices are of questionable legality, and with the use of terms such as ‘toolbox’ or ‘delaying tactics’ in a pejorative manner to describe them.*” It rejected “*any suggestion that the lawfulness of these practices can be judged by the intent of the companies who use them*” considering the conducts in question “*primarily concerns patents which, by their nature, are intentionally exclusionary of imitators.*”⁵

6. On the other hand, the issue has to do with a broader dilemma and controversial topic: which role should Competition Law have in the framework of a sector-specific regulatory structure designed to remedy anticompetitive harm?

II. The misuse of intellectual property rights (IPRs) related procedures in the pharmaceutical sector

7. It stems from the *AstraZeneca* case that misusing public procedures and regulations in order to prevent generic firms from competing can under certain circumstances amount to an abuse of a dominant position in breach of Article 102 TFUE.⁶

8. In a nutshell, it was the first decision and a rather striving example by which the European Commission found that a pharmaceutical company abused its dominant position by adopting strategies designed to delay or limit generic entry.

⁴ *Ibid.*, p. 16.

⁵ Response to the preliminary report in the pharmaceutical sector inquiry, available at <http://62.102.106.100/content/default.asp?PageID=559&DocID=6178> (5 November 2012).

⁶ T-321/05, *Astrazeneca v. Commission*, 1 July 2010. In the case C-457/10P, *Astrazeneca v. Commission*, 6 December 2012, the CJ upheld the GC’s judgement.

1. The first abuse: Supplementary protection certificates (SPCs)

9. On the first abuse related to the extension of the patent rights, the court upheld the European Commission’s decision pursuant to which AstraZeneca abused its dominant position by supplying misleading information to national patent offices for supplementary protection certificates. Council Regulation n° 1768/92 of 18 June 1992 in relation to the creation of a supplementary protection certificate for medicinal products provides for the creation of a supplementary protection certificate. Its purpose is to extend the duration of the exclusive right guaranteed by a patent. SPC is designed to compensate for the reduction in the period of effective protection conferred by the patent, corresponding to the period between the filing of a patent application in respect of a medicinal product and the granting of authorization to place that product on the market.

10. In sum, the legal reasoning of the General Court was based on the following assumptions:

→ The dominant position and the objective concept of abuse, the “*special responsibility doctrine*” and the “*competition on the merits*”: the Court held that “*it follows from the objective nature of the concept of abuse (Hoffmann-La Roche v. Commission, paragraph 239 above, paragraph 91) that the misleading nature of representations made to public authorities must be assessed on the basis of objective factors and that proof of the deliberate nature of the conduct and of the bad faith of the undertaking in a dominant position is not required for the purposes of identifying an abuse of a dominant position.*” Notwithstanding, the court considered that “*although proof of the deliberate nature of conduct liable to deceive the public authorities is not necessary for the purposes of identifying an abuse of a dominant position, intention none the less also constitutes a relevant factor which may, should the case arise, be taken into consideration by the Commission.*” It also stated that “*Article 82 EC [102 TFUE] prohibits a dominant undertaking from eliminating a competitor and thereby strengthening its position by using methods other than those which come within the scope of competition on the merits (AKZO v. Commission, paragraph 243 above, paragraph 70, and Irish Sugar v. Commission, paragraph 352 above, paragraph 111). It is also apparent from the case-law that an abuse of a dominant position does not necessarily have to consist in the use of the economic power conferred by a dominant position (see, to that effect, Europemballage and Continental Can v. Commission, paragraph 267 above, paragraph 27, and Hoffmann-La Roche v. Commission, paragraph 239 above, paragraph 91).*”⁷ In this regard, supporting the application to have the General Court’s judgment set aside and the contested decision annulled, the EFPIA argued that “*if the GC’s interpretation of ‘competition on the merits’ is to be followed, an ‘objectively misleading’ representation in reality means an ‘objectively wrong’ representation. If that standard were to be applied,*

⁷ T-321/05, *AstraZeneca AB and AstraZeneca plc v. European Commission*, § 352 to 359.

