The European Commission's Pharmaceutical Sector Inquiry and Competition Law Enforcement

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A. Introduction

In the recent past certain practices common in the pharmaceutical industry have raised a significant amount of attention from a competition law perspective.[1] This interest was in particular substantiated by European Commission's launch of its inquiry into the pharmaceutical sector in January 2008 and its final report published on 8 July 2009.[2]

The vast majority of antitrust cases run by the European Commission in this sector have been parallel trade cases, i.e. the examination of whether parallel trade of pharmaceuticals was unjustifiably hindered within the internal market.[3] However, in

1 See e.g. *Kjolbye*, Article 82 EC as Remedy to Patent System Imperfections: Fighting Fire with Fire?, World Competition 32 (2009), pp. 163-188; *Berg/Köbele*, Grenzen kartellrechtlichen Handelns nach der EU-Untersuchung des Arzneimittelsektors, Pharma Recht 2009, pp. 581-591.

2 Further details and the full texts of the Commission Communication on the final report as well as the final report as technical annex to the communication are available at the website of DG Competition, http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html (20/9/2010). See also press release IP/09/1098 and MEMO/09/321.

recent times, attention has shifted to the analysis of other practices of pharmaceutical companies that revolved around the potential misuse of the regulatory framework in the pharmaceutical sector. The sector inquiry has helped to identify certain types of practices that warrant closer competition law scrutiny.

When applying competition law in the pharmaceutical sector, its highly regulated nature though will have to be taken into account, e.g. the fact that prices and reimbursement levels for pharmaceuticals are often fixed in negotiations between undertakings and the Member States. Also, the pharmaceutical sector like almost no other one is highly dependant on patent protection, which allows for a sound recouping of substantial investments in R&D. That being said, it goes without saying that these elements do not exempt the sector from competition law scrutiny.

The first case decided by the Commission in this respect concerned certain practices of the originator company AstraZeneca.[4] In its decision in 2005 the Commission had imposed a fine of € 60 million on the company for abusing its dominant position on the market of proton pump inhibitors thereby infringing Art. 102 TFEU (Art. 82 EC at the time). Amongst the practices challenged by the Commission was the submission of misleading information to patent offices with the aim of obtaining supplementary protection certificates (i.e. a prolongation of its exclusive rights as to a specific pharmaceutical product). The General Court in its decision of 1 July 2010 has largely confirmed the Commission's decision, albeit reduced the fine from € 60 to € 52 million.[5]

This article will first give an overview of the reasons for and procedural aspects of the pharmaceutical sector inquiry (B.) before focussing on its main findings (C.). It will then turn to issues of competition law enforcement in the pharmaceutical sector (D.), in particular areas of competition law concern, the interplay of intellectual property rights (IPR) and competition law in general as well as the recent *AstraZeneca* judgement and patent settlements in particular. This article will not examine parallel trade issues.[6]

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3 See e.g. Commission Decision 87/409, *Sandoz*, OJ L 222 of 10/8/1987, p. 28; ECJ, case C-277/87, *Sandoz*, Rec. 1990, I-45; CFI, case T-168/01, *GlaxoSmithKline*, Rec. 2006, II-2969; ECJ, case C-468/06, *Sot. Lelos kai Sia/GlaxoSmithKline*, Rec. 2008, I-7139; ECJ, joined cases C-501/06 P, C-513/06 P, C-515/06 P and C-519/06 P, *GlaxoSmithKline*, not yet reported.

4 Commission Decision of 15/6/2005, case No. COMP/A. 37.507/F3, *AstraZeneca*; see also *Fagerlund/Rasmussen*, AstraZeneca: the first abuse case in the pharmaceutical sector, Competition Policy Newsletter 2005-3, p. 54; *de Souza*, Competition in Pharmaceuticals: the challenges ahead post AstraZeneca, Competition Policy Newsletter 2007-1, p. 39; *Negrinotti*, Abuse of Regulatory Procedures in the Intellectual Property Context: the AstraZeneca Case, ECLR 29 (2008), pp. 446-459; *Murphy/Liberatore*, Abuse of Regulatory Procedures – the AstraZeneca Case, ECLR 30 (2009), pp. 223-229.

5 See CFI, case T-321/05, *AstraZeneca*, not yet reported.

6 On this topic see *Schnichels*, The Application of European Competition Law to the Pharmaceutical Sector – Some Personal Thoughts, in: Hawk (ed.), International Antitrust Law & Policy,

B. Reasons for and Procedural Aspects of the Commission's Inquiry into the Pharmaceutical Sector

The European Commission is empowered, in certain cases, to carry out an inquiry into a particular sector of the economy, namely where circumstances suggest that competition may be restricted or distorted within the common market according to Art. 17 of Council Regulation (EC) 1/2003.[7]

The inquiry into the pharmaceutical sector was accordingly initiated in response to information that competition in the pharmaceutical market in the European Union may not be working well. This was indicated by a decline in innovation measured by the decreasing number of novel medicines reaching the market each year and by instances of delayed market entry of generic medicines.

The sector inquiry aimed at investigating the underlying causes by focussing in particular on company behaviour including the use of patent strategies. This does not mean that the sector inquiry ignored other causes. However, as a competition authority, the Directorate General for Competition of the European Commission (DG COMP) is mainly looking at company behaviour which might distort competition. The sector inquiry was launched on 15 January 2008[8] with upfront inspections, carried out at the premises of a number of pharmaceutical companies (originator and generic companies) in the EU. Subsequently, requests for information (Questionnaires) were sent to 70 originator and generic companies as well as to public authorities dealing with marketing authorizations and pricing and reimbursement, wholesalers, associations of insurance companies, doctors, patients, pharmacists and consumers.[9]

For the in-depth analysis 219 medicines were selected. These medicines were in their majority either blockbusters (i.e. medicines with an annual turnover of at least 1 billion dollars) or other well selling medicines facing loss of exclusivity in the period 2000 to 2007 or both. This sample covered approximately 50 % of the total prescription market and a great variety of products across various therapeutic areas. Also, the 70 respondent companies accounted for 80 % of the total turnover generated with prescription medicines in the EU in 2007.

Fordham Competition Law Institute 2010, pp. 405-442.

7 Council Regulation (EC) No 1/2003 of 16/12/2002 on the implementation of the rules on competition laid down in Art. 81 and 82 of the Treaty, OJ L 1 of 4/1/2003, p. 1.

8 The legal basis for the inquiry was the Commission Decision of 15/1/2008 initiating an inquiry into the pharmaceutical sector pursuant to Art. 17 of Council Regulation (EC) No 1/2003, case No. COMP/D2/39.514.

