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DISTORTION OF COMPETITION IN THE EU PHARMACEUTICALS MARKET

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1. Introduction

Everyday millions of people around the world benefit from access to “innovative, safe and affordable medicines”¹ and it is therefore in the interests of public health that the pharmaceutical industry around the world, as well as in Europe continues to innovate to product new products. It is also important that the industry remain competitive in order to protect consumers from high prices which could decrease their access to medicines. Generic medicines are seen as a key factor in maintaining competition within the pharmaceutical industry and ensuring that medicines are available to all consumers. Generic medicines themselves are simply “substitutes for originator medicines with the same active ingredient and the same quality, safety and therapeutic efficacy as the originator medicines” and can be anywhere from 10 – 80% cheaper than originator products.² It is therefore important that generic medicines are able to enter the market as soon as possible.

This paper will present some of the strategies employed by originator companies in the European Union (EU) pharmaceutical industry to prolong the patent protection of their bestselling products. By doing so, they delay and hinder the market entry by generic manufacturer with generic (and often much cheaper) versions of these blockbuster drugs. It is arguable that the employment of these patent strategies has resulted – or certainly has the potential to result – in a distortion of competition within the industry. This issue was definitely thought to be serious enough that the European Commission (Commission) launched in January 2008, an inquiry into the EU pharmaceutical sector. The Commission sought to determine the causes of what was perceived to be the poor functioning

¹ European Commission, Executive Summary of the Pharmaceutical Sector Inquiry Report [2009] 1. Accessed on 10 March 2015 from: http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/citizens_summary.pdf (hereafter Commission Executive Summary)

² Pieter Dylst, Arnord Vulto and Steven Simoons, (Dylst et al) ‘Overcoming challenges in the market access of generic medicines in the European Union’ (2012) 9(1) *Journal of Generic Medicines* 21.

of competition within the sector. The final report of the Commission's findings was published in July 2009.

As such, this paper will be presented using the findings and the conclusions of the Commission's sector inquiry as its guide. The Commission was particularly concerned by the use of settlement agreements in patent disputes to block or delay market entry of generic manufacturers. Part 2 will therefore begin with a brief introduction of what are patent settlements before describing some of the Commission's findings on the use of patent settlements in the pharmaceutical industry. Finally an in-depth examination of the facts of the Commission's 2013 decision in the Lundbeck case will be undertaken in order to show how patent settlements may be used to delay generic entry into the market, and the types of agreements which may run afoul of Article 101 Treaty on the Functioning of the European Union (TFEU).

Part 3 will then look at some of the practices identified by the Commission that make up part of the 'toolbox' of strategies used by originator companies to extend the life of their patent protected products and to ensure the continuation of their monopoly within that particular product market. Particularly this part will examine the practices of patent evergreening, the use of patent thickets and the (mis)use of the regulatory framework. With regard to this last practice, a case study of the landmark AstraZeneca case will be undertaken as an example in which an originator was found to have abused its dominant position in contravention of Article 102 TFEU by providing misleading information to the regulatory authorities, but also by separately exercising its legal right to withdraw its market authorisation for a product.

Finally part 4 will present some criticisms of the Commission's sector inquiry findings, as well as of its findings in the Lundbeck and AstraZeneca cases. The criticisms of these two cases in particular highlight how the findings have created some legal uncertainty within the industry. The Lundbeck case is of particular importance as it was the first in a string of several of cases in which the Commission found settlement agreements to be infringing competition law.

This case is now pending appeal and it remains to be seen if the European Courts (General Court and Court of Justice) will approve the Commission's decision or if it will agree with some of the criticisms that have been levelled against this decision. Until then however, it is arguable that originator companies in the pharmaceutical industry, who rely heavily on being able to protect and enforce their patent rights, are now in a situation in which engaging in what might otherwise be legitimate and legal action under patent law, may constitute an infringement of EU competition law.

2. Patent Settlements

As is the case in all forms of legal dispute and litigation, settlements within the context of patent law is a means for the parties concerned to resolve a dispute. Typically, a patent settlement will involve payment by the patent infringer to the patent owner, and an agreement by both parties to abide by the conditions of the settlement agreement. Like all other out of court settlements, patent settlements provide a number of benefits to the parties involved and arguably to society as a whole. For the parties, the avoidance of lengthy litigation means significant cost savings, speedy resolution of any uncertainties as well as greater control over the outcome through settlement negotiations. For new entrants to a market, a settlement could mean the difference between their product entering the marketing within a year as compared to a few years, and the risks associated with the cost of lengthy litigation is also minimised.³ For the wider society, out of court settlements reduce court congestion and delay.

Patent settlements however, differ from other settlements of litigation in that through their very nature, issues of competition are raised. Depending on the type of patent settlement, competition within the market may either be encouraged or weakened. For example, where two companies holding patents on complementary products agree to cross license their products to each other, they may then be able to produce a higher quality product or lower their productions costs allowing them to compete more effectively in that product market.⁴ On the other hand, a patent settlement may also have the effect of restricting competition between two rival companies within the same market.⁵

³ Joel Schrag, *The Value of a Second Bite at the Apple: The Effect of Patent Dispute Settlements on Entry and Consumer Welfare* [2006] 1. Accessed on 20 June 2015 from: <https://www.ftc.gov/reports/value-second-bite-apple-effect-patent-dispute-settlements-entry-consumer-welfare>

⁴ Carl Shapiro, 'Antitrust limits to patent settlements' (2003) 34(2) *RAND Journal of Economics* 391, 394.

⁵ Ibid.

2.1 The EU Pharmaceutical Market

That patent settlements can be a tool to both encourage as well as weaken competition is also true within the context of the European pharmaceutical market. Patents are seen as an essential tool by which originator pharmaceutical companies can ensure protection of their innovations, which are usually the product of lengthy, costly and risky research and development.⁶ The pharmaceutical industry relies heavily on patents to promote innovation and encourage investments, arguably more so than any other technology based industry.⁷ Patent protection is a particularly important 'reward' for originator companies as it provides them with a limited time of exclusivity in the market during which it can enjoy high profits to compensate for the cost intensive research and development it undertook to produce the product. However, because patent applications are filed very early on the research and development stage, the actual time of patent protection on the marketed product will generally be much less than the 20 years provided by the patent.⁸ It is for this reason that originators try their best to prolong their patent protection for as long as possible.

Once these patents have expired, generic drug manufacturers may then enter the market with the same drug, ultimately leading to lower prices and more choice for the consumers.⁹ Things however, do not always go so smoothly. Patent related disputes often arise between originator and generic drug companies, either due to a potential patent infringement by the generic manufacturer, or through a challenge of the validity of the patent held by the originator company. As with most legal disputes, these disputes are resolved either through litigation or settlement between the parties. As discussed above, settlements in patent

⁶ Jonas Severin Frank and Wolfgang Kerber, *Patent Settlements in the Pharmaceutical Industry: An Antitrust Perspective* (11 June 2013) Accessed on 19 June 2015 from: http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2277508, 12.

⁷ Aaron S. Kesselheim, 'Intellectual Property Policy in the Pharmaceutical Sciences: The Effect of Inappropriate Patents and Market Exclusivity Extensions on the Health Care System' (2007) 9(3) *The AAPS Journal* E306.

⁸ Dylst et al (n 2) 22.

⁹ Frank and Kerber (n 6).

related proceedings can be beneficial to both the parties to the dispute and to society as a whole by saving time and money and by the relieving the courts' burden. While settlement agreements between parties in patent related disputes are therefore generally viewed favourably, an agreement "that would lead to the de facto prolonging of the monopoly of the originator firms beyond the beyond the duration of the patent, would be an anticompetitive (cartel) agreement and therefore prohibited".¹⁰

According to the Commission findings from the 2008/2009 pharmaceutical sector inquiry ('sector inquiry'), 207 settlement agreements were concluded between pharmaceutical companies and generic drug manufacturers between January 2000 and June 2008.¹¹ These settlements were mainly concluded in the context of litigation cases, as well as in out of court disputes and opposition proceedings.¹² The Commission categorised the settlement agreements into two main categories based on whether the agreement limited the ability of the generic manufacturer to enter the market (category B) or not (category A).¹³ Those settlements found to limit generic manufacturer entry were then further separated into those that involved a value transfer from the originator company to the generic manufacturer (category B.II) and those that either did not involve any value transfer or involved a transfer from the generic manufacturer to the originator (category B.I).¹⁴ The Commission found that 108 of the 207 (52%) of all settlements concluded did not limit the entry of generic drug manufacturers into the market; the remaining 99 settlements included conditions that would effectively restrict the market entry of the generic drug manufacturer.¹⁵ 45% of those settlements involved a value transfer from the originator company to the generic drug company.¹⁶

¹⁰ Ibid.

¹¹ European Commission, Technical annex to the Executive Summary of the Pharmaceutical Sector Inquiry Report, 8 July 2009, COM(2009) 351 Final. Accessed on 18 June 2015 from: http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf

¹² Ibid.

¹³ Ibid [741].

¹⁴ Ibid [742]

¹⁵ Ibid, 270 [743].

¹⁶ Ibid.