dominant undertakings would have to be infallible in their dealings with regulatory authorities. Thus, even an error that was made unintentionally and immediately rectified could give rise to liability under Article 82 EC.” The EFPIA sustained that “it is legally indefensible to apply that concept to patent applications, since a number of such applications would have to be rejected each year on the ground that those applications were not objectively correct, as their objective did not satisfy the patentability criteria.”⁸ Notwithstanding, the CJ sustained that, contrary to what the EFPIA submitted, the GC “did not hold that undertakings in a dominant position had to be infallible in their dealings with regulatory authorities and that each objectively wrong representation made by such an undertaking constituted an abuse of that position, even where the error was made unintentionally and immediately rectified. (...) the General Court pointed out (...) that the assessment of whether representations made to public authorities for the purposes of improperly obtaining exclusive rights are misleading must be made in concreto and may vary according to the specific circumstances of each case.”⁹

→ The unlawful acquisition of an exclusive right can constitute an abusive conduct even if it does not have the effect of eliminating all competition.¹⁰

→ “The existence of remedies specific to the patent system is not capable of altering the conditions of application of the prohibitions laid down in competition law.”¹¹

→ It is pointless to discuss whether the solution would be different according to United States Law, as argued by *Astrazenca*, because it cannot take precedence over European Union law.¹²

2. The second abuse: Deregistration

11. AstraZeneca was also found to abuse its dominant position for deregistration of the marketing authorizations, combined with its withdrawal from the market of Losec capsules and launch of Losec MUPS tablets, in order to delay or make more difficult the marketing of generic medicinal products and to prevent the parallel imports (one should be mindful of the fact that if the market authorization is withdrawn, the generics must do its own critical trials of the drug and the whole process slows down their entry into the market). Nevertheless, the GC found out that the case causal affect between deregistration and a fall in imports into Denmark and Norway was not proven, reducing, therefore, the fine.

⁸ C-457/10 P, *AstraZeneca AB and AstraZeneca plc v. European Commission*, § 72.

⁹ C-457/10 P, *AstraZeneca AB and AstraZeneca plc v. European Commission*, § 99.

¹⁰ *Ibid.*, § 364-365.

¹¹ *Ibid.*, § 366.

¹² Joined Cases T-191/98, T-212/98 to T-214/98, *Atlantic Container Line and Others v. Commission*, § 1407; S. Gallasch, *Astrazenca v. Walker Process – a Real EU-US divergence or just an attempt to compare apples to oranges?*, *European Competition Journal*, Vol. 7, n° 3, December 2011, pp. 505-526; O. Rickardsson, *Patent misuse and sham – Development of new principles under EU Competition Law*, available at http://www.kkv.se/upload/Filer/Forskare-studenter/uppsatser/2011/Ola_Rickardsson_88-2011.pdf (5 November 2012).

12. The court’s decision was based on the following major legal grounds:

→ “The special responsibility doctrine” above mentioned.¹³

→ The illegality of abusive conduct under Article 102 TFUE is unrelated to its compliance or non compliance with other legal rules.¹⁴ Notwithstanding, the appellant – AstraZeneca – contended that it had the right to withdraw a marketing authorization given that it could not be granted and at the same time prohibited by the European Union. Accordingly, EU regulation of pharmaceutical matters confers on the holder of a marketing authorization the right to request the withdrawal of that authorization.¹⁵

→ The case-law on “essential facilities” cannot be applied. The case-law on “essential facilities” relates, in essence, to circumstances in which a refusal to supply by an undertaking in a dominant position, by virtue, in particular, of the exercise of a property right, may constitute an abuse of a dominant position. The Court stressed that AstraZeneca “had no longer conferred the exclusive right to make use of the results of the pharmacological and toxicological tests and clinical trials placed in the file”. Indeed, Advocate General Jan Mazak considered “that the appellants have not demonstrated that any of AZ’s proprietary rights were expropriated or that a compulsory licence has been granted to AZ’s competitors due to the application of Article 102 TFEU in the contested decision.”¹⁶

→ There is no convincing objective justification to the selective requests for deregistration of the marketing authorizations.¹⁷ The AstraZeneca’s performance lacked grounding given that the patented drug neither harmed public health nor undermined AstraZeneca’s economic condition.