9 Both instruments (inspections and requests for information) are tools provided for in the context of a sector inquiry according to Art. 17 of Council Regulation (EC) 1/2003: The inspections were based on Commission Decisions pursuant to Art. 20(4) and 17 of Council Regulation (EC) No 1/2003. The requests for information were based on Art. 18 and 17 of Council Regulation (EC) No 1/2003.

C. Findings of the Sector Inquiry

This section will first give an overview of the main characteristics of the pharmaceutical market before presenting the main results of the analysis of different competitive relationships in the pharmaceutical sector.

I. Main Market Features and Trends

The pharmaceutical sector is essential for the health of Europe's citizens who need access to innovative, safe and affordable medicines. On average approximately € 430 were spent on prescription medicines in 2007 for each European citizen and this amount is expected to increase in future as the population in Europe ages. Overall, in 2007, the market for prescription and non-prescription medicines for human use in the EU was worth over € 138 billion ex-factory and € 214 billion at retail prices. The pharmaceutical market thus accounted for close to 2 % of the annual EU GDP.

The European pharmaceutical sector is highly regulated, in particular as regards marketing authorizations and procedures governing pricing and reimbursement status. Patents are of crucial importance to protect the innovative efforts of originator companies, also for their incremental innovation. Despite significant efforts a Community patent protecting innovation throughout the EU does not yet exist.[10]

The structure of the pharmaceutical market is quite unique. On the supply side, there are essentially two types of companies: originators and generics.

Originator companies are active in research, development (including approval procedures), manufacturing, marketing and supply of innovative medicines. Their products are usually protected by patents, which ensure that a fair compensation for

[10] A legislative proposal for a Community Patent and a Specialised Patent Judiciary has been adopted by the Council on 4/12/2009, see press release IP/09/1880; for the legislative proposals see Proposal for a Council Regulation on the Community patent, COM (2000) 412 final; Proposal for a Council Decision establishing the Community Patent Court and concerning appeals before the Court of First Instance, COM (2003) 828 final; Proposal for a Council Decision conferring jurisdiction on the Court of Justice in disputes relating to the Community patent, COM (2003) 827 final; Communication from the Commission to the European Parliament and the Council – Enhancing the patent system in Europe, COM (2007) 165 final. For the most recent draft text on the Community patent, see http://register.consilium.europa.eu/pdf/en/09/st08/st08588.en09.pdf (20/9/2010). For the most recent draft text on the unified patent judiciary, see http://register.consilium.europa.eu/pdf/en/09/st07/st07928.en09.pdf (20/9/2010). Currently in the EU patents can either be obtained by filing national patent applications at the patent offices of each respective Member State or by filing a single centralized patent application at the European Patent Office (EPO) on the basis of the European Patent Convention (EPC). The "European patent" granted by the EPO after its examination however still needs to be validated in the respective Member States and hence is just a bundle of national patents that need to be enforced separately in each Member State, for further details see Pharmaceutical Sector Inquiry, Commission Staff Working Document, (fn. 2), Technical Annex, p. 101 et seq.

R&D efforts plus an award for the risks taken can be earned, obviously depending on the commercial success of the drug. The protection through patents is limited in time, encouraging companies to bring the innovative product to market as quickly as possible and to continue their R&D activities so that new patent protected products can be launched. Whilst the effective protection period from product launch to first independent generic entry increased significantly over the last years in Europe, the industry is currently confronted with a number of challenges. In particular, many bestselling medicines (also referred to as "blockbusters") lost exclusivity in recent years and many will follow in the years to come. This will mean a significant reduction of the revenues and an urgent need to fill the "pipeline" with new products. In this respect, originator companies seem to rely to a large degree on successful R&D activities of smaller companies and universities (in 2007, 40 % of the products undergoing marketing authorization were not developed by the originator companies). In the changing environment originator companies see personalised medicines and biotechnology as important future targets. They also started acquiring generic companies.[11]

The second category of companies active on the supply side, the manufacturers of generic products, can enter the market with medicines that are equivalent to the original medicines, however only upon patent expiry of the originator products and when the so-called data exclusivity period for the originator product expired (so-called loss of exclusivity).[12] The generic companies have a different cost structure than originator companies, which between 2000 and 2007 spent on average 17 % of their turnover from prescription medicines on R&D (of which 1.5 % into basic research and 15.5 % into clinical trials/approval procedures) and 23 % on marketing and promotion. Generic companies spent most on manufacturing (51 %) and 7 % on R&D. Typically the generic companies are smaller in size than the originators, even if there are nowadays a few global players. In recent times one can observe a trend of mergers between generic companies.[13]

On the demand side, the pharmaceutical sector is unusual in that, for prescription medicines, the ultimate consumer (the patient) is not the decision maker. Decisions

11 Commission Decision of 4/2/2009, case No. COMP/M.5253, *Sanofi-Aventis/Zentiva*.

12 National and Community data exclusivity rules currently protect the data on clinical trials provided by the originator company to obtain market authorization from being used by generic or other competitors to obtain market authorization for their competing product through the abridged procedure for a period of six or ten years depending on the state that granted market authorization and on whether it was obtained through a centralized procedure or through national procedures. See also Directive 2001/83/EC, OJ L 311 of 28/11/2001, p. 67; and Regulation (EEC) No 2309/93, OJ L 214 of 24/8/1993, p. 1. For applications for market authorizations submitted after 30/10 resp. 20/11/2005 a new harmonised regime of data exclusivity applies according to Directive 2004/27/EC, OJ L 136 of 30/4/2004, p. 34; amending Directive 2001/83/EC and Regulation (EC) No 726/2004, OJ L 136 of 30/4/2004, p. 1. The first generic products benefitting from this new regime can enter the market as of 2013.

13 Commission Decision of 19/12/2008, case No. COMP/M.5295, *TEVA/BARR*.

are generally taken by the prescribing doctors and sometimes by pharmacists (e.g. when a product turned generic and various versions of the medicine are available and can be dispensed). Yet, neither the patient, nor the doctor or the pharmacists directly bear the costs of the medicines, as these are generally covered and/or reimbursed by national health (insurance) schemes.[14] The pharmaceutical sector is also unusual in that prices are often the result of negotiations between the pharmaceutical companies and the national health administrations. Where this is not the case, i.e. in countries with so-called free pricing, prices are dependent on the reimbursement status. Due to this market structure doctors, pharmacists and patients are usually not very price sensitive for prescription medicines, even though various (national) mechanisms to control the budgets for prescription medicines exist, in particular for genericised products. This might also have implications for the definition of the relevant markets.