The value of patent settlements can be seen from the fact that 69% of those settlements that did not prevent market entry by the generic manufacturers also did not involve any value transfer between the parties.¹⁷ These types of ‘walk away’ settlements are a clear example in which the parties believe that continuing litigation would be a waste of time and resources – for example, the originator agrees to drop its counteractions in return for the generic company discontinuing its patent validity challenge against the originator¹⁸ – resulting in a resolution of the dispute on mutually beneficial terms. Settlements that involved some form of value transfer were generally for compensation of damages incurred either by the generic manufacturer or the originator as a result of the litigation proceedings.¹⁹

The Commission generally considers patent settlements that fall into category A (do not limit the entry of the generic manufacturer into the product market) and those that fall into category B.I (limits the entry of the generic manufacturer but does not involve a value transfer from the originator to the generic manufacturer) to be *prima facie* unproblematic in the context of European competition law.²⁰ Generally category B.I settlements were characterised by situations in which the generic company accepted the validity of the originator’s patent (often as a result of a court decision) and as such agrees not to enter the market until after the expiry of the originator’s patent.²¹ Furthermore, in some cases where there has been a court ruling, the generic manufacturer has been ordered by the court to pay damages for its infringement of the originator’s patent.²² However, settlements in category B.I may still be found to be anti-competitive in instances where the patent relied upon may not be valid or the conditions contained in the settlement go beyond the scope of the patent.²³

¹⁷ Ibid, 272 [752].

¹⁸ Ibid, 273.

¹⁹ Ibid 273 – 274.

²⁰ Peter L’Ecluse et al, ‘Patent settlement agreements: the state of play in the EU and the US’ [2012] *Life Sciences multi-jurisdictional guide*. Accessed on 19 June 2015 from: <http://us.practicallaw.com/6-518-2068?q=&qp=&qo=&qe=>

²¹ European Commission (n 11) 275 [759].

²² Ibid [760].

²³ L’Ecluse et al (n 60).

Most importantly for the Commission's inquiry were the settlements that fell into category B.II. Although the settlements in this category could prima facie be deemed anti-competitive due to their cartel like nature, the Commission assesses each case individually on its merits, and therefore some of these agreements may still be compliant with competition regulations.²⁴ These settlement agreements restricted the market entry of the generic manufacturer and also included some form of value transfer from the originator company to the generic manufacturer. Specifically, 23 agreements involved the originator making a payment to the generic manufacturer, 29 agreements involved the granting of a licence by the originator to the generic manufacturer, nine involved either a supply or distribution agreement and finally one involved a 'side-deal' with the generic manufacturer.²⁵

The next section will look at the Commission's recent decision in the Lundbeck case as an example of how patent settlements may found to be anticompetitive. In that case, Lundbeck's agreements with four different generic manufacturers came under the Commission's scrutiny particular because they involved reverse payments from Lundbeck to the generic manufacturers and because they went beyond the scope of the patent.

2.2 Case Study: Commission Decision *Lundbeck*

The Commission handed down its decision in the *Lundbeck* case on 19 June 2013. The case concerned the Danish pharmaceutical company Lundbeck and four generic manufacturers, Merck, Arrow, Alpharma and Ranbaxy. Between January 2002 and December 2003, Lundbeck concluded six agreements in total with these companies in relation to the anti-depressant citalopram.²⁶ When Lundbeck concluded these agreements, its patent protection on the citalopram compound and "two original production processes had expired", such that it was no longer

²⁴ European Commission (n 11) 277 [763]

²⁵ Ibid [765].

²⁶ *Lundbeck* (Case AT.39226) Commission Decision 19 June 2013. Accessed on 10 June 2015 from: http://ec.europa.eu/competition/antitrust/cases/dec_docs/39226/39226_8310_11.pdf (hereafter *Lundbeck*)

able to prevent the production and sale of citalopram by generic drug manufacturers.²⁷ Lundbeck continued to enjoy patent protection on other production techniques of the drug.²⁸ The agreements between Lundbeck and each of the generic manufacturers were concluded in the context of a dispute between them in which Lundbeck claimed infringement of their patent rights, infringement or that the patent was invalid.²⁹ Most of the agreements were concluded prior to the commencement of any litigation proceedings.³⁰

The Commission identified three main issues with the agreements concluded by Lundbeck. Firstly, all the agreements were between Lundbeck and one of its potential competitors.³¹ Secondly, rather than resolving any actual or potential patent dispute, the agreements merely postponed the issues by postponing the market entry of each of the generic manufacturers.³² Finally, the Commission noted that agreements achieved outcomes for Lundbeck that they would not have been able to achieve had they tried instead to enforce their patents before the domestic courts.³³ The Commission assessed the validity of the agreements under Article 101 of the Treaty of the Functioning of the European Union ('TFEU') and found that the agreements infringed this article because their object was to restrict competition within the internal market.³⁴ The Commission commenced formal proceeding against Lundbeck on 7 January 2010.³⁵

In the course of its investigations into Lundbeck's dealings, the Commission found that the agreements with these four generic manufacturers were made in the context of its wider strategy to prevent or postpone generic entry into the citalopram market.³⁶ "In 2002, Lundbeck's sales of citalopram in the EEA amounted to EUR [400-600] million", and it was therefore heavily reliant on the

²⁷ Ibid, 13[3].

²⁸ Ibid.

²⁹ Ibid [4].

³⁰ Ibid.

³¹ Ibid [6].

³² Ibid.

³³ Ibid.

³⁴ Ibid, 14 [7].

³⁵ Ibid, 15 [14].

³⁶ Ibid 57 [133]-[134].

revenue generated from the sales of citalopram.³⁷ Documents obtained from Lundbeck revealed that by 1997 they had concluded that generic entry into the citalopram market could take place as early as 2000 and that this was “the greatest threat to the company’s future profitability, given the company’s strong dependence on sales of citalopram”.³⁸ As such, Lundbeck developed a strategy to prevent generic entry into the market which included the following policies:

- Creating a window of opportunity for its successor product escitalopram;
- Patenting processes to manufacture citalopram;
- Intervening in marketing authorisation procedures for generic citalopram;
- Eliminating the competitive threat of upcoming citalopram generic manufacturers;
- Persuading generic suppliers to stop their efforts to enter the market.³⁹

The agreements concluded between Lundbeck and the four generic manufacturers arose within the context of the above listed policies. It is part of the last policy listed above, persuading generic manufacturers not to enter the market especially, that the agreements arose. Lundbeck had tried to dissuade generic manufacturers initially by threatening or actually starting litigation for infringement of its process patents. In total, it had commenced 85 legal proceedings in nine different EEA member countries between 2002 and 2006.⁴⁰ It was when these generic manufacturers were unfazed by this litigation that Lundbeck ultimately resorted to concluding agreements in which it would transfer value to the generic manufacturer in exchange for them postponing its entry into the citalopram market.⁴¹ In total, Lundbeck transferred a total of EUR 66.8 million as part of the agreements made with these four generic manufacturers.⁴² Each of these agreements will be considered in turn beginning from the earliest to the most recent.

³⁷ Ibid 17 [26].

³⁸ Ibid 57 [133].

³⁹ Ibid 58 [134].

⁴⁰ Ibid 77-78 [185].

⁴¹ Ibid 78-79 [186].

⁴² Ibid 80 [193].

2.2.1 Agreements with Merck

The Commission's detailed investigation of the circumstances surrounding the deal between Lundbeck and Merck reveal the motivations of each of these companies. As discussed above, Lundbeck's ultimate goal was to prevent the entry of generic products on the citalopram market that could threaten its high sales of citalopram. On Merck's part, the motivation for entering into the deal was to be the first generic company to sell citalopram in the UK market.⁴³ A "Settlement and Supply Agreement" was concluded between Lundbeck and Merck on 24 January 2002 for the period of one year and covering the supply and sales of citalopram in the UK.⁴⁴

The agreement's preamble stated that as a result of a notice of possible infringement of "certain Intellectual Property" of Lundbeck, Merck "has agreed not to launch the Products subject to payment in accordance with the terms of this Agreement".⁴⁵ Article 2.2 of the agreement states that Merck is to deliver to Lundbeck all of its stock of citalopram (purchased from the Indian manufacturer Natco) for the price of £2 million.⁴⁶ Article 2.3 of the agreement goes on to state that Merck further agrees to deliver to Lundbeck the rest of the citalopram it is due to receive from Natco in return for payment of £1 million.⁴⁷ The citalopram supplied by Natco to Merck would then be destroyed by Lundbeck. The agreement also contains provisions for the supply of citalopram tablets by Lundbeck to Merck for resale within the UK, with Merck agreeing to purchase citalopram exclusively from Lundbeck.⁴⁸ By the terms of this agreement, instead of becoming a competitor in the citalopram market, Merck became instead a distributor of Lundbeck citalopram in the UK market. This agreement between Lundbeck and Merck was after the initial period of one year further extended twice to cover the periods of February 2003 to July 2003 and August 2003 to

⁴³ Ibid 100-101 [257].

⁴⁴ Ibid 103 [267].

⁴⁵ Ibid 103 – 104 [267].

⁴⁶ Ibid 104 [267].

⁴⁷ Ibid 105 [267].

⁴⁸ Ibid.

