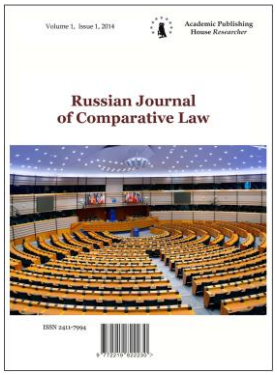
Published in the Slovak Republic
Russian Journal of Comparative Law
Has been issued since 2014.
E-ISSN 2413-7618
2019, 6(1): 34-40

DOI: 10.13187/rjcl.2019.1.34
http://ejournal41.com



Patent Protection of Pharmaceutical Products in USA

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Abstract

The article deals with the analysis of patent rights correlation and regulation of medicines circulation procedure in USA beginning from the development process to the medicine registration by the regulatory authority. Author considers the application of the Bolar exemption and the practice of maintenance of Unified register, which includes data on effective patents at the initiative of the rights holders upon new medicine registration. The practical aspects of patent linkage system as well as an introduction into circulation of the so-called "branded generics" are considered in the article.

Keywords: patent, Medicine, USA, EU, pharmaceutical product, invention.

1. Introduction

For observing the balance of legitimate interests of rights holders and society, it is important to determine the mutual influence and correlation between the effect of patent rights and regulation of the procedure for circulation of medicines on the market from the development process to the registration of a pharmaceutical product by an authorized body. The drug approval process in the United States is regulated in accordance with the US Food, Drug, and Cosmetic Act (Federal Food, Drug and Cosmetic Act), adopted by Congress in 1938. In 1962, the Act was amended (Kefauver-Harris Amendments), and when registering a medicine, not only evidence of its safety should be given, but also data of its effectiveness, adverse reactions of the medicine should be provided.

2. Materials and methods

The following methods were used: logical, legal modeling method, as well as systematic and comparative legal methods of research of US and EU legal acts. The article was also based on acts of courts, as well as foreign analysis on the regulation of relations on the protection of inventions.

3. Discussion

In general, the regulation of the medicines circulation process is divided into four phases: an research, preclinical and clinical studies, and a procedure for new medicine registering.

The research stage includes measures to find the active substance with a certain type of pharmacological activity, which as a result may have a certain effect for therapeutic indications as a potential pharmaceutical product. As a part of this phase, new substances can be created or modified ones already created. Only potentially successful substances in terms of the indicators required for a medicine can be subject to patent.

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At the stage of preclinical studies there is a significant elimination of medicine candidates. At this stage, preliminary information about the toxicity, efficacy and other characteristics of the medicine are obtained. These characteristics include markers such as pharmacological properties, pharmacokinetics and metabolism. This research stage of medicine development is labor intensive, costly and very important (Guidance, 2005). In general, the period from research to the end of preclinical studies can take from three to six years.

Prior to initiating clinical trials of candidate medicines, a company organizing clinical trials must submit an application to the FDA to obtain permission to conduct clinical trials of a new drug. The statement includes a list of side effects, data on manufacturing, the results of preclinical studies, the chemical structure of the candidate drug, the mechanism of its action. The application must contain a detailed clinical research plan, on the basis of which the FDA makes a positive decision on the admission of the medicine to clinical trials, in the absence of an unreasonable risk for the participants in such study.

In the course of clinical trials of new medicines, four interrelated phases are identified, the last of which is possible after allowing the use of a new medicine in medical practice and its commercialization. Before the end of the first three phases of clinical studies preceding the registration of drugs, it takes from six to seven years.

The data obtained within the steps described above is included in the application for registration of a new medicine sent to the FDA, which can last more than two years. In general, the period from the research stage to the launch of a medicine on the market can take from 10 to 15 years (Qualification Process, 2005). In practice, a patent application is filed at the research stage, and by the time the medicine is approved by the FDA, the remaining period of patent protection may be only five years.

In generic development, research is not required. It is enough to use the available information about the original medicine in circulation. It takes from 3 to 5 years to develop a generic. It is not required to prove the safety and efficacy of the medicine, when submitting a generic for registration it is sufficient to refer to the research data conducted by the manufacturer of the original drug.

The adoption of the 1984 Hatch-Waxman Act was aimed at smoothing clashes between the interests of the developers of original medicines and generics for the purpose of providing society with the necessary pharmaceutical products. To achieve this goal, the Act approved provisions not only regarding the extension of patent protection, but also reducing the risk of liability of developers who are researching generics, as well as the conditions for an abbreviated procedure for registering generics.