In Europe, the distribution of pharmaceutical products is carried out by full line and/or short line wholesalers. In a limited number of Member States pharmaceutical companies recently started to sell directly to pharmacies (so-called DTP), by relying on selected wholesalers for the logistical operations. In many Member States hospitals carry out tender procedures to directly meet their demand from suppliers, a trend that has recently been followed by certain health insurance schemes (see e.g. Dutch preference policy).[15]

A specific feature of the European markets is the existence of parallel traders that buy medicines in low cost Member States and sell them in high price Member States. This leads to intra-brand competition for medicines in the country of destination prior to patent expiry. The originator companies question the benefits for consumers and argue that parallel trade has a negative impact on their R&D activities. Parallel traders contest this view.[16]

II. Competition between Generic and Originator Companies

The first focus of the sector inquiry deals with competition between originator and generic companies. To assess this competitive relationship it is necessary to look at the economic impact of generic medicines on the market.

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14 In line with the jurisprudence of the ECJ certain public health schemes cannot be considered to be undertakings in the sense of Art. 81 and 82 EC (now Art. 101 and 102 TFEU), see in particular ECJ, case C-205/03 P, *FENIN*, Rec. 2006, I-6295, para. 26; and ECJ, joined cases C-264/01, C-306/01, C-354/01 and C-355/01, *AOK Bundesverband u.a.*, Rec. 2004, I-2493, para. 51 et seq.

15 For details see section B.2.3.5 in the Commission's Final Report on the Sector Inquiry into Pharmaceuticals, (fn. 2).

16 On this topic see *Schnichels*, (fn. 6).

1. Findings on Generic Entry and Impact

As regards the impact of generic entry, the sector inquiry found that in markets where generic medicines become available, average savings to the health system (as measured by the development of a weighted price index of originator and generic products) are almost 20 % one year after the first generic entry, and about 25 % after two years (EU average). In rare instances even price drops of as much as 80-90 % after generic entry could be observed. Obviously, there are significant differences between medicines and Member States. For example, in certain Member States the price for the originator product remains largely stable, even after generic entry, whilst in other Member States the prices dropped much sharper than the average, in particular for the generic versions of the product. By comparison, the price of medicines, which were not confronted with generic entry, stayed stable and even slightly increased.

Based on a sample of medicines used for in-depth investigation that faced loss of exclusivity in the period 2000 to 2007 (representing an aggregate post-expiry expenditure of about € 50 billion over this period in 17 Member States) the sector inquiry report estimates that this expenditure would have been about € 15 billion higher without generic entry. However, the savings from generic entry could have been 20 % higher (or € 3 billion), if generic entry had taken place without delay (the average delay is about 8 months after loss of exclusivity). These estimates are probably very conservative as the calculations are based on the submission of the originator companies on when their products lose exclusivity, even though many expiry dates are contested by generic companies. Also volume effects were not taken into account: 3 years after generic entry the consumption of the medicines increases on average by 60 % in Europe.

2. Practices of Originator Companies vis-à-vis Generic Products

The sector inquiry examined in particular strategies of originator companies used in response to (imminent) generic market entry: It was found that originator companies design and implement a variety of strategies in order to ensure continued revenue streams from their medicines. Internally they often refer to these strategies as "tool box". The successful implementation of the strategies may have the effect of delaying or blocking generic entry. The preliminary and final reports of the sector inquiry underline, however, that company behaviour may not be the only cause for the delay of generic entry on the market and points to regulatory shortcomings. The reports also underline that the use of instruments by originator companies is often legitimate, as they have a right to defend their products against premature market entry. The report therefore stresses that an assessment in individual cases would be required to find a potential violation of EC competition law, even though some general trends are a matter of concern.

a) Importance of IPRs for the Pharmaceutical Sector

Patents are the key for the pharmaceutical industry, which is characterised by long R&D phases and long product life cycles. Patents grant the originator companies an exclusivity period during which they can recoup their R&D expenses (including for failed projects) and be rewarded for their innovative efforts/risks taken. Obviously, the actual recoupment depends amongst others on the expenses previously incurred and the commercial success of the medicines concerned. In this light, the sector inquiry report highlights the need for strong intellectual property rights, also for incremental innovation. It underlines the importance of the IPRs for the pharmaceutical sector and calls for further improvement of the existing patent system. At the same time, the call for a strong and efficient patent system does not mean that EC competition law does not need to be respected.

b) Patent Strategies

The sector inquiry looked in detail at patent strategies of originator companies. Its aim was to help understand whether originator companies develop and employ strategies with the purpose of blocking or delaying generics.

The sector inquiry found that originator companies aimed to extend the breadth and duration of protection of a product by filing numerous patent applications for the same molecule, forming so-called "patent clusters". In some cases, individual blockbuster medicines are protected by up to 100 patent families translating into 1300 national and EPO patents and pending patent applications across the EU Member States. This creates a dense web of patents around the originator company's blockbuster product which can lead to uncertainty for generic companies as to which of these patents they will possibly have to face. From a commercial perspective a generic company that wants to enter the national markets has to confront the sum of all patents in these Member States. This is particularly problematic if it later turns out that the underlying patents were invalid and even worse, if the originator company was aware of this.

Quotes from strategy documents and e-mails gathered during the course of the inquiry, in particular during the inspections, confirm the intention of originator companies to delay generic entry on the basis of their patenting behaviour. As indicated earlier, originator companies are of course entitled to seek additional patent protection for their products. But this does not exclude competition scrutiny.

Furthermore, the increased filing of divisional patent applications, in particular before the EPO, has been an object of complaint by the generic industry as a potential instrument to prevent or delay generic entry. A divisional patent application is created where the applicant, either voluntarily or at the request of the examining office, divides out from a patent application ("parent patent application") one or

several (possibly narrower, but at times identical) patent applications ("divisional"). Such a division must be undertaken as long as the parent patent application is still pending. However, once created, a divisional has a life of its own, i.e. even if the parent patent application is later refused or revoked. The divisional has the same priority date as the parent patent application. In other words, if granted, a divisional will, in principle, provide the same duration of patent protection as the parent application. Also, the divisional application cannot extend the scope of the parent application.

However, applicants can use this procedure to "reset the clock" and gain more time for patent examination, thus extending the period of pending applications. As each divisional application has to be assessed individually, a successful challenge of a parent application will not create legal certainty for the challenger, as long as several other divisional applications are still pending. In such cases, generic companies pointed out, it is virtually impossible to predict when which divisional application will possibly be granted. As a consequence, they are unsure as to what they can reproduce without infringing any patents, even if the parent patent application was refused or revoked.[17] Divisionals thus essentially prolong the period of uncertainty and create an additional burden on entrants to verify the likelihood of success for these applications.

