

12. AT THE CROSSROADS BETWEEN COMPETITION LAW AND INTELLECTUAL PROPERTY: PATENT SETTLEMENT AGREEMENTS IN THE PHARMACEUTICAL SECTOR

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ABSTRACT

The pharmaceutical sector is being subject to increasing competition law scrutiny. This is not surprising, given the significant potential for distortion of competition in this market; and the sheer importance of this market for public health policy.

The most prominent competition concerns may stem from pharmaceutical patents and the monopoly power that they confer; power that is susceptible to various abuses, such as preventing the market entry of rival generic companies, entering into trade restricting settlement agreements, and misusing supplementary protection certificate rights and regulatory processes.

Many such abusive practices are currently under scrutiny by the European Commission, particularly patent settlement agreements between originators and generics which have the effect of delaying entry of cheaper medicines into the EU market and distorting competition.

This article begins by offering a general overview of the interplay between competition law and intellectual property (IP) rights in the pharmaceutical sector. It then focusses specifically on the norms relating to 'pay-for-delay' agreements, discussing various cases from the EU in this regard. It also discusses some national case law from the UK, Italy and Turkey and touches upon comparative aspects of the approaches to similar issues under US law.

It is argued that competition law may take priority over IP rights; hence pharmaceutical companies ought to be more careful about their practices and agreements with other market participants to mitigate the risk of attracting competition law liability including heavy monetary fines. In assessment of patent settlement agreements there should be neither per se permission nor per se prohibition, instead the rule of reason or the (rebuttable) presumption of illegality. In any case, a deep analysis of the agreements, circumstances of the case and economic rationale/public health imperatives are essential.

Keywords: *patent settlement agreements, pharmaceuticals, generics, originators, anticompetitive,*

compulsory licensing, EU, Turkey, sanctions, abuse of dominance, competition law

1. INTRODUCTION

We are witnessing an increasing enforcement of competition law across various sectors, including the pharmaceutical sector. Anticompetitive agreements (patent settlement agreements, restrictions in distribution agreements), abuse of dominance (tying, refusals to license, excessive pricing) and merger control constitute the main pillars of competition law, which may also be regarded as the main concerns in IP-related industries.

The most common concern for the competition authorities is the possible violation of competition law in IP-related industries due to the existence of patents, trademarks, and copyright, which grant exclusive power that may potentially be abused by IP rights holders to the detriment of consumer welfare as well as innovation. Hence, competition law is applicable to the area of IP and may be invoked by consumers and any interested/affected third parties to ensure that the IP rights holders are not abusing their (dominant, if not monopolistic) positions.

At the same time, IP rights holders may rely on competition law to protect themselves from unfair competition and encourage more competition and innovation in the relevant market.

There has been a tension between IP law and competition law in the pharmaceutical sector. The pharmaceutical sector may be considered a 'strategic' sector for most jurisdictions, and competition authorities worldwide have started to focus their efforts on ensuring effective competition by way of controlling potentially anticompetitive practices. This is due to the importance of the pharmaceutical sector in the health system, and a great potential for distortion of competition in this market due to the existence of patents, which may confer limited monopoly rights on pharmaceutical companies that could lead to various abuses, such as, to name a few, the impediment to parallel trade and/or prevention of market entry of rival generic companies.

Practices preventing or delaying the entry of generic rivals into the pharmaceutical market, particularly, the contents of patent settlement agreements, have been under the

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scrutiny of the European Commission in recent years.¹ This is because the generic-side competition is essential for a proper functioning of the market as well as consumer welfare. Over the past few years, the European Commission has been monitoring patent settlement agreements in order to identify those settlements which could potentially be problematic from a competition law perspective — namely those that limit generic entry against a significant value transfer from an originator to a generic company. Patent settlement agreements between originators and generics very often delay the entry of cheaper medicines into the market and ‘extend the period of monopoly profits.’²

This article gives a general overview of the interplay between competition law and IP rights (focusing on the pharmaceutical sector), analyses the potentially problematic ‘pay-for-delay’ agreements from the point of view of competition law, and provides highlights of the latest investigations into the pharmaceutical sector in relation to patent settlement agreements at the EU and national level, including Turkey.

It is concluded that pharmaceutical companies should be more aware of their practices and agreements with other market participants: they should not assume that ‘their intellectual property rights will stand in the way of finding an antitrust infringement’³ - their behavior will be scrutinized closely by the competition authorities and there are high chances that competition law may take priority over their IP rights.

As for the Competition Authority’s approach to such agreements, there should be neither per se permission nor per se prohibition, instead the rule of reason or the (rebuttable) presumption of illegality. In any case, a deep analysis of the agreements, circumstances of the case and economic rationale are essential.

2. HIGHLIGHTS OF INTERPLAY BETWEEN COMPETITION LAW AND IP IN THE PHARMACEUTICAL SECTOR IN THE EU

The competition rules applicable to the pharmaceutical sector are not harmonised within the EU single market,⁴ however, pharmaceutical companies are obliged to comply with the EU competition rules⁵. There are a number of areas which can potentially be problematic from the competition law perspective and where pharmaceutical companies should be particularly careful not to violate the law.

First of all, parallel trade, patent settlements (pay –for delay), SPC and deregistration of pharmaceutical products may fall under art. 101 of the Treaty on the Functioning of the European Union (TFEU) and can be considered as anticompetitive and forbidden practices under certain circumstances.⁶

Secondly, the most prominent competition concerns stem from pharmaceutical patents and the dominance power that they confer. Dominance invokes a special responsibility for an undertaking to behave in a certain way in the market. Abuse of dominance is prohibited under art. 102 of the TFEU.

¹ In July 2009, the European Commission launched an inquiry into the pharmaceutical sector, the outcome of which is summarised in the European Commission Communication on the final report, <<http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/>> Accessed 6 August 2014. It continues to monitor this sector. In this respect in December 2015 it published its *6th Report on the Monitoring of Patent Settlements* <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/patent_settlements_report6_en.pdf> (2 December 2015) Accessed 15 May 2017.

