

THE PROTECTION OF PHARMACEUTICALS IN BULGARIA IN THE CONTEXT OF EU COMPETITION LAW

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ABSTRACT

This paper discusses the interaction of European Union (EU) competition law, the exhaustion of intellectual property rights (IPRs), and access to pharmaceuticals in the European Union. In the European Union, pharmaceuticals can be protected through both trademarks and patents. However, following the first sale of a product into the market, the IPR holder cannot prevent its further redistribution by other competitors in the same market. This tension between IPRs and EU competition law raises several important questions with respect to differential pricing in EU member States, the exhaustion of IPRs, as well as the usage and distribution of generic medicines. In the context of addressing competition law and IPRs in the European Union, this paper focuses on the structure and impact of these regimes on access to pharmaceuticals in Bulgaria, which is one of the most recent members of the European Union.

Introduction

One of the key objectives of the European Union is to provide for the free movement of goods and services across its member States. Consequently, it would be inconsistent for the intellectual property laws of member States to hinder such movement by allowing IPR holders to prevent parallel importation across the territory. The regulation of intellectual property law has traditionally been a matter of national regulation. However, insofar as they have the potential to hamper free trade and competition among member States, these national IP regimes are also subject to EU law. This is how the domestic protection of the monopoly rights may conflict with the free movement of goods, thus hampering competition among commercial players operating across the single market. For the purposes of this paper, the notion of competition law is to be understood as the body of legal rules designed to promote and protect rivalry and freedom in the market. Intellectual property law encompasses the entire body of law relating to patents, copyright, trademarks, designs, service marks, know-how and associated rights, such as plant breeders' rights and broadcasting rights.

The pharmaceutical sector enjoys many exceptions with respect to general competition rules in the European Union. The first justification for a special regime protecting pharmaceuticals is rooted in public policy. The second reason is the influence of the US doctrine of 'essential facilities',¹ which provides for exemptions, at the discretion of the European Commission, based on concepts such as 'educational purposes' or 'the benefit of humanity'.²

On other hand, one should not underestimate the opportunity to simultaneously protect pharmaceuticals through trademarks and patents. Both are strong instruments which may impede free

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¹ E.T. Sullivan and H. Hovenkamp, *Antitrust Law, Policy, and Procedure: Cases, Materials, and Problems*, (LexisNexis Publishers, 2004).

² *NDC Health v. IMS Health*: Interim measures, COMP D3/38.044 OJ 2002 L 59, 18.

competition between member States. These potential impediments have led to major developments, such as the implementation of an 'exhaustion of rights' regime, the imposition of duties on supply, the introduction of compulsory licences, the distribution of generic medicines, and even parallel importation.

This paper will analyse how the corresponding EU provisions are implemented with respect to pharmaceuticals within the territory. In particular, there will be particular focus on Bulgaria and a discussion on how the expiration of patents and the doctrine of exhaustion have led to the enhanced use of generic drugs and increased access to medicines in the region.

The means of intellectual property protection for pharmaceuticals

As previously mentioned, pharmaceuticals can be protected through both trademarks and patents. Trademarks not only differentiate the goods or services of one trader from those of another, they also provide guarantees of quality. Apart from these functions, trademarks rights also constitute significant economic resources for the rights holder.³ Additionally, they confer the right to prevent unfair or unauthorized uses of the mark. The rights holder also controls the first market entry of the goods bearing his trademark. Thereafter, this right extinguishes, or is 'exhausted'. The proprietor of the trademark cannot further control the subsequent movement of the goods through the market. Hence, parallel imports would be permissible in the defined market to which the exhaustion regime applies.⁴ Owing to globalization, it has become crucial to restructure the legal grounds for trademark protection, and to establish a balanced global trading system through the free movement of goods worldwide. Globalization has led to the greater movement of goods, which means trademarked products are now crossing borders in larger volumes. Thus, exhaustion is becoming more important as rights holders within one territory lose their ability to influence how their goods are dealt with in another territory.