On the basis of observations of patent filings for the top 20 best-selling medicines the sector inquiry found a continuous increase of patent applications throughout the lifetime of a product, i.e. originator companies keep on filing new patent applications for their blockbusters, often only after product launch. A number of these filings only occur shortly before expiry of the compound patent, again prolonging the period of uncertainty.

c) Patent Disputes and Litigation

The patent strategies mentioned above may eventually lead to non-litigious patent disputes as well as litigation. In this respect, it needs to be underlined that enforcing patent rights is a fundamental right which is not put into question by the sector inquiry. But the inquiry showed that litigation can also be an efficient way of creating obstacles for competitors, in particular smaller competitors. Originator companies may sometimes consider litigation not so much on its merits, but rather as a signal to deter generic entrants.

The sector inquiry found almost 460 patent disputes outside legal proceedings on the sample of 219 medicines alone. Interestingly, almost all of these patent disputes between originator and generic companies (91 %) were initiated by an originator company.

17 In reaction to such complaints the EPO recently changed its rules on voluntary divisional patent applications limiting the filing period.

As regards litigation, the inquiry found that, in the period 2000 to 2007, originator companies engaged in nearly 700 cases of patent litigation with generic companies concerning the sample of products investigated. Here, 54 % of the cases were initiated by an originator company, however when considering the cases where a final judgment was taken (149) it is noteworthy that generic companies won almost two thirds (62 %) of them. However, on average, it took 2.8 years for a final judgment to be reached by court.

Moreover, in about half of all cases where an originator company requested an interim injunction ordering the generic not to sell its product or ordering it to withdraw the product from the market, such an injunction was granted. This happened in 112 cases of the sample. On average, an interim injunction lasted for 18 months. When analysing the final outcome of cases in which interim injunctions were granted, it would appear that almost 50 % of them were favourable to the generic companies (including favourable settlements).

d) Patent Opposition Procedures

The sector inquiry also examined opposition procedures including appeals before the European Patent Office (EPO), involving generic companies as opponents against the patents of originator companies. Opposition procedures, in this particular context, allow generic companies to request a review by the European Patent Office of whether the conditions for granting the patent are met. Thus, these procedures can serve as an important tool for opponents, such as generic companies, in order to ensure patent quality and to remove patents that do not meet the agreed standard.

In opposition procedures, a European patent can be either maintained or rejected or amended. Counting only rejections as a success the sector inquiry found that in the majority (60 %) of opposition procedures in which a final decision was reached, generic companies were successful. In a further 15 % the scope of the patent was reduced. While, in theory, opposition procedures could represent an efficient legal remedy for generic companies to challenge invalid patents, they unfortunately do not bring clarity and legal certainty in a timely manner. Almost 80 % of procedures took more than two years before a final decision was reached. For some extreme cases, it took up to nine years.

e) Patent Settlements

Patent settlement agreements are commercial agreements to settle actual or potential patent-related disputes, e.g. questions of patent infringements or patent validity. They are concluded in the context of patent disputes, opposition procedures or litigation where no final adjudication has been handed down. Although the content of

individual settlements will vary according to the circumstances of the case, the common aim of a settlement is to end the disagreement.

The sector inquiry quantifies and classifies the settlement agreements concluded between originator and generic companies and relating to the European market (or parts thereof) without taking any position on the legality under antitrust law.

The inquiry found that 207 settlements were concluded between originator companies and generic companies in the time period between January 2000 and June 2008, roughly 25-30 per year. They related to 49 different medicines, most of which were best-selling and lost exclusivity between 2000 and 2007. About half of the originator and generic companies that cooperated with the sector inquiry had entered into such settlement agreements. Most of the settlements resulted from litigation in the courts, but some also resulted from out of court disputes and/or opposition proceedings.

It transpired from the sector inquiry that the most relevant factors originator companies consider before entering into a settlement agreement are the strength of their position in the patent litigation, their chances of obtaining an interim injunction to prevent the sale of the generic product and the importance of the product at issue and its market size. For generic companies, the most important factor when deciding whether to settle are the costs of litigation. This is not surprising considering that the generic companies do not benefit from any revenues during that time period, unless they have launched the product at risk.

About half of the settlements uncovered during the sector inquiry (99) limited the market entry of the generic product in some form. This is for example achieved by an explicit agreement that the generic product can only enter the market after a certain date or the settlement obliges the generic company to withdraw its product from the market or the generic company is not free to launch its own product, but instead is granted a license or a distribution agreement by the originator. In the latter case, the originator company exercises a certain control over the generic company's activities regarding the product in question.

Of these 99 settlements, 45 involved a value transfer from the originator to the generic company. Several forms of value transfers have been found and 15 settlements involved more than one type of value transfer. 51 % of the settlements included a payment from the originator company to the generic firm, 64 % included a license agreement, 20 % included a supply and/or distribution agreement and 2 % included a "side deal", i.e. a deal not related to the patent issues at stake in the litigation. More than € 200 million in cash were transferred from originator to generic companies in direct payments, not taking into account the indirect value transfer due to royalty-free licenses for example.

If the granting of a license was agreed, the license was always limited in scope and covered only certain versions and dosages of the product. Most of the license

agreements (59 %) were royalty-bearing, while 41 % were royalty-free to the generic company. None of the settlements examined contained an undertaking by the originator company not to launch an authorised generic of its product for a given time after market entry of the generic company, a clause that has gained importance in the US in recent years and might gain importance also in Europe considering the recent trend that originator companies acquire (controlling) stakes in generic competitors.

f) Interventions before Regulatory Bodies

Originator companies also intervened before national marketing authorization and pricing and reimbursement authorities to call into question the quality or safety of generic products or to claim that obtaining the marketing authorization would violate their patent rights. In this respect, it is interesting to note that marketing authorization bodies are not entitled under EU law to verify the patent status of the generic product.[18]

The sector inquiry confirmed that – where an initial intervention before the authority does not lead to the desired result – originator companies take the national authorities to court in a significant number of cases. The vast majority of these court cases were, however, lost by the originator companies. In fact, originator companies won only 2 % of cases launched against marketing authorization bodies.

