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EU AND US APPROACHES TO DELAYED ACCESS TO GENERIC DRUGS BY ENFORCEMENT OF A PATENT OR SPC PROCURED BY FRAUD¹

Abstract

This article examines the impact of pharmaceutical patent protection on the introduction of generic drugs on the market. Basing itself on the Court of Justice of the European Union (CJEU) AstraZeneca case and US case law it examines, in particular, the way in which pharmaceutical companies may have created artificial barriers to entry for the market launch of generic drugs, so as to maintain market dominance by way of "life cycle management strategies".

Moreover, it compares the different ways, in which the EU and US have chosen to address the problem of the abuse of regulatory procedures by fraud with its purpose of delaying generic drug approvals. It also seeks to answer the question of whether the existence of a legal entitlement to a patent under the rules of patent law excludes competition-law liability.

Keywords

abuse of regulatory procedure – intellectual property law – antitrust law – generic drugs

I. INTRODUCTION

Despite the number of differences in patent protection systems, the EU and US confront common problems in patent protection in the pharmaceutical sector. One of such issues is how to prevent abuses relating to the introduction of generic drugs² on the market.

Recent research indicates that the development of a new drug costs

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² Pioneer drugs are brand names or patented versions of drugs manufactured by branded pharmaceutical companies. They are usually placed on the market after long and costly research. Generic drugs are a medical products similar to pioneer drugs, made and placed on the market after the patent expires.

pharmaceutical companies more than 2 billion dollars³. On the other hand, generic drugs have grown in the past 25 years from 20 per cent of prescriptions to 70 per cent today⁴.

The high costs of drug development limit the profitability of pioneer drugs without adequate patent protection. Patent law grants a temporary monopoly to an innovation. It protects an innovator from those who try to produce generic drugs. Without a patent, it is simple to produce the substitute drug without any need to recreate the innovator's efforts to discover a new drug and without repeating the expansive, long-term tests. Therefore, pharmaceutical companies which produce generics do not bear the economic risk of the innovation.

Pioneer drug companies try to limit the access of competitive generics by using a variety of instruments to extend the commercial life of their products as long as possible without generic entry⁵. Some of these actions are legal: the Food and Drug Administration (FDA) in the US and the European Medicines Agency (EMA) have implemented some exclusivity provisions to extend the life cycle of a patented product free of generic competition⁶. However, certain behaviour may be considered an abuse of the exclusive rights, and consequently the abuse of the competition law⁷.

Until 2005, the Commission and national authorities in Europe, during the pharmaceutical sector inquiry, focused primarily on reverse-payment settlements and other agreements that delay generic entry⁸. For that reason,

³ J. Avorn, *The \$2.6 Billion Pill – Methodologic and Policy Considerations*, *New England Journal of Medicine* 2015, 372:20, p. 1877, DOI: 10.1056/NEJMp1500848 [last accessed: 01.02.2016].

⁴ C. Scott Hemphill, B.N. Sampat, *When Do Generics Challenge Drug Patents?*, *Journal of Empirical Legal Studies* 2011, vol. 8, issue 4, p. 614.

⁵ See for example: *European Commission Pharmaceutical Sector Inquiry Report*, <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html>. Press release IP/09/1098, 8.07.2009 [last accessed: 01.02.2016] and M. Hall, *EU Competition Law in the Pharmaceutical Sector: What Has Happened Since 2009?*, *International Committee, ABA Section of Antitrust Law* 2011, vol. 1, p. 4.

⁶ To provide an overview of the nonpatent exclusivity provisions in the United States and EU see: C. Hathaway, J. Manthei, C. Scherer, *Exclusivity Strategies in United States and European Union*, *Food and Drug Law Policy Forum* 2009, vol. 3, pp. 34-39.

⁷ This paper focuses only on misuse of patent rights and the abuse of regulatory procedures. Other artificial barrier strategies like litigation, revised payments, and the evergreening of pharmaceutical patent protection are not considered owing to the page limit. For a discussion on how trademarks are used to block generic substitution in the context of the access to generic medicines see: A. Lamote, P. L'Ecluse, C. Longeval, *Generic Entry: a Challenge to Traditional EC Competition Law*, *Life Sciences* 2009, vol. 10, pp. 73-82.

⁸ For example the fines imposed on a pharmaceutical company by the UK competition authority for selling its products to hospitals at very low prices, whilst selling the same products via pharmacies at very high prices to patients, a strategy that could be sustained as doctors were found to be strongly influenced by the brands used in hospitals (NAPP case), See: *EC Executive Summary of the Pharmaceutical Sector Inquiry Report, 8 July 2009*, Press release

it is necessary to focus on the case of *AstraZeneca*⁹ – the first European case in which a pharmaceutical company was fined for an abuse of its dominant position in relation to “life cycle management strategies” and to compare, in relevant aspects, the approach outlined by the CJEU to the US antitrust law.