In March 2018 the European Commission published its *8th Report on the Monitoring of Patent Settlements* (covering period: January-December 2016) http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/patent_settlements_report8_en.pdf, accessed 25 September 2018

² Lawrence S, Bond E, Patent settlement agreements and competition law in the UK (2016) <[http://www.bristows.com/assets/pdf/Patent%20Settlement%20IPM\(1\).PDF](http://www.bristows.com/assets/pdf/Patent%20Settlement%20IPM(1).PDF)> accessed 10 June 2017

³ Hancher L, Sauter W, ‘A dose of competition: EU antitrust law in the pharmaceuticals sector’ (October 2016) *Journal of Antitrust Enforcement*, Volume 4, Issue 2, October 2016, p. 381–410

<<https://academic.oup.com/antitrust/article/4/2/381/2196289/A-dose-of-competition-EU-antitrust-law-in-the>> accessed 15 October 2017

⁴ This market is regulated at the national level, i.e. national pricing and re-imbursement rules for medicines are not harmonised within the EU market.

⁵ In addition to competition law, state rules are also applicable to pharmaceutical companies. State aid is an advantage/support in any form conferred on a selective basis to companies by public authorities. Because a company that receives the government support gains a competitive advantage over its rivals, the Treaty of the Functioning of the EU (TFEU) generally prohibits state aid, unless it can be justified by the general economic development. State aid rules envisage the notification/exemption system. The EC is in charge of ensuring that the state aid is compliant with the TFEU. State aid may raise concerns when tax exemptions or direct grants are given to pharmaceutical companies, providing unfair treatment to other operators in this market, or by over compensating publicly-owned hospitals.

⁶ Article 101 TFEU is a general prohibition of (horizontal and/or vertical) agreements between two or more independent undertakings which restrict competition (e.g. price-fixing and/or market sharing etc.).

Thirdly, mergers between pharmaceutical companies are of particular concern when it comes to multinational companies with strong market positions. It is important to ensure that a new merger neither impedes generic competition, nor limits competition in research and development.

This paper focusses on anticompetitive practices and abuse of dominance in the pharmaceutical sector, since those are most common there. Very often these violations come together in one case (see for instance the Servier case below) - a violation of art.101 TFEU and also abuse of a dominant position under art.102 TFEU.

A. ABUSE OF DOMINANCE VIA SUPPLEMENTARY PROTECTION CERTIFICATES

Supplementary protection certificates (SPCs) are a unique intellectual property right that extends the duration of the exclusive rights of a pharmaceutical company for its products under patent protection. It enters into force after the expiry of a patent upon which it is based. Such certificates compensate for the length of time needed to obtain authorisation to put products on the market.⁷ A lifetime of an SPC is up to five years and can be extended up to five and a half years under the paediatric rules.⁸

The methods used by pharmaceutical companies in trying to prolong patent protection for their products may very often breach competition law, as such methods prevent or delay the entry of generic products into the market. AstraZeneca was fined €60 million for abusing the patent system for authorisation of pharmaceutical products to delay the entry of generics. AstraZeneca made misleading representations to national patent offices to obtain SPCs for longer periods than it would otherwise have, or in some cases to obtain SPCs which the patent offices would not even have granted in the absence of the misleading representations.⁹

The case is significant as it is the first time that an abuse of the regulatory processes was held to be an abuse of a dominant position under EU competition law. This approach was confirmed by the Court of Justice of the EU and can be expected to result in more similar cases being brought (not limited to the pharmaceutical sector only). The European Commission, just as any competition authority, has jurisdiction to ensure that activities of

undertakings comply with competition rules; it does not have a jurisdiction to redress and penalize for other offenses, i.e. fraud. However, it does have power to sanction any anticompetitive behaviour and abuses by imposing heavy fines. According to this case, a lack of transparency can be sufficient for there to be an abuse of a dominant position since 'abuse of dominance is an objective concept and must be assessed on objective factors, and proof of the deliberate nature of the conduct and of the bad faith of the dominant undertaking is not required.'¹⁰ At the same time there must be an anti-competitive effect on the market resulting from such behavior – or at least sufficient evidence of a potential anti-competitive effect, which was the case in AstraZeneca.

B. ANTICOMPETITIVE PRACTICES VIA PATENT SETTLEMENT AGREEMENTS

Patent settlement agreements (PSAs),¹¹ like any other agreements, are subject to competition law, and under certain circumstances, these agreements may be considered contrary to competition law.

It is unacceptable that a company pays off its competitors to stay out of its market and delay the entry of cheaper medicines. Agreements of this type directly harm patients and national health systems, which are already under tight budgetary constraints. The Commission will not tolerate such anticompetitive practices.¹²

As the expiry of the patent term approaches and medicines lose patent protection, originators are increasingly confronted with the prospect of competition from generics (with significantly lower prices). Originators in many instances enter into patent-related procedures, disputes or litigation to delay the entry of generics into the market. Normally originators claim that their patents have been infringed by generics who have introduced their own versions of the product prior to the expiry of the patents. Generics, in turn, deny such infringement and contest the validity of the patents. In such circumstances, patent settlement agreements are a fast and economical way to end patent disputes, particularly where both parties recognise the merits of settlement and decreased litigation costs.

On the other hand, PSAs can be detrimental to competition in the market if:

⁷ More than 8,000 SPCs for medicinal and plant protection products were filed in Europe between 1991 and 2003.

⁸ Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products [1992] OJ L 182

⁹ More information is in section 4 below.