Even where generic companies can ultimately enter the market as the intervention was unsuccessful, the intervention might have had very significant consequences. When comparing the duration of approval procedures in which an intervention took place with procedures in which no such intervention took place the former lasted on average four months longer. In the inspection material one originator company reported about significant additional revenues obtained through such interventions.

g) Life Cycle Strategies

Incremental research is important as it can lead to small but important steps in innovation and thus can lead to second generation products that address unmet patient needs. The generic industry is, however, more critical towards second generation products, and speaks about so-called ever-greening strategies. Generic companies argue that second generation products are often based on first generation products

18 Art. 81 of Regulation (EC) No 726/2004 and Art. 126 of Directive 2001/83/EC provide that an authorization to market a medicinal product shall not be refused, suspended or revoked except on the grounds set out in the Regulation and the Directive. Considering that patent status is not included in the grounds set out in the Regulation and the Directive, it cannot be used as an argument to refuse, suspend or revoke a marketing authorization.

and have little or no added value for patients, a view that is shared by consumer associations.

For the sample of 219 molecules originator and generic companies reported that approximately 40 % of all medicines were subject to this practice, i.e. they were either a first generation product for which subsequently a second generation product was launched or a second generation product for which an earlier version existed. For the narrower sample of medicines that faced expiry in the period 2000 to 2007 the percentage figures increased even to 53 %. Not surprisingly, there were significant discrepancies between the reports of generic and originator companies.

Originator companies confirmed that they launch second generation products on average one year and five months prior to the loss of exclusivity of the first generation product. Timing appears to be crucial when switches occur and significant marketing and promotion efforts are undertaken by originator companies when switches are envisaged.

Originator companies confirmed that the switch to the next generation must take place before the generic version of the first generation product is launched as was also illustrated by quotes from strategy documents. Generic companies on the other hand submitted that they had difficulties to enter the market when a second generation product was launched successfully by the originator company and the patient base was switched. Often the launch of the second generation product is accompanied by a withdrawal from the market of the first generation product.

h) Cumulative Use of Instruments

In many instances, originator companies used two or more instruments from the "tool-box" in parallel and/or successively in order to protect the revenue streams from their (best-selling) medicines which can lead to cumulative delays. Again, it needs to be underlined in this respect that the use of an instrument does not mean that it violates the competition rules.

III. Competition between Originator Companies

The second focus of the sector inquiry concentrated on the competitive relationship amongst originator companies.[19]

19 Other reasons given by the originator industry for the decline in innovation measured in the decrease of new medicines reaching the market include increased scientific complexities, high attrition rates in late stage development due to regulatory risk aversion and uncertainty about the financial rewards.

1. Patent Strategies

Again, it has to be underlined in this context that the importance of patents for this sector in particular is not put into question. As already mentioned earlier, patents are very important for pharmaceutical companies to recoup investments and to be rewarded for innovative efforts/risks taken. Also, any patent application needs to be assessed on its own merits taking into account the criteria for patentability. In its analysis of patent strategies, the sector inquiry focused on so-called "defensive patents". These can be described as patents which are not foreseen to be used for innovation, but primarily pursue the purpose of blocking the development of competing products.

Whilst all patents have a legitimate exclusionary function, defensive patents might under certain circumstances come under competition scrutiny, e.g. when the patent turns out not to be valid and the originator company was aware of it (i.e. deliberately created legal uncertainty for the opponent) or when the originator company refuses to grant a license to a competitor in order to develop and launch a new product. Obviously the specific circumstances of the case will need to be considered in investigations.

In the course of the sector inquiry a significant number of originator companies confirmed that they engage in such defensive patenting activities. Some also reported that they had been victim of such activities. The use of defensive patenting activities was particularly confirmed by several quotes of originator companies that were gathered during the inquiry as well as the statement by several companies to have filed such defensive patents.

The sector inquiry also tried to estimate the potential area of patent "conflicts" between originator companies in the pharmaceutical sector. In total, at least 1.100 instances were found, where there is an overlap between a product or R&D project of one originator company with the patents of another one. In view of this, the sector inquiry looked at the request for licenses and refusals and found – on its sample alone – 99 cases where a license was requested. In nearly 20 % the requesting party did not obtain a license for a variety of reasons. This lead to the R&D projects being abandoned or significantly delayed, e.g. because the other originator company was trying to invent around the defensive patent.

2. Patent-Related Exchanges, Disputes, Litigation and Oppositions

The sector inquiry also confirmed that originator companies engage in patent litigation with other originator companies. Thus, almost 40 % of respondent originator companies were involved in patent litigation with another originator company. In total, 66 litigation cases were reported for the 219 medicines of the sample only. This is probably a conservative estimate due to the selection of the medicines,

which contain many medicines already facing generic entry – and therefore were rather late in their product life cycle.

Of the court cases reported, two thirds (64 %) were settled, most of the settlements containing a license agreement. Of the remaining cases, a limited sample, the originator company enforcing its patent won in less than 25 % of cases. In other words, the originator company challenging the patents won in the vast majority of cases.

The final report also showed that, between 2000 and 2007, the applicant originator companies were very successful when challenging the patents of other originator companies before patent offices (opposition procedures and appeals). During that period, they prevailed in approximately 70 % of final decisions rendered by the EPO (including the Boards of Appeal). In a further 19 % the original scope of the patent was reduced.

IV. Comments on the Regulatory Framework

Many comments were received on the existing regulatory framework, mostly relating to patents, marketing authorizations and pricing and reimbursement.

1. Fragmented Patent System

Originator and generic companies as well as their associations pointed to the urgent need for a Community patent and a unified and specialised patent judiciary. They argued that many of the issues identified in the sector inquiry could be successfully addressed if progress were made on these important legislative dossiers. The sector inquiry provided compelling evidence for the need to take the necessary measures. 30 % of the litigation cases were duplicates of parallel cases in other Member States and in 11 % of the cases conflicting judgments were rendered, putting legal certainty into question. Last but not least, the total costs of the patent litigation analysed in the report amount to € 420 million. It could be significantly less if a Community patent and a specialized patent judiciary existed.

In addition, generic companies and some originator companies also called upon the patent offices and most prominently the EPO, to which most applications go, to ensure a high quality of patents granted and effectively counter strategies that may cause unnecessary delays such as divisionals. They also called for better and faster procedures.

2. Marketing Authorization

With respect to procedures governing marketing authorizations, companies, industry associations and national agencies reported most prominently about bottlenecks that can lead to obstacles and delays of market entry.

Some originator companies also said that they would favour further international harmonization, in particular between the EU and the US. First steps are under way to achieve this.

Furthermore, generic companies submitted that originator companies intervene in marketing authorization procedures for their products claiming the generic product to be less safe, less efficient than or not equivalent to the corresponding originator product or even violating their patent rights, which is illegal under European law. They also expressed concern about the lack of transparency when such interventions take place.