On the basis of the EU law, the high level of controversy raises the possibility of applying the competition rules to IP rights¹⁰. The tension between competition policy and IP rights can be reconciled by recognizing how market competition is consistent with innovation and by acknowledging the competition standards that shape the scope of intellectual property rights¹¹. Competition policy, especially antitrust law, condemns exclusionary conduct and patent law grants exclusionary rights. These exclusionary rights are seen as the price of rewarding – and thus encouraging–innovation¹². The existence and exercise of an industrial property right are not of themselves incompatible with competition law. Only in exceptional circumstances may the “exercise” of a right constitute an infringement of the EU competition rules and, in particular, if the company is dominant and its behaviour is likely to lead to the elimination of competition in a relevant market¹³. Therefore, one should examine the application of competition law in Europe to the specific concept of patent misuse doctrine and compare the specifics of such misuse to the more evolved US law.

Having this in mind, this article is organized as follows. Part I begins with a description of the pharmaceutical regulatory framework in the EU. Part II analyses the legal background in this area in United States law. Part III describes the controversies surrounding the application of the competition law regime to intellectual property rights in the pharmaceutical sector; Part IV presents the *AstraZeneca* case; part V is based on the *AstraZeneca* case and the US misuse of patent doctrine; it presents the problem of delayed

IP/09/1098, <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html> [last accessed: 01.02.2016].

⁹ Case T-321/05 *AstraZeneca v. Commission*, General Court judgment of 1.07.2010, EU:T:2010:266, and case C-457/10P *AstraZeneca v. European Commission*, judgment of the European Court of Justice (First Chamber) of 6.12.2012, EU:C:2003:546.

¹⁰ See, for instance: Commission Communication of 16.07.2008 on an Industrial Property Rights Strategy for Europe, COM(2008) 465 final .

¹¹ S. Ghosh, *Intellectual Property Rights: The View from Competition Policy*, Northwestern University Law Review Colloquy 2009, vol. 103, pp. 344-345.

¹² Ch.R. Leslie, *Antitrust and Patent Law as Component Parts of Innovation Policy*, The Journal of Corporation Law 2009, vol. 34, p. 1259.

¹³ Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee – An Industrial Property Rights Strategy for Europe, COM/2008/0465 final.

access to generic drugs, and considers whether the abuse of regulatory procedures or, in a broader perspective, the existence of a legal entitlement to the patent under the rules of patent law, can be considered a competition law infringement and, consequently, whether it may be the basis of an action under art. 102 TFEU.

II. THE PHARMACEUTICAL REGULATORY FRAMEWORK IN THE EU

The approval system of drugs was established in the European Union fifty years ago in 1965 with the adoption of Directive 65/65¹⁴ and the Second Council Directive 75/319/EEC of 20 May 1975 on the approximation of provisions laid down by law, regulation, and administrative action relating to medicinal products¹⁵, and by Council Directive 75/318/EEC of 20 May 1975 on the approximation of the laws of the Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of medicinal products¹⁶. Council Directive 93/39/EEC of 14 June 1993 amended Directives 65/65/EEC, 75/318/EEC and 75/319/EEC in respect of medicinal products¹⁷. Then Council Regulation 2309/93¹⁸ laid down procedures for the authorization and supervision of medicinal products for human and veterinary use and established a European Agency for the Evaluation of Medicinal Products.

Today, generic and pioneer drugs for human use authorised by the Member States have to meet the requirements of Regulation (EC) No 726/2004¹⁹ amending Regulation (EC) 2309/93 and Directive 2001/83/EC²⁰. Directive 2001/83/EC lays down harmonised rules for the authorisation, supervision, and pharmacovigilance of medicinal products for human

¹⁴ Council Directive 65/65/EEC of 26.01.1965 on the approximation of provisions laid down by Law, Regulation, or Administrative Action relating to proprietary medicinal products, OJ 22, 09.02.1965, pp. 0369–0373.

¹⁵ OJ L 147 of 9.6.1975, p. 13.

¹⁶ OJ L 147 of 9.6.1975, p. 1.

¹⁷ OJ L 214 of 24.8.1993, p. 22.

¹⁸ Council Regulation (EEC) No 2309/93 of 22.07.1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products (OJ L 214 of 24.8.1993, p. 1).

¹⁹ Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31.03.2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and established a European Medicines Agency (OJ L 136 of 30.04.2004, p. 1).

²⁰ Directive 2001/83/EC of the European Parliament and of the Council of 6.11.2001 on the Community code relating to medicinal products for human use, OJ L 311 of 28.11.2001, p. 67 (Consolidated version: 16.11.2012).

use within the Union. According to this act, an authorisation holder of a generic drug is not allowed to place a product on the market before the patent on the reference product has expired.

The period that elapses between the filing of an application for a patent for a new medicinal product and authorisation to place the medicinal product on the market makes the period of effective protection under the patent insufficient to cover the investment put into the research. In order to provide sufficient protection for the investment in development of medicinal products, Council Regulation (EEC) No 1768/92²¹ introduced a uniform solution at the EU level: a supplementary protection certificate ("SPC") for medicinal products subject to a marketing authorisation procedure. Regulation No 1768/92 has been codified and repealed by Regulation (EC) No 469/2009²². SPC is ancillary to a previously granted national or European patent, with the intention of a view to extending the duration of the rights that the patent confers on its holder. It confers the same rights as the basic patent and is subject to the same limitations and the same obligations. The regulation sets at 15 years the duration of the exclusive rights enjoyed by the holder of both a patent and a certificate from the time the medicinal product in question first obtains authorisation to be placed on the market in the EU²³.