October 2003.⁴⁹ In total, between January 2002 and October 2003, Lundbeck transferred a total of approximately EUR 19.4 million to Merck.⁵⁰

Financial documents provided to the Commission showed that both companies profited greatly from the agreement. The agreement guaranteed that so long as Merck purchased a certain amount of citalopram from Lundbeck it would realise a profit of £5 million.⁵¹ As a result of the agreement, Merck earned an estimated £7 million net profit. For its part, Lundbeck, maintained its sales profits from its own sales of citalopram and its supply to Merck. As a result of all the agreements it concluded, Lundbeck's sales of citalopram and its successor product escitalopram in 2002 alone amounted to up to EUR 90 million, a sharp contrast to the expected 56 per cent loss of sales it expected to experience as a result of generic entry into the market.⁵²

Further to the agreement covering the UK, in October 2002, Merck and Lundbeck also concluded another agreement covering the European Economic Area (EEA) excluding the UK.⁵³ Once again the preamble of the agreement stated that Lundbeck believed its intellectual property rights were being infringed and although Merck disputes this allegation, "Lundbeck and GUK [Merck] have arrived at a settlement in order to avoid costly and time-consuming litigation, the outcome of which cannot be predicted with absolute certainty".⁵⁴

In accordance with Article 1.1 of the agreement, Merck agreed that "subject to payment of the Settlement Amount, it shall cease the sale and supply of pharmaceutical products containing Citalopram in the Territory to its Affiliates and/or to any third party...during the term of this Agreement and shall use all reasonable efforts to ensure that Natco ceases to supply Citalopram and products containing Citalopram in the Territory for the term of this

⁴⁹ Ibid 117 [307].

⁵⁰ Ibid.

⁵¹ Ibid [268].

⁵² Ibid 82 [198].

⁵³ Ibid 128 [348].

⁵⁴ Ibid.

Agreement”.⁵⁵ In return for this undertaking, Lundbeck would compensate Merck to the amount of EUR 12 million payable in monthly instalments over the duration of the agreement.⁵⁶ The benefit of this agreement to Lundbeck is clear. Not only would Merck be prevented from selling citalopram in the EEA excluding the UK, Lundbeck the terms were drafted such that Lundbeck was only obliged to make the monthly payments is Natco was also prevented from selling its citalopram in the EEA, whether to Merck or any other third party.⁵⁷

2.2.2 Agreements with Arrow

Lundbeck’s agreement with Arrow Generics Limited covering the UK was also concluded on 24 January 2002.⁵⁸ This agreement was however of a completely different nature to one between Merck and Lundbeck. The terms of this agreement covered Arrow’s conduct during and after the period of litigation for patent infringement commenced by Lundbeck against Arrow in the Patents Court of the English High Court.⁵⁹ The preamble of the agreement stated that Arrow had obtained a licence to import citalopram from a third party and that Lundbeck believed this importation constituted an infringement of its patent rights.⁶⁰ It further stated that Lundbeck had “threatened interim injunction proceedings and intends to pursue the alleged infringement in the Patents Court”.⁶¹ As such, the duration of the agreement was “from the date of signature until a final unappealable, enforceable UK-court decision has been rendered or until 31 December 2002, whichever event occurs first”.⁶²

In this agreement, Arrow undertook not to “make, dispose of, offer to dispose of, use or....import or keep for disposal or otherwise” any form of citalopram which Lundbeck alleges to be in violation of its proprietary rights.⁶³ What is of

⁵⁵ Ibid.

⁵⁶ Ibid. 129 [348].

⁵⁷ Ibid [349].

⁵⁸ Ibid 144 [392].

⁵⁹ Ibid 145 [394].

⁶⁰ Ibid [393]

⁶¹ Ibid.

⁶² Ibid 144 [392].

⁶³ Ibid 145 [394].

importance is that Arrow further undertook in Article 2.2 not to seek a cross-claim for damages for any loss it has incurred during the term of the agreement even if it were later found that Lundbeck's patent rights had not been infringed or were not valid.⁶⁴ In return for these undertakings, Lundbeck would compensate Arrow a total of £5 million over the course of four instalment payments.⁶⁵ Even if the UK court later found that Lundbeck's rights had not been infringed or indeed was invalid, this payment of £5 million would also constitute "full and final compensation from Lundbeck".⁶⁶ This amount of money was calculated to reflect the amount of profits Arrow could reasonably have expected to raise if it had successfully traded in the UK citalopram market during the term of the agreement.⁶⁷

As such, not only did Lundbeck prevent Arrow from entering the UK citalopram market, it also ensured that they did not counter-claim against them for damages in the on going patent litigation. The benefits to them are clear. For its part Arrow justified its position on the grounds that as a newly formed company, it was trying to protect its financial interests in the best way possible "by reaching an agreement with Lundbeck on the best possible commercial terms it could secure".⁶⁸ However, although Lundbeck lodged a claim for infringement in the Patent Court in January 2002, it never submitted the Particulars of Claim and the proceeding was no longer pursued.⁶⁹ As such, no ruling was ever made as to the validity of Lundbeck's patents or whether Arrow had infringed them.⁷⁰ Before the original infringement claim was stayed however, the court issued two consent orders – drafted by the parties – in February 2002 and again in January 2003, preventing Arrow from making, importing or selling Citalopram in the UK in accordance with the terms of the agreement.⁷¹ This agreement between Lundbeck and Arrow was extended once from January 2003 to March 2003,⁷²

⁶⁴ Ibid 146 [397], [398].

⁶⁵ Ibid.

⁶⁶ Ibid 147 [400].

⁶⁷ Ibid.

⁶⁸ Ibid [402].

⁶⁹ Ibid 149 [410].

⁷⁰ Ibid 150 [410].

⁷¹ Ibid 153 [429].

⁷² Ibid.

during which Lundbeck agreed to pay Arrow the sum of £450, 000,⁷³ and then again in June 2003 for the period of April 2003 to January 2004 during which Lundbeck agreed to pay the sum of £1.5 million.⁷⁴ The second extension was later terminated in October 2003.⁷⁵ Between January 2002 and October 2003, Lundbeck transferred a total of £6.8 million to Arrow as part of their agreement in relation to the UK.⁷⁶

In June 2002 Arrow and Lundbeck concluded a second agreement citalopram in the Danish market. The preamble of the agreement stated that the parties were concluding the agreement with the intention of avoiding any further litigation between them (in reference to the infringement proceedings commenced in the UK) because of the costs and risks involved with such litigation.⁷⁷ As such, Arrow undertook a “Consent Injunction” by which it agreed not to import, manufacture, produce, sell or market any citalopram products in Denmark until a “final, unappealable, judicial decision in the Infringement Litigation...has been rendered by the Courts in the UK”.⁷⁸ Arrow would also deliver to Lundbeck its existing stock of citalopram tablets.⁷⁹ As consideration for this ‘Consent Injunction’, Lundbeck would compensate Arrow for the amount of USD 500,000, which similarly to the UK agreement, would also constitute a full and final compensation to Arrow in the event that Lundbeck are unsuccessful in their infringement proceedings.⁸⁰ It would also compensate Arrow for the value of its current stock of citalopram tablets in the sum of USD 147,000.⁸¹

2.2.3 Agreement with Alpharma

⁷³ Ibid 154 [433].

⁷⁴ Ibid 155 [438]-[440].

⁷⁵ Ibid 156 [444].

⁷⁶ Ibid 158 [447].

⁷⁷ Ibid 160 [456].

⁷⁸ Ibid [457].

⁷⁹ Ibid 161 [461].

⁸⁰ Ibid 161 [459]-[460].

⁸¹ Ibid [467].

Lundbeck's agreement with Alpharma was concluded on 22 February 2002 for the period until 30 June 2003, and was in regards to all of the EU and Norway.⁸² Under the terms of this agreement, Alpharma agreed to stop the importation and sales, including through its affiliates and licensees, of all "pharmaceutical products containing Citalopram" within the EU and Norway.⁸³ Should Alpharma or any of its affiliates or licensees breach this term of the agreement, they further agree to submit to an interim injunction by any competent court within the territory.⁸⁴ In return Lundbeck would undertake the following actions:

- Dismiss the pending infringement lawsuit against Alpharma in the UK;
- Purchase all of Alpharma's stock of Citalopram products for the amount of USD 11 million;
- Pay Alpharma a further USD 1 million in compensation.⁸⁵

The agreement expired in June 2003 and was not extended.⁸⁶ By this time, Lundbeck had paid Alpharma a total of USD 11.1 Million.⁸⁷

2.2.4 Agreement with Ranbaxy

Lundbeck concluded an agreement with Ranbaxy Laboratories in India on 16 June 2002, covering the EEA as well as certain other third countries for the duration of 360 days.⁸⁸ Similarly to all the other agreements discussed above, the preamble to this agreement stated that Lundbeck believed its intellectual property rights were being infringed by the actions of Ranbaxy - namely the filing of two process patents relating to the manufacture of Citalopram in India - and that although these allegations were disputed, the two parties have decided to come to an agreement to avoid the time and high costs associated with litigation the outcome of which could not be predicted with any certainty.⁸⁹ At

⁸² Ibid 179 [521].

⁸³ Ibid 180 [523].

⁸⁴ Ibid [524].

⁸⁵ Ibid [523] – [525].

⁸⁶ Ibid 184 [546].

⁸⁷ Ibid [547].

⁸⁸ Ibid 190 [567].

