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LIMITING THE IPRS OF PHARMACEUTICAL COMPANIES THROUGH EU COMPETITION LAW: THE FIRST CRACK IN THE WALL

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Abstract

The exclusivity granted to pharmaceutical companies through intellectual property rights (IPRs) may in certain circumstances run counter to the main objectives for which these rights are intended. EU competition law has stepped in to correct systemic failures that have adversely affected the competitiveness of the sector and the public interest of individuals in access to improved and affordable medicines. In the case of *AstraZeneca v Commission*, the General Court of the European Union found, for the first time, that a pharmaceutical company had abused its dominant position by (mis)using regulatory patent procedures to eliminate or restrict the market entry of competitors of generic medicines.[1] To understand the way by which EU competition law intersects with IPRs and safeguards (patent regulations) requires an appreciation of the tensions (Part I) that underlie the expansive application of competition rules in the pharmaceutical sector (Parts II, III) as well as of the new policies that have emerged (Part IV).

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[1] *AstraZeneca AB and AstraZeneca plc v European Commission*, Case T–321/05, European Union General Court (Sixth Chamber, extended composition), Judgment of 1 July 2010.

1. Describing the tension between IPRs and EU competition policies

In theory, IPRs are justified on the basis that they can encourage investment, research, innovation, competitiveness, economic growth and consumer benefits. In practice, however, innovation has declined[2] and national health care systems are under considerable financial strain,[3] while access to medicines is unsatisfactory given the sharp differences that exist between and within member states.[4]

For the pharmaceutical industry 'there is no fundamental difference between the pharmaceutical industry and other hi–tech industries in the use of patents to protect incremental innovation'.[5] It may however be fundamentally different in other ways, as explained by then Competition Commissioner, Neelie Kroes, who at the launch of a sector inquiry in 2008 said:

> I have focused on solving competition problems that make a difference to the *lives of individuals*. Few things make more of a difference than this. The pharmaceuticals sector is vital to the *health of Europe's citizens*. As well as being a *vital sector of the economy*, medicines are a *major expense*.'[6]

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[2] The Commission of the European Communities (EC Commission), in its 2008 Communication, "Safe, Innovative and Accessible Medicines: a Renewed Vision for the Pharmaceutical Sector", COM (2008) 666 final, available at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:52008DC0666:EN:NOT (accessed 30 March 2011), at 3: "Europe has been losing ground in pharmaceutical innovation. The centre of gravity for research has moved to the US and Asia. New international competitors emerge." See also "Remarks by the President in State of Union Address", 25 January 2011, available at http://www.whitehouse.gov/the–press–office/2011/01/25/remarks–president–state–union–address (accessed 28 March 2011), in which Barack Obama declared that "no workers are more productive than ours. No country has more successful companies, or grants more patents to inventors and entrepreneurs. …We need to out–innovate, out–educate, and out–build the rest of the world".

[3] Communication of the EC Commission, "Executive Summary of the Pharmaceutical Sector Inquiry Report", COM (2009) 351 final, available at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2009:0351:FIN:EN:PDF (accessed 30 March 2011), at 2.

[4] Communication of the EC Commission, "Safe, Innovative and Accessible Medicines", note 2, at 3: "Shortcomings in the availability of medicines have been identified. In 2008, European patients still suffer from inequalities in availability and affordability of medicines". See also Communication of the EC Commission, "Solidarity in Health: Reducing Health Inequalities in the EU", COM (2009) 567 final, available at http://ec.europa.eu/health/ph_determinants/socio_economics/documents/com2009_en.pdf (accessed 30 March 2011).

[5] EU Pharmaceutical Sector Inquiry, "Response to the Commission's Preliminary Report by the Association of the British Pharmaceutical Industry", 29 January 2009, Reference 39514, Directorate General for Competition, Anti–trust Registry, available at http://ec.europa.eu/competition/consultations/2009_pharma/abpi.pdf (accessed 28 March 2011).