Article 3 of the regulation No 469/2009 sets out the conditions for obtaining a certificate. The medical product or its active ingredients must be protected by a basic patent in force in the Member State in which the application is submitted, a valid authorisation to place the product on the market as a medicinal product should have been granted, the product must not have already been the subject of a certificate, and the above-mentioned authorisation has to be the first authorisation to place the product on the market as a medicinal product. Under Article 13 of Regulation No 469/2009, the certificate takes effect upon the expiry of the basic patent for a period equal to the period which elapsed between the date on which the application for a patent was lodged and the date of the first authorisation to place the product on the market in the Community reduced by a period of five years. Nevertheless, the duration of the certificate may not exceed five years from the date on which it takes effect.

²¹ Council Regulation (EEC) No 1768/92 of 18.06.1992 concerning the creation of a supplementary protection certificate for medicinal products (OJ 1992 L 182, p. 1).

²² Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6.05.2009 concerning the supplementary protection certificate for medicinal products (OJ 2009 L 152, p. 1).

²³ Eighth recital of Regulation No 469/2009.

III. THE PHARMACEUTICAL REGULATORY FRAMEWORK IN THE US

The Federal Food, Drug, and Cosmetic Act (FFDCA)²⁴ passed by the Congress in 1938, provides for additional periods of exclusivity for pioneer drugs based on medical studies completed after the initial approval process, if such studies support new indications of the drugs, which typically means that the drugs can be used in new patient populations or to treat different conditions. Drug manufacturers can apply for this additional exclusivity through a supplemental new drug application (“NDA”)²⁵.

Pursuant to the FFDCA, in the United States a manufacturer and distributor of drugs – both pioneer and generics – is regulated by the Food and Drug Administration (FDA). Competition between brand-name and generic drugs is regulated by the Drug Price Competition and Patent Term Restoration Act, informally known as the Hatch-Waxman Act²⁶, enacted by the Congress in 1984.

Generally it should be noticed that, in the US, generic drugs can be marketed once the pioneer drug’s twenty year patent protection and FFDCA exclusivity periods expire. The first provision of Title I Hatch-Waxman Act established a new FDA procedure for generic drugs to be approved, based on the authorisation of an equivalent pioneer drug. While a pioneer drug approval requires submission of extensive and lengthy documents in a NDA to the FDA, a generic version of the drug can bypass a part of this process by filing an Abbreviated New Drug Application (ANDA) for the generic version of the previously approved pioneer drug²⁷. The Hatch-Waxman Act also provides for a market exclusivity period that can delay the approval of ANDA’s: a six months of exclusivity to any marketing or patent exclusivity with the drug in paediatrics populations²⁸, a five-year period of market exclusivity period for NDA’s involving new chemical entities²⁹, and a three-year period of market exclusivity for NDA’s

²⁴ Food, Drug, and Cosmetic Act of 1938, Pub. L. No. 75-717, 52 Stat. 1040 (1938).

²⁵ Case *Astrazeneca Pharmaceuticals Lp, Appellant v. Food & Drug Administration, et al., United States Court of Appeals, District of Columbia Circuit. Appellees. No. 12-5227*. Decided: 26.04.2013. See more at: <http://caselaw.findlaw.com/us-dc-circuit/1629384.html#sthash.696rhVdZ.dpuf> [last accessed: 01.02.2016].

²⁶ Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

²⁷ More on the Act’s main provisions and goals: J. Rosenthal, *Hatch-Waxman Use or Abuse - Collusive Settlements between Brand-Name and Generic Drug Manufacturers*, Berkeley Technology Law Journal 2002, vol. 17, pp. 317-335, available at: <http://scholarship.law.berkeley.edu/btlj/vol17/iss1/19> [last accessed: 1.02.2016].

²⁸ 21 U.S.C. § 355a.

²⁹ 21 U.S.C. § 355(c) (3) (E) (ii) and 505(b)(2).

containing new clinical studies (especially approving a generic drug application for a new dosage form or use) essential to the approval of the application³⁰. Moreover the Hatch-Waxman Act, allows the obtaining of seven years' exclusivity period for orphan drugs³¹. The market exclusivity period is separate from patent protections.

The FDA procedure for generic drugs states that a generic drug maker has a special incentive to challenge a patent, particularly if the patent is believed to be invalid or not infringed. The first generic company to file an Abbreviated New Drug Application is entitled, upon FDA approval, to a 180-day exclusive right to market its product in competition with the brand-name firm before other generic firms may enter³². The 180-day exclusivity period for the first applicant begins running upon the occurrence of one of two events, whichever is earlier – commercial marketing by the first applicant, or a court decision in favour of the applicant³³.