¹⁰ Black S, Moore S, Ecj Ruling Dismisses Astrazeneca's Appeal In Abuse Of Dominance Case, 2012
<https://www.lexology.com/library/detail.aspx?g=b36f264d-5978-4c18-ba0e-9d1cb559fc89>

¹¹ Also known as reverse payment settlement agreements

¹² See European Commission, 'Press Release of 19 June 2013 IP/13/563, Antitrust: Commission fines Lundbeck and other pharma companies for delaying market entry of generic medicines' <http://europa.eu/rapid/press-release_IP-13-563_en.htm?locale=en> accessed 5 August 2017

- entry of generic products is delayed;
- there is a decline in the number of new medicines and less competition from the generics' side; and
- consumers and national health systems have to pay higher prices, as two years after market entry, generic products are on average 40 percent cheaper than the originator products.

Therefore, special attention to PSAs is stemming from the public health imperative, i.e. anticompetitive PSAs deprive customers of cheaper or affordable healthcare, as well as novel medicines. 'Ultimately, it may be the consumer who pays the price for a delay in market entry resulting from such agreements'¹³ and any benefits to the society are likely to be outweighed by the negative effects of the anticompetitive PSA. In this context, an assessment of each individual case would be necessary.

3. ASSESSMENT OF PATENT SETTLEMENT AGREEMENTS

PSAs can be regarded as commercial agreements to settle patent-related disputes, e.g. issues of patent infringement or patent validity.

On the one hand, the aim of PSAs is to find a mutually acceptable compromise and discontinue a dispute. Such practices are generally accepted as a legitimate way of privately ending a dispute which saves courts and/or competent administrative bodies' time and effort. Hence, PSAs can be viewed as positive for society.

On the other hand, as already mentioned, PSAs may be problematic from a competition law perspective. This concerns, in particular, those PSAs that lead to a delay of generic entry in return for a value transfer or payment by the originator company to the generic company. So far, in all PSA cases investigated by competition authorities, 'initial concerns stemmed from the fact that the settlements under scrutiny involved large payments from a patent holder to the generic entrant.'¹⁴ Settlement agreements containing restrictions beyond the exclusionary zone of the patent (e.g. beyond its geographic scope, its period of protection etc.) or involving patents for which the patent holder knows that the patentability criteria are not met (e.g. lack of inventive step, incorrect, misleading or incomplete information etc.) can also be regarded as problematic agreements.¹⁵

PSAs can be categorised into two types: with no limitation of generic entry; and with a limitation of generic entry (with or without the transfer of money).

Agreements that do not restrict the generic company's ability to market its own product are normally agreements that simply discontinue proceedings without any further commitment on any of the parties, and without any payment. Some form of payment from the originator to the generic is acceptable if it covers litigation costs and/or damages, i.e. in case of an interim injunction invoked against a generic that was prevented from marketing its products. There could also be a payment from generic to originator, i.e. when the generic company had riskily entered the market before the expiration of the patent.

Mutual compensation or mutual royalty-free licences are also acceptable under PSAs that do not restrict generics' entry into the market and are normally unproblematic from a competition law perspective.

Agreements that foresee a limitation on the generic company's ability to market its own product without payment from the originator to the generic company can raise competition concerns and require competition law scrutiny on a case-by-case basis. Such agreements normally contain a 'non-challenge clause', i.e. a clause stating that the generic company will refrain from challenging the validity of the originator's patent, and/or 'non-compete clause', i.e. a clause preventing market entry until the patent has expired. Agreements that foresee a limitation on the generics' entry with payment from the originator to the generic company for agreeing to delay the generic product launch and/or for discontinuing the patent challenge are problematic and require the highest degree of competition law scrutiny on a case-by-case basis.¹⁶

The European Commission considers that PSAs infringe art. 101 TFEU by their objects, i.e. restrict competition by their very nature, without any assessment of actual or likely anticompetitive or pro-competitive effects,¹⁷ (the main difference with the US, where the rule of reason approach is applicable to such cases) when the following conditions are met:

- the generics are potential competitors;
- there is a significant restriction on business activity/behaviour of the generics; and

¹³ GENERIC PHARMACEUTICALS -- Note by the European Union -- DAF/COMP/WD(2014)62, OECD, 2014. p.8. <http://ec.europa.eu/competition/international/multilateral/2014_jun_generic_pharmaceuticals_en.pdf> accessed 1 October 2018

¹⁴ Regibeau P, 'Further thought on 'pay-for-delay' settlements' 2014 2 Concurrences 12, p. 19

¹⁵ European Commission, *Report on the Monitoring of Patent Settlements (6th) (period: January-December 2014)* (2

December 2015) <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/patent_settlements_report6_en.pdf> accessed 15 May 2017

¹⁶ See, for instance, Citalopram case below.

¹⁷ Killick J, Berghe P, 'Applying a by object test to patent settlements is very different from the rule of reason', 2014, 2 Concurrences 21

- there is a value transfer from the originators to the generics.

4. ANTITRUST INVESTIGATIONS IN THE PHARMACEUTICAL SECTOR

A. EU LEVEL

There has been a number of cases where infringements of competition law have been found and high fines have been imposed on pharmaceutical companies.¹⁸ Many of those cases involve a significant restriction on the business activity of the generics and a substantial value transfer from the originators to the generics (violation of art.101 TFEU); and/or delay of the generics' market entry via misuse of regulatory strategies primarily (violation of art.102 TFEU).

A notorious example of the latter is AstraZeneca case. The European Commission fined the Anglo-Swedish group **Astra-Zeneca** (2005) €60 million for misusing regulatory and patent strategies for one of its medicinal products, Losec. In particular, AstraZeneca was found guilty of delaying the market entry of rival generic products by:

- deliberately making misleading representations before the patent offices and/or courts of several EEA Member States (which prevented them from being able to correctly identify the date of first marketing authorization), and thereby inducing them to grant extended patent protection for Losec in the form of SPCs to which the product was not entitled; and
- preventing parallel imports by deregistration of Losec's marketing authorisations (at that time, generic products could only be marketed, and parallel importers only obtain import licenses, if there was an existing reference marketing authorisation for the product).