[6] Europa Press Release, "European Commissioner launches sector inquiry into pharmaceuticals", SPEECH/08/18, 16 January 2008, available at http://europa.eu/rapid/pressReleasesAction.do?reference=SPEECH/08/18&format=HTML&aged=1&language=EN&guiLanguage=en (accessed 30 March 2011) (emphasis added).

The development of EU competition law does not therefore concentrate exclusively on economic approaches that directly concern IPRs[7] but also takes into consideration various public interests, namely economic competitiveness, public expenditure and access to health care.[8] In principle, the public interest is determined by the interaction between the EU Competition department and the EU organs (including the other departments of the EU Commission), all of which are influenced by political forces and social realities at both national and international levels.[9]

The July 2009 Commission inquiry into the pharmaceutical sector demonstrated that pharmaceutical companies systematically misuse their exclusive IP rights in order to eliminate competitors and keep the price of medicines artificially high. The findings indicate that pharmaceutical companies put much of their energy into developing a variety of patent strategies to extend the commercial life of their medicines,[10] rather than investing in research and development in order to produce new drugs.[11] As a result of the inquiry, scrutiny of pharmaceutical company practices with respect to their IPRs has been intensified.

2. Using EU competition law against misuse of the patent system: the AstraZeneca case

Practices that do not concern competition on the merits of the products, which are carried out by an undertaking in a market–dominant position in order to deter or eliminate competitors, can be challenged by EU competition rules. The General Court

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[7] See for example the application of the criterion of "risk of the elimination of the competition on the market" in *Microsoft Corp v Commission*, Case T–201/04, Court of First Instance (Grand Chamber), Judgment of 17 September 2007, 560–563. See, generally, S Bishop and M Walker, *The Economics of EC Competition Law: Concepts, Application and Measurement* (London: Sweet & Maxwell, 3rd ed, 2010).

[8] D Chalmers, Ch. Hadjiemmanuil, G. Monti, A. Tomkins, *European Union Law* (Cambridge: Cambridge University Press, 2007) at 929: "competition law can be enforced to serve a wider range of goals than merely the pursuit of economic efficiency".

[9] A Kupzok, M Sturny-Luder and G Surblyte, "Foundations and limitations of an economic approach to competition law – conference of the Max Planck Institute for Intellectual Property, Competition and Tax Law, March 2009" (2010) 41:2 *International Review of Intellectual Property and Competition Law* 210–226, at 226: "The need was also emphasised to recall that according to the doctrine of separation of powers the addressee of the question as to what aims competition law should pursue is the legislature rather than the European Commission or the courts". See also Europa Press Release "Commission fines AstraZeneca €60 million for misusing patent system to delay market entry of competing generic drugs", IP/05/737, 15 June 2005, available at http://europa.eu/rapid/pressReleasesAction.do?reference=IP/05/737 (accessed 29 March 2011), where Commissioner Neelie Kroes states: "I fully support the need for innovative products to enjoy strong intellectual property protection so that companies can recoup their R[esearch] & D[evelopment] expenditure and be rewarded for their innovative efforts. However, it is not for a dominant company but for the legislator to decide which period of protection is adequate." See also, in regard to the varying emphases placed on the public interest by the US legislative forces G Seib, "Sharp debate offers voters a real choice on the economy", *The Wall Street Journal*, 10 September 2010, available at http://online.wsj.com/article/SB10001424052748703960004575481632050588468.html (accessed 29 March 2011).

[10] Communication of the EC Commission, note 3, at 10–15.

[11] *Ibid*, at 7–8: "From 2000 to 2007, non–generic pharmaceutical companies spent on average 17% of their turnover from prescription medicines on research and development and 23% on marketing and promotional activities."

of the European Union (previously Court of First Instance) recently applied Article 82 *EC* (now Article 102 of the *Treaty on the Functioning of the EU - TFEU*) to find that AstraZeneca, a Swedish/British pharmaceutical company, abused its dominant position by misusing the regulatory procedures of the patent system to hinder the market entry of competitors.