IV. ANTI-COMPETITIVE ABUSES OF THE IP SYSTEM IN THE PHARMACEUTICAL SECTOR

The debate over anti-competitive practices in the pharmaceutical sector should focus on finding a trade-off between the interests of drugs manufacturers, both pioneer and generic. Maintaining the balance between the branded pharmaceutical companies and their generic competitors requires taking into account two important factors: rewarding innovative pioneer drugs research and granting and ensuring wide access to inexpensive and safe generic versions of drugs.

The controversies surrounding the application of the competition law regime to intellectual property rights are well known³⁴. While some commentators stressed the legitimacy of antitrust intervention in

³⁰ 21 U.S.C. § 355(c) (3) (E) (iii), § 355 (j)(5)(F)(iii)-(iv) and 505(b)(2).

³¹ 21 U.S.C. §§ 360aa to 360 dd. Orphan drug means a drug intended for use in a rare disease or condition.

³² Hemphill, Scott, Sampat, Bhaven, *supra* note 4, p. 622.

³³ *Purepac Pharmaceutical Company, Appellant, v. Michael A. Friedman, M.D., Acting Commissioner of Food and Drugs, Food and Drug Administration, Appellee*. Nos. 98-5334, 98-5335 and 98-5337. U.S. Court of Appeals for the District of Columbia Circuit - 162 F.3d 1201 (D.C. Cir. 1998). More at: <http://caselaw.findlaw.com/us-dc-circuit/1179516.html#sthash.t7w6vEvS.dpuf> [last accessed: 1.02.2016].

³⁴ For a comparative analysis of these two legal regimes and its correlations see: D. Miąsik, *Stosunek prawa ochrony konkurencji do prawa własności intelektualnej [The Interface Between Intellectual Property Rights and Competition Policy]*, Warszawa 2012, *passim*; M. Kolasiński, *Obowiązek współpracy gospodarczej w prawie antymonopolowym [The Obligation of Economic Cooperation in Antitrust Law]*, Toruń 2009, p. 237.

intellectual property rights³⁵, others have expressed concern about the dangers of overzealous antitrust enforcement³⁶. Sanctioning a dominant firm for its abuse of intellectual property rights may violate basic property rights. Moreover, in the EU context it may interfere with the free movement of goods protected by the Treaty. On the other hand, abuse of intellectual property rights, especially in the pharmaceutical sector, constitutes a barrier to, and discrimination in, free trade and distorts competition between companies.

It is necessary to note that having an intellectual property rights and consequently a dominant position does not mean that companies introducing innovative products on the market should refrain from acquiring a comprehensive portfolio of intellectual property rights or from enforcing those rights. Both European and US courts pointed out in that regard that a dominant position is not prohibited, only its abuse³⁷.

While regarding the relevance attached to intellectual property rights and rights conferred by pharmaceutical regulations for the existence of a dominant position, in settled case-law the CJEU pointed out, that, although the mere possession of intellectual property rights cannot be considered to confer such a position, their possession is none the less capable, in certain circumstances, of creating a dominant position, in particular by enabling an undertaking to prevent effective competition on the market³⁸.

V. DELAYED ACCESS TO GENERIC DRUGS BY ENFORCEMENT OF A PATENT OR SPC PROCURED BY MISLEADING REPRESENTATIONS IN ASTRAZENECA CASE

The European Commission's interest in the issue of enforcement of a patent procured by misleading representations dates back to at least 2005. In that year, the Commission adopted a decision relating to a proceeding under Article 102 TFEU³⁹ (ex 82 EC Treaty) and Article 54 of the EEA

³⁵ See: B. Berg, *Das AstraZeneca-Urteil des Gerichts der Europäischen Union*, *Europäische Zeitschrift für Wirtschaftsrecht* 2011, p. 94.

³⁶ Comparative analysis in: Miąsik, *supra* note 34, pp. 274-275.

³⁷ Court of Justice of the European Union in Joined Cases C-395/96 P and C-396/96 P *Compagnie maritime belge transports and Others v. Commission* [2000] ECR I-1365, par. 37; or United States Court of Appeals, Federal Circuit in case: *Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700, 708 (Fed.Cir. 1992).

³⁸ Joined Cases C-241/91 P and C-242/91 P *RTE and ITP v. Commission* [1995] ECR I-743, Magill, p. 46,47, and Case T-321/05 *AstraZeneca v. Commission*, p. 270.

³⁹ Consolidated version of the Treaty on the Functioning of the European Union, OJ C 326, 26.10.2012, pp. 47-390.

Agreement⁴⁰, by which it found that AstraZeneca AB and AstraZeneca plc – a pharmaceutical group active, worldwide, in the sector of inventing, developing, and marketing innovative products – had committed two abuses of a dominant position, in breach of article 102 TFEU and Article 54 of the EEA Agreement⁴¹.

What is immediately apparent on the face of the *AstraZeneca* decision is that this was the first time that the Court had an opportunity to clarify if a mere intention fraudulently to obtain a patent or SPC, an application for a patent or SPC made fraudulently, or the grant of a patent or SPC, which is incapable of immediate enforcement, can amount to an abuse of a dominant position.