As a result of the investigation, the European Commission concluded that AstraZeneca's conduct amounted to an

¹⁸ Even though the pharmaceutical companies have already been faced with heavy fines, there is a risk that they will sustain further financial losses for their anticompetitive conduct via private actions for damages. According to the rules on private enforcement, any person or company affected by anticompetitive behaviour as described in the above cases may bring the matter before the courts of the EU Member States and seek damages. The case law of the Court of Justice of the EU and Council Regulation 1/2003 both confirm that in cases before national courts, a European Commission decision is binding proof of illegal behaviour. Damages may be awarded without any reduction, irrespective of the amount of fine already imposed by the European Commission on the companies concerned. In addition, the private enforcement mechanism is expected to be used more widely in the EU following the adoption of Directive on actions for damages brought under the domestic national law for

abuse of its dominant position. The European Commission's decision was appealed to the General Court.¹⁹ The General Court confirmed the European Commission's findings, but reduced the fine to €52.5 million, as, in the General Court's opinion, the European Commission did not provide evidence that AstraZeneca's conduct was of a nature which intended to exclude parallel imports. At the same time, the General Court rejected the argument that the conditions of competition would not be normal or the same on the pharmaceutical market and that exceptional circumstances would be required for a pharmaceutical manufacturer to hold a dominant position. Finally, the General Court confirmed that, to constitute an abuse, a company's behaviour:

- does not necessarily need to have a direct effect on competition (the capacity to restrict competition may be indirect); and
- does not require an intent to cause harm (since abuse of dominance is an objective concept).

The General Court rejected AstraZeneca's arguments that 'there could be no abuse under Article 102 TFEU where there was no enforcement of the SPCs it had obtained by means of the misleading representations.' In the General Court's opinion, however, 'the question of whether AstraZeneca had ever enforced the SPCs to which it was not entitled was irrelevant; it sufficed for the finding of abuse that the SPCs had been obtained as their mere existence would deter generic competitors from entering.'²⁰ AstraZeneca had also argued that there could be no abuse under art. 102 TFEU unless the misleading representations had been made in bad faith or were fraudulent in nature. Again, the General Court rejected the applicant's arguments. Hence, a mere lack of transparency on the part of a dominant company was enough to determine an abuse.

The case was further appealed to the CJEU.²¹ The CJEU rejected all of AstraZeneca's arguments, including its challenge of the relevant market definition and of the

infringements of competition law, which will make it easier for victims of anticompetitive practices to obtain compensation.

¹⁹ The General Court is one of the EU's judicial institutions of the European Union. Decisions of the General Court can be appealed to the Court of Justice (CJEU), but only on a point of law. Before the Lisbon Treaty came into force on 1 December 2009, it was known as the Court of First Instance. // Glossary of summaries <https://eur-lex.europa.eu/summary/glossary/general_court.html> accessed 25 September 2018

²⁰ Nordlander K, Harrison P, 'General Court's AstraZeneca Judgment Set to Embolden Commission', CPI Antitrust Journal, September 2010(2), p.6 // <https://www.competitionpolicyinternational.com/assets/0d358061e11f2708ad9d62634c6c40ad/NordlanderSEP-102.pdf>

²¹ *AstraZeneca AB v European Commission* (C-457/10 P) [2013]

finding that AstraZeneca's patent and regulatory strategies constituted an abuse of a dominant position. The CJEU upheld the General Court's decision and the European Commission's analysis in full. The case demonstrates an important difference between the EU and how US courts deal with finding infringement. Under the US regime,²² only where patents have been obtained fraudulently, can they be challenged under competition law (to be precise, in order to find an infringement of Section 2 of the Sherman Act, misrepresentations must be intentional, and the dominant undertaking must take actions aimed at enforcing the fraudulently obtained patents). In the EU it is not necessary to demonstrate bad faith or fraudulent intent of the company – it is sufficient that the company's conduct (that is characterized by a manifest lack of transparency) is contrary to the special responsibility of a dominant undertaking not to impair by its conduct genuine undistorted competition.²³ Specifically, in relation to PSAs, there have been numerous investigations conducted by the European Commission with a subsequent confirmation of the correctness of the authority's finding by the Court of Justice of the EU.

For instance, in the **Citalopram case**²⁴ the European Commission fined the Danish pharmaceutical group Lundbeck €93.8 million and four generic companies (Alpharma, Arrow, Ranbaxy, and Merck) a total of €52.2 million. The European Commission found that the companies concluded agreements concerning Citalopram antidepressants to prevent the market entry of rival generic versions of Citalopram following patent expiry. The agreements involved significant value transfers (by way of direct payments, as well as the purchase of generic Citalopram stock for destruction) from Lundbeck to its generic competitors. The European Commission concluded that the agreements thus constituted pay-for-delay agreements, which violated art.101 TFEU.

The case was appealed before the General Court. Lundbeck believed that the European Commission's decision

contains several 'serious legal and factual errors'²⁵ and requested that the Court annul the decision and/or reduce the fine imposed. Eventually, the General Court in September 2016 rejected Lundbeck's arguments in full and upheld the European Commission's findings and ruled that pay-for-delay agreements were in breach of EU competition law.²⁶ The General Court noted that irrespective of any patent dispute, generic competitors agreed with Lundbeck to stay out of the market in return for value transfers [...] which constituted a "buying-off of competition,"²⁷ which is a restriction of competition by object that cannot be tolerated. Moreover, such agreements could not be justified by a legitimate need for IP rights protection.

This approach is slightly different when compared to the US. While the FTC and European Commission share the view that patent settlement agreements may be detrimental to competition, the US Supreme Court in the **Actavis case**²⁸ (with facts similar to that of the Lundbeck case) rejected the FTC's 'presumptively illegal' standard for the assessment of such agreements, and instead adopted a 'rule-of-reason' approach.²⁹ Therefore, in the US, it is for the competition authority and/or complainants to prove that the settlement agreement harms competition.