Abuse of dominant position was found on two grounds: first, the pharmaceutical company had provided misleading information (misstatements or material omissions) to patent attorneys, national courts and patent offices in various states in order to extend IP protection by obtaining a supplementary protection certificate (SPC) for its highly successful medicine ulcer drug Losec.[12] Second, by withdrawing its market authorisations for the capsule form of Losec in selected countries in order to substitute its tablet form, the company delayed (and could have delayed) the market entry of generic products, because, at the time, generic medicines could only be approved if the existing market authorisation of the original form of the product was still in place.

In its reasoning, the European Court stresses that behaviour, which is taken without an 'objective justification'[13] and which does not constitute 'competition on the merits',[14] can fall foul of the anti–competitive provisions of Article 102 *TFEU*. What is crucial is whether the effect of that behaviour is capable of impairing competition in the relevant market. That the behaviour was illegal[15] or has an actual anti–competitive effect,[16] or that the pharmaceutical company had acted deliberately or in bad faith (proved on some occasions) was not dependent on the applicability of Article 102.[17]

The fact that some competitors or national patent authorities were able to detect the company's misrepresentations did not prevent the application of EU competition law.[18] This reaffirms the basic point that competition law aims at correcting systemic failures, and as a result, its applicability is not dependent on the actual distortion of competition in the relevant market.[19] The Court also emphasised that "[w]here behaviour falls within the scope of the competition rules, those rules apply irrespective of whether that behaviour may also be caught by other rules, of national

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[12] A SPC extends patent protection (up to five years maximum) when time has elapsed between the date of the initial patent application in a Member State and its first market authorisation. See Council Regulation (EEC) No 1768/92 of June 18, 1992 concerning the creation of a SPC for medicinal products, OJ L 182, 2.7.1992, 1, available at http://eur-lex.europa.eu/LexUriServ/site/en/consleg/1992/R/01992R1768-20070126-en.pdf (accessed 30 March 2011).

[13] *AstraZeneca v Commission*, note 1, at 352 and 672.

[14] *Ibid*, at 354.

[15] *Ibid*, at 677: "It must be observed, in this respect, that, in the majority of cases, abuses of dominant positions consist of behaviour which is otherwise lawful under braches of law other than competition law."

[16] *Ibid*, at 366.

[17] *Ibid*, at 813: "the concept of abuse of a dominant position is an objective concept and does not require that an intention to cause harm be established" citing *Aéroports de Paris* v *Commission*, [2000] ECR II–3929. See also *AstraZeneca v Commission*, note 1, at 356.

[18] *AstraZeneca v Commission*, note 1, at 360: "the question whether [the behaviour] is abusive in nature cannot depend on the contingencies of the reactions of third parties."

[19] *Ibid*, at 360, 362, 366, 826.

origin or otherwise, which pursue separate objectives."[20] In this respect, competition law is not dependent on a parallel legal process through which such an effect *may* be corrected.

The decision in *AstraZeneca* has clarified that an undertaking in dominant position cannot use the regulatory procedures of the patent system, in the absence of objective justification regarding competition on the merits of its products, when the effect of its conduct is capable of impairing competition – in that case, the market entry of generic medicines in circumstances in which patent exclusivity was expiring.

3. The applicability of EU competition law and the IPRs of pharmaceutical companies

The application of EU competition law in regard to IPRs is not limited to correcting systemic failures of the patent law system evidenced by the ability of pharmaceutical companies to use that institution to their advantage to eliminate or restrict competition.[21] The rules of competition can be used to target IPRs directly in order to protect undistorted competition on the market.[22] In theory, IP and competition law complement one another, as they share the common aims of innovation, competition and benefits to consumers. In the pharmaceuticals market, however, consumer benefits are an immediate imperative, an agenda that is being advanced by increasing domestic pressure, resulting in political pressure and affecting EU policies, including those of competition. The pressure to reduce public spending on national health care systems is felt strongly 'in times of economic difficulty such as these'.[23] One of the peculiarities of the pharmaceutical market is that consumer benefits and public health care spending are two sides of the same coin.