3. Conclusions

13. There are several legal consequences arisen from the CJ’s judgment, related with the misuse of Intellectual Property Rights (IPRs) related procedures that are worth mentioning.

14. Broadening the concept of “special responsibility”, both the European Commission and the GC pushed the limits and deepened the scope of article 102 TFUE.¹⁸ “This case showed once more how wide and unclear the notion of the special responsibility of dominant undertaking actually is.”¹⁹ As a result, the *AstraZeneca* judgment seems to be a

¹³ T-321/05, *AstraZeneca AB and AstraZeneca plc v. European Commission*, § 671-673.

¹⁴ *Ibid.*, § 677.

¹⁵ C-457/10P, opinion of Advocate General Ján Mazák, § 73, 15 May 2012.

¹⁶ *Ibid.*, § 93.

¹⁷ T-321/05, *AstraZeneca AB and AstraZeneca plc v. European Commission*, § 685-694.

¹⁸ C-322/81, *Michelin v. Commission*, 9 November 1983; C-62/86, *AKZO v. Commission*, 3 July 1991; C-333/94 P, *Tetra Pak v. Commission*, 14 November 1996; C-395/96P, 396/96P, *Compagnie Maritime Belge transports SA*, 16 March 2000; C-487/99P, *Irish Sugar Plc v. Commission*, 10 July 2001; T-203/01, *Michelin v. Commission*, 30 September 2003; T-201/04, *Microsoft v. Commission*, 17 September 2007.

¹⁹ N. Tuominen, *Patenting strategies of the EU Pharmaceutical Industries: Regular Business Practice or Abuse of Dominance*, *World Competition*, Issue 1, p. 47.

rather striking example of how carefully pharmaceutical undertakings in a dominant position should hereinafter behave. For practitioners, with regard to misrepresentations, one should bear in mind that the CJ seems to emphasize the need of a consistent and linear conduct characterized by highly misleading representations and by a manifest lack of transparency. In other words, “it cannot be inferred from that judgment that any patent application made by such an undertaking which is rejected on the ground that it does not satisfy the patentability criteria automatically gives rise to liability under Article [102] EC.”²⁰

15. Although one can argue that pharmaceutical undertaking might be subject to a certain degree of uncertainty arising out of a broad interpretation of “special responsibility”, especially taking into account the simultaneous insecurity that might come out from the apparent pattern shift in the European Commission’s relevant market definition process, *AstraZeneca*’s practices are undoubtedly unlawful.²¹ Accordingly, first and foremost, the abuse of rights doctrine could have performed a main role given that “*Astrazeneca’s conduct concerning the misleading information granted to the national patent offices, so as to unlawfully extend the SPC terms, could be construed as seeking to gain a financial or other advantage by an abusive use of Community Law. Analogously, AstraZeneca’s conduct concerning the selective withdrawal of market authorizations could be interpreted as violating the purpose of the provision (i.e. the public health) so to take advantage of delayed entry of generic drug producers and parallel importers.*”²²

16. As far as the *AstraZeneca* decision is concerned, it follows from the above mentioned the European Commission’s decision seems to be solid and reasonable which led the CJ to uphold it.

17. It goes without saying that *AstraZeneca*’s practices are not in compliance neither with EC Law nor with the patent law system. Hence, the importance of the case has more to do with the misuse of IPRs related procedures given that, strictly speaking, there was no collision between IPRs and European Competition Law. Nevertheless, the mentioned abuses aimed to broaden the scope of IPRs, which might trigger the discussion concerning the balance between the IPRs system and Competition Policy. Account must be taken of the fact that the court, endorsing the European Commission’s decision, stressed that the illegality of abusive conduct under Article 102 TFUE is unrelated to its compliance or

non-compliance with other legal rules, which might foster the EC to keep extending the scope of application of article 102 TFUE regardless of the solutions provided by the patent law system. Accordingly, the European Commission stressed that “*intellectual property rights are not exempted from the application of competition rules. The exercise by a company of its intellectual property rights can amount to an agreement restricting competition under Article 81 EC [101 TFUE] or an abuse of a dominant position under Article 82 EC [102 TFUE].*”²³