⁸⁹ Ibid.

the time of conclusion, no litigation had been commenced between the two parties on the matter of citalopram.⁹⁰

The agreement obliged Ranbaxy not to claim any rights associated with its patent applications in India or on any other manufacturing methods it uses within the territory covered by the agreement.⁹¹ Ranbaxy further agreed to “cancel, cease and desist from any manufacture or sale of pharmaceutical products” containing citalopram within the territory covered by the agreement.⁹² In return, Lundbeck agreed to pay USD 5 million payable over the course of five instalments. It also agreed to sell citalopram to Ranbaxy in the UK; “Ranbaxy would be entitled to sell in the [UK] every month up to 10% of Lundbeck’s last month’s sales volume of citalopram in the [UK]”.⁹³ Both parties also undertook not to initiate proceedings against the other in relation to the patents listed in the agreement during the period of the agreement.⁹⁴

In February 2003, Lundbeck and Ranbaxy agreed to extend the agreement by another six months until 31 December 2003 with Lundbeck agreeing to pay Ranbaxy USD 4.5 million as consideration for the extended period.⁹⁵ In total, Lundbeck paid Ranbaxy USD 9.5 million over the total term of the agreement. It also transferred to Ranbaxy the value of £ 3 million in the form of lost profits as a result its distribution agreement with Ranbaxy.⁹⁶

2.2.5 Application of Competition Law and Decision

The Commission point outs that although patent holders have the right under the law to unilaterally enforce its patent rights, this does not mean that settlement agreements concluded voluntarily between two parties in order to settle a patent

⁹⁰ Ibid.

⁹¹ Ibid 191 [568].

⁹² Ibid.

⁹³ Ibid [570]-[571].

⁹⁴ Ibid [572].

⁹⁵ Ibid 193 [579].

⁹⁶ Ibid 195 [587].

dispute is beyond the reach of competition law.⁹⁷ It is irrelevant what the purpose of the agreement was. In reaching this conclusion, the Commission quoted the General Court in case of *Bayer AG and Maschinenfabrik Hennecke v Heinz Süllhöfer*, which said “[i]n its prohibition of certain ‘agreements’ between undertakings, Article 85(1) [now 101(1) of the Treaty] makes no distinction between agreements whose purpose is to put an end to litigation and those concluded with other aims in mind”.⁹⁸

As such, the six settlement agreements concluded by Lundbeck were assessed in the context of the competition provisions of the TFEU, specifically Article 101 of the TFEU. Although some of the agreements were concluded in relation to activity in the EEA and strictly speaking should therefore be assessed by reference to Article 53 EEA, the Commission noted that since these two Articles were identical, it was possible to, and the Commission did in fact carry out the competition assessment of all the agreements by reference to Article 101 TFEU.⁹⁹

Article 101(1) TFEU states:

1. “The following shall be prohibited as incompatible with the internal market: all agreements between undertakings, decisions by associations of undertakings and concerted practices which may affect trade between Member States and which have as their object or effect the prevention, restriction, distortion of competition within the internal market, and in particular those which:
 - a. directly or indirectly fix purchase or selling prices or any other trading conditions;
 - b. limit or control production, markets, technical development, or investment;
 - c. share markets or sources of supply;
 - d. ...

⁹⁷ Ibid 199 [599] –[600].

⁹⁸ Ibid [600].

⁹⁹ Ibid 197 [595].

e. ...”¹⁰⁰

Therefore patent settlements that have the object or effect of distorting competition within the internal market will be found to infringe Article 101(1) TFEU and hence, be prohibited. The Commission held the opinion that where an originator company concludes an agreement in which it agrees to pay large sums of money to a generic manufacturer in order to ensure that that generic manufacturer exits or does not enter the market for a certain period of time, such an agreement “merits the full scrutiny of competition law” because the result of as an agreement is that the generic manufacturer has for a period agreed to give up its efforts to enter or operate in the market, thereby restricting and distorting competition in the market.¹⁰¹ They further held that the payment of actual or potential competitors to stay out of the market or not to challenge an existing patent goes beyond the rights afforded to patent holders by patent law.¹⁰²

The Commission found that the agreements between Lundbeck and the generic manufacturers were all the more problematic because they achieved outcomes for Lundbeck that went beyond the scope of their patent. More specifically, Lundbeck managed to achieve outcomes, namely that its actual or potential competitors were prevented from entering the market for a certain period of time, that it could never have achieved through a court ruling in litigation. Even if a court had found that the generic company was infringing on the Lundbeck’s patent rights through its manufacturing process, there is nothing in patent law that can prevent the generic company from entering the market by using a different manufacturing process that is not patent protected.¹⁰³ It is important here to remind oneself that at the time of the agreements, Lundbeck’s compound patent on citalopram and its original process patents had expired. The generic companies were therefore free to manufacture the citalopram using these

¹⁰⁰ Consolidated Version of The Treaty of the Functioning of the European Union [2012] OJ C326/47, art 101(1).

¹⁰¹ *Lundbeck* (n 22) 220 [640].

¹⁰² *Ibid* [641].

¹⁰³ *Ibid* 220 [642].

original manufacturing processes which were no longer patent protected, and to then enter the citalopram market. The commission found that the commitments made by the generic manufacturers in this case not to enter into the citalopram market could therefore not be justified under patent law.¹⁰⁴

Article 101(1) TFEU prohibits any agreement between undertakings that has the object or effect of being anti-competitive. Dealing with the difference between anti-competitive by object or effect, the Commission observed that it was well established jurisprudence of the European Union Courts that “an agreement restricts competition ‘by object’ when the agreement’s objective aim, inherent tendency or necessary consequence is to restrict competition”.¹⁰⁵ The subjective intentions of the parties entering into the agreement is therefore irrelevant but may be taken into account,¹⁰⁶ nor is it relevant whether the agreement attempted to achieve other legitimate objectives.¹⁰⁷ It was held by the court in *Allianz Hungária Biztosító Zrt and Others v Gazdasági Versenyhivatal* that it was sufficient to show that an agreement had the *potential* negative effect on competition for it to be anti-competitive by object.¹⁰⁸

In order to determine whether each of the agreements entered into by Lundbeck were anti-competitive by object, the Commission formulated a sort of three step test:

- “The originator and the generic producer were at least potential competitors;
- The generic producer committed itself in the agreement to limit, for the duration of the agreement, its independent efforts to enter one or more EEA markets; and
- The agreement was related to a transfer of value from the originator to the generic producer, which substantially reduced the incentives of the generic producer to independently pursue its efforts to enter the market

¹⁰⁴ Ibid 221 [642].

¹⁰⁵ Ibid 223 [649].

¹⁰⁶ Ibid [648].

¹⁰⁷ Ibid 226 [653].

¹⁰⁸ Ibid 223 [648]

with a generic product”.¹⁰⁹

Here, the Commission found that all six agreements entered into by Lundbeck with the generic manufacturers met this test and were therefore anti-competitive by object. It found that when the agreements were entered into, each of the four generic manufacturers were in fact potential competitors of Lundbeck, despite the fact that the generic manufacturers believed they were infringing on Lundbeck’s patents.¹¹⁰ That the agreements limited the ability of the generic manufacturers to enter the market in return for a value transfer is clear from the above discussion. The Commission further took into account three further factors in deciding that agreements were anti-competitive by object and were therefore infringing Article 101(1) TFEU, namely:¹¹¹

- That in each agreement, the amount paid by Lundbeck to the generic manufacturer equated roughly to the amount of profit the generic manufacturer would have expected to earn if it had entered the market;
- That Lundbeck achieved outcomes from the agreements that were beyond the scope of the patent; and
- That in no agreement did Lundbeck commit not to commence infringement proceedings once the duration of the agreement had expired.

As a consequence of its anti-competitive activities, the Commission issued Lundbeck a fine of 93.8 million euros, and the four generic manufacturers a total fine of 52.2 million euros. All parties to the case have appealed the Commission’s decision.

The Commission’s decision and approach to analysing reverse payment settlements has been criticized by commentators and practitioners (see section 3 below), and we will have to wait a few years for the decision of the European Court before the law is settled in this regard. However, what is clear from the

¹⁰⁹ Ibid 228 [661].

¹¹⁰ James Killick, Jérémie Jourdan and Jerome Kickinson ‘ The Commission’s Lundbeck Decision: A Critical Review of the Commission’s Test For Patent Settlement Agreements’ [2014] *Competition Policy International*, 3.

¹¹¹ Ibid 229 [662].

Lundbeck case is that patent settlements can be used by an originator company to act in an anti-competitive manner by allowing it to achieve outcomes outside the scope of its patent. Outcomes such as maintaining the monopoly afforded to it by its patent beyond the life of that patent, by preventing market entry of actual or potential competitors for a certain period of time. Patent settlements can become especially problematic for EU competition authorities when a competitor such as a generic manufacturer, is paid to stay out of the market, giving it less incentive to take the effort to enter the market independently. This ultimately distorts competition within the internal market and adversely affects the interests of consumers.

3. Other tools in the ‘toolbox’

In the final report of its sector enquiry, the Commission identified some of the strategies employed by pharmaceutical companies to delay the entry of generic manufacturers into the market.¹¹² This so called ‘toolbox’ consists of strategies including patent settlements, patent evergreening and the use of the regulatory framework. This next chapter will examine the practice of patent evergreening and the misuse of the existing regulatory framework by pharmaceutical companies to extend their patent protection beyond the limit of the basic patent, with the aim of erecting barriers to entry of generic competitors and maintaining their high sales numbers. With regard to the latter practice, the chapter will look in detail at the Court of Justice’s decision in the AstraZeneca case of 2013.

3.1 Patent ‘Evergreening’

One way in which originator companies in the Pharmaceutical industry may distort competition within the EU market is through the means of patent evergreening. As it is not a formal legal concept, definitions of evergreening differ. However it is generally used to describe the various strategies employed by patent holders to extend their patent rights. Dwidevdi et al define evergreening as “a term referring to the numerous ways in which patent owners of pharmaceutical products use the patent laws to extend their monopoly privileges beyond periods that are normally allowed by law”.¹¹³ More Specifically the European Generic Medicines Association has defined evergreening as the practice of “repeatedly creating line extensions and so-called ‘next generation’ drugs, incorporating minor, normally therapeutically insignificant, variations to a product and patenting it as a new medication”.¹¹⁴ Similarly the European Consumer Association understands the concept of evergreening as follows: “a specific tactic used by originators to extend patents by seeking to obtain as many

¹¹² Nicoleta Tuominen, ‘Patent Strategies of the EU Pharmaceutical Industry: Regular Business Practice or Abuse of Dominance’, 35(1) *World Competition* 27, 31.