EU competition law, as expressed by the provisions of Article 102 *TFEU*, is not of general applicability but comes into play only if an undertaking is in a dominant position in the relevant market. Competition law does not restrict all holders of IPRs but only those that have become dominant. Although this establishes a threshold of application of EU competition law, in reality the boundaries are not clear–cut, since IP rights confer exclusivity and a monopolistic potential that is often a key factor in an undertaking becoming dominant. Thus, on one hand, IPRs attract investment necessary for innovation that can drive competition and guarantee economic growth, while, on the other, the boost provided by IPRs may facilitate the dominance of the

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[20] *Ibid*, at 366. See also the argument of the Commission, *ibid*, at 656.

[21] By vexatious litigation, for example. See Communication of the EC Commission, notes 3 and 10.

[22] *Microsoft Corp v Commission*, note 7 above. See also G de Bronett, "EU competition policy and generic medicines", speech delivered at the first EGA Legal Affairs Forum in London, 2 February, 2005, available at http://ec.europa.eu/competition/speeches/text/sp2007_17_en.pdf (accessed 28 March 2011): "As a matter of law, however, no limitation applies to the scope of competition law in the pharmaceutical sector."

[23] EU Competition Commissioner Neelie Kroes, Press Release, "Antitrust: consumer welfare at the heart of Commission fight against abuses by dominant undertakings", IP/08/1877, 3 December 2008, regarding the publication of the Commission's guidance on its enforcement priorities in applying EC Treaty rules on abuse of a dominant market position. Available at http://europa.eu/rapid/pressReleasesAction.do?reference=IP/08/1877&format=HTML&aged=0&language=EN&guiLanguage=en (accessed 30 March 2011).

rights-holder and the potential abuse of its position, thereby negating the original justification of IPRs.

In the *AstraZeneca* case, the European Court rejected the arguments of the pharmaceutical company and those of the European Federation of Pharmaceutical Industries and Associations – the collective body of the industry – that 'intellectual property rights do not constitute a relevant factor for the purposes of determining the existence of a dominant position.'[24] It specified that IPRs are 'capable, in certain circumstances, of creating a dominant position, in particular by enabling an undertaking to prevent effective competition on the market'.[25]

There are, of course, other factors that help an undertaking to become dominant, for there are many market players with IPRs that are not dominant. The Court looked also at: the bargaining power of the pharmaceutical company to negotiate with national authorities pricing and reimbursement levels higher than those of its competitors[26]; its financial strength[27]; its first–mover status[28]; and the high market share that it had for a prolonged period of time.[29]

All these factors are considered with reference to the relevant market. In *AstraZeneca* the pharmaceutical market sector was, for the first time, defined for the purposes of the examination of Article 102. In that case, it was found that the category of pathology for which the medicine is destined must first be identified (ie. acid–related gastric conditions).[30] The next step was to consider the key substances used by the undertaking and its competitors, respectively, in the marketed medicines. The key substance of the AstraZeneca's product was omeprazole, a proton pump inhibitor (PPI), while that of the competitors was H2–receptor inhibitor. It was held that because PPIs have a greater therapeutic effectiveness than H2–inhibitors[31] the latter could not pose a competitive constraint on the former. This was also proved by the higher prices that AstraZeneca managed to impose for its product.[32] As a result, the use of medicines with H2–inhibitors was gradually confined to the treatment of less severe forms of the target disease.[33] The definition of the relevant market is therefore determined first by the category of pathology and then the phase of treatment that is

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[24] *AstraZeneca v European Commission*, note 1, at 270.