A key principle of the European Union is the freedom of movement for goods and services. In the context of intellectual property, this has led to the doctrine of exhaustion, which has become entrenched in EU jurisprudence.⁵ As the basic right of a trademark holder includes offering for sale, importing or exporting under a sign identical or similar to the trademark, there are many opportunities for a trademark holder to interfere with the further exploitation of his goods after he has parted company with them.

³ Nadia Ianeva, *Registration of Non-Conventional Signs Under the Community Trademark Regime*, (Wissenschaftlicher Verlag Berlin, 2008).

⁴ Valentine Korah, *Intellectual Property Rights and the EC Competition Rules*, (Hart 2006).

⁵ Whereas the freedom of movement is governed by Articles 28-29 of the EC Treaty, Article 30 of the EC Treaty stipulates that:

... the provisions of Articles 28 and 29 shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified on grounds of public morality, public policy or public security; the protection of health and life of humans, animals or plants; the protection of national treasures possessing artistic, historic or archaeological value; or the protection of industrial and commercial property. Such prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States.

This means that governments of member States may still justify certain trade barriers when *inter alia* culture or industrial and commercial property might be endangered.

Similarly the protection provided by trademarks and patents are limited in duration. Once that time has lapsed, the intellectual property right expires. This entitles competitors to free and open use of the right. Patent expiration leads to the widespread usage of generic pharmaceuticals in many countries. In Eastern Europe the market share of generic pharmaceuticals is more than 70 per cent.⁶

Exhaustion of intellectual property rights

In EU law, the doctrine of exhaustion has been developed by the European Court of Justice.⁷ The doctrine has an important role in overcoming the constraints posed by the territorial nature of national IP regimes.

Bearing in mind that pharmaceuticals are protected by both patents and trademarks, issues of exhaustion, expiration and parallel imports immediately arise. Furthermore, owing to the large production of generic pharmaceuticals which are not patented, and of those for which patent protection has expired, these issues demand further examination in the European context.

Parallel importation⁸ refers to the importation of goods outside the distribution channels that have been contractually negotiated by the trademark owner. Based upon the right of importation that a trademark confers upon the owner, the latter may try to oppose such importation in order to control differential pricing across markets. This would allow the trademark holder to prevent goods priced for cheaper markets from being imported into a higher priced market and undercutting sales of the same product. Therefore, where international exhaustion applies, the placement of a product on a market abroad leads to the extinguishment of the trademark holder's exclusive right to import the product. Thus, the rights holder will have no remedy against parallel importation.

As the EU regime functions on the basis of regional exhaustion, parallel trading is only allowed between countries within the trading bloc. The consequence of allowing parallel importation within the region is that traders may exploit price differentials between markets. They can then pass on the savings to their consumers in the form of lower prices. The regional exhaustion rule has been codified in the Harmonization Directive.⁹ Thus, after the first sale, the trademark does not entitle the holder to prohibit its use in relation to goods which have been put on the market in the European Union.¹⁰

According to Article 30 of the EC Treaty, 'quantitative restrictions on imports and all measures having equivalent effect shall, without prejudice to the following provisions, be prohibited

⁶ Christine Godt, *Differential Pricing of Pharmaceuticals inside Europe: Exploring Compulsory Licences and Exhaustion for Access to Patented Essential Medicines*, (Nomos, 2010).

⁷ See Case 78/70 *Deutsche Grammophon Gesellschaft GmbH v. Metro-SB Grossmärkte* [1971] ECR, 487.

⁸ Christiane Freytag, *Parallelimporte nach EG-und WTO-Recht: Patente und Marken versus Handelsfreiheit*, (Duncker & Humblot, 2001).

⁹ First Directive 89/104/EEC of the Council, of 21 December 1988, to approximate the laws of the Member States relating to trade marks (OJ EC No L 40 of 11 February 1989, page 1).

¹⁰ First Directive 89/104/EEC of the Council, of 21 December 1988, to approximate the laws of the Member States relating to trademarks, OJ EC No L 40 of 11.2.1989, page 1, Article. 7.

between Member States'.¹¹ However, the Community's ability to use this provision to restrict the abuse of intellectual property rights is limited by the Treaty itself.¹²

The EU policy on the compatibility of national and regional trademark law was originally formulated in one of the first leading cases where the Sterling Winthrop Group held the 'Negram' trademark in the United Kingdom and the Netherlands. Another company, Centrafarm, imported the same drug into the Netherlands from the United Kingdom. The Dutch subsidiary of Sterling Winthrop invoked its trademark rights in an attempt to keep the goods out.¹³ The Court concluded that since Negram had been lawfully marketed in the United Kingdom with the consent of the trademark holder, the trademark holder's rights had been exhausted.