Interestingly, the General Court referred on several occasions to the Actavis judgment; and both judgments are similar such that they upheld that PSAs are subject to competition law scrutiny, and both considered the amount of value transferred in the process of assessing the legality of the PSA.³⁰

The question remains open – which of the antitrust rules shall be regarded as the most appropriate for the assessment of the patent settlement agreement, particularly considering that 'nobody denies the

²² According to the U.S. jurisprudence (including the Supreme Court judgment in Walker Process)

²³ General Court's judgement, para 493

²⁴ *Lundbeck* (Case COMP/AT.39226) Commission Decision C(2013) 3803 [2013] OJ C 80

²⁵ 'Lundbeck appeals European Commission decision', 2013, <<http://investor.lundbeck.com/releasedetail.cfm?ReleaseID=788105>> accessed 5 August 2017

²⁶ Case T-460/13 Sun Pharmaceutical Industries and Ranbaxy v Commission, T- 467/13 Arrow Group and Arrow Generics v Commission, T-469/13 Generics (UK) v Commission, T-470/13 Merck v Commission, T-471/13 Xellia Pharmaceuticals and Alpharma v Commission and T-472/13 Lundbeck v Commission [2016] OJ C 325

²⁷ 'Commission welcomes General Court judgments upholding its Lundbeck decision in first pharma pay-for-delay case' (2016)

<http://europa.eu/rapid/press-release_MEMO-16-2994_en.htm> accessed 5 May 2017

²⁸ *Federal Trade Commission v. Actavis, Inc.* 570 U.S. ___, 133 S. Ct. 2223 (2013)

²⁹ Clancy M, Geradin D, and Lazerow A, 'Reverse-payment patent settlements in the pharmaceutical industry: An analysis of US antitrust law and EU competition law' <<http://awa2015.concurrences.com/IMG/pdf/rever.pdf>> accessed 15 October 2017

³⁰ Sidiropoulos K, 'Reverse Payment Settlements in the Pharma Sector after the General Court's Judgment in Lundbeck' (Oxford Business Law Blog, 2016) <<https://www.law.ox.ac.uk/business-law-blog/blog/2016/12/reserve-payment-settlements-pharma-sector-after-general-court%E2%80%99s>> accessed 15 October 2017

possibilities of efficiency advantages of patent settlements.³¹

Some scholars summarize the antitrust rules as:

(1) *Per se* permission: Parties are free to make patent settlements with agreed entry dates (up to the patent expiration date) and reverse payments (formal scope of the patent);

(2) *Per se* prohibition: Parties are allowed to make patent settlements only on agreed entry dates but no reverse payments are allowed (or the variant "no reverse payments beyond litigation costs");

(3) Full rule of reason: Such an antitrust assessment of patent settlements would require a case-by-case analysis of all positive and negative effects of the patent settlement; and

(4) Presumption of illegality: (High) reverse payments would lead to a presumption of illegality that could be rebutted by a number of efficiency effects.³²

In our opinion, there should be neither *per se* permission nor *per se* prohibition, instead the rule of reason or the (rebuttable) presumption of illegality. In any case, a deep analysis of the agreements, circumstances of the case and economic rationale are essential.

In the **Fentanyl case**,³³ the European Commission was concerned about a so-called 'co-promotion' agreement between the Dutch subsidiaries of the US pharmaceutical company Johnson & Johnson (Janssen-Cilag) and the Swiss company Novartis (Sandoz), entered into in 2005. The main aim of the agreement was to avoid the companies competing against each other, thus depriving users of fentanyl in the Netherlands from access to a cheaper painkiller. The agreement foresaw monthly payments from Janssen-Cilag to Sandoz for as long as no generic product was launched in the Dutch market. Consequently, Sandoz

abstained from entering the market with generic fentanyl patches for the duration of the agreement from July 2005 until December 2006. This may have delayed the entry of a cheaper generic medicine for 17 months and kept prices for fentanyl in the Netherlands artificially high. The key concern was that 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. The European Commission concluded that the agreement breached Article 101 TFEU and imposed fines of €10,798,000 on Johnson & Johnson and €5,493,000 on Novartis.

In the **Modafinil case**,³⁴ the companies Cephalon and Teva settled patent infringement disputes in the UK and the US concerning Modafinil (a treatment for sleeping disorders).³⁵ As part of the settlement agreement, Teva undertook not to sell its generic Modafinil products on EEA markets before October 2012 and a series of side deals were included in the settlement agreement. The European Commission opened an investigation to assess whether the patent settlement agreement violated EU competition law. The investigation is still on-going. On 17 July 2017, the European Commission sent a Statement of Objections to Teva with its preliminary view that a patent settlement agreement concluded with Cephalon was in breach of EU competition law since the originator company Cephalon agreed on paying the generic company Teva to keep its cheaper generic version of Cephalon's sleep disorder drug out of the market. The sending of a Statement of Objections does not prejudice the outcome of the investigation.³⁶

The **Perindopril (Servier) case**³⁷ concerns an investigation launched by the European Commission on the practices of the French pharmaceutical company Servier and several of its generic competitors³⁸ for potentially delaying the generic entry onto the market of Perindopril, a cardiovascular medicine. The European Commission concluded

³¹ Wolfgang Kerber W, Frank S, 'Patent Settlements in the Pharmaceutical Industry: What Can We Learn From Economic Analysis?' ASCOLA Conference, Tokyo, 2015, p. 5 <http://ascola-tokyo-conference-

2015.meiji.jp/pdf/ConferencePapers/Parallel%20Sessions/Wolfgang%20Kerber_Frank_2015_Patent%20Settlements_14052015_02.pdf> accessed 10 October 2017

³² Ibid at footnote 49, p. 11

³³ Fentanyl (Case COMP/AT.39685) Commission Decision C(2013) 8870 [2013] OJ C 142

³⁴ Cephalon (Case COMP/AT.39686) case is pending, details of the investigation are available at <http://ec.europa.eu/competition/elojade/isef/case_details.cfm?proc_code=1_39686> accessed 5 July 2018

³⁵ Cephalon owned the patents for the drug and its manufacture. After certain Cephalon patents on the modafinil compound expired in EEA, Teva entered the UK market for a short period of time with its cheaper generic product. According to the EC's press release,

following a lawsuit concerning an alleged infringement of Cephalon's processing patents on modafinil, the companies settled their litigation in the UK and the US with a world-wide agreement.