[25] *Ibid*.

[26] *Ibid*, at 164, 165, 259, 262.

[27] *Ibid*, at 239, 260.

[28] *Ibid*, at 260.

[29] *Ibid*, at 242, 245, 253.

[30] *Ibid*, at 62.

[31] *Ibid*, at 63.

[32] See note 26 above. See also P Meller, "European Commission is Expected to Rule that AstraZeneca Abused Patent", *The New York Times*, 15 June 2005, available at http://query.nytimes.com/gst/fullpage.html?res=9B00E2DF163BF936A25755C0A9639C8B63 (accessed 30 March 2011): "Losec was one of the best–selling prescription drugs in the world, with sales of around $ 6 billion a year."

[33] *Ibid*, at 69 and 72.

medically required. Accordingly, PPIs and H2–inhibitors found themselves in different phases of treatment, and hence in separate markets.[34]

It can therefore be said that EU competition law, as it applies to the pharmaceutical sector, relates to IPRs as they affect the determination of dominance. They are taken into account along with other factors, all of which depend on the definition of the relevant market. IPRs are a relevant factor in finding an undertaking in dominant position but, as discussed in the previous section, it is the abuse of that position that is prohibited by Article 102 *TFEU*.

4. Future development

The exclusive rights to which pharmaceutical companies are entitled by the acquisition of intellectual property can be restricted by EU competition law, if an undertaking has become dominant in the relevant market and has abused its dominant position. Whether or not IP regulation exists to prevent such an eventuality, the application of EU competition law will correct systemic failures, rather than simply addressing a given factual situation. Such failures are examined in light of the aim of undistorted competition and the public interest in access to affordable and improved medicines.

Oversight of the pharmaceutical sector has been intensified by a closer scrutiny of practices that abuse the regulatory procedures of the IP system while facilitating acquisition or maintenance of market exclusivity.[35] Additional pressure is brought to bear by parallel developments and political strategies to reduce major inequities in health between and within Member States.[36] There is also emphasis on the *EU Charter of Fundamental Rights*, which, in Article 35, recognises the right of access to preventive health care and the right to benefit from medical treatment. It is also acknowledged the cross–sectoral work that is necessary to give effect to Article 168 *TFEU* (former Article 152 *EC*), which pursues the provision of a high level of human health protection in the definition and implementation of Union policies and activities.[37] That the public interest in access to health care is growing in importance alongside research investment for innovation, economic competitiveness and the market exclusivity of IPRs is a clear indication of the need for further development of EU competition law in the pharmaceutical sector.

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[34] *Ibid*, at 73.

[35] Europa Press Release, "Antitrust: Commission opens formal proceedings against Les Laboratoires Servier and a number of generic pharmaceutical companies", MEMO/09/322, 8 July 2009, available at http://europa.eu/rapid/pressReleasesAction.do?reference=MEMO/09/322&format=HTML&aged=0&language (accessed 30 March 2011); A Jack and N Tait, "EU regulators raid AstraZeneca and Nycomed", *Financial Times*, 3 December 2010, available at http://www.ft.com/cms/s/0/23455dd2-fed7-11df-ae87-00144feab49a.html#axzz1I4tVkzwN (accessed 30 March 2011); Europa Press Release, "Antitrust: Commission confirms unannounced inspections in pharmaceutical sector", MEMO/10/647, 3 December 2010, available at http://europa.eu/rapid/pressReleasesAction.do?reference=MEMO/10/647 (accessed 30 March 2011).

[36] EC Commission, DG Public Health, White Paper: "Together for Health: A Strategic Approach for the EU 2008–2013", COM(2007) 630 final, 23 October 2007, available at http://europa.eu/legislation_summaries/public_health/european_health_strategy/c11579_en.htm (accessed 30 March 2011).

[37] *Ibid*, at 1 and 4.