¹¹³ Gaurav Dwivedi, Sharanabasava Hallihosur and Latha Rangan (Dwivedi et al), ‘Evergreening: A deceptive device in patent rights’ (2010) 32 *Technology in Society* 324.

¹¹⁴ Scott Parker and Kevin Mooney, ‘Is ‘evergreening’ a cause for concern? A legal perspective’ (2007) 13(4) *Journal of Commercial Biotechnology* 235, 236.

patents as possible during the development of the product and the marketing phase, and to obtain a patent extension for new manufacturing processes, new coating and new uses of established products. [...] Originators can also slightly change an active ingredient and present an old medicine as a new product and register a new patent”.¹¹⁵

Whatever the definition used, it is important to note that the methods employed by pharmaceutical companies to extend these monopoly privileges, these so called evergreening strategies, maybe both lawful and unlawful, and form part of a company’s wider strategy to become more competitive within the market.¹¹⁶ While applying for subsequent patents on minor variations to the original drug or exploiting statutory loopholes are not unlawful, other practices such as misleading regulatory authorities could be found to be unlawful. What is problematic about patent evergreening is often not the methods employed themselves, but the effect utilising these various strategies has on competition in the relevant market. Where the object or effect of evergreening is potentially anticompetitive by creating legal barriers to entry into the market, this conduct could run afoul of the EU’s competition laws, particularly 102 TFEU, where the conduct constitutes an abuse of a dominant position.¹¹⁷

3.2 Patent clusters/thickets and follow on patents

Filing secondary or follow on patents in order to create a patent cluster is widely considered to be the very definition of what the practice of evergreening is, as can be seen from the definitions of evergreening provided by the European Consumers Association and the European Generic Medicines Association, discussed above.

A follow on patent is where a patent is filed after the filing of the primary patent in relation to a specific aspect of that primary pattern, for example the uses of that patent. Patent clusters or thickets occur where several follow on patents are filed in relation to that one primary patent. This strategy works to create several

¹¹⁵ Martina Törnvall, (2013) *The Use and Abuse of Patents – Evergreening in the Pharmaceutical Sector*, 38

¹¹⁶ Ibid 37.

¹¹⁷ Ibid 40.

layers of protection making it very difficult for competitors to properly ascertain the extent of the originator's patent protection.¹¹⁸ This strategy of patent clustering is becoming increasingly prevalent in the pharmaceutical industry. Traditionally patents in the pharmaceutical industry would cover only the main properties of the drug, such as chemical composition, manufacturing process and primary use.¹¹⁹ However, in order to further increase their competitive advantage originator companies are filing more and more follow on patents for a single drug.¹²⁰ These patents cover several "nonessential features"¹²¹ of the one drug including "an expansive number of uses, packaging of the drug, dosing regimen, dosing route, dosing range, methods of treatment, delivery systems" etc.¹²² Pharmaceutical companies are even going so far as to patent the metabolites that are naturally produced by the body after use of the patented drug.¹²³

Having to navigate their way through all these patents surrounding just one drug has arguably led to the situation in which generic manufacturers are left with a choice of either to wait out the period of protection of all the patents associated with the drug, or attempt to enter the market and risk costly litigation.¹²⁴ Part of the patent clustering strategy is that pharmaceutical companies do not apply for all the various patents in the cluster covering the product at the same time. It is common to apply for patents for uses, dosing patterns etc five to ten years after filing the primary patent.¹²⁵ As such, the various patents do not run over the course of exact same 20 year period, the result of which is that even after the 20 year protection period of the primary patent filed is over, one or more of the subsequent patents filed in relation to that product may still be active thereby effectively extending patent protection on that product by longer than 20

¹¹⁸ Tuominen (n 112) 33.

¹¹⁹ Dwivedi et al (n 113) 325.

¹²⁰ Ibid.

¹²¹ Kristof Roos et al, 'Patent-related barriers to market enter for generic medicines in the European Union: A review of weaknesses in the current European patent system and their impact on market access of generic medicines' (2008) 5(4) *Journal of Generic Medicines* 255, 260.

¹²² Ibid.

¹²³ Ibid.

¹²⁴ Tuominen (n 112) 33.

¹²⁵ Christian Sternitzke, 'An exploratory analysis of patent fencing in pharmaceuticals: The case of PDE5 inhibitors' (2013) 42 *Research Policy* 542, 544.

years.¹²⁶

Another way in which follow on patents may be used to shut out competition in a specific market involves the patenting and subsequent launch of a successor drug to the original bestselling drug. The timing of the launch is critical with such actions. Before the patent expiry of the first drug, a pharmaceutical company launches the successor drug and then invests in an extensive and aggressive marketing campaign to switch doctors and patients onto the newly launched drug.¹²⁷ As such, by the time the patent on the first drug expires, and a generic version is launched into the market, the majority of consumers will have already switched to using the new drug.¹²⁸ Since most consumers have already switched to the newly patented drug, generic manufacturers no longer have the incentive to enter into the market with generic versions of the original drug.¹²⁹

While it is arguable that such a practice is simply part of a pharmaceutical company's efforts to stay competitive in a market, criticism of the practice comes from the fact that the follow on patent is often on a substance that is chemically very similar to the original patent, with only very minor changes having been made. Changes that often have very little therapeutic benefit to the patients consuming the drug.¹³⁰ As such, originator companies could theoretically obtain two periods of patent protection on what is essentially the same drug by using such follow on patenting strategies. It is clearly an effective means of retaining a majority market share on their bestselling drugs and is widely used by pharmaceutical companies: in the final report of its sector inquiry, the Commission found that successor drugs were launched for 40% of the drugs that they examined between 2000 and 2007.¹³¹ The strength and quality of the patents on these successor drugs was a concern that was raised often by both generic manufacturers and consumer associations over the course of the Commission's sector inquiry.¹³² Adding credibility to the view that these

¹²⁶ Dwivedi et al (n 113) 326

¹²⁷ Tuominen (n 112) 34.

¹²⁸ Ibid.

¹²⁹ Dwivedi et al (n 113) 327.

¹³⁰ Ibid.

¹³¹ Commission Executive Summary (n 1), 14

¹³² Ibid.

secondary drug patents are of a lower quality is the fact that the Commission found that generic manufacturers won approximately 60% of challenges to such patents in relation to the medicines examined by the Commission.¹³³

In light of these considerations, it is clear how follow on patents and patent clusters may be used as a means of shutting out competition from the market and therefore may be problematic in terms of competition law. From a competition point of view, the question of the quality of follow on patents (that make up a patent cluster) is also potentially problematic. As noted above, there is widespread concern and criticism within the industry from generic manufacturers and consumers alike, as well as from legal commentators as to the strength and quality of these follow on patents, with some arguing that a large majority of these patents should not have been granted at all.¹³⁴ Kristof et al argue that follow on patents “stretch the limits of the patentability criteria and disrupt the delicate balance underlying the patent system”.¹³⁵ It is important to remember here that the granting of a patent is effectively the granting of a monopoly within the market over a product or process. Although monopolies are seen as inherently anticompetitive, the monopoly of 20 years granted by a patent is seen as a reward and encouragement of innovation and development. As such, the granting of a weak or invalid patent could be problematic from a competition law point of view, as it grants a monopoly in cases where arguably very little innovation or development has taken place.

3.3 Misuse of the Regulatory framework - Case Study: *AstraZeneca v Commission*

The AstraZeneca case, handed down on 6 December 2012, provides a good example of the conduct of a pharmaceutical company in relation to regulatory authorities, specifically national patent offices which was found to amount to an abuse of a dominant position contrary to Article 102 TFEU. Article 102 of the TFEU states that “[a]ny abuse by one or more undertakings of a dominant position within the internal market or in a substantial part of it shall be

¹³³ Frank and Kerber (n 6).

¹³⁴ Kristof Roox et al (n 121) 261.

¹³⁵ Ibid 262.

prohibited as incompatible with the internal market in so far as it may affect trade between Member States”.¹³⁶ The case also provides an example of the legitimate use of a statutory right by a company, but with the sole intent of achieving an anti-competitive outcome through the use of this right. This conduct was again found to be an abuse of a dominant position contrary to Article 102 TFEU.

3.3.1 Legal context

Before detailing the facts of the case, it is first important to understand the legal context in which the facts of the case operated. In 1992, the European Council introduced a Regulation¹³⁷ (‘SPC Regulation’) which allowed for the application by a holder of a national or European patent for an extension of protection on that patent for an additional maximum period of five years. At that time, Article 3 of Council Directive 65/65/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products stated that “no medicinal product may be placed on the market of a Member State unless a marketing authorisation has been issued by the competent authorities of that Member State”.¹³⁸ This marketing authorisation (‘MA’) was valid for five years and could be renewed for further five year periods three months for the expiry date of the prior authorisation.¹³⁹ It was with regard this requirement of obtaining a MA that the supplementary protection certificate was introduced. It was recognised that the large period of time that elapses between the filing of a patent and obtaining a MA can be so long as to render the period of effective protection under the patent “insufficient to cover the investment put into research”.¹⁴⁰

¹³⁶ Consolidated Version of The Treaty of the Functioning of the European Union [2012] OJ C326/47, art 102.