³⁶ The Statement of Objections in Teva/Cephalon case, just as in any other case, is a formal step in European Commission's investigations into suspected violations of EU antitrust rules to inform the parties concerned in writing of the objections raised against them. There is no legal deadline for the European Commission to complete antitrust inquiries into anticompetitive conduct. The duration of an antitrust investigation depends on a number of factors, including the complexity of the case, the extent to which the undertaking concerned cooperates with the Commission and the exercise of the rights of defence.

³⁷ Perindopril (Servier) (Case COMP/AT.39612) Commission Decision C(2014) 4955 [2014] OJ C 393

³⁸ Teva Pharmaceutical Industries, Unichem and its subsidiary Niche, as well as Matrix, which is now known as Mylan Laboratories, Krka and Lupin.

that Servier had: acquired competing technologies for the production of Perindopril to preserve its position with regard to Perindopril, which was about to reach the end of its patent protection; and induced its generic challengers to conclude patent settlements.

By concluding the agreements, the competitors violated Art.101 TFEU and Servier also abused its dominant position under art.102 TFEU. The European Commission imposed a €427.7 million fine³⁹ on the companies.

As opposed to the above cases, the European Commission did not only refrain from imposing a fine but also specifically asked the undertakings to enter into the patent settlement agreement and find ‘a mutually acceptable solution to their dispute within the limits of antitrust rules’ in **Boehringer and Almirall (lung disease treatments) case**.⁴⁰ The Spanish pharmaceutical company Almirall complained to the European Commission claiming that the German pharmaceutical company Boehringer had filed patent applications for new treatments of COPD relating to three broad categories of active substances. The categorical substance-based applications were so broad that they included a new active substance that Almirall had discovered which could potentially block or considerably delay the market entry of Almirall’s competing medicines. Eventually Boehringer agreed to remove the alleged blocking positions in the EU and grant a licence for two countries outside Europe, which lifted the obstacles to the launch of Almirall’s products and the European Commission closed the antitrust investigation. The patent settlement in this case did not involve any value transfer; and moreover, it was viewed as ‘the most efficient and speedy way to ensure that consumers will be able to benefit from Almirall’s product.’⁴¹

The above cases demonstrate the European Commission’s, on the one hand, strict approach towards agreements that limit generic entry into the market and hence competition in the market, and on the other hand, encouragement to enter into patent settlement agreements (without a value transfer though) if it ensures that the consumers may benefit from it in the most efficient and speedy way. By imposing heavy fines the European Commission aims to prevent similar violations of competition law from happening and it seems that it has succeeded. According to the 8th Report On the Monitoring of Patent Settlements,

the number of pay-for-delay agreements, which restrict generic entry and show a value transfer from the originator to the generic company, ‘have stabilized at a low level’. In the period covered by the sector inquiry (1 January 2000 to 30 June 2008), such agreements represented 22% of all settlements reported. This percentage has decreased over the years to reach 11% in 2016.⁴² These figures prove the effectiveness of the current control mechanism. Hence, the competition authorities should continue monitoring and scrutinizing such settlements.

B. NATIONAL LEVEL

Inspired by the European Commission’s practice, patent settlement agreements have also been more actively investigated at a national level by the competition authorities of (non-)EU member states.

(i) ITALY

The Competition Authority of Italy fined **Pfizer** €10.6 million for abuse of dominance in the market for commercialising glaucoma medicines based on the active ingredient Latanoprost. The investigation was initiated upon a complaint lodged by the generic producer Ratiopharm. The Authority found that the company implemented an exclusionary strategy designed to obstruct the entry of generic drugs into the market by obtaining (via abuse of administrative procedures and SPCs) an artificial extension to patent protection in Italy. The decision was at first overturned by the Italian Administrative Tribunal which found Pfizer’s actions to be legitimate and without “a clear exclusionary intent.”⁴³ However, the Competition Authority appealed to the Italian Highest Administrative Court, which in 2014 upheld the original decision of the Competition Authority finding that Pfizer infringed art.102 TFEU.⁴⁴

In addition, the Competition Authority of Italy, upon a complaint from the Italian Ophthalmological Society and an association of private healthcare facilities in 2013, conducted an investigation into the pay-for-delay agreement between Novartis and Roche Holding AG. It was alleged that the agreement kept Roche’s Avastin off the Italian market to the advantage of Novartis’ sales of Lucentis. These products have equivalent effects for treating eye diseases, although Lucentis is more expensive than Avastin. As a result of the investigation, in 2014 the

³⁹ European Commission Press Release, ‘Commission fines Servier and five generic companies for curbing entry of cheaper versions of cardiovascular medicine’ <http://europa.eu/rapid/press-release_IP-14-799_en.htm> accessed 5 May 2017

⁴⁰ Commission welcomes improved market entry for lung disease treatments, European Commission Press release, IP/11/842, 2011 http://europa.eu/rapid/press-release_IP-11-842_en.htm?locale=en accessed 5 September 2018

⁴¹ Ibid at footnote 37.

⁴² Ibid at footnote 2, para 49.