It is worth briefly sketching the genesis of the *AstraZeneca* case. In 1993 and 1994, AZ submitted applications to a number of national patent offices within the EEA in order to obtain supplementary protection certificates for active substance patents for omeprazole, an active ingredient in Losec. It did so on the basis of Council Regulation No 1768/92 of 18 June 1992⁴². The Commission determined that AstraZeneca has made misleading representations to patent agents, national patent offices and national courts, so as to obtain SPC's for longer periods than it would have obtained or preserve SPC's for omeprazole, to which AZ was not entitled. The Commission considered that the AZ actions were a part of an intentional strategy on the part of SPC, designed to keep manufacturers of generic products away from the relevant market and it imposed on the applicants jointly and severally a fine of 60 million euro.

By an application lodged at the registry of the General Court on 25 August 2005, the appellants brought an action for annulment of the decision in issue. The AZ observed that the enforcement of a patent can amount to an abuse of a dominant position only when the undertaking has wilfully acquired or enforced the patent knowing that it is invalid. In support of their argument, AZ referred to United States law. In their submission, under the US law, an antitrust action is justified where the patent was procured by knowingly and wilfully misrepresenting facts to the patent office. In that regard, neither gross negligence nor recklessness, nor the existence of inequitable conduct are sufficient to prove fraud. Moreover, in United States law, actual enforcement of the patent is necessary for application of the antitrust rules, mere acquisition of a patent

⁴⁰ The Agreement on the European Economic Area, which entered into force on 1.01.1994, OJ L1, 03.01.1994, p. 1.

⁴¹ Case COMP/A.37.507/F3 – AstraZeneca.

⁴² Commission Decision, para 143.

being insufficient, since the immediate cause of the anticompetitive effect must be the conduct of the patent owner and not the action of the public agency⁴³.

By the judgment under appeal, the General Court upheld the contested decision in large part and stated that AZ adopted a consistent course of conduct over time, characterised by the communication to the patent offices of misleading representations for the purposes of obtaining the issue of SPCs, to which it was not entitled or to which it was entitled for a shorter period. In accordance with the settled case-law of the Court, the concept of a single and continuous infringement relates to a series of actions, which form part of an “overall plan” because their identical object distorts competition within the common market⁴⁴. The General Court held that, although the practice of an undertaking in a dominant position cannot be characterised as abusive in the absence of any anti-competitive effect on the market, such an effect does not necessarily have to be concrete, and it is sufficient to demonstrate that there is a potential anti-competitive effect. It emphasizes that whether the information is misleading must be assessed on the basis of the specific circumstances of each individual case. Representations designed to obtain exclusive rights unlawfully constitute an abuse only if it is established that, in view of the objective context in which they are made, those representations are actually liable to lead the public authorities to grant the exclusive right applied for. Moreover, the General Court referring to the objective nature of the concept of abuse stressed that it was not necessary to establish a deliberate intent to deceive, though such an intent would be taken into account. It also held that the effect which those actions may have had on normal competition is not a conclusive criterion in assessing the proper amount of the fine. Factors relating to the intentional aspect, and thus to the object of a course of conduct, are more significant than those relating to its effects⁴⁵.

CJEU upheld the General Court’s finding that AstraZeneca had abused its dominant position by supplying misleading information to national authorities and patent offices. The Court of Justice emphasised that AstraZeneca had engaged in a deliberate attempt to mislead the patent offices through “consistent and

⁴³ Case T-321/05 *AstraZeneca v. Commission*, pp. 63, 312, 316-317.

⁴⁴ See *inter alia*: Case C-49/92 P *Commission v. Anic Partecipazioni* [1999] ECR I-4125, p. 81, and Joined Cases C-204/00 P, C-205/00 P, C-211/00 P, C-213/00 P, C-217/00 P and C-219/00 P *Aalborg Portland and Others v. Commission* [2004] ECR I-123, p. 258.

⁴⁵ Case T-321/05 *AstraZeneca v. Commission*, pp. 893, 895 and 902.

linear” conduct consisting of “highly misleading representations” and a “manifest lack of transparency”, which fell outside the scope of competition on the merits⁴⁶.

VI. MISLEADING REPRESENTATIONS TO THE PATENT OFFICE – – A VIEW FROM EUROPE AND THE UNITED STATES

Maintaining the balance between the branded pharmaceutical companies and their generic competitors requires taking into account two important factors: rewarding innovative pioneer drugs research and granting and ensuring wide access to inexpensive and safe generic versions of drugs. Effective patent protection stimulates drug research and development, but patents are, in essence, legal monopolies. For that reason, generally, exercising this right should not violate antitrust laws. Only in a situation where the patentee’s actions go beyond that which it is specified under the patent, the risk of an antitrust violation comes into existence.