18. The interaction between Competition Law and the patent system is being subject to hard debate. Patent protection creates market power, tends to foster distorting economic outcomes and creates clear opportunities for anti-competitive behavior, as, for instance, evidenced by the *AstraZeneca* case. Although it is essential for rewarding Research & Development (R&D), one may wonder whether there are alternative mechanisms for rewarding pharmaceutical R&D activities. Indeed, there are alternative policies that should be discussed. “*Many OECD countries directly fund pharmaceutical research, through systems of grants and contracts*” (...) Another approach is to offer a prize for a successful innovation which meets a pre-defined standard. Yet another approach would be to preserve patent rights but for a government or large insurer to negotiate with the owner of a successful patent to buy out the patent rights and then to manufacture the drug directly and distribute it at marginal cost.”²⁴

19. Within the framework of the mentioned debate, the European Commission practice has been subject to a flurry of criticism taking into consideration the weakened incentives on innovation that might arise from the extension of the application of article 102 TFUE to abusive patent strategies.²⁵ New forms of abuse identified by the European Commission in the pharmaceutical inquiry raise two main antagonisms: the tension between the legal exercise of a right and the abuse of dominant position; indeed, it might not always be a straightforward approach to scrutinize whether a particular strategic patenting is a regular business practice or an abusive practice and “*considering that the ‘new abuses’ [identified by the European Commission in the pharmaceutical inquiry] are not included in the guidance paper (...) some specific guidelines would be helpful.*”²⁶ On the other hand, the issue has to do with a broader dilemma and controversial topic: which role should Competition Law have in the framework of a sector-specific regulatory structure designed to remedy anticompetitive harm? One should deem to be adequate a minimalist approach of antitrust law? In the *trinko* case, the Supreme Court of the United States seems to answer affirmatively this latter question, considering that “*antitrust*

²⁰ C-457/10 P, *AstraZeneca AB and AstraZeneca plc v. European Commission*, § 99.

²¹ “*In older cases involving originator pharmaceutical companies, the third level, referred to as ATC3, which allows medicines to be grouped in most cases according to their therapeutic indications, i.e. their intended use, has generally been taken as the starting point for market definition in the Commission’s analyses. However, in recent cases involving generic companies the Commission, based on its market investigation, has tended to identify competition issues – where such issues arose – more often at the molecule level, at the ATC4 level, or on the basis of a group of molecules. This is because generic pharmaceutical companies typically produce copies of originator drugs which therefore can normally be viewed as the closest substitute to those drugs. As set out in the Commission’s horizontal merger guidelines, the higher the degree of substitutability between the merging firms’ products, the more likely it is that the merging firms will raise prices significantly.*” in Case No COMP/M.5865 – TEVA/RATIOPHARM, of 03/08/2010, § 12, available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32010M5865:EN:HTML> (5 November 2012).

²² M. Maggioni, M. Montagnani, *Astrazeneca’s Abuse of IPR-Related Procedures: a hypothesis of anti-trust offence, abuse of rights and IPR misuse*, *World Competition*, Vol. 34, Issue 2, p. 258.

²³ Pharmaceutical Sector Inquiry, part 2, p. 537, available at http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part2.pdf (5 November 2012).

²⁴ *OECD Journal of Competition Law and Policy*, vol. 4, n° 3, p. 136, OECD 2002.

²⁵ L. Kjolbye Article 82 EC as remedy to patent system imperfections: fighting fire with fire, p. 188, vol. 32, n° 2, 2009.

²⁶ M. Siragusa, Chapter 10 – The EU Pharmaceutical Sector inquiry. New Forms of Abuse and Article 102 TFUE, p. 189 in *Competition law and intellectual property: a European perspective*, edited by Caggiano, Giandonato; Muscolo, Gabriella; Tavassi, Mariana, *International Competition Law Series*, Volume 50, 2012, Kluwer Law International.

analysis must always be attuned to the particular structure and circumstances of the industry at issue. Part of that attention to economic context is an awareness of the significance of regulation. (...) one factor of particular importance is the existence of a regulatory structure designed to deter and remedy anticompetitive harm. Where such a structure exists, the additional benefit to competition provided by antitrust enforcement will tend to be small, and it will be less plausible that the antitrust laws contemplate such additional scrutiny.”²⁷

20. Therefore, “one question still remains open to debate: is patent law an element within the framework of competition rules or is it rather itself the framework of innovation competition?”²⁸ One thing is for certain though: the creation of a single Community patent and a unified and specialized patent litigation system, as suggested by the European Commission, would undoubtedly influence the interface between both bodies of law, encompassing shifts in legal solutions regarding regulatory abuses or litigation abuses. The majority of scholars and stakeholders sustain that Competition Law can’t be the exclusive answer and that a reform of intellectual property rules appears to be necessary.²⁹

21. Facing up to this the state of play, one shall not doubt that in the next few years deep changes in the game will take place in the EU legal order, hopefully enlightening the players on its rules because a fair game can only be played by clearing up the rules.

III. Patent settlements

1. The pharmaceutical sector inquiry

22. The European Commission defines patent settlement as “agreements to settle actual or potential patent-related disputes. Patent settlement agreements are concluded in order to resolve claims in patent disputes, opposition procedures or

²⁷ Supreme Court of the United States, *Verizon Communication v. Law Offices of Trinko*, LLP 540 U.S 682, (2004), available at <http://transition.fcc.gov/oc/documents/opinions/2004/02-682-011304.pdf>, pp. 11-12.

²⁸ Tuominen, Nicoleta, Patenting Strategies of the EU Pharmaceutical Industry-Crossroad between Patent Law and Competition Policy, Research Papers in Law 1/2011, p. 26, available at http://www.coleurope.eu/content/studyprogrammes/law/studyprog/pdf/ResearchPaper_1_2011_Tuominen.pdf. Regarding compulsory licensing: i) the case law from the CJ have been subject to an enormous criticism (*Vide* C-283/87, *Volvo v. Veng*, 5 October 1988; C-241/91P and C-242/91 P, *Radio Telefis Eireann*, 6 April 1995; T-201/04, *Microsoft v. Commission*, 17 September 2007; C-418/01, *IMS Health*, 29 April 2004); ii) as pointed out by the European Commission, “the Italian competition authority found out that the refusal of an originator company to grant a licence for the production of an active ingredient, needed by producers of generic medicines to access national markets where the originator did not have any exclusive rights, constituted an infringement of Article 82 [102 TFUE] of the Treaty” in Pharmaceutical Sector Inquiry, part 1 (...), p. 523. iii) The Commission considered settlement agreements that limit generic entry and include a value transfer from an originator company to one or more generic companies as an example of potentially anticompetitive agreements. In this context, the European Commission stressed that “value transfer could consist in granting a patent licence to the generic company. A patent licence enables the generic company to enter a market with a product but, as explained above, the commercial freedom of the generic company is limited by the terms of the licence agreements which, for instance, can include limitations on the quantity of the types of products that the generic company may sell” in Pharmaceutical Sector Inquiry, part 1, p. 269 (...).

²⁹ *Vide*, for instance, M. Siragusa, Mario, Chapter 10 – The EU Pharmaceutical Sector inquiry, New Forms of Abuse and Article 102 TFUE, p. 188 in Competition law and intellectual property: a European perspective, edited by Caggiano, Giandonato; Muscolo, Gabriella; Tavassi, Mariana, *International Competition Law Series*, Volume 50, 2012, Kluwer Law International.

litigation where no final adjudication has been handed down or there has not yet been a court proceeding. The primary aim of a settlement agreement is to end the dispute, opposition procedure or litigation.”³⁰

23. As the European Commission recognized that settlements are a generally accepted way of ending disputes, opposition procedures and litigation given that “the parties may prefer to discontinue the dispute or litigation because it proves to be costly and time-consuming, and might also be unpredictable in its outcome.”³¹ Furthermore, “Pharmaceutical companies in the EU see patent litigation cases as fact-intensive, legally complex, lengthy and costly. The conclusion of a settlement agreement is seen as an alternative way forward to continuing litigation until final judgment.”³² The importance of the motives that lead originator and generic companies to settle agreements are different though. Most generic companies present as major concerns avoiding the costs related to litigation and also the impact on personnel costs. As far as originator companies are concerned, the most important factor that they take into account when considering a patent settlement is the strength of their position in the case.³³

24. The European Commission categorized settlement agreements in the following manner: those limiting generic entry were categorised as B-type, whereas those that do not limit generic entry were categorised as A-type. For all the agreements encompassed in category B, those which included a value transfer from the originator company to the generic company were categorised as B.II, whereas agreements which do not include such a value transfer were categorised as B.I. From a Competition Law perspective, category A should be tendentiously classified as irrelevant. In contrast, agreements falling within the scope of category B.II should be subject to the European Commission’s scrutinization. It is noteworthy that regarding category B.I, the European Commission consider that some of those agreements might be relevant from a Competition Law perspective, in particular “settlements outside the exclusionary zone of the patents and/or settlement agreements on a patent for which the patent holder knows that it does not meet the patentability criteria, e.g. where the patent was granted following the provision of incorrect, misleading or incomplete information.”³⁴

2. European Commission’s monitoring of patent settlement agreements

25. It stems from its findings that the European Commission considered that reverse payments are prone to raise anticompetitive concerns pursuant to article 101 TFUE.

³⁰ Pharmaceutical Sector Inquiry, part 1 (...), p. 254.

³¹ *Ibid.*, p. 255.

³² *Ibid.*, p. 262.

³³ *Ibid.*, pp. 266-267.

³⁴ 2nd Report on the Monitoring of Patent Settlements (period: January-December 2010), published on 6 July 2011, available at http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/patent_settlements_report2.pdf (5 November 2012).

26. Accordingly, in the wake of the sector inquiry, the European Commission launched a first patent monitoring exercise. The number of B.II settlements reported compared to the period investigated in the course of the sector inquiry have decreased from 22% to 10%. As an explanation for this shrinkage, the European Commission pointed out as explanations: i) “the increased awareness of companies and their legal advisors regarding the question whether such agreements might attract competition law scrutiny” and ii) “the fact that the Commission announced a continued monitoring of patent settlements and the opening of competition proceedings in the Servier case.”³⁵ Notwithstanding, the European Commission stressed that “to better understand the use of this type of agreement in the European pharmaceutical sector and to identify settlements that delay generic market entry in a potentially anti-competitive manner the monitoring exercise will be continued for at least another year to see whether any further action is needed.”³⁶

27. In this context, the results of the first patent monitoring exercise i) sparked off a second one, which showed a continuing decline of settlements potentially problematic under EU antitrust rules – and ii) encouraged the Commission to open three formal proceedings with respect to patent settlements.³⁷ This second patent monitoring was followed by a third, which led the European Commission to conclude that the number of B.II settlements stabilized at a low level, stating though that the monitoring exercise might continue in order to examine further the development of the foregoing trends. Regarding formal proceedings, the European Commission hitherto closed procedural case against Servier along with the investigation in pharmaceutical companies AstraZeneca and Nycomed and opened procedures against Johnson&Johnson and Norvartis.³⁸

3. Practical significance

3.1. What can the EU learn from the USA experience?

28. Given that the European Commission’s orientation with regard to reverse payments takes into consideration the practice in the USA, in particular the FTC’s (Federal Trade Commission) enforcement policy, it deems noteworthy the legal reasoning applied by the FTC and the US courts.³⁹

29. In the USA, the assessment of patent settlement’s lawfulness is the subject of ongoing controversy, in which FCT and US courts tend to take different approaches. On the one hand, the “scope of the patent test” is largely endorsed by the latter. In sum, “courts have gravitated toward the scope of the patent test under which reverse payments are permitted so long as (1) the exclusion does not exceed the patent’s scope, (2) the patent holder’s claim of infringement was not objectively baseless, and (3) the patent was not procured by fraud on the PTO”⁴⁰ Nevertheless, in the *K-Dur* case, the U.S. Third Circuit expressly rejected the mentioned “scope of the patent test” that has been almost uniformly adopted by other courts of appeals and, in sharp contrast, suggested a rule of reason analysis “based on the economic realities of the reverse payment settlement rather than the labels applied by the settling parties. Specifically, the finder of fact must treat any payment from a patent holder to a generic patent challenger who agrees to delay entry into the market as *prima facie* evidence of an unreasonable restraint of trade, which could be rebutted by showing that the payment (1) was for a purpose other than delayed entry or (2) offers some pro-competitive benefit.”⁴¹

30. Rather than adopt what it considered “an un rebuttable presumption of patent validity,” the U.S Third Circuit simply considered a patent as a legal conclusion reached by the Patent Office.⁴² Accordingly, based on several Supreme Court views, it stressed that given that valid patents are a limited exception to a general rule of the free exploitation of ideas, the public interest supports judicial testing and elimination of weak patents. In this sense, in fact, one may endorse the view of the Court given that reverse payments do not assure the lawfulness of the patent underpinning the sharing of monopoly rents between would-be competitors.

31. Furthermore, The U.S Third Circuit also judged the “scope of the patent test” improperly restrictive to the application of antitrust law and contrary to the policies underlying the HatchWaxman Act, considering that even though judicial preference for settlement should be deemed generally laudable, it should not displace countervailing public policy objectives, as it is the Hatch-Waxman Act. Under Hatch-Waxman Act, manufacturers of generic drugs are encouraged to challenge weak or invalid patents on brand name drugs so consumers can enjoy lower drug prices by a 180-day exclusivity period as reward for successfully challenging. The U.S Third Circuit stressed that “patent challenges are necessary to protect consumers from unjustified monopolies by name brand drug manufacturers.”⁴³

³⁵ 1st Report on the Monitoring of Patent Settlements (period: mid 2008 -end 2009), p. 13, published on 5 July 2010, available at http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/patent_settlements_report1.pdf (5 November 2012).

³⁶ *Ibid.*

³⁷ Commission opens formal proceedings against Les Laboratoires Servier and a number of generic pharmaceutical companies, in http://europa.eu/rapid/press-release_MEMO-09-322_en.htm?locale=en; Commission opens formal proceedings against pharmaceutical company Lundbeck, in http://europa.eu/rapid/press-release_IP-10-8_en.htm?locale=en; Commission opens investigation against pharmaceutical companies Cephalon and Teva, in http://europa.eu/rapid/press-release_IP-11-511_en.htm?locale=en (5 November 2012).

³⁸ *Vide* <http://ec.europa.eu/competition/sectors/pharmaceuticals/news.html> (5 November 2012).

³⁹ Pharmaceutical Sector Inquiry, part 1 (...), pp. 286 - 291.

⁴⁰ *Vide* United States Court of appeals for the third circuit, n° 10-2077, *In Re: K-DUR* Antitrust Litigation, July 16, 2012, p. 16, available at http://newsandinsight.thomsonreuters.com/uploadedFiles/Reuters_Content/2012/07_-_July/3rd_Circuit%20K-Dur_Decision.pdf (5 November 2012). In this sense, *vide In Re: Tamoxifen Citrate* Antitrust Litigation, United States Court of Appeals for the second circuit, 466 F.3d 187 August 10, 2006; *Schering-plough Corporation, Upsher-Smith Laboratories, Inc. v. FCT*, United States Court of Appeals for the eleventh circuit, March 8 2005; *In Re: Ciprofloxacin Hydrochloride* Antitrust Litigation, United States Court of Appeals, Federal Circuit, October 15 2008.

⁴¹ *In Re: K-DUR*(...), pp. 32-33.

⁴² *In Re: K-DUR* (...), p. 27.

⁴³ *In Re: K-DUR* (...), p. 32.

32. The *K-Dur* is a landmark case underpinning the views that FTC have been taken for years, pursuant to which brand-name pharmaceutical companies shall not pay generic-drug companies to stay out of the market. This case might be a far reaching change although, as above mentioned, US courts tend to take a different approach. Sooner or later, it will be up to the Supreme Court to settle the question of whether reverse-payment settlements can be challenged on antitrust grounds when they do not seek the expansion of the monopoly provided by the patent.

33. What is more, still in the USA context, the President's 2013 Budget Proposal clearly enshrines a sharp willingness to scrutinize reverse payments: *"the high cost of prescription drugs places a significant burden on Americans today. The Administration proposes to increase the availability of generic drugs and biologics by authorizing FTC to stop companies from entering into anti-competitive deals, known also as 'pay for delay' agreements, intended to block consumer access to safe and effective generics. Such deals can cost consumers billions of dollars because generic drugs are typically priced significantly less than their branded counterparts. These agreements reduce competition and raise the cost of care for patients both directly, through higher drug and biologic prices, and indirectly through higher health care premiums."*⁴⁴

3.2. Conclusion

34. In a nutshell and plainly speaking, the experience in the European Union is far from being as enriching as it in the US.

35. Even though, it is noteworthy the Luxembourg Court's view in *Bayer v. Sülhöfer*, pursuant to which *"article 85 (1) [101(1)TFUE] makes no distinction between agreements whose purpose is to put an end to litigation and those concluded with other aims in mind."*⁴⁵

36. As discussed above, reverse payments are currently the subject of close scrutiny by the European Commission, albeit it used to take the view that in the context of a settlement and non-assertion agreement, non-challenge tended to be considered to fall outside of article 101 (1) TFUE.⁴⁶

37. Therefore, pharmaceutical companies should behave very carefully with regard to patent settlements restricting generic entry. It is not safe to rely on the *"scope of the patent test"*. Companies should consider whether their compliance procedures need updating.

38. That being said, following the example from both the FTC and the *K-Dur* case, should the burden of proof rest on the shoulders of the European Commission? The following telltale sign seems to answer the question positively: *"during the public consultation, some stakeholders expressed concern that all settlement agreements which were characterized as B.II in the report were deemed anticompetitive. In this regard it is important to underline, as stated in the beginning of this chapter, that any assessment of whether a certain settlement could be deemed compatible or incompatible with EC Competition Law would require an in-depth analysis of the individual agreement, taking into account the factual, economic and legal background."*⁴⁷ So, will a bold and tentatizing presumption of illegality come into play? Perhaps not, but that is up to the near future to unveil. Be that as it may, the state of play in the EU is described by a rather narrower scrutiny over the lawfulness of settlements agreements. There is a call for clearing up the game rules, specially urged by innovation and Public Health concerns. Given that the level of the playing field is mostly being established in regard to the US experience, the upshot is that the rules of the game are, once again, a hurdle to certainty. ■

⁴⁴ Fiscal Year 2013 Cuts, Consolidations, and Savings Budget of the U.S. Government, p. 171, available at <http://www.whitehouse.gov/sites/default/files/omb/budget/fy2013/assets/ccs.pdf> (5 November 2012).

⁴⁵ C-65/86, *Bayer AG v. Heinz Sulhofer*, 27 September 1998, § 15.

⁴⁶ Guidelines on the application of Article 81 of the EC Treaty to technology transfer agreements (2004/C 101/02), § 209, available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2004:101:0002:0042:EN:PDF> (5 November 2012).

⁴⁷ Pharmaceutical Sector Inquiry, part 1 (...), p. 277. In the same sense, P.L. Parcu & M.A. Rossi, Chapter 9 – Negotiated Foreclosure and IPRs: Recent Developments in *op.cit.* edited by Caggiano, Giandonato; Muscolo, Gabriella; Tavassi, Mariana.

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