⁴³ ‘Italian court annuls patent misuse decision’ (2012) <<http://www.lexology.com/library/detail.aspx?g=545aae29-f938-4243-b050-0e9de7e589c8>> accessed 5 August 2017

⁴⁴ ‘Highest Italian court: use of patent rights can conflict with competition rules’ (2014) <<http://www.lexology.com/library/detail.aspx?g=8550714d-2327-4c70-9850-860f0336d1a3>> accessed 5 August 2017

Competition Authority found that Novartis and Roche were colluding, and the companies were fined €182.5 million.⁴⁵

(ii) UNITED KINGDOM

The UK Office of Fair Trading⁴⁶ investigated whether patent settlement agreements concluded between GlaxoSmithKline (GSK) and generic companies (Alpharma, Generics (UK) and Norton Healthcare Limited (IVAX)) infringed competition law.⁴⁷ It concluded that:

- the generic companies were each attempting to enter the UK market with a generic Paroxetine product in competition with GSK's branded product;
- GSK challenged the generic companies with allegations that their products would infringe GSK's patents;
- to resolve these disputes, the parties concluded agreements delaying the entry of the generic products onto the market and involving substantial payments from GSK to the generic companies; and
- the settlement agreements breached competition law and GSK abused its dominant position.

The OFT closely followed the approach taken by the European Commission in the Lundbeck case in assessing the agreements, and it emphasized that 'the large sums transferred were a "strong indication" that GSK perceived the generics as competitive threats.'⁴⁸ As a result of this

investigation, the OFT imposed a fine totalling £45 million on GSK and the generic companies for their anticompetitive conduct.

(iii) TURKEY

There is insufficient information on how the patent settlement agreements in the pharmaceutical sector⁴⁹ are treated in Turkey. The Turkish Competition Authority (TCA) published a pharmaceutical sector report in 2013 (Report). As stated in the Report, the pharmaceutical sector was one of the first sectors to be subject to competition law in Turkey.⁵⁰ Merger control and anti-trust issues are major aspects of the TCA's workload in this sector. As for patent settlements, the TCA does not have sufficient information on how often parties enter into these agreements.⁵¹ It is therefore fair to say that these agreements are rare in Turkey but we are not in a position to come to a credible conclusion on this matter yet.

The TCA very often refers to the European Commission's and FTC's assessments of the pay-for-delay agreements⁵² and does not go into detailed analysis under Turkish competition law. Also, to the best of our knowledge, the TCA has not yet rendered a decision on that front.

The TCA only noted that originators in Turkey are constantly initiating lawsuits against generics. The cases are mentioned as 'patent cases' and 'patent infringement cases.'

⁴⁵ 'Italy Fines Novartis, Roche \$251 Million Over Eye Drug' (2014) <<http://www.bloomberg.com/news/2014-03-05/italy-fines-novartis-roche-251-million-over-eye-drug.html>> accessed 5 August 2017

⁴⁶ The Office of Fair Trading was responsible for protecting consumer interests throughout the UK. It closed on April 1, 2014, with its responsibilities passing to a number of different organisations including the Competition and Markets Authority and the Financial Conduct Authority.

⁴⁷ 'To Fight or Not To Fight; Pharmaceutical Patent Settlements' (Competition Bulletin, 2013) <<http://competitionbulletin.com/2013/05/03/to-fight-or-not-to-fight-pharmaceutical-patent-settlements/>> accessed 5 August 2017

⁴⁸ Lawrance S, Bond E, 'Patent settlement agreements and competition law in the UK' (2016) at p. 2 <[http://www.bristows.com/assets/pdf/Patent%20Settlement%20PM\(1\).PDF](http://www.bristows.com/assets/pdf/Patent%20Settlement%20PM(1).PDF)> accessed 10 June 2017

⁴⁹ 'The Turkish pharmaceutical sector is subject to intense public regulation and also the structure of demand is shaped by doctors, rather than consumer choice. Regarding drug manufacturers, it can be seen that the majority of the original pharmaceutical companies are operating on a global level. On the other hand, the generic drug companies are seen to be mainly local scale'. See Organization for Economic Co-operation and Development, 'Global Forum on Competition - Competition Issues In The Distribution Of

Pharmaceuticals, Contribution from Turkey' , DAF/COMP/GF/WD(2014), <<http://www.rekabet.gov.tr/File/?path=ROOT%2F1%2FDocument%2FGenel+%C4%B0%C3%A7erik%2FOECD%2FCOMPETITION+ISSUES+IN+THE+DISTRIBUTION+OF+PHARMACEUTICALS.pdf>> accessed 10 October 2017

⁵⁰ Pharmaceutical IP and competition law in Turkey: overview, Thomson Reuters Practical Law, 2018, at para [13] <[https://uk.practicallaw.thomsonreuters.com/0-522-5042?originationContext=document&transitionType=DocumentItem&contextData=\(sc.Default\)&firstPage=true&bhcp=1/](https://uk.practicallaw.thomsonreuters.com/0-522-5042?originationContext=document&transitionType=DocumentItem&contextData=(sc.Default)&firstPage=true&bhcp=1/)> accessed 5 July 2018]

⁵¹The Pharmaceutical Sector Report, Turkish Competition Authority, at para [671], <<http://www.rekabet.gov.tr/Dosya/sector-raporlari/8-rekabet-kurumu-ilac-s>> accessed 5 July 2018

⁵²The Pharmaceutical Sector Report, para 544, 'As seen in the findings of the FTC- the US competition authority, settlement agreements may have provisions that may be subject to competition rules.' For instance, such settlement agreements may foresee a payment by the originators to generics, which in turn cause a delay in market entrance of the generic product's market entrance. FTC determined that in such a case, consumers and insurance companies are harmed by the delay. Due to the negative effect of these agreements on competition, measures have been imposed under the competition rules.