¹³⁷ Council Regulation (EEC) 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products [1992] OJL182/1.

¹³⁸ Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products [1965] OJL22/369.

¹³⁹ Ibid, art 10(1).

¹⁴⁰ Case C-457/10P *AstraZeneca v Commission* [2012] ECR - I, 5 [8].

As such, an application for a certificate was heavily dependent on the date on which MA authorisation was obtained. Applicants had to apply for the supplementary protection certificate within six months of obtaining MA, and had to state explicitly on the application the date of the MA for the product.¹⁴¹ The length of the supplementary protection certificate, which came into effect at the end of the original patent, would be “equal to the period which elapsed between the date on which the application for a basic patent was lodged and the date of the first MA for the product in the Community, reduced by a period of five years”.¹⁴² Crucially for this case, Article 19(1) of the SPC Regulation stated that any product for which the first MA in the Community was obtained after 1 January 1985 may be granted a certificate, however certificates in Denmark and Germany may only be granted on products which obtained first MA after 1 January 1988.¹⁴³

3.3.2 Facts

AstraZeneca is a multinational pharmaceutical group active in the invention, development and marketing of pharmaceutical products, of which ‘Losec’ was one of its main products.¹⁴⁴ Losec was an omeprazole-based product used to treat “gastrointestinal conditions linked with hyperacidity”.¹⁴⁵ In May 1999, two generic manufacturers, Generics UK Ltd and Scandinavian Pharmaceuticals Generics AB made complaints to the Commission against the UK and Swedish arms of the AstraZeneca group for conduct which prevented them from entering a number of omeprazole markets in the EEA.¹⁴⁶ In its decision the Commission found that AstraZeneca’s conduct was an abuse of a dominant position in violation of Article 82 EC (now Article 102 TFEU) and Article 54 of the EEA Agreement and imposed a total fine of EUR 60 million on the company.¹⁴⁷

¹⁴¹ Ibid [10]-[11].

¹⁴² Ibid 6 [12].

¹⁴³ Ibid [13].

¹⁴⁴ Ibid 6 [15].

¹⁴⁵ Ibid.

¹⁴⁶ Ibid [16].

¹⁴⁷ Case C-457/10P *AstraZeneca v Commission* [2012] ECR - I, 4 [1].

The Commission held that AstraZeneca had committed two abuses its dominant position in the omeprazole markets in the EEA by firstly providing misleading information to the national patent authorities of several EEA Member States leading them to grant supplementary protection certificates for which AstraZeneca was in fact not entitled or only entitled for a shorter period,¹⁴⁸ and secondly by deregistering its MA for Losec capsules in Denmark, Sweden and Norway, AstraZeneca essentially prevented generic omeprazole manufacturers from entering the market for as long as possible.¹⁴⁹

The decision of the Commission was upheld on appeal by the General Court, whose decision was subsequently upheld by the Court of Justice.

3.3.3 Decision of the Court of Justice

The Court of Justice noted that it was settled case law that Article [102] prohibited a company that is a dominant position in the market from using methods “other than those which come within the scope of competition on the merits” to remove competition from that market.¹⁵⁰ The conduct which AstraZeneca engaged in which was found to be outside the scope of competition on the merits was as follows: between 1993 and 1994, AstraZeneca applied for supplementary protection certificates for Losec in Belgium, Denmark, Germany, Ireland, Luxembourg, the Netherlands and the UK. When doing so, it supplied to each of these national patent authorities the date of March 1988 as the date of first MA for the drug. It did not however, inform any of these authorities the legal basis underpinning its choice of that date, namely that it believed that the date of first MA in the context of the SPC Regulation should be interpreted as the date at which all necessary administrative steps had been completed and the MA became effective, the date on which the national government of a state approved the price of the product.¹⁵¹ AstraZeneca also did not inform the national authorities of its MA in France which was issued on 15 April 1987 and which

¹⁴⁸ Case C-457/10P *AstraZeneca v Commission* [2012] ECR - I, 6 [18].

¹⁴⁹ Ibid 6-7, [19].

¹⁵⁰ Ibid 16, [75].

¹⁵¹ David W. Hull, ‘The AstraZeneca Judgment: Implications for IP and Regulatory Strategies’ (2010) 1 (6) *Journal of European Competition Law & Practice* 500, 501.

would constitute the first MA issued in the Community for the purposes of Directive 65/65.¹⁵²

It was not disputed by AstraZeneca that had it disclosed the actual date of first MA in the Community, it would not have been entitled to a supplementary protection certificate in Denmark or Germany¹⁵³ because, as discussed above, in these two Member States, only product for which first MA was obtain after 1 January 1988 were eligible for certification. By misleading the national authorities in Denmark and Germany as to the date of first MA, AstraZeneca were therefore able to obtain an extension on its patent protection for Losec which it was not entitled to under the law. The MA for Losec was granted in Luxembourg on 16 November 1987, and it was only after the express request of the national patent offices of Belgium, the Netherlands and Luxembourg did AstraZeneca notify them of this date.¹⁵⁴ Again it had failed to notify them of the correct first MA date of 15 April 1987, and it was therefore able to obtain certificates in these three Member States based on the later date.

AstraZeneca consistently mislead the national patent authorities when applying for supplementary protection certificates for Losec. In Austria, Finland and Norway, it obtain certificates based on the false date of 21 March 1988, and it was only after several questions from the Irish and UK authorities did it eventually notify them of the original French MA of 15 April 1987.¹⁵⁵ It even continued to make these misleading representations in the German, Finnish and Norwegian courts in proceedings commenced against it by generic manufacturers.¹⁵⁶

It is clear that by providing the national authorities with misleading information, AstraZeneca were able to obtain certificates where it was not entitled to in Denmark and Germany, certificates for protection of six months longer than it

¹⁵² Case C-457/10P *AstraZeneca v Commission* [2012] ECR - I, 16 [77].

¹⁵³ *Ibid* [78].

¹⁵⁴ *Ibid* 18, [87].

¹⁵⁵ *Ibid* [91].

¹⁵⁶ *Ibid* [92].

was entitled to in Belgium, Luxembourg and the Netherlands and certificates for protection of 11 months longer than it was entitled to in Austria, Finland and Norway. Although the concept of abuse is an objective one and it is not necessary for the undertaking to intend to act in an abusive manner,¹⁵⁷ it is clear from the evidence that was before the court that AstraZeneca were aware and had taken the conscious decision to mislead the national authorities.¹⁵⁸ This is clear from, amongst other evidence, the fact that they used their alternate interpretation of the date of first MA for applications relating to omeprazole products, but had used the traditional interpretation in applications relating to other products.¹⁵⁹ Based on these facts, that Court of Justice held that AstraZeneca's conduct was not consistent with competition on the merits, or with the special responsibility held by companies in a dominant position not to distort competition within the internal market.¹⁶⁰ The Court held that despite the fact that several of the certificates were subsequently revoked,¹⁶¹ it is clear from the evidence that AstraZeneca's conduct of misleading the national authorities did in fact enable them to obtain exclusive rights which they were either not entitled to, or were only entitled to for a shorter period.¹⁶² Furthermore, the Court also held that these unlawful certificates not only "to a significant exclusionary effect after the expiry of the basic patents, but they are also liable to alter the structure of the market by adversely affecting potential competition even before that expiry".¹⁶³

AstraZeneca's second abuse of its dominant position while not related to its patent rights, demonstrates how the legitimate use of a statutory right could nonetheless run afoul of EU competition law.

As part of the information to be submitted to authorities in order to obtain MA, pharmaceutical companies, originator and generic alike, must submit evidence of the pharmacological and toxicological tests as well as clinical trials it has

¹⁵⁷ Ibid 14 [63].

¹⁵⁸ Ibid 17-18 [80]-[90].

¹⁵⁹ Ibid 17 [80].

¹⁶⁰ Ibid 19 [98].

¹⁶¹ Ibid 20 [102].

¹⁶² Ibid 21 [107].

¹⁶³ Ibid [108].

conducted. However, Directive 65/65 provides in Article 4 for this evidence submitted by originator companies to be subsequently taken into account by national authorities when assessing application by generic manufacturers for MA of a generic version of previously approved drug.¹⁶⁴ The intent of this abridged version of the MA approval procedure was to avoid unnecessary further testing on animals or humans.¹⁶⁵ Article 4 provides this abridged approval procedure on the basis that after six or ten years, the originator company no longer has exclusivity over the clinical data it had previously submitted to the authorities.¹⁶⁶

AstraZeneca had requested deregistration of the MAs for Losec capsules in Denmark, Sweden and Norway when it launched Losec in a different form.¹⁶⁷ This essentially meant that although AstraZeneca had by then lost its exclusive rights to it, all the test and trial results it relied upon for its MA would nonetheless no longer be available to be relied upon by generic manufacturers seeking MA for the same drug. The Commission found in the original decision that this constituted an abuse of a dominant position because it amounted to the artificial protection of products that were no longer patent protected.¹⁶⁸ This decision was upheld by the General Court which held that this action was “designed to prevent manufacturers of generic products from making use of their right to benefit from the results of those tests and trials, was not based in any way on the legitimate protection of an investment which came within the scope of competition on the merits”.¹⁶⁹ Generic manufacturers in these three Member States seeking MA for generic omeprazole would therefore have to carry out the necessary pharmacological and toxicological tests and clinical trials at the expense of considerable time and money before being able to obtain MA.