Both in the US antitrust law and EU competition law dominant companies have been found to abuse the regulatory system with the aim of excluding competition and with the ultimate result of harming consumers. The most relevant cases in which an abuse of intellectual property rights has been found, both in the U.S. and in Europe, are related to undertakings which had a dominant position on the markets of their respective patented products. Immediately apparent on the face of the *AstraZeneca* judgement is that it prompted a discussion on the application of EU law whose requirements and standards for the finding of a novel type of abuse are comparatively lax compared to the US concept of patent misuse, especially the so-called Walker Process Doctrine⁴⁷. Thus, the inquiry on how patent misuse might function in the EU patent law has to start from analysing applications from US doctrines and jurisprudence.

Basing itself on the US Court of Appeals, the patent misuse doctrine, born from the equitable doctrine of unclean hands, is a method of limiting the abuse of patent rights which is separate from the antitrust laws⁴⁸. The

⁴⁶ Case C-457/10P *AstraZeneca v. European Commission*, pp. 93-99, 105-112.

⁴⁷ S. Gallasch, *Astrazeneca v. The Walker Process – A Real EU-US divergence or just an attempt to compare Apples to Oranges?*, European Competition Journal 2011, vol. 7, no. 3, pp. 505-526; I. Lianos, *New Challenges in the Intersection of Intellectual Property Rights with Competition Law – A View from Europe and the United States*, CLES Working Paper Series 2013, vol. 4, pp. 81-82, available at: <https://www.ucl.ac.uk/cles/research-paper-series/research-papers/cles-4-2013> [last accessed: 1.02.2016].

⁴⁸ The Supreme Court first recognized a patent misuse defence in 1917 in *Motion Picture Patents Co. v. Universal Film Manufacturing Co.*, 243 U.S. 502 (1917). *Motion Picture* overruled

patent misuse doctrine bars infringement suits by patentees, who have “misused” their patent grant, either by using the patent to violate the antitrust laws or by extending their patent monopoly in some other way⁴⁹. This doctrine cannot be used to start a case. It is merely an affirmative defence, therefore a defendant does not refute what the plaintiff claims, but reacts by invoking an exception or a counterclaim. Unlike abuse of rights, it is linked to the effects of patents on competition⁵⁰. It is a judicial type of tool to use on the perceived anticompetitive practices of patent owners⁵¹. As was noticed by M. Maggolino, it has always been construed in order to deem illegal those practices of patentees which improperly extend the scope of patents⁵². The key inquiry under this fact-intensive doctrine is whether, by imposing the condition, a patentee has “impermissibly broadened” the “physical or temporal scope” of the patent grant with anticompetitive effect. If the defendant can prove that the patentee misused its patent, the patent is rendered unenforceable⁵³.

There are several examples of the “impermissible broadening” of using a patent, which enjoys market power in the relevant market. The typical examples of patent misuse are restraining competition in an unpatented product or employing the patent beyond its term⁵⁴. Much of the US Supreme Court’s early patent misuse doctrine was developed in cases involving a challenge to some form of tying arrangement⁵⁵. A tying arrangement is

Henry v. A.B. Dick Co., 224 U.S. 1 (1912), indicating that a tying arrangement in which the patentee required exhibitors to show only its movies on its patented projector was a misuse of the patent. Then legislation limited the application of patent misuse to the tying of staple products and with regard to tying arrangements. About the historical development of the patent misuse doctrine see: M.A. Lemley, *The Economic Irrationality of the Patent Misuse Doctrine*, California Law Review 1990, vol. 78, p. 1609, available at: <http://scholarship.law.berkeley.edu/californialawreview/vol78/iss6/5> [last accessed: 01.02.2016] and D. Lim, *Patent Misuse and Antitrust Law: Empirical, Doctrinal and Policy Perspectives*, Chaltenham 2013, pp. 38-90.

⁴⁹ The nature and scope of antitrust protection in the patent area, and the contrasts between the antitrust laws and the patent misuse doctrine is describe by Lemley, *supra* note 48, p. 1610.

⁵⁰ M. Temmerman, *The Legal Notion of Abuse of Patent Rights*, NCCR Trade Regulation Working Paper 2011, no. 23, p. 3.

⁵¹ J.M. Webb, L.A. Locke, *Intellectual Property Misuse: Developments In The Misuse Doctrine*, Harvard Journal of Law & Technology 1991, vol. 4, p. 258.

⁵² M. Maggolino, *Intellectual Property and Antitrust: A Comparative Economic Analysis of U.S. and EU Law*, Northampton 2011, p. 38.

⁵³ United States Court of Appeals, Federal Circuit. case: *B. Braun Medical, Inc. v. Abbott Laboratories and Np Medical, Inc.*, Defendants/cross-Appellants, 124 F.3d 1419 (Fed. Cir. 1997). See more at: <http://caselaw.findlaw.com/us-federal-circuit/1096773.html#sthash.4JFqhlTx.dpuf> [last accessed: 1.02.2016].

⁵⁴ *Ibidem*.