3. Pricing and Reimbursement

With respect to pricing and reimbursement procedures, companies complained in particular about the delays and uncertainties created by the national procedures. The delays would reduce the time during which originator companies can reap the benefits of their innovation. Whilst additional efforts to speed up procedures are certainly to be welcomed, it should also be noted that the effective protection period of originator products increased from 10.5 years in 2000 to more than 14 years in 2007 (effective protection is measured from product launch of the originator product to the first product launch of an independent generic product).

Generic companies voiced concerns about delays in the pricing and reimbursement procedures as a result of the additional requirements introduced by some Member States. They pointed in particular to the fact that some Member States request evidence that the patents of the originator companies are not violated. The latter was often based on interventions by originator companies. They also called for immediate pricing and reimbursement status for their product and more transparency.

Generic companies also called for measures facilitating generic uptake after loss of exclusivity.

V. Policy Recommendations

As a consequence of the aforementioned findings, the Commission made a number of recommendations announcing first that it will apply increased scrutiny under EC competition law to the sector and bring specific cases, where appropriate. The first enforcement action is already under way.[20] The Commission also clarified that the application of EC competition law would not be sufficient and highlighted the areas in which further work should be undertaken. In the light of the comments

[20] See below section D.II.3.

received the areas concerned are: patents, marketing authorizations and pricing and reimbursement issues.

As far as the regulatory framework is concerned, the Commission reaffirmed the urgent need for the establishment of a Community patent and of a unified specialized patent litigation system in Europe. A major break was achieved during the Competitive Council of 4 December 2009, which reached political consensus on the Community patent and the specialized patent court.[21] With respect to patent law the sector inquiry also fully confirmed the relevance of the recent initiatives of the European Patent Office to ensure a high quality standard of patents granted and to accelerate procedures ("raising the bar") as well as the limitation of the period during which voluntary divisionals may be applied for.

With respect to marketing authorization, the Commission announced that it will focus on the full implementation and effective enforcement of the regulatory framework, e.g. regarding the deadlines foreseen for marketing authorization processes. Further analysis is under way looking into the cooperation between authorities and building up capacities/expertise throughout the EU. The Commission also reminded stakeholders of the prohibition of patent linkage and the need to stop unwarranted interventions or negative information campaigns.

Concerning pricing and reimbursement, the Commission invites Member States to consider provisions that would grant pricing and reimbursement status to generic products automatically where the corresponding originator product already benefits from such a status. It also invites Member States to consider policies facilitating rapid generic uptake and/or generic competition, such as INN prescription for doctors instead of brand prescription or the obligation on pharmacists to dispense the cheapest available product. Another mechanism that might be considered is tendering which has the potential of bringing down prices at the level of consumers. However, the final report does not recommend the general use of this instrument and warns that not only the short term effects on prices should be considered when designing tenders, but also the medium and long term effects on the market structure. Currently, the Commission is examining the potential need for a review of existing EU rules in the area of pricing and reimbursement (Transparency Directive 89/105/EEC).

21 For details see http://www.se2009.eu/polopoly_fs/1.26592!menu/standard/file/CC%20 patent.pdf (20/9/2010) and http://www.se2009.eu/en/meetings_news/2009/12/4/breakthrough _for_eu_ patent_during_the_swedish_presidency (20/9/2010).

D. Competition Law Enforcement in the Pharmaceutical Sector

Subsequent to the sector inquiry, the Commission identified several areas as potentially concerning from a competition law point of view. Some of them involved the use of exclusive, in particular patent rights. This inevitably leads to the discussion of the relationship between intellectual property rights (IPRs) and competition law enforcement which will be briefly touched upon before looking at the areas of competition law concern.

I. Relationship of IPRs and Competition Law Enforcement

Hardly any area is as dependant on innovation and patent protection as the pharmaceutical sector. Scientific progress made in the last decades has benefited the treatment of patients in a way unimaginable some fifty years ago. These achievements could not have been made without significant investment by the pharmaceutical industry (but also by other stakeholders such as universities) into R&D. Such investments can only be secured as long as innovative achievements can be protected by IPRs, namely patents. The European legislator has reacted to the specificities of the pharmaceutical sector. Pharmaceutical companies thus do not only benefit from up to 20 years of patent protection. Under certain conditions the exclusivity periods can be extended through supplementary protection certificates (SPCs) with a maximum duration of five years.[22]

These IPRs create incentives for pharmaceutical companies to continue investing into R&D and innovating. At the same time, though, they also create exclusive rights for a certain period as regards the commercial use of their inventions. During that period any competition on price, i.e. through the entry of generic versions of the invention is excluded. This has often been proclaimed as evidence of the tension inherent in the relationship between IPRs and competition law.[23]

However, closer examination of the two legal areas rather reveals their compatibility and the same ultimate aim, namely consumer welfare. This is in particular confirmed by the Guidelines on the application of Art. 81 EC (now Art. 101 TFEU) to technology transfer agreements which clarify that competition law does not only aim at protecting static competition, but also promotes dynamic competition. In

22 Council Regulation (EEC) No 1768/92 of 18/6/1992 concerning the creation of a supplementary protection certificate for medicinal products, OJ L 182 of 2/7/1992, p. 1.

23 The relationship of these two areas of law has been the object of academic debate for some time now. See e.g. *Heinemann*, Immaterialgüterschutz in der Wettbewerbsordnung, 2002; *Devlin*, The Stochastic Relationship between Patents and Antitrust, Journal of Competition Law & Economics 5 (2009), pp. 75-122.

this respect, IPRs are generally seen to lead to increased consumer welfare.[24] Thus, both legal systems are in fact complementary to each other.[25]

This discussion in fact is led by most competition authorities around the world where a functioning IPR system exists. In this respect, reference is made to the recent discussions at the OECD on patents, innovation and competition, which show the interest of several industrialised countries to explore the relationship between competition law and the acquisition and use of IPRs.[26]

From the above mentioned, though, it does not follow that the area of intellectual property law is exempt from competition law scrutiny. In fact, where there are indications that a market player misuses IPRs, namely the patent system or its procedures against the rationale of patent law thereby causing consumer harm, competition law can be invoked to restore the competitive process, albeit under specific circumstances. A careful application of competition law to such cases, depending, of course, on their particular circumstances, will furthermore not have a stifling effect on innovation. Rather the opposite seems to be likely, that competition enforcement will restore the incentive to innovate where such a misuse can be rectified. This has been confirmed by the General Court in its recent *AstraZeneca* judgement against the claim of the applicant as regards an infringement of Art. 82 EC (now Art. 102 TFEU):[27]

> "[...] Nor can the applicants object that a finding of an abuse of a dominant position in cases where misleading representations have been made to patent offices for the purposes of obtaining intellectual property rights to which an undertaking is not entitled, […] run counter to the public interest in encouraging innovation. It is quite clear that, where established, such behaviour is indeed contrary to the public interest, as weighed up and applied by the legislator. As the Commission observes, such misuse of the patent system potentially reduces the incentive to engage in innovation, since it enables the company in a dominant position to maintain its exclusivity beyond the period envisaged by the legislator."