The Court held that the deregistration of its MAs in Denmark, Sweden and Norway was done with the “sole aim of excluding from the market, at least

¹⁶⁴ Ibid 22 [115].

¹⁶⁵ Ibid.

¹⁶⁶ Ibid 27 [151].

¹⁶⁷ Ibid 7 [19].

¹⁶⁸ Ibid.

¹⁶⁹ Ibid 22 [117].

temporarily, competing manufacturers of generic products”¹⁷⁰ and was not within the scope of competition on the merits. The Court reiterated that companies in a dominant position have the special responsibility to ensure that it does not distort competition within the market and that they cannot “use regulatory procedures in such a way as to prevent or make more difficult the entry of competitors on the market, in the absence of grounds relations to the defence of the legitimate interest of an undertaking engaged in competition on the merits or in the absence of objective justification”.¹⁷¹ The Court did not find that such an objective justification existed in this case.

The Court further rejected the claim by the AstraZeneca that since the right to withdraw a MA or not to renew it on its expiry is granted to a MA holder by Directive 65/65, this right “cannot logically be prohibited and, at the same time, granted by the European Union”.¹⁷² It held that the General Court was correct in pointing that conduct in compliance with other legal rules does not preclude the finding that that conduct is nonetheless illegal under Article 102 TFEU, “the illegality of abusive conduct...is unrelated to its compliance or non-compliance with other legal rules”.¹⁷³ The General Court had further noted 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”.¹⁷⁴

¹⁷⁰ Ibid 23 [123].

¹⁷¹ Ibid 25[134].

¹⁷² Ibid 23 [125].

¹⁷³ Ibid 25 [132].

¹⁷⁴ Ibid.

4. Criticism of the Commission's decisions

It is clear from the discussion so far that there are real possibilities for the abuse of intellectual property rights, particularly patent rights, to act contrary to EU competition law in the pharmaceutical industry. However, there has also been much criticism of the Commission's decisions in the AstraZeneca and Lundbeck cases.. Some commentators argue that the Commission's handling of AstraZeneca and Lundbeck cases has led to greater legal uncertainty and could have the effect of discouraging innovation in an industry so heavily reliant on the protection of intellectual property rights.

4.1 Criticism of Lundbeck

The main criticism of the Lundbeck case is the fact that the Commission came to the conclusion that the reverse payment settlements concluded between Lundbeck and the four generic manufacturers were “presumptively illegal” as they were anti-competitive by object.¹⁷⁵ This conclusion was based on the three step test, discussed in detail above, that showed that Lundbeck and the generic manufacturers were potential competitors and that a value transfer was made from Lundbeck to these generic manufacturers in exchange for a commitment from them not to compete with Lundbeck in the EEA for a certain period.¹⁷⁶

Killick et al have questioned if this three step test is in fact a good basis upon which to determine if a settlement agreement constitutes a restriction by object.¹⁷⁷ Firstly they argue that the Commission's definition of what constitutes a ‘potential competitor’ is very loose and appears to be inconsistent the definition provided by the General Court in a previous case.¹⁷⁸ The Commission in this case, appears to identify any generic manufacturer with the *potential* to “invalidate a patent or escape a finding of infringement” as a potential

¹⁷⁵ Michael Clancy, Damien Geradin and Andrew Lazerow (Clancy et al), ‘Reverse-payment patent settlements in the pharmaceutical industry: An analysis of U.S antitrust laws and EU competition laws’ (2014) 59(1) *The Antitrust Bulletin* 153, 168.

¹⁷⁶ Ibid 168 – 169.

¹⁷⁷ Killick et al (n 110) 5.

¹⁷⁸ Ibid.

competitor without considering how likely the chances of the generic manufacturer actually achieving these outcomes.¹⁷⁹ This definition critically does not “allow for any distinction between a generic company ready to enter the market and one that has serious hurdles to overcome”.¹⁸⁰ It further goes against the higher bar set by the General Court in the *Visa* case, in which it defines a potential competitor as a company with a real and concrete possibility of entering the market within a short period of time.¹⁸¹ Secondly, Killick et al also criticise the fact that this three step test does not take into account the nature of settlement agreements and the context in which settlement agreements are reached between the parties in a patent dispute.¹⁸² All settlement agreements are characterised by mutual concessions made by the parties, as such, the mere “presence of a value transfer to the benefit of the generic company cannot be enough to infer the existence of a restriction by object”.¹⁸³ Furthermore, it is also a common consequence of settlements in genuine patent disputes that the generic manufacturer will agree not to enter the market for a certain period of time.¹⁸⁴

Other commentators have criticised the fact that the Commission appears to have made a judgment about the strength of Lundbeck’s patents when it concluded that it achieved outcomes through the settlements that were beyond the scope of the patent.¹⁸⁵ The Commission treated a payment by an originator company to a generic manufacturer is a *prima facie* indication that the originator has a weak patent.¹⁸⁶ Zafar argues that this is particularly problematic given that more often than not, even patent experts can have difficulties predicting the outcome of patent litigation.¹⁸⁷ It is for the national patent courts to decide on

¹⁷⁹ Ibid.

¹⁸⁰ Ibid 6.

¹⁸¹ Ibid 5 – 6.

¹⁸² Ibid 6.

¹⁸³ Ibid.

¹⁸⁴ Ibid.

¹⁸⁵ William Choi, Bruce Den Uyl and Mat Hughes (Choi et al), ‘Pay-For Delay Practices in the Pharmaceutical Sector: *Lundbeck*, *Actavis*, and Others’ (2014) 5(1) *Journal of European Competition Law & Practice* 44, 48.

¹⁸⁶ Osman Zafar, ‘*Lundbeck*, and *Johnson & Johnson* and *Novartis*: The European Commission’s 2013 ‘pay-for-delay’ decisions’ (2014) 5(4) *Journal of European Competition Law & Practice* 207, 209.

¹⁸⁷ Ibid.

issues of infringement and validity, and that patent law is very complex is clear from the fact that it is possible for different national courts to come to different conclusions when presented with the same set of facts.¹⁸⁸ The Commission has neither the jurisdiction nor the expertise to evaluate the validity, strength or quality of patents.

Some commentators¹⁸⁹ have suggested that the Commission should follow instead the approach taken by the US Supreme Court in its consideration of reverse payment settlements in the *Actavis* case of 2013. Although the US Federal Trade Commission had taken a similar approach as the Commission in considering reverse settlement agreements as being by definition anti-competitive, this was rejected by the Supreme Court which adopted instead the rule of reason approach.¹⁹⁰ By this approach, the Federal Trade Commission or other plaintiff must prove to the court that the reverse settlement agreement does in fact harm competition within the particular market.¹⁹¹ As noted above, the Lundbeck case is now pending appeal before the General Court. It therefore remains to be seen if the court will agree with the approach taken by the Commission or if it will adopt a similar approach to that of the US Supreme Court.

4.2 Criticism of AstraZeneca

The approach of the Commission in the AstraZeneca case, later upheld by the General Court and the Court of Justice, has also been criticised by certain commentators. Hull particularly has argued that the decision has created legal uncertainty within the industry, especially for dominant companies that depend significantly on the use of intellectual property and regulatory strategies to protect its markets.¹⁹² In relation to AstraZeneca's use of misleading information to national patent offices as an abuse of its dominant position, Hull contends that

¹⁸⁸ Ibid.

¹⁸⁹ Killick et al (n 110) 8;

¹⁹⁰ Clancy et al (n 176) 171.

¹⁹¹ Ibid.

¹⁹² Hull (n 151) 503.

the Court has “set a low threshold for a finding that a dominant company supplied misleading information”.¹⁹³ The Court stressed that there was no requirement of an intent to mislead, it is sufficient that the information provided was likely to mislead the patent office and that this was capable of having anti-competitive effects.¹⁹⁴ This broad interpretation of what might constitute misleading information, coupled with the fact that the Court was keen to stress that the assessment of whether information was misleading or not would need to be done on a case by case basis could lead to much uncertainty. Hull highlights this uncertainty by questioning whether the failure by a dominant company to disclose to the patent authority the weaknesses in its patent claim would thus also amount to supplying misleading information as this might lead the patent authority to granting the patent.¹⁹⁵

As discussed, the Commission also found that AstraZeneca abused its dominant position by withdrawing its market authorisation, by preventing generic manufacturers from entering the market for as long as possible; this finding was upheld by the Court of Justice. However, commentators have criticised this finding in particular to be contrary to the principle of commercial freedom.¹⁹⁶ The Court’s position implies that a dominant company may not take any commercial decision that could result in making it more difficult or costly for a generic company to compete within the market.¹⁹⁷ Will companies in a dominant position therefore be obliged to take into account the ‘welfare’ of its generic competitors before exercising its commercial freedom? The Court’s approach seems to suggest so.

The Court’s finding that AstraZeneca supplying misleading information to the national patent authorities, together with the withdrawal of its marketing authorisation, amounted to conduct that was not competition on the merits, has

¹⁹³ David W. Hull, ‘The Application of EU Competition Law in the Pharmaceutical Sector’ (2012) 3(5) *Journal of European Competition Law & Practice* 473, 476.

¹⁹⁴ *Ibid.*

¹⁹⁵ Hull (n 151) 502.

¹⁹⁶ Maria Isabel Manley and Anna Wray, ‘New pitfall for the pharmaceutical industry’ (2006) 1(4) *Journal of Intellectual Property Law & Practice* 266, 268.