Most of the lawsuits are decided in favour of the generics. The TCA, therefore, determined that the originators are initiating lawsuits against the generics just to delay their competition. That is to say, originators are abusing their 'right of litigation.' However, since initiating a lawsuit is a rightful action under the law, the legitimacy of such behaviour cannot be evaluated by the TCA.⁵³

Having said that, the TCA evaluated the situation from both originators' and generics' perspective:

- Generics generally argue that the reason behind the vast number of patent cases decided in favour of the generics is the originators' allegedly abusive behaviour, i.e. generics claim that originators know that they will lose the case, but initiate the lawsuit anyway to delay competition;
- Whereas originators generally argue that the reason behind their unsuccessful litigations is the weakness in Turkish patent legislation. The weakness, according to the originators claim, was due to the difference between the Turkish Patent Institution's (TPE) procedure and European Patent Office's (EPO) procedure. For instance, for the EPO procedure, third-party claims may be raised even after patenting. Depending on the legitimacy of the claims, the EPO sometimes changes the content of the patent. For TPE procedure, however, the claims could be raised only until the patenting (therefore, the patent content of the same product could be different in Turkey and the EU, which from time-to-time constitutes the ground for dismissal in the Turkish Courts).
- With the adoption of new Industrial Property Law 6769 (came into force on January 10, 2017), this deficiency was eliminated. Currently, any interested third party may challenge the patent ('out of court') and the Authority may cancel them upon submission of a petition within six months following the publication of the patent in the patent bulletin.

In evaluating the above, the TCA refers many times to the EC reports and sometimes takes EU data as the basis for its findings for the Turkish market in the absence of reliable data on that matter.

This suggests that the pharmaceutical sector, and particularly agreements between the originators and

generics, will continue to be under special attention/scrutiny of the TCA. In fact, in the TCA's Memorandum,⁵⁴ the following is directly suggested as part of the next steps to be taken:

assessing the agreements between brand and generic drug firms by taking into account those characteristics of the sector which enable multi-market communication.⁵⁵

The above practices of the competition authorities worldwide towards patent settlement agreements send a clear message to pharmaceutical companies that they should be more careful while deciding on the terms of the market access of generics. It is clear that the national approach to assessing such agreements shall continue to be in line with that of the European Commission, which is currently rather strict and negative about patent settlement agreements particularly in assessing the financial value of such deals.

There is a 'nearly unanimous consensus'⁵⁶ among scholars and competition authorities that the size of payments is an important criterion for the anticompetitive effects of the patent settlement agreement, and the net value transfer from originators to generics can be used as an assessment criterion of such practices.

5. CONCLUDING REMARKS

Based on the analysis of the cases, it may be concluded that on the one hand, the European Commission follows a strict approach towards agreements that limit generic's entry into the market and hence competition in the market, and on the other hand, encourages them to enter into patent settlement agreements (without a value transfer though) if it ensures that consumers may benefit from it in the most efficient and speedy way. Such pro-competitive patent settlement agreements can be considered an opportunity for both generics and originators as they prevent high litigation costs and provide certainty as to the outcome of the dispute.

However, special care is required when negotiating patent settlement agreements; especially if the settlements involve restrictions on the entry of generic products onto the market with a value transfer from originators to generics (e.g. any payment from originators under the patent-settlement agreements cannot exceed generic profits). Any language that might suggest an anticompetitive intent or exclusion should be avoided.⁵⁷

⁵³ The Pharmaceutical Sector Report, para 670

⁵⁴ Turkish Competition Authority, *Memorandum Concerning The Pharmaceutical Sector Inquiry Report* (2013) <<http://www.rekabet.gov.tr/en/Guncel/pharmaceutical-sector-inquiry-report-was-published-906246bb22684d5784e54c294a651584>> accessed 10 October 2017

⁵⁵ *Ibid* at p. 5

⁵⁶ *Ibid* at footnote 49, at p. 5

⁵⁷ Zafar O, Lundbeck, and Johnson & Johnson and Novartis: The European Commission's 2013 'pay-for-delay' decisions, *Journal of European Competition Law & Practice*, 2014, at p. 3, <<https://www.bristows.com/assets/documents/JECLP%20->

Rather, the focus should always be on protecting legitimate IP rights.

There is always a risk for the originators (and at the same time an opportunity for generics) that generic companies or competitors may challenge the originators' IP rights. In addition, patent settlements may be challenged by competitors and more regularly fall under the scrutiny of competition authorities in the EU under art. 101 TFEU, resulting in substantial financial losses for pharmaceutical companies.

Multinational companies ought to bear in mind an important difference between the EU and how US authorities deal with finding an infringement related to such agreements: in the EU the "buying-off of competition" is a restriction of competition by object that cannot be justified by a legitimate need for IP rights protection; while in the US according to the 'rule-of-reason' approach the actual harm to competition by the settlement agreement must be shown to find a violation.

PSA's 'trouble' may come together with the finding of an abuse of dominance. Indeed, another danger for the pharmaceutical companies is related to their dominance in the market, which, as mentioned, entails a special responsibility. Again, the EU and US authorities diverge in their approaches in finding an infringement related to abuse of dominance. Under the US regime, in order to find an abuse of dominance, actions of the undertakings concerned must be intentional, and aimed at enforcing the fraudulently obtained patents. In the EU it is not necessary to demonstrate bad faith or fraudulent intent of the company – it is sufficient that the company's conduct is contrary to the special responsibility of a dominant undertaking not to impair by its conduct genuine undistorted competition. Hence, the EU's approach is stricter than that of the US.

Recent approaches of the Competition Authorities worldwide towards patent settlement agreements send a clear message to pharmaceutical companies that they should be more careful while deciding on the terms of market access of the generics. It is clear that the national approach to assessing such agreements shall continue to be in line with that of the European Commission, which is currently rather strict and negative about patent settlement agreements particularly in assessing the financial value of such deals.

The European Commission's strict approach towards agreements that limit generic's entry into the market and hence competition in the market, imposing heavy fines aims at preventing similar violations of competition law from happening. Considering that the number of pay-for-delay agreements, which restrict generic entry and show a

value transfer from the originator to the generic company, have decreased over the years, it is recommended that the competition authorities continue monitoring and scrutinizing such settlements.

Additionally, in the author's opinion, applying the rule of reason approach towards patent settlement agreements makes more sense (reverse payments would lead to a presumption of illegality that could be rebutted by a number of efficiency effects), but this would also mean more work for the European Commission.

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