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24 "Indeed both bodies of law share the same basic objective of promoting consumer welfare and an efficient allocation of resources. Innovation constitutes an essential and dynamic component of an open and competitive market economy." Commission Notice, Guidelines on the application of Article 81 of the EC Treaty to technology transfer agreements, OJ C 101 of 27/4/2004, p. 2, para. 7.

25 This evaluation is equally shared by colleagues of the U.S. Department of Justice and the Federal Trade Commission, Antitrust Enforcement and Intellectual Property Rights: Promoting Innovation and Competition, 2007, www.ftc.gov/reports/index.shtm (20/9/2010), p. 1; see also *Devlin*, (fn. 23), p. 98.

26 See OECD Policy Roundtables, Competition, Patents and Innovation, 2006, http://www.oecd.org/dataoecd/26/10/39888509.pdf (20/9/2010).

27 CFI, case T-321/05, *AstraZeneca*, not yet reported, para. 367.

Nevertheless, competition authorities are obviously well advised not to try to correct any potential failures in the patent system. Furthermore, they must take into account the effects of their intervention on the incentive to innovate and balance such effects against those of the perceived consumer harm. Ultimately, it will depend on the particular circumstances of each case whether an intervention is necessary.

II. Areas of Competition Law Concern

Areas of competition law concern identified by the Commission following the results of the sector inquiry comprise so-called defensive or vexatious patenting, interventions before national regulatory bodies and patent settlements. This list should, however, not be viewed as exhaustive. The following subsections will focus on defensive patenting and patent settlements.[28]

1. Defensive Patenting

As explained above, the notion of defensive patenting is used where the application for a patent is made for the sole purpose of blocking the development of a new innovative product by a competitor. Such patenting behaviour might of course also be aimed at preventing the emergence of a generic version of a medicine, the basic patent of which is about to expire. Obviously, it will depend on the individual circumstances of the case whether a violation of European competition law can be proven. Competition authorities should in this context not undertake any (re-)evaluation of patents concerned. That is an exclusive task of the relevant patent offices.

However, particular circumstances of the case may suggest the anticompetitive nature of such patenting behaviour, as e.g. subjective intent of the company. Thus, the behaviour might for example be particularly problematic if it turns out that the patent does not meet the patentability criteria and the company concerned was aware of this (vexatious patenting). Some go even further suggesting an abuse of a dominant position where a patent is obtained but clearly objectively unjustified and where the patent holder knew that the application was without merit or where a reasonable person would have known that there was no reasonable basis for the patent.[29]

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28 For an overview of refusal to license problems in this respect see *Schnichels/Sule*, The Pharmaceutical Sector Inquiry and its Impact on Competition Law Enforcement, Journal of European Competition Law and Practice 2010, p. 104 et seq.

29 See *Temple Lang*, Current European Competition Law Questions for Pharmaceutical Companies, in: Baudenbacher (ed.), Current Developments in European and International Competition Law, 16th St. Gallen International Competition Law Forum 2009, p. 94.

Where a dominant undertaking knows that it does not fulfil the patentability criteria and yet submits misleading information to the patent office in order to obtain a patent this could possibly constitute an abuse of a dominant position pursuant to Art. 102 TFEU. Note in this context that the General Court in its recent *AstraZeneca* judgement has pointed out

> "[...] that the submission to the public authorities of misleading information liable to lead them into error and therefore to make possible the grant of an exclusive right to which an undertaking is not entitled, or to which it is entitled for a shorter period, constitutes a practice falling outside the scope of competition on the merits which may be particularly restrictive of competition. Such conduct is not in keeping with the special responsibility of an undertaking in a dominant position not to impair, by conduct falling outside the scope of competition on the merits, genuine undistorted competition in the common market."[30]

Thus, the submission of misleading information to public authorities leading to the wrongful grant of an exclusive right may constitute an infringement of Art. 102 TFEU, obviously one main condition being that the submitting party is a dominant undertaking.

The General court has also underlined that subjective intention in this context may be a relevant factor when assessing the behaviour even if the concept of the abuse of a dominant position is an objective one:

> "[...] although proof of the deliberate nature of conduct liable to deceive the public authorities is not necessary for the purposes of identifying an abuse of a dominant position, intention none the less also constitutes a relevant factor which may, should the case arise, be taken into consideration by the Commission."[31]

In view of the above, certain instances of defensive or vexatious patenting may very well be areas of competition scrutiny, in particular where the patentability criteria are not met and the undertaking concerned was aware of this. The submission of misleading information in order to obtain an exclusive right could also be of relevance in this context.

2. Patent Settlements

One particular instrument identified in the sector inquiry that can potentially lead to a delay of generic entry are patent settlements.[32] As in any other area of commercial

30 CFI, case T-321/05, *AstraZeneca*, not yet reported, para. 355.

31 Ibid., para. 359.

32 See above section C.II.2.e).

disagreement, the parties concerned have a legitimate interest in finding a mutually acceptable compromise for their disagreement. In particular, the parties may prefer to discontinue the dispute or litigation because it proves to be too costly, time-consuming and/or risky as regards its outcome. Settlements are thus a generally accepted, legitimate way of ending private disagreements. They can also save courts and/or competent administrative bodies such as patent offices time and effort to decide on the matter and can therefore have some positive impacts on the interest of society.

a) Potentially problematic Patent Settlements

However, as pointed out in the Final Report of the sector inquiry, some patent settlements in the pharmaceutical sector may prove to be problematic from a competition law perspective. Of particular interest are settlements that may lead to a delay of a generic entry in return for a value transfer (e.g. a payment) by the originator company to the generic company. Other examples of possibly problematic agreements relate to settlements that contain restrictions beyond the exclusionary zone of the patent, meaning that they would reach beyond its geographic scope, its period of protection or its material scope, e.g. beyond the patent claims. Such agreements would not appear to be directly related to any IP rights granted by the patents concerned. Furthermore, problematic agreements include settlement agreements on a patent for which the patent holder knows that it does not meet the patentability criteria. An example for this would be a situation where the patent was granted following the provision of incorrect, misleading or incomplete information.