⁵⁵ United States Court of Appeals, Federal Circuit case *Mallinckrodt*, 976 F.2d at 704, 24

“the sale or lease of one item (the tying product) on the condition that the buyer or lessee purchases a second item (the tied product) from the same source”⁵⁶. In the decision in the case *Morton Salt Co. v. G.S. Suppiger Co.*, the United States Supreme Court held as an example that a tying arrangement, where the patent licence was conditioned upon the purchase of a separate, staple product amounted to patent misuse, because in such a case “the patent is used as a means of restraining competition with the patentee’s sale of an unpatented product”. The plaintiff Morton Salt brought suit on the basis that the defendant had infringed upon Morton’s patent in a salt-depositing machine. The salt tablets that the machine deposited were not themselves a patented item, but Morton’s patent license required that licensees use only salt tablets produced by Morton⁵⁷. A good example of exploiting the patent beyond the end of the protection term is a case *Brulotte v. Thys Co.*⁵⁸. In *Brulotte* the United States Supreme Court held that when a patent owner licenses a patented invention to a buyer of the equipment that embodies the invention and, in addition to the purchase price, requires the licensee to pay royalties for use of the invention, the licensee is not obligated to pay royalties beyond the date of termination of the patent, notwithstanding contract terms to the contrary⁵⁹. The post-patent royalty provision was “unlawful *per se*”, because it continued “the patent monopoly beyond the patent period”⁶⁰.

The main aspects of the US common law patent misuse doctrine were

USPQ2d at 1176.

⁵⁶ *Amerinet Inc. v. Xerox Corp.*, 972 F.2d 1483, 1498 (8th Cir. 1992), available at <http://caselaw.findlaw.com/us-8th-circuit/1139833.html#sthash.A6Ai6Rlc.dpuf> [last accessed: 1.02.2016]. Generally about patent exhaustion cases see: W.P. Skladony, *Commentary on Select Patent Exhaustion Principles in Light of the LG Electronics Cases*, *The Intellectual Property Law Review* 2007, vol. 47, no. 3, pp. 252-253.

⁵⁷ The decision of the United States Supreme Court *Morton Salt Co. v. G.S. Suppiger Co.*, 314 U.S. 488, 490-91, 62 S.Ct. 402, 86 L.Ed. 363 (1942), See more at: <http://caselaw.findlaw.com/us-federal-circuit/1073936.html#sthash.HRQL4lrC.dpuf> [last accessed: 01.02.2016].

⁵⁸ The United States Supreme Court, *Brulotte v. Thys Co.*, 379 U.S. 29 (1964).

⁵⁹ About the *Brulotte* decision in its historical and conceptual context see: H. See, F.M. Caprio, *The Trouble with Brulotte: The Patent Royalty, Term and Patent Monopoly Extension*, *Utah Law Review* 1990, vol. 4, p. 813; Miąsik, *supra* note 34, pp. 274-275.

⁶⁰ On June 2015, the US Supreme Court upheld a prohibition against a patent owner collecting royalties following the patent’s expiration in *Kimble et al. v. Marvel Entertainment, LLC*, 576 U.S. (2015). Contrary Justice Alito, The Chief Justice and Justice Thomas in their dissenting to decision in *Kimble* notice that: “That decision in *Brulotte v. Thys Co.* was not based on anything that can plausibly be regarded as an interpretation of the terms of the Patent Act. It was based instead on an economic theory – and one that has been debunked. The decision interferes with the ability of parties to negotiate licensing agreements that reflect the true value of a patent, and it disrupts contractual expectations.(...) A licensing agreement that provides for the payment of royalties after a patent’s term expires does not enlarge the patentee’s monopoly or extend the term of the patent. It simply gives the licensor a contractual right”.

reflected in § 271 (d) US Code, stating that: “No patent owner otherwise entitled to relief for infringement or contributory infringement of a patent shall be denied relief or deemed guilty of misuse or illegal extension of the patent right by reason of his having done one or more of the following: (1) derived revenue from acts, which, if performed by another without his consent, would constitute contributory infringement of the patent; (2) licensed or authorized another to perform acts which if performed without his consent would constitute contributory infringement of the patent; (3) sought to enforce his patent rights against infringement or contributory infringement; (4) refused to license or use any rights to the patent; or (5) conditioned the license of any rights to the patent or the sale of the patented product on the acquisition of a license to rights in another patent or purchase of a separate product, unless, in view of the circumstances, the patent owner has market power in the relevant market for the patent or patented product on which the license or sale is conditioned”.

Well established in the US antitrust law patent misuse is fraud-on-the-patent-office violation⁶¹. The US Supreme Court decision of *Walker Process Equipment*, established that the fraudulent procurement of a patent or the enforcement of a patent knowingly obtained by fraud on the U.S. Patent and Trademark Office (PTO) may be the basis of an action under Section 2 of the Sherman Act⁶². A claim of Walker Process fraud is a sword to impose antitrust liability and treble damages upon a patentee. Antitrust liability under section 2 of the Sherman Act may arise when three conditions have been met: a patent has been procured by knowing and wilful fraud, the patentee has market power in the relevant market, and has used its fraudulently obtained patent to restrain competition. Moreover, a finding of Walker Process fraud must be based on independent and clear evidence of deceptive intent together with a clear showing of reliance, i.e., that the patent would not have issued but for the misrepresentation or omission. Fraud therefore should be premised on a knowing, wilful and intentional act, misrepresentation or omission before the Patent and Trademark Office⁶³.