¹⁹⁷ *Ibid.*

also been criticised as being an undesirably narrow interpretation of competition on the merits.¹⁹⁸ Intellectual property and regulatory strategies are arguable aimed specifically at excluding competition from the market and the ability of companies, originator and generic manufacturers alike to use such strategies is critical to their ability to compete in the market successfully. A narrow definition of competition on the merits could therefore render conduct that is generally accepted as normal competitive behaviour as abusive and contrary to EU competition law.¹⁹⁹ Such a situation not only fosters uncertainty, it could also prevent dominant companies from fully exploiting their intellectual property rights, thereby producing a result that is “tantamount to amending the [IP] rules through the back door and risks upsetting the incentives that the legislator put in place”.²⁰⁰

¹⁹⁸ Hull (n 193) 476.

¹⁹⁹ Ibid.

²⁰⁰ Ibid 477.

5. Conclusion

The Commission launched an inquiry into the European Pharmaceutical sector in response to concerns that competition in the sector may not be functionally well. There was a decreasing number of ‘new chemical entities’ entering the market as well as delayed market entry of generic medicines.²⁰¹ The inquiry found that, between the investigated period of 2000 to 2007, generic medicines were delayed from entering the market after the loss of exclusivity by an average of eight months.²⁰² In its final report, the Commission found that originator companies employed a ‘toolbox’ of patent strategies including patent settlements, patent evergreening and the misuse of the regulatory framework to extend the commercial life of their drugs, contributing to this delay in entry by generic manufacturers.²⁰³ The Commission concluded that some of these practices warrant closer scrutiny by national competition authorities, together with the Commission to ensure that they are not being used in a manner that has the “potential to restrict or distort competition in the market.”²⁰⁴ Despite identifying these potentially problematic practices, the Commission was keen to stress that whether or not conduct by an originator company does have the potential to restrict or distort competition must be determined by looking at the individual facts of the case.²⁰⁵

That a finding of infringement under Article 101 TFEU or of an abuse of dominant position under Article 102 TFEU is highly dependent on the facts of the case at hand is clear from the two cases described in this paper. In relation to settlement agreements between originator companies and generic manufacturers, the Commission found that agreements in which a value transfer takes place from the originator to the generic manufacturer in exchange for the

²⁰¹ Domink Schnichels and Satish Sule, ‘The Pharmaceutical Sector Inquiry and its Impact on Competition Law Enforcement’, (2010) 1(2) *Journal of European Competition Law & Practice* 93, 94.

²⁰² Fabio Domanico and Elena Kamilarova, ‘Final results of the Commission pharmaceutical sector inquiry: competition and regulatory concerns to address’ (2009) 3 *Competition Policy Newsletter* 26, 28.

²⁰³ *Ibid* 27.

²⁰⁴ Commission Executive Summary (n 1), 19.

²⁰⁵ *Ibid* 20.

generic manufacturer to stay out of the market for a certain period of time to be particularly problematic and in need of closer competition scrutiny.²⁰⁶ The Commission's strict approach to such reverse payment settlements can clearly be seen in the Lundbeck case. There, the Commission held that the agreements concluded between Lundbeck and four generic manufacturers constituted an infringement of Article 101 TFEU. Employing a three step test, the Commission held that agreements concluded between originator companies and generic manufacturers that are (1) potential competitors, (2) in which the originator makes a value transfer to the generic manufacturer, (3) in exchange for generic manufacturer not to enter the market for a certain period of time, are likely to result in a restriction or distortion of competition within the market. There has been much criticism of the Commission in this case for appearing to take the position that all reverse payment settlements are by object anti-competitive, while at the same time continuing to stress that cases must be assessed on their individual facts, thereby creating legal uncertainty on the matter. Whether the General Court agrees with the Commission's position, especially in light of the Commission's sector inquiry findings, or adopts a rule of reason approach similar to that of the US Supreme Court remains to be seen.

The Commission (and the Court of Justice for upholding this decision) has further been criticised for its decision in the landmark AstraZeneca case, decided by the Commission before the launch of the sector inquiry. In this case, it was held that AstraZeneca had abused its dominant position contrary to Article 102 TFEU by misusing the regulatory framework applicable at the time. The Commission's broad definition of misleading information and narrow construction of competition on the merits has led many commentators to argue that the Commission has again created legal uncertainty within a sector so highly dependent on the protection and enforcement of its intellectual property rights.

While clearly critical of the anti-competitive potential of the patent related strategies employed by originator companies, the Commission nonetheless acknowledges that also exist concerns with regard to the regulatory framework

²⁰⁶ Domanico and Kamilarova (n 202) 30.

that need to be addressed.²⁰⁷ The Commission's report called for the urgent creation of a unified patent litigation system within the union as well as the creation of a single patent recognised throughout the European Union.²⁰⁸ It also recommended stricter enforcement of the regulatory framework in relation to market authorisation as well as the streamlining of the market authorisation process.²⁰⁹ Finally it also recommended that the Member States improve their pricing and reimbursement systems for generic medicines and implement regimes which encourage competition within the generics sector of the pharmaceutical sector.²¹⁰

Unfortunately the Commission does not offer any competition guidance in its sector inquiry report, and in fact explicitly states that providing guidance in this respect is not its intention. Stakeholders and legal practitioners in the sector will have no choice but to wait for future decisions by the Commission and the Court of Justice in order to receive some guidance and clarity as to how the balance between intellectual property rights and competition law is to be maintained in the EU pharmaceutical sector.

²⁰⁷ Ibid 29.

²⁰⁸ Commission Executive Summary (n 1), 20

²⁰⁹ Ibid 22.

²¹⁰ Ibid 25 – 26.

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Kurzfassung

Patentschutz zählt zu den wichtigsten Konzepten der globalen Pharma- und Arzneimittelindustrie: Es beinhaltet das vermarkte Recht auf Exklusivität eines Produktes, und wird im Allgemeinen als das konsequente und gerechte Ergebnis jahrelanger kostspieliger Forschung und aufwendiger Studien angesehen. Aus diesem Grunde steht bei vielen Pharmaunternehmen der Schutz und das Umsetzen von Patentrechten gegen Konkurrenzunternehmen an vorderster Stelle. Darüber hinaus geht es vielen Unternehmen um eine möglichst langfristige Verlängerung bereits existierender Patente.

Dem gegenüber stehen in Form von generischen Pharmaunternehmen die Prinzipien einer wettbewerbs-orientierten Marktwirtschaft, durch die sichergestellt ist, dass die Bevölkerung von neuen und günstigen Präparaten profitieren kann. In dem 2009 veröffentlichten Gutachten "Pharmaceutical Sector Inquiry Report" der Europäischen Kommission wurde deutlich, dass viele Urheber-Unternehmen eine komplexe Patent-Vermarktungsstrategie verfolgen, um die Markteinführung generischer Produkte durch Konkurrenzunternehmen zu verzögern. Die Europäische Kommission stellte weiterhin fest, dass solche Vermarktungsstrategien, die beispielsweise zu einer Unterdrückung des Wettbewerbs führen, ernsthaft von Wettbewerbsaufsichtsbehörden geprüft werden müssten. Alle Urheber-Unternehmen seien innerhalb ihrer Patent-Vermarktung an das Wettbewerbsrecht gebunden.

Diese Magisterarbeit beschäftigt sich mit einigen der von der Europäischen Kommission identifizierten Patent-Vermarktungsstrategien. Anhand der zwei exemplarischen Fallstudien *Lundbeck* und *AstraZeneca* werden die Kernpunkte der jeweiligen Patent-Vermarktungsstrategien herausgearbeitet, die nach dem Gutachten der Europäischen Union gegen das EU Wettbewerbsrecht verstoßen. Durch eine tiefergehende Analyse der Sachlage und des Gutachtens wird im Rahmen dieser Arbeit deutlich, dass die Europäische Union juristisch eine Situation der Rechtsunsicherheit geschaffen hat: Es ist zu erwarten, dass es für

viele Urheber-Unternehmen zunehmend schwierig sein wird einzuschätzen, inwiefern und in welchem Maße ihre Patentrechte umgesetzt werden können ohne gegen das Wettbewerbsrecht zu verstoßen. Die Entscheidung wird in Zukunft bei dem Europäischen Gerichtshof liegen, Klarheit in diese Angelegenheit zu bringen.

Abstract

Patent protection is the cornerstone of the pharmaceutical industry around the world. The exclusivity and right to exclude others that it provides is seen as the just rewards for innovation and years of time and cost intensive research and development. As such, originator companies fiercely protect and enforce their patent rights against all potential infringers. They also seek to extend the life of their patents for as long as possible. On the other hand, healthy competition within the relevant markets, especially from generic medicines manufacturers, is essential to ensuring that the public has access to innovative and affordable medicines. In its 2009 Pharmaceutical Sector Inquiry Report, the European Commission found that originator companies regularly employ a wide range of patent related strategies in order to delay or market entry of generic manufacturers, to the detriment of effective competition within the market. It concluded that some of these strategies warrant closer scrutiny by the competition authorities. Originator companies must still adhere to competition law when exercising their patent rights. This paper will examine some of the patent strategies identified by the Commission. Case studies of the *Lundbeck* and *AstraZeneca* cases will be presented as prime examples of where the Commission has found the use of patent strategies to be in violation of EU competition law. However, closer examination of these decisions, taken in the wider context of the Commission's sector inquiry findings, will reveal that the Commission has created much legal uncertainty within the sector. Originator companies will find it increasingly difficult to know the extent to which their patent rights can be used without infringing competition law. It will now be up to the European Court of Justice to provide more clarity on the matter.

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