Ultimately, it may be the consumer in such cases who pays the price for such a delay in market entry and therefore any benefits to society identified above are more than outweighed by the negative effects of the agreement between potential competitors and where competition law intervention might be required. In this context, obviously, an assessment of each individual case would be necessary. It has to be pointed out that the discussion on the compatibility of patent settlements with antitrust law is quite advanced in the US where competition agencies, namely the US Federal Trade Commission have brought several actions against pharmaceutical companies for infringing US antitrust law through patent settlements.[33]

When the Commission launched the sector inquiry in January 2008, many stakeholders expressed surprise that the Commission intended to look into patent settlements. They argued that patent settlements – including patent settlements with reverse payments – are a common feature in the US because the legislative framework provides incentives to enter into such settlements. But they claimed that patent settlements are a "non-issue" in the EU. It was said that, in particular, it would not

33 For an overview of the US situation see *Schnichels/Sule*, (fn. 28), p. 106 et seq.

make sense for an originator company to conclude patent settlements with a value transfer to the most likely/most advanced generic company, as nothing would stop the next generic company in line from launching the product. This statement proved, however, to be incorrect, as the empirical information gathered during the sector inquiry showed with 45 settlements entailing a restriction of generic market entry and a value transfer from the originator to the generic company concerned.[34]

b) The European Commission's Patent Settlement Monitoring Exercise of 2010

Taking into account that patent settlement agreements might call for antitrust scrutiny, the Commission announced in the Final Report for the Sector Inquiry a continued monitoring of patent settlements. This exercise was launched in January 2010 and took the form of a short questionnaire sent to a selected number of pharmaceutical companies requesting them to transmit copies of the settlements. Its results were published in a report on 5 July 2010.[35]

It confirmed the increasing use of patent settlements in the European pharmaceutical sector since 2000. This patent monitoring exercise unearthed that 93 agreements were concluded between originator and generic companies in the 18 months examined (July 2008 to December 2009; = 5.2/month), compared to 207 in the period covered by the sector inquiry (2000 to June 2008, i.e. 102 months; = 2/month).

This being said, it is noteworthy that the number of settlements which restrict generic entry and show a value transfer from the originator to the generic company and which might attract competition law scrutiny, decreased significantly compared to the period investigated in the course of the sector inquiry, even if they are still being concluded. In the period of 2000 until 2007, covered by the sector inquiry, these settlements constituted 22 % of the settlements reported (45 out of 207). In the period examined in the monitoring exercise, 1 July 2008 to 31 December 2009, only 10 % of the settlements fell into the same category (9 out of 93). Also, the direct value transfer seems to have decreased significantly. An explanation for these developments may be the increased awareness of companies and their legal advisors regarding the question whether such agreements might attract competition law scrutiny. Also, the fact that the Commission announced a continued monitoring of patent settlements and the opening of competition proceedings in the *Servier*[36] case might have had a deterrent effect.

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34 See above section C.II.2.e).

35 1st Report on the Monitoring of Patent Settlements of 5/7/2010, http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/patent_settlements _report1.pdf (20/9/2010).

36 See below section D.II.3.

Thus, most of the concluded patent settlements in the monitoring period appear unproblematic from a competition law perspective. The number of settlements, which do not restrict generic entry in any form (so-called category A) has increased. They went from 52 % during the period examined in the sector inquiry (108 out of 207) to 57 % during the reporting period (53 out of 93). A similar increase could be observed for another category of settlements that are – disregarding special circumstances[37] – in principle unproblematic. These agreements foresee a limitation on the generic company's ability to market its own medicine but do not foresee a value transfer to the generic company. They increased from 26 % (54 of 207) in the sector inquiry to 33 % (31 of 93) for this reporting period.

The monitoring exercise has also shown the sector's concern that the Commissions' heightened focus would result in an increase in court litigation was largely unfounded as the number of settlement agreements has actually increased in general.

The commission has announced that it will repeat the monitoring exercise, which proved to be of limited burden for the companies concerned, in 2011.

3. Procedures opened after the Sector Inquiry

Finally it needs to be pointed out that the Commission opened proceedings against pharmaceutical companies in two cases.

The first one concerns the originator company Les Laboratoires Servier[38] for suspected breaches of the EU rules on restrictive business practices (Art. 101 TFEU) and on abuse of a dominant market position (Art. 102 TFEU). The decision to open proceedings also concerned a number of generic companies as regards a number of individual, possibly restrictive, agreements between each of them and Servier. The opening of formal proceedings followed unannounced inspections carried out by the Commission in November 2008 in several Member States. The Commission proceedings concern unilateral behaviour by Servier, and agreements which may have the object or effect of hindering entry onto the market of generic perindopril, a cardio-vascular medicine originally developed by Les Laboratoires Servier, on the EEA markets.

The second case concerns the originator company Lundbeck[39] and equally potential breaches of EU rules on restrictive business practices and on the abuse of a

37 Such special circumstances could be settlements outside the exclusionary zone of the patent or settlements on patents, on which the originator company knew that the patentability criteria are not met.

38 See press release MEMO/09/322, Commission opens formal proceedings against Les Laboratoires Servier and a number of generic pharmaceutical companies.

39 See press release IP/10/8, Commission opens formal proceedings against pharmaceutical company Lundbeck.

dominant market position under Art. 101 and 102 TFEU. Here, the Commission in particular intends to investigate unilateral behaviour and agreements by Lundbeck which may hinder the entry of generic citalopram into markets in the European Economic Area. Citalopram, originally developed by Lundbeck, is an anti-depressant drug known as a selective serotonin reuptake inhibitor (SSRI).

E. Conclusion

Following the sector inquiry a number of areas have been highlighted by the Commission as raising competition law concerns, namely defensive and vexatious patenting behaviour and certain kinds of patent settlements that restrict generic entry and show a value transfer from the originator to the generic company. It goes without saying that these are not the only areas that may attract attention by the Commission within its competition law scrutiny.

With view to patenting behaviour, the recent *AstraZeneca* decision of the General Court may be of significant relevance in so far as it has already confirmed that the submission of misleading information in order to obtain an unjustified exclusive right can under certain circumstances constitute a competition law infringement. As regards patent settlements the Commission has pointed out that the specific category of settlements mentioned above may be problematic from a competition law view point. On the other hand, the recent patent settlement monitoring exercise has shown a significant decrease of this type of settlements while the overall number of settlements has increased. This development, possibly due to increased awareness of the undertakings, has been welcomed by the Commission. It remains to be seen how future cases in this area will shape competition law enforcement in the pharmaceutical sector.