This decision has been confirmed by Article 7(1) of Directive 89/104 on the approximation of law of the Member States relating to trademarks.¹⁴ Article 7(2) stipulates that there is no application of exhaustion in cases where there are legitimate reasons for the proprietor to oppose the further commercialization of the goods. However, Sterling Winthrop could not rely on its Dutch mark to prevent imports from the United Kingdom, where the products had been marketed by a company in the same group. The doctrine of exhaustion also implies the notion of consent.¹⁵ It is clear now that the consent principle only applies where the owners of the trademark in the importing and exporting States are the same. It could also apply where they are different, but are economically linked.¹⁶

In *Van Zuylen v. HAG* the Court bypassed the doctrine of exhaustion in relation to trademarks. The Court conceived the 'doctrine of common origin', which in certain instances is contrary to the doctrine of exhaustion.¹⁷ The doctrine of common origin means that where similar or identical trademarks share a common origin but are owned by different trademark holders in different member States, neither could invoke its trademark rights to prevent the importation of goods lawfully marketed under the mark by other owners in other member States. However, this doctrine was later reversed by the Court. In *HAG II*, the Court returned to the original principle of exhaustion.¹⁸

It is important to note that the key argument supporting the Court's reversion to the doctrine of exhaustion was influenced by the specific subject matter of trademarks. The Court reaffirmed that trademarks are indicators of product origin and guarantors of quality.

¹¹ Article 30 EC Treaty, Official Journal C 325, 24/12/2002 P. 0047 - 0047. Note: Now Article 36 of the Treaty on the Functioning of the European Union.

¹² Ibid. 'The provisions of Articles 28 and 29 shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified on grounds of public morality, public policy or public security; the protection of health and life of humans, animals or plants; the protection of national treasures possessing artistic, historic or archaeological value; or the protection of industrial and commercial property. Such prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States'.

¹³ *Centrafarm BV v. Winthrop BV* Case 16/74 [1974] ECR 1183.

¹⁴ See *supra* footnote 7.

¹⁵ Regarding the importance of the consent, see Norbert Reich, *Understanding EU Law*, (Intersentia, Antwerpen-Oxford 2005).

¹⁶ Regarding the importance of the consent, see Norbert Reich, *Understanding EU Law, IHT Internationale Heiztechnik GmbH v Ideal-Standard GmbH* Case C-9/93 [1994] ECR I-2789.

¹⁷ *Van Zuylen v. HAG* Case 192/73 Hag I [1974] ECR 731.

¹⁸ *SA CNL-SUCAL NV v. HAG GF AG*. Case C-10/89 Hag II, [1990] ECR I-3711.

The Court's decision in the *Ideal Standard Case* is also significant.¹⁹ The decision stipulated that when the rights holder voluntarily loses ownership over the trademark (e.g. assignment), the doctrine of exhaustion cannot be invoked by the assignor due to the lack of control over the product under the mark.

Further cases decided by the European Court of Justice highlight other problems and complications in this area. A particular situation is where an importer re-packages or alters the packaging of the goods.²⁰ The European Court of Justice held that if the use of the trademark would have the effect of artificially partitioning the market, then the doctrine of exhaustion cannot be relied on. However, it is permissible if the repackaging has no adverse effect on the original condition of the goods, and as long as users will not be misled or confused by it. There is also the requirement that the trademark owner must be notified of the repackaging.²¹

Similarly, the case of *Silhouette International Schmied GmbH and Co. KG v. Hartlauer Handelsgesellschaft mbH*²² concerned a superior range of spectacle frames that were manufactured and sold internationally by the Austrian claimants under the mark 'Silhouette'. A batch of the previous season's 'Silhouette' spectacle frames were offloaded in Norway (which is not an EU member) and later sold in Bulgaria on the condition that any marketing of the products would only occur in former East Bloc countries. However, through a series of further transactions, the frames were imported into Austria by the defendant, who then sold the spectacles through its chain of outlets that were not part of Silhouette's distribution system. If the former Austrian law had still been applicable, an extensive rule of international exhaustion would have protected the defendant. But the European Court of Justice considered the case and decided that Article 7 of the Trademark Directive had priority over the Austrian legislation.²³ National rules providing for international exhaustion were therefore contrary to this provision. Therefore, Silhouette could prevent the sale in Austria of the sunglasses that had been first sold in Bulgaria.²⁴

In *Sebago v. GB Unic*, the European Court of Justice ruled that it was insufficient that the rights holder had provided general consent for the marketing (within the European Union) of products identical to those for which exhaustion was being claimed.²⁵ Consent had to be proven for the actual products in question.²⁶

Further case developments have described and prescribed the implied notions of consent, the strict rules of repackaging and advertising, and the notion of the 'specific subject-matter' of a trademark.²⁷

¹⁹ *IHT v. Ideal Standard Case* C-9/93, [1994] ECR I-2789, paragraphs 41-43.

²⁰ See *Hoffmann-la Roche v. Centrafarm Case* 102/77 [1978] ECR 1139; and *Centrafarm BV v. American Home Products Corp Case* 3/78 [1978] ECR 1823.

²¹ *Pfizer v. Eurim-Pharm Case* 1/81 [1981] ECR 2913.

²² *Silhouette International Schmied GmbH & Co. KG v. Hartlauer Handelsgesellschaft mbH Case* C-355/96 [1990] ECR I-4135.

²³ William R. Cornish, *Intellectual Property: Patents, Copyrights, Trademarks and Allied Rights*, (Sweet and Maxwell, 2007).

²⁴ Lionel Bently and Brad Sherman, *Intellectual Property Law*, (Oxford, 2004).

²⁵ *Sebago v. GB Unic Case* C-173/98 [1999] ECR I-4103.

²⁶ See also *Zino Davidoff SA v. A&G Imports*; *Levi Strauss v. Tesco Cases* 416/99 [2001] ECR I-8691.

²⁷ *Parfums Christian Dior SA v. Evora BV Case* C-337/95 [1998] RPC 166; *Bristol-Myers Squibb v. Paranova A/S Case* C-427/93, [1996] ECR 3457.

The pharmaceutical protection regime in Bulgaria

The generic drug industry in Bulgaria

Relative to other Eastern European States, Bulgaria's industrial policy has fostered a relatively efficient generic pharmaceutical industry.²⁸ This has led to a 70 per cent local market share for generics made in Bulgaria.²⁹ The production is exported, primarily to States of the former Soviet Union. However, several large foreign companies also have agencies in Bulgaria.³⁰

According to existing legislation, pharmaceutical manufacturers may market their products directly through authorized distributors. They may also participate in government procurement tenders organized by the Ministry of Health, the National Health Insurance Fund and the country's hospitals through wholesalers acting as their authorized distributors. However, consumers reportedly have a more favourable opinion of imported medicines and frequently prefer these products if they can afford them.³¹

Before 1991, the production and distribution of pharmaceuticals in Bulgaria was highly centralized under the remit of the State Pharmaceutical Company. The Company was also in charge of a network of pharmacies, specialist warehouses and depots, importers and distributors of medicinal drugs, as well as sanitary suppliers.

A combination of decentralization policies and the transition to a market economy broke this monopoly. The *Pharmaceuticals and Human Medicine Pharmacies Act* of 1995 created the basis for the restructuring and privatization of the production and distribution of pharmaceuticals. Most pharmacies are now privatized. In 2004, the total number of pharmacies in Bulgaria was 4518, compared with 4000 in 2003 and 1020 in the year 2000. The number of pharmacies is beginning to peak due to the limited number of certified pharmacists.³²

Foreign manufacturers are represented in Bulgaria in two ways. The first is through the establishment of representative offices which are not legal business entities. These offices only perform promotional and marketing-related activities. The actual sale of drugs is carried out directly

²⁸ Report by the Bulgarian Ministry of Health, 2007.

²⁹ For further information see also Christine Godt, *Differential Pricing of Pharmaceuticals inside Europe: Exploring Compulsory Licences and Exhaustion for Access to Patented Essential Medicines*, (Nomos, 2010). The market leader of Bulgarian production is the Actavis Group with its three subsidiaries Dupnitsa, Razgrad and Trojan (formerly known as Balkanpharma, which was fully taken over by an Island company in 2000) as well as Sopharma AD, which carries out production in five plants and is currently expanding strongly into Eastern Europe. Together, they provide 77 per cent of medicines sold in Bulgaria. However, in terms of the absolute sales value, the imported medicines (which are considerably more expensive) are predominant. At the same time, the demand is great for pharmaceuticals, especially for the nervous system, heart and vascular-diseases, as well as respiratory diseases. Nearly half of all imported pharmaceuticals come from Germany, France and Switzerland. GlaxoSmithKline holds the biggest market share (7 per cent) followed by Novartis (6,1 per cent).

³⁰ See the List of Members of the Association of Research-Based Pharmaceutical Manufacturers in Bulgaria published at <http://www.arpharm.org/members.php> (last update 10 May 2011).

³¹ See *supra* footnote 29.

³² L. Georgieva, P. Salchev, R. Dimitrova, A. Dimova, O. Avdeeva, *Bulgaria - Health System Review, Health Systems in Transition*, O. Avdeeva/M. Elias, eds., Vol. 9, No. 1, (World Health Organization, 2007) <<http://www.euro.who.int/Document/E90023.pdf>>.

from the foreign legal entities to authorized dealers. The dealer then redistributes the drugs to pharmacies and also participates in tenders.

Alternatively, foreign companies establish local subsidiaries that are legal business entities with drug distribution licences in Bulgaria. These subsidiaries may participate directly in tenders by the Ministry of Health and the National Health Insurance Fund. Though they are permitted to sell drugs directly to pharmacies, their lack of personal distribution networks tends to impede this goal. For that reason, they also authorize local wholesalers to participate in hospital tenders on their behalf.

Recently, a greater number of foreign pharmaceutical companies have been establishing local subsidiaries that are licensed as wholesalers under Bulgarian law.³³ The licences are issued by the Ministry of Health in conjunction with the Bulgarian Drug Agency. More than 100 international pharmaceutical companies are represented in Bulgaria. Twenty-three of them are members of the Association of Research-Based Companies. The majority are members of the Association of Foreign Pharmaceutical Manufacturers in Bulgaria.

Pharmaceutical consumption trends in Bulgaria

Since 1999, pharmaceutical consumption has been increasing at a rate faster than that of the total health expenditure. This was particularly the case in 2001 and 2002. While consumption has increased, the total number of packages sold decreased from 164 million in 2003 to 153 million in 2004. The main customer for all pharmaceuticals in Bulgaria is the National Health Insurance Fund, which subsidizes outpatient drugs for vulnerable groups and for 21 university hospitals, 28 multidisciplinary hospitals, 64 haemodialysis centres, and numerous dispensaries across the country.³⁴

The intellectual property protection regime for pharmaceuticals in Bulgaria

Strong intellectual property protection is a relatively recent phenomenon in Bulgaria. The country has signed and ratified the Madrid Convention and other WIPO treaties. As a Member of the World Trade Organization, Bulgaria must also be compliant with the *Agreement on Trade-Related Aspects of Intellectual Property Rights* (TRIPS).³⁵

Bulgaria introduced a 20-year patent protection term for pharmaceuticals under the *Patent Act*. In 2003, the Government introduced a six-year data exclusivity period for pharmaceuticals. This move provides additional market protection for originator pharmaceuticals, by preventing health authorities from accepting applications for generic medicines during the period of exclusivity. In 2007, Bulgaria responded to pressure from the European Communities by raising the data exclusivity period to '8+2' years in order to comply with EC Regulation No. 726/2004.

Supplementary protection certificates are available under the new Chapter 6 of the *Bulgarian Patent Act*.³⁶ For high-tech and biotechnological products the period of market exclusivity is ten

³³ Regulated in Chapter 5, Article 146 et seq. Pharmaceuticals in Human Medicine Act, last amendment 12 Aug. 2008.

³⁴ Nadia Ianeva, 'Protection and regulation of pharmaceuticals in Bulgaria', in Christine Godt, *Differential Pricing of Pharmaceuticals inside Europe*, (Baden-Baden: Nomos, 2010), page 170.

³⁵ Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization, signed in Marrakesh, Morocco on 15 April 1994.

³⁶ Chapter 6, Article 72(k), Patent and Utility Models Act, *Bulgarian State Journal* No. 64/2006, entered into force on 1 January 2007.

years.³⁷ However, the Bulgarian Government also introduced a Roche-Bolar³⁸ provision in 2003. The provision enables generic manufacturers to begin developing generic versions of drugs for the purposes of regulatory approval, two years before the patents expire.³⁹

Fears that EU enlargement would open the floodgates to cheap parallel imports from Eastern Europe have turned out to be unfounded. In fact, some international pharmaceutical brands are more expensive in Bulgaria than they are in Western European countries. According to statistics, in relative terms, the Bulgarian patient pays ten times more for medicines than the average German patient. In December 2003, the Bulgarian Government introduced a new catalogue of drugs that may be eligible for reimbursement, but are not automatically covered.

The central legal source for the protection of pharmaceuticals is the *Bulgarian Pharmaceuticals in Human Medicine Act (PHMA)* which came into force on 13 April 2007. The legislation is designed to align Bulgarian pharmaceutical law with the EU *acquis*.⁴⁰ The new law regulates the production and export of medicinal products and active chemical ingredients. It also governs the commercial and licensing regime for the trade and parallel importation of pharmaceutical products. In institutional terms, it regulates the role of the Bulgarian Drug Agency, which is an executive body under the Ministry of Health that is in charge of domestic pharmaceuticals regulation.

Additionally, the PHMA provides a pharmaceutical pricing framework, whereby the lowest prevailing price of the same or similar product among EU member States is to be used as a reference.

The National Health Insurance Fund provides full or partial reimbursement to patients for pharmaceuticals. The disease groups eligible for reimbursement include diabetes, sclerosis, multiple sclerosis, metabolic disorders, as well as cardiovascular, neurological and gastroenterological diseases. National and regional budgets subsidize pharmaceuticals for particular demographic groups, including low-income households, children, the unemployed, the retired, and members of the armed forces.

In March 2009, the Bulgarian Ministry of Health announced that seven or eight rare diseases would be included in Regulation 34 of the *Ministry of Health Act, 2005*. According to that regulation, a regime for granting drugs for eight rare diseases, such as thalassemia major and Gaucher's Disease, has been adopted.

Depending on the prices of the medications for new diseases, the Ministry will consider the possibility of designating a portion of the purchase price to patients. By 2013, the Ministry plans to establish a treatment system which will involve the creation of a register of patients that suffer from such diseases. The system will also provide for diagnostics and prophylaxis. One of the key goals of the new programme is to enable the examination of new born babies with the objective of finding inborn or genetic diseases.

³⁷ See *supra* footnote 27.

³⁸ Canada-Patent Protection of Pharmaceutical Products, http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds114_e.htm

³⁹ Fact Sheet 'Overview of the Bulgarian and Romanian Pharmaceutical Markets', <http://www.researchandmarkets.com/reports/314606/>

⁴⁰ Collins English Dictionary: 'the accumulated legislation, legal acts, court decisions which constitute the body of European Union law'.

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The PHMA was followed by secondary legislation, which is currently undergoing amendment. The key achievement of the legislation has been to remove legislative obstacles to the intra-EU pharmaceutical trade. However, for imports from outside the EEA and Switzerland, an import permit must be obtained in advance.

Conclusion

The protection of intellectual property rights versus access to pharmaceuticals will remain a complicated issue. The aim of this article was to present the means of protection for pharmaceuticals, the doctrine of exhaustion and its implementation in the EU context. The Bulgaria case study is one illustration of the difficulties of balancing the needs of stakeholders, especially in situations of budgetary constraints.

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