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GENERIC PHARMACEUTICALS

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NOTE ON THE COMMISSION'S RECENT ENFORCEMENT OF EU ANTITRUST RULES IN THE PHARMACEUTICAL SECTOR

1. Introduction

1. The Commission has in recent years investigated practices by pharmaceutical companies that may have undermined effective competition in the pharmaceutical markets, in particular practices to delay or hamper the introduction of generic medicines upon patent expiry.

2. Thanks to generic competition, patients can have access to affordable healthcare: through generics they can get their treatment significantly cheaper. It also ensures that public health systems can remain economically sustainable in times of budgetary constraints. Pharmaceutical expenditure absorbs significant portions of budgets of governments and households. It is therefore crucial that European citizens are not deprived of cheaper health bills by anticompetitive practices. Moreover, competition by generics is also a dynamic force which stimulates pharmaceutical companies to continue to invest in research and to develop innovative treatments, as they cannot rely forever on their current blockbuster products.

3. In 2008, the Commission launched the Pharmaceutical Sector Inquiry (SI) aimed at uncovering the causes of the apparent low levels of competition in this sector. The SI final report, published in July 2009, showed a decline in the number of novel medicines reaching the market and identified significant delays in the market entry of generic drugs. SI findings suggested that company practices are among the causes, but do not exclude other factors such as shortcomings in the regulatory framework.¹

4. The use of specific practices by originator and generic companies in order to delay generic entry has since been subject to increased scrutiny by competition authorities if used in a way that may constitute an infringement under Article 101 or 102 of the TFEU. These potentially anti-competitive practices notably include the misuse of the patent and regulatory systems and the so-called pay-for-delay agreements (often in the context of patent settlements).

5. A number of antitrust investigations have been conducted, some of which are still under way. The Commission has adopted decisions in the Citalopram case² and the Fentanyl case,³ and the investigations of the Perindopril case⁴ and the Modafinil case⁵ are under way.

¹ The full texts of the Commission Communication on the final report (hereinafter: Commission Communication) as well as the final report as technical annex to the communication are available at the website of DG Competition: <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html>. See also Press Release IP/09/1098 and MEMO/09/321.

² http://europa.eu/rapid/press-release_IP-13-563_en.htm

³ http://europa.eu/rapid/press-release_IP-13-1233_en.htm

⁴ http://europa.eu/rapid/press-release_IP-12-835_en.htm

⁵ http://europa.eu/rapid/press-release_IP-11-511_en.htm

6. The Commission has also been monitoring patent settlements between pharmaceutical companies, focusing its attention on those that might limit or delay the market entry of generic drugs. As a result of this exercise, the Commission has published since 2010 yearly reports on the monitoring of patent settlements, providing figures on the evolution of the number and types of patent settlement agreements signed by pharmaceutical companies in Europe.

7. Regarding the misuse of the patent and regulatory systems, in December 2012 the Court of Justice of the EU dismissed an appeal brought by AstraZeneca against the judgement by the General Court of 2010, which had largely upheld the Commission's decision of 2005.⁶ The Court's judgement made it clear that misuse of regulatory procedures, including the patent system, may infringe EU competition rules.

8. This contribution aims at providing an overview of these recent developments on the Commission's efforts to enforce EU competition law in European pharmaceutical markets. The document is structured as follows: in Section 2 we provide the background and discuss the relevance of the Courts' judgements on the AstraZeneca case, in Section 3 we summarise the public information available on the Commission's investigations concerning pay-for-delay agreements, and in Section 4 we describe the main findings of the Commission's patent settlement monitoring exercise.

2. The AstraZeneca case

9. On 15 June 2005 the Commission adopted a decision on inter-brand competition by which it found that AstraZeneca had committed two abuses of a dominant position. AstraZeneca was fined for abusing its dominant position by misusing the rules for the grant of supplementary patent certificates and marketing authorisations to delay generic entry of its ulcer treatment drug Losec.

10. The first abuse consisted mainly of a pattern of allegedly misleading representations made before the patent offices in Germany, Belgium, Denmark, Norway, the Netherlands and the United Kingdom. The second abuse consisted of the submission of requests for deregistration of the marketing authorisations for Losec capsules in Denmark, Norway and Sweden, combined with the withdrawal from the market of Losec capsules and the launch of a new version of that product (Losec MUPS tablets) in those three countries. The abuses found constituted abuses of regulatory proceedings.

11. This was the first Commission's decision on abuse of dominance in the pharmaceutical markets. It fined AstraZeneca €60 million due to its infringements of Article 102 TFEU and Article 54 of the European Economic Area (EEA) Agreement (IP/05/737).

12. AstraZeneca appealed the Commission's decision, but in July 2010 the General Court⁷ very largely dismissed the appeal by AstraZeneca, upholding the Commission's decision. With this judgement, the General Court confirmed that Article 102 of the TFEU, which prohibits abuses by dominant companies, applies to the pharmaceutical sector. The General Court annulled part of the Commission's decision in respect of the second abuse, insofar as it concerned the restrictions on parallel trade in two of the three countries concerned, resulting in a lowering of the fine from 60 to 52.5 million euros.

13. In relation to the first abuse, the General Court confirmed that AstraZeneca's conduct amounted to "a consistent and linear course of conduct, characterised by the communication to the patent offices of misleading representations for the purpose of obtaining the issue of SPCs (Supplementary Protection Certificates) to which it was not entitled or to which it was entitled for a shorter period".⁸ Through its

⁶ Judgment in *AstraZeneca v Commission*, C-457/10 P, EU:C:2012:770

⁷ Judgment of 1 July 2010, *AstraZeneca v Commission*, T-321/05, ECR, EU:T:2010:266

⁸ Paragraph 598 of the judgement.

conduct, AstraZeneca obtained additional so-called SPC protection in several countries. Such intellectual property protection constituted a principal entry barrier for generic versions of an original medicine. The General Court rejected AstraZeneca's claims that its conduct constituted normal competition and that it could be explained by errors or unauthorised behaviour by AstraZeneca's patent agents. More generally, the General Court found that the assessment 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.

14. As regards the second abuse, the General Court validated the Commission's conclusion that a key purpose underlying AstraZeneca's deregistration of market authorisations for Losec in selected EEA countries was to exclude competition from generic firms and parallel traders. The General Court ruled that the purpose of a market authorisation was to confer the right to market a pharmaceutical product and not to exclude competitors from the market. Moreover, the General Court stated that an undertaking which holds a dominant position has a special responsibility under Article 102 and that it cannot therefore use regulatory procedures in such a way as to prevent or make more difficult entry of competitors on the market, in the absence of grounds relating to the defence of legitimate interests of an undertaking engaged in competition on the merits or in the absence of objective justification.

15. The General Court also found that the illegality of abusive conduct under Article 102 is unrelated to the compliance or non-compliance by an undertaking of other legal rules and that in the majority of cases abuses of dominant positions consist of behaviour which is otherwise lawful under branches of law other than competition law.

16. AstraZeneca appealed the General Court's judgement, but in December 2012 the Court of Justice of the EU⁹ dismissed the appeal, in what became the first ruling by the Court of Justice on a Commission's decision on the abuse of a dominant market position in the pharmaceutical sector.

17. The Court of Justice's judgement clarified a number of issues of principle in relation to market definition, dominance and the concept of an abuse in the meaning of Article 102 TFEU. In particular, it confirmed that misuses of regulatory procedures could in certain circumstances constitute abuses of a dominant position within the meaning of EU antitrust rules (Article 102 of the TFEU). The judgment also confirmed the Commission's method to define the relevant product market and existence of a dominant position in that case. The judgment also confirmed that intellectual property rights constitute a factor relevant to the determination of dominance.

3. The legal and economic assessment of pay-for-delay agreements

18. In the pharmaceutical sector, once the SPC period has expired and the active ingredient is no longer protected, that active ingredient can in principle be used by generic companies to produce and sell generic medicines containing the identical active ingredient in question. In that situation, the originator and the generics involved in the development of the generic versions of the same product may be at least potential competitors, if not already actual ones. They should therefore, in principle, show independent commercial conduct.

19. Often potential generic entrants challenge the validity of the patents or protection enjoyed by originators, either seeking a declaration of invalidity by a court or entering the market at risk. Conversely, originators may claim that a potential generic competitor may be infringing some of its patents. In this context, originator and generic companies are generally entitled to reach an agreement and settle their

⁹ Judgment in *AstraZeneca v Commission*, C-457/10 P, EU:C:2012:770

patent litigation, avoiding the costs of pursuing litigation to judgement. Patent settlements can bring real benefits through avoided litigation costs and earlier generic entry.

20. The jurisprudence has established that agreements between companies regarding patents, including agreements dealing with or settling patent disputes, are not immune from competition law scrutiny.

21. The overwhelming majority of patent settlement agreements are in fact entirely legitimate. However, an agreement between an originator and its potential generic competitors to prevent generic entry in exchange for a value transfer from the originator can be a restriction of competition contrary to Article 101 of the TFEU. This is notably the case when the value transfer induces the delay in market entry by the generic potential entrant.

22. The Commission's efforts to enforce antitrust rules in the pharmaceutical sector has materialised in a number of investigations concerning pay-for-delay agreements. The Commission has adopted decisions in the Citalopram case¹⁰ and the Fentanyl case,¹¹ and the investigations of the Perindopril case¹² and the Modafinil case¹³ are under way.

3.1 *The Citalopram case*

23. In July 2013, the Commission adopted the decision of imposing a fine of €3.8 million on Lundbeck and fines totalling €2.2 million on several producers of generic medicines for delaying generic market entry of the drug Citalopram. According to the Commission's findings, the agreements between Lundbeck and its generic competitors concerning Citalopram – namely, Alpharma, Merck, Arrow and Ranbaxy - violated Article 101 of the TFEU that prohibits anticompetitive agreements. The Citalopram decision has been the first prohibition decision by the Commission concerning pay-for-delay patent settlement agreements.

24. Citalopram is a medicine developed by Danish pharmaceutical company Lundbeck to treat the symptoms of major depression. In 2002, this product, which was Lundbeck's best-selling medicine, was nearing the end of its life cycle. After Lundbeck's basic patent for the Citalopram molecule had expired, it only held a number of related process patents which provided a more limited protection. At that point, it therefore became possible for competitors to enter the market with generic versions of Citalopram. Indeed, one of them started to sell generic Citalopram while others were all preparing to launch their own versions of the product.

25. However, when these generic competitors were close to entering the market, Lundbeck agreed with each of them that they would stay out. Instead of competing, the generic producers agreed not to enter the market in return for substantial payments and other inducements from Lundbeck amounting to tens of millions of euros. Lundbeck paid significant lump sums, purchased generics' stock for the sole purpose of destroying it, and offered guaranteed profits in a distribution agreement. The agreements gave Lundbeck the certainty that the generics producers would stay out of the market for the duration of the agreements without giving the generic producers any guarantee of market entry thereafter. Lundbeck did not prevent market entry by successfully enforcing its patent rights; rather, it simply paid other companies so that they would not compete, giving them the equivalent of what they would have earned if they had entered the

¹⁰ http://europa.eu/rapid/press-release_IP-13-563_en.htm

¹¹ http://europa.eu/rapid/press-release_IP-13-1233_en.htm

¹² http://europa.eu/rapid/press-release_IP-12-835_en.htm

¹³ http://europa.eu/rapid/press-release_IP-11-511_en.htm

market. This means they shared the monopoly rents among themselves: internal documents even spoke of this group of companies as a "club" and referred to "a pile of dollars" to be shared.

26. All this occurred at the expense of patients who were deprived of access to cheaper medicines. It also harmed public health systems, which for a longer period had to artificially bear the costs of an expensive medicine – and one of the most widely prescribed antidepressants. The difference in price was not small: in the UK once generic versions of Citalopram did enter the market, prices dropped on average by 90%.

3.2 *The Fentanyl case*

27. After investigating an agreement between J&J and Novartis, in December 2013 the Commission concluded that it was an anticompetitive agreement with the object of delaying the market entry of a cheaper generic version of the painkiller Fentanyl in the Netherlands, infringing Article 101 of the TFEU. The Commission imposed fines of €10.7 million on J&J and €5.4 million on Novartis.

28. The Fentanyl case constitutes an example of a pay-for-delay agreement that is unrelated to any patent dispute or litigation. This type of agreement has been referred to as "naked" pay-for-delay agreement.

29. Fentanyl is a painkiller 100 times more potent than morphine. It is used notably for patients suffering from cancer. US pharmaceutical company Johnson & Johnson (J&J) initially developed Fentanyl and commercialised it in different formats since the 1960s. In 2005, J&J's protection on the Fentanyl depot patch had expired in the Netherlands and the Dutch subsidiary of Swiss firm Novartis, Sandoz, was on the verge of launching its generic Fentanyl depot patch. It had already produced the necessary packaging material.

30. However, in July 2005, instead of actually starting to sell the generic version, Sandoz concluded a so-called "co-promotion agreement" with Janssen-Cilag, J&J's Dutch subsidiary. The agreement provided strong incentives for Sandoz not to enter the market. Indeed, the agreed monthly payments exceeded the profits that Sandoz expected to obtain from selling its generic product, for as long as there was no generic entry. Consequently, Sandoz did not offer its product on the market. The agreement was stopped in December 2006 when a third party was about to launch a generic Fentanyl patch.

31. The agreement therefore delayed the entry of a cheaper generic medicine for seventeen months and kept prices for Fentanyl in the Netherlands artificially high - to the detriment of patients and taxpayers who finance the Dutch health system.

32. According to internal documents there would be no entry into the Dutch market in exchange for "a part of [the] cake". Instead of competing, Janssen-Cilag and Sandoz agreed on cooperation so as "not to have a depot generic on the market and in that way to keep the high current price". Janssen-Cilag did not consider any other existing potential partners for the so-called "co-promotion agreement" but just focused on its close competitor Sandoz. Sandoz engaged in very limited or no actual co-promotion activities.

3.3 *The Perindopril case*

33. An investigation by the Commission is under way about a number of agreements between the French pharmaceutical company Servier and several generic companies concerning the cardio-vascular drug Perindopril. These agreements may have hindered the entry of generic Perindopril into markets in the EU.

34. In July 2012, the Commission informed the French pharmaceutical company Servier and several of its generic competitors of its objections against practices potentially delaying the generic entry of

Perindopril. At that stage, the Commission took the view that the patent settlement agreements concluded by Servier with Niche/Unichem, Matrix (today Mylan Laboratories Limited), Teva, Krka and Lupin, as well as Servier's acquisition of key competing technologies were aimed at delaying or preventing the market entry of cheap generic versions of Perindopril, in violation of EU antitrust rules. The sending of a statement of objections does not prejudice the final outcome of the investigation, whose decision is still pending.

3.4 *The Modafinil case*

35. In April 2011, the Commission opened a formal antitrust investigation to assess whether an agreement between US-based pharmaceutical company Cephalon and Israel-based generic drugs firm Teva might have had the object or effect of hindering the entry of generic Modafinil in the European Economic Area. Modafinil is a medicine used for the treatment of certain types of sleeping disorders.

36. In December 2005 Cephalon and Teva settled patent infringement disputes in the United Kingdom and the United States concerning Modafinil. As part of the settlement agreement Teva undertook not to sell its generic Modafinil products in the EEA markets before October 2012. A series of side deals were included into the settlement agreement, which has also been subject to antitrust litigation in the United States initiated by the US antitrust authority FTC. Hence, the Modafinil case provides an example where the alleged infringement of Article 101 of the TFEU could have taken the form of a patent settlement agreement with a value transfer consisting in a series of side deals.

4. The Commission's patent settlement monitoring exercise

37. As announced in the Commission's Communication concluding the SI, it has been considered important to continue monitoring the patent settlements between originator and generic companies over time.¹⁴ The main objectives of the monitoring exercise are to better understand the use of this type of agreement in Europe and to identify those settlements that delay generic market entry to the detriment of the European consumer possibly in violation of European competition law.¹⁵

38. As already discussed above, like in any other area of commercial disagreement, the parties concerned have a legitimate interest in finding a mutually acceptable compromise. In particular the parties may prefer to discontinue the dispute or litigation because it is too costly, time-consuming and/or risky as regards its outcome. Settlements are thus a generally accepted, legitimate way of ending private disagreements. They can also save courts and/or competent administrative bodies such as patent offices' time and effort. Therefore, they can have some positive impact in the interest of society.

39. However, some patent settlements in the pharmaceutical sector may prove to be problematic from a competition law perspective. The pay-for-delay patent settlements extensively discussed in this document are of particular interest, as they may lead to a delay of generic entry in return for a value transfer by the originator company to the generic company. Other examples of possibly problematic agreements relate to settlements that contain restrictions beyond the exclusionary zone of the patent, meaning that they would reach beyond its geographic scope, its period of protection or its exclusionary scope. Such agreements would not appear to be directly related to the IP rights granted by the patents concerned. Furthermore, problematic agreements include settlement agreements on a patent which the patent holder knows does not meet the patentability criteria. An example of this is a situation where the patent was granted following the provision of incorrect, misleading or incomplete information. Ultimately, it may be the consumer who pays the price for a delay in market entry resulting from such agreements and therefore any benefits to society

¹⁴ <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html>

¹⁵ Commission Communication, p. 20.

are more than outweighed by the negative effects of the agreement between potential competitors. In this context, obviously, an assessment of each individual case would be necessary.

4.1 *A categorisation of patent settlement agreements*

40. In the SI final report, the Commission proposed a categorisation of patent settlement agreements which has been used for the purpose of this monitoring exercise. Agreements that do not restrict the generic company's ability to market its own product are categorised as A-type, while those limiting generic entry are categorised as B-type. Agreements limiting generic entry are further categorised in two groups: (i) B.I settlements, which comprise those settlements where no value transfer from the originator to the generic company took place; and (ii) B.II settlements which foresee a value transfer from the originator to the generic.

41. Typically, category A settlements should be unproblematic from a competition law perspective, as they allow immediate market entry by the generic company with its own product (unilateral conduct of the originator company that might have caused generic delay would remain subject to competition law scrutiny).

42. The same applies to category B.I settlements. Nonetheless, some settlement agreements in this category may attract competition law scrutiny. This may be the case for settlements concluded outside the exclusionary zone of the patent 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.

43. By contrast category B.II settlements are likely to attract antitrust scrutiny since they limit access to the market and contain a value transfer from the originator to the generic. Nonetheless, this is not to suggest that agreements falling into this category would always be incompatible with EU competition law. This needs to be assessed on the basis of the circumstances of each individual case.

4.2 *Evidence from the monitoring exercise*

44. The last monitoring exercise undertaken by the Commission covered the period of 1 January 2012 until 31 December 2012, i.e. 12 months.¹⁶ It unearthed 183 patent settlement agreements concluded in the EEA. In line with the upward trend described in the previous monitoring reports, the last exercise confirmed the increasing use of patent settlements in the European pharmaceutical sector measured by the number of patent settlements concluded. The annual average of 24 patent settlements concluded in the period covered by the sector inquiry steadily increased to 183 settlements in the year 2012. Also, the number of INNs which were the subject of settlements increased significantly from less than 10 INNs in the first three years of the millennium to more than 40 in 2012. As with the former three exercises, the results of the last monitoring exercise showed that the Commission's investigative activity did not hinder companies from concluding settlements.

45. The amount of B.II settlements (i.e. settlements which restrict generic entry and show a value transfer from the originator to the generic company) stabilized at a low level. In the period covered by the sector inquiry, B.II settlements represented 22% of all settlements reported, or five settlements per year on average. This percentage decreased steadily over the years to reach 7% in the period of the last exercise or 12 in absolute terms.

¹⁶ All Reports on the Monitoring of Patent Settlements published by the Commission can be found at the following link: <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html>

46. The statements of certain stakeholders during the SI that the Commission would be forcing companies to litigate each patent dispute until the end has proved to be unfounded, given the substantial increase in settlements overall. In addition, 93% of the settlements fall into categories not raising prima facie any need for competition law scrutiny. Companies, in most cases, seem to have been able to solve their disputes in a manner that is typically considered unproblematic from a competition law perspective.

5. Conclusion

47. The Commission has been over the last years resolute in enforcing EU antitrust rules in the pharmaceutical sector. This effort has led to the finding of a number of infringements of both Articles 101 and 102 of the TFEU.

48. The decision on the AstraZeneca case was the first decision by the Commission finding an abuse of dominance in the pharmaceutical sector, constituting an infringement of Article 101 of the TFEU. The Courts upheld the Commission's view that misuse of regulatory procedures, including the patent system, may infringe EU competition rules.

49. Since the closing of the SI, a number of investigations have been under way concerning agreements whereby an originator used value transfers to induce potential generic competitors not to enter the market. These investigations have already led to two prohibition decisions being adopted by the Commission due to infringement of Article 101 of the TFEU.

50. Rewards to innovation and effective competition both crucially contribute to patients having access to affordable medicines today and better innovative medicines tomorrow. Misusing regulatory procedures to exclude competitors or paying competitors to stay out of the market at the expense of European citizens are distortions of effective competition that have nothing to do with the legitimate protection of intellectual property: these are illegal practices that the Commission is determined to fight against.