⁶¹ For details see: Ch. R. Leslie, *Antitrust, Inequitable Conduct, and the Intent to Deceive the Patent Office*, UC Irvine Law Review 2011, vol. 1, pp. 325-356.

⁶² *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, 382 U.S. 172 (1965).

⁶³ See U.S. Court of Appeals for the Federal Circuit – *Nobelpharma Ab v. Implant Innovations, Inc.*, 141 F.3d 1059 (Fed. Cir. 1998).

VII. CONCLUDING REMARKS

Ten years after the AZ decision one may reach some broad conclusion relating to whether the patent infringement can be considered an infringement of a competition law, and, consequently, whether it may be the basis of an action under art. 102 TFEU. The main conclusion of this assessment is that the existence of a legal entitlement to the patent under the rules of patent law, does not exclude competition-law liability⁶⁴. Article 102 TFEU applies to applications for acquiring or extending an intellectual property right. In keeping with the realistic approach which had guided it, the CJEU took account of certain specific and objective factors:

- the intent and purpose (bad faith): the misleading representations to the patent office's made by an undertaking in a dominant position in order to obtain extended patent protection cannot be characterised as an abuse unless it is an action which is conceived in the framework of a plan with its goal being to eliminate competition. It does not breach competition when a wrong representation is made in good faith. Simple unintentional mistakes in a patenting process could not be held to be an abuse
- specific circumstances of the case: for assessment of the specific circumstances of the case it is necessary to establish, whether an undertaking abused its dominant position in making representations to a public authority.

In the US, similar infringements have met with a more subtle approach and, owing to the different nature of the proceedings, they cannot be directly applicable to EU law. According to the Walker Process, the fraudulent procurement or extension of a patent can form the basis for an antitrust claim under section 2 of the Sherman Antitrust Act. A patentee who brings an infringement suit may be subject to antitrust liability for the anti-competitive effects of that suit, if the alleged infringer proved that the asserted patent was obtained through knowing and wilful fraud. In order to strip a patentee of its exemption from the antitrust laws because of its attempting to enforce its patent monopoly, an antitrust plaintiff is first required to prove that the patentee obtained the patent by knowingly

⁶⁴ J. Drexler, *AstraZeneca and the EU Sector Inquiry: When Do Patent Filings Violate Competition Law?*, Max Planck Institute for Intellectual Property and Competition Law Research Paper 2012, no. 12-02, pp. 28-29, available at: <http://ssrn.com/abstract=2009276> [last accessed: 1.02.2016].

and wilfully misrepresenting facts to the PTO. The plaintiff in the patent infringement suit must also have been aware of the fraud when bringing suit.

The US patent laws do not expressly give any private right of action against patentees for damages for overcharging for a patented article simply because the patent was or may have been obtained by means of a fraud on the Patent Office⁶⁵. By contrast, in the EU, if misleading statements are regarded as an abuse, it cannot be excluded that they may be the basis of public and private enforcement of EU competition law on the basis of art. 102 TFEU. The Commission can impose fines on undertakings that have infringed these provisions⁶⁶. Article 102 TFEU creates rights and obligations for individuals⁶⁷, which can be enforced by the national courts of the Member States⁶⁸ and, consequently, it cannot be excluded that generic producers could claim compensation for the harm suffered, where there is a causal relationship between that harm (barriers to entry for the market launch of the generic drugs) and an infringement of the EU competition rules (intention fraudulently to obtain a patent or SPC, an application for a patent or SPC made fraudulently, or the grant of a patent or SPC, which is incapable of immediate enforcement).

To sum up, it must be remembered that effective patent protection stimulates drug research and development. For that reason, generally, exercising this right should not be held to violate competition laws. Only in a situation where the patentee's actions go beyond that which is specified under the patent, does the risk of an anticompetitive violation come into existence. Therefore, one must agree with the position, that competition law liability in patent filing cases has to remain the very rare exception rather than a basis for frequent enforcement action⁶⁹.

⁶⁵ Compare: *Zenith Laboratories, Inc. v. Carter-Wallace, Inc.*, 530 F.2d 508 (3d Cir.).

⁶⁶ Council Regulation (EC) No. 1/2003 of 16.12.2002 on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty (OJ L 1, 4.01.2003, p. 1) gives the Commission and the national competition authorities powers to apply article 102 of the Treaty.

⁶⁷ Article 6 of Regulation No. 1/2003.

⁶⁸ The EU right to compensation for harm resulting from infringements of the European Union and national competition law. It has been strengthened by adopting the Directive 2014/104/EU of the European Parliament and of the Council of 26.11.2014 on certain rules governing actions for damages under national law for infringements of the competition law provisions of the Member States and of the European Union, OJ L 349/1, 5.12.2014.

⁶⁹ Drexl, supra note 64, p. 29.