With regard to reducing the risk of liability of generic developers, the Hatch-Waxman Act established a “safe harbor provision” or “Bolar exemption”, according to which actions reasonably aimed at preparing for an abbreviated registration procedure do not violate patent rights (The Code, § 271 (e) (1)).

Until 1984, there was a practice in the USA for manufacturers of generics to apply for registration of their medicine before the patent expires on the original drug in order to market it immediately after the patent protection expires, since the application approval process takes a long period of time (Engelberg, 1999 : 39).

In 1984, an exception was introduced on the experimental use of a patented medicine, which is not applied to cases of commercial use of the invention. Experimental use is limited to purely scientific research purposes or to “mere curiosity, entertainment purposes, or solely within the framework of philosophical research” (Peppenhausen v. Falke). The exemption for experimental use does not apply to cases of commercial use of the invention.

The starting point for introducing an exemption for experimental use, in which the basis was whether the use was commercial or not, was the decision in the case of Roche vs Bolar (Roche Products, Inc. v. Bolar Pharmaceuticals Co., Inc.), in which the court resolved the question whether the patented substance of a medicinal product could form the basis of an application for registration of a new medicinal product before the expiration of the remaining six-month patent term. The Bolar company, which produced the product, reproduced from the original drug Valium, produced by the Roche company, used the original product for the purposes of conducting bioequivalence studies and then registering the FDA product.

In a decision of the Court of Appeal of the Federal Court in the case of Roche v. Bolar on April 23, 1984, the approach of the Bolar Company was criticized. Before the expiration of the patent for the Roche medicine, the Bolar company, a generic developer, received the active ingredient of the original medicine. Bolar Company organized the studies necessary to apply for registration of its generic drug, derived from the original drug, the patent for which was owned by Roche. The remaining term of the patent for the Roche product was an additional six months. When considering the dispute in the first instance, the court ruled that the actions of the Bolar company are not a violation of the current patent, because they are subject to an exception based on the common law on "experimental use", and, as a result, are not a violation of the patent.

The first instance decision of the court was revised by the Court of Appeal, which, in its decision, explained that the exemption was not applicable for commercial research – that is, for registration purposes for further market launch (Roche Products, Inc. v. Bolar Pharmaceuticals Co., Inc.). Thus, in the decision under consideration, a rule was fixed on the need for the actual expiration of the term of patent protection, during which the generic developer cannot even submit an application for registration of a medicine.

At the same time, the decision of the Court of Appeal subsequently caused much controversy, and also caused the attention of the US Congress, which already considered the conflict of interests of innovative pharmaceutical companies and generic manufacturers (Voet, 2008: 123). One of the results of the consideration of this problem was the adoption of the Hatch-Waxman Act in 1984.

Taking into account that the act of registration in itself allows the manufacturing, use, offering for sale, sale and import of the claimed invention, it was found that filing an application for an abbreviated procedure for registering a generic with a valid patent is a violation of patent rights (The Code, § 271 (e) (2)). Thus, the result of the revision of the decision in the case of "Roshe v. Bolar" was laid in the basis of US law.

The Hatch-Waxman Act restructured the balance of rights and legitimate interests of rights holders, on the one hand, in terms of extending the term of a patent for a pharmaceutical product, taking into account the time spent during the registration procedure, and the public interest through affordable priced generics whose manufacturers were given the opportunity to bring their drugs to the market immediately after the expiration of the patent for the original drug (Kucukarslan S. and Cole J., 1994 : 511).

Although the court ruled that the exemption for experimental use in the dispute resolution was not applicable in the case of the Roche vs Bolar case, as the Bolar medicine could subsequently be put into circulation when it received approval from the FDA, the exemption was subsequently extended to preparatory measures for the application to the FDA.

The US Supreme Court ruled (Merck KGaa v. Integra Lifesciences I, Ltd.) that the use of the patented compound in preclinical studies is allowed under paragraph 271 (e) (1) of the US Code, if there is a reasonable reason to believe that the compound under investigation will be The subject of the application for registration of the medicine at the FDA and the result of the study will be data relevant to the application for conducting clinical trials or the application for registration of a new drug.

From the point of view of the limits of application of the exemption under consideration, a case-law decision (Merck KGaa v. Integra Lifesciences I, Ltd.) became a case in which the plaintiff claimed patent infringement, being the owner of five patents for a number of chemical compounds that promote the formation of organ or tissue, and that have been the subject of preclinical studies conducted by researchers for the purpose of the generic company.

The court ruled that preclinical studies aimed at identifying one of the drugs – candidates for further clinical studies are not subject to the exception set in the Hatch-Waxman Act, since the data on the results of such studies did not form the basis of the information considered by the FDA during the registration procedure. However, the Supreme Court later revised the decision and concluded that any use of patented compounds reasonably associated with the process of preparing information sent to the authorized drug registration authority, including data from preclinical studies, may fall under the established exception.

However, if there is no intention to develop the medicine in the future, the provided exception does not apply. Thus, conducting a study, the results of which will not be directly part of the application for registration of a drug, but which are necessary for the development of a medicinal product, with existing patent rights, is valid and applies not only to clinical results, but also to preclinical studies, which contributes to more effective use of the "Bolar exemption" and

stimulates the early entry into the market of modified, new and innovative drugs immediately after the expiration of the patent.

And the requirement to use the data obtained as a result of using the medicine for experimental purposes, which was under patent protection during the study period, is an additional guarantee for the market entry of new products and a restriction on the misuse of the patented invention, which can be qualified as illegal use.

Simultaneously with the possibility to use the patented invention for research purposes, the Hatch-Waxman Act provided an opportunity for generic companies to take steps to prepare for the registration procedure with reference to the data of the clinical studies of the originator company during the patent term.

Based on the establishment of an Abbreviated New Drug Application (ANDA) in the Act, in order to facilitate the introduction of affordable reproduced drugs into circulation, the need for generic companies to conduct their own preclinical studies was eliminated. According to the requirements of this procedure, the applicant company must prove that its preparation has proven pharmaceutical equivalence and bioequivalence with respect to the original medicine. Evidence is data from bioequivalence studies between generic and original drug without reference to research data on the safety and efficacy of the drug (FTC, 2002).

The practice of generic manufacturers applying for registration of their drug before the expiration of a patent for the original medicine in order to bring it to the market immediately after the expiration of the term of patent protection (Engelberg, 1999: 39), which existed in the United States until 1984, was revised to ensure the effectiveness of legal protection of the rights of patent holders, as well as for the purpose of eliminating unused patents that restrict competition.

So, when applying for registration of a new drug, the applicant, who is the manufacturer of the original drug, must notify the FDA of all valid patents for the declared medicine. The data concerning patent rights are recorded in the Orange Book (Electronic orange book, 2010). This information is necessary to determine the term for approval of an application submitted under the abbreviated procedure. The original medicine manufacturer is obliged, in turn, to notify the FDA of patents for medicine that he owns, including information about changes related to a patent for an approved medicine, within 30 days of their introduction. Generic companies applying for an abbreviated registration procedure must confirm one of four conditions, according to the list of patent data on the declared product presented in the Registry.

Among them, paragraph 4: a patent which term has not expired is not used or invalidated, or the manufacturing, use, offer for sale, sale or import of a generic claimed to the abbreviated registration procedure will not constitute a violation of patent rights.

The applicant within the abbreviated registration procedure, referring to the conditions of paragraph 4, must notify the patent owner and the applicant for registration of a new medicine (New Drug Application – NDA) if these are two different persons, within 20 days of submitting an application for registration, substantiating in detail the actual and legal circumstances of filing an application on the basis of paragraph 4. The patentee, in turn, has the right to file a claim within 45 days for violation of his rights. During this time, the applicant can not apply for a court ruling on the absence of patent infringement. If the patent owner fails to file a claim within the 45 days submitted, the FDA has the right to approve the application and / or the applicant can use the opportunity to get a court ruling on the invalidity of the patent, its non-fulfillment or the absence of patent infringement.

If the patent holder files a claim within 45 days after receiving the notice of filing the application on the basis of paragraph 4 by the applicant, the application can be approved only if one of the following conditions is met: the patent has expired or the court has decided that there is no patent infringement or recognition patent invalid.

In the USA, the described system has the name “patent linkage”. In essence, this term denotes the mechanism for ensuring the protection of patent rights for a pharmaceutical product under the legal regulation of the circulation of drugs - the mechanism for ensuring patent clearance for pharmaceutical products.

The EU has not established a “patent linkage” system when registering pharmaceutical products with the European Medical Agency (EMA – European Medicines Agency), according to which such a system hinders the introduction of generics to the market (Bhardwaj et al., 2013: 316-322).

В Regulation (EC) № 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (Regulation 726/2004) and Directive of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (Directive 2001/83/EC) it was established that the registration of a medicine can be denied only on the grounds established in the acts among which there is no connection with the effect of patent rights on a pharmaceutical product. Although, for example, in Hungary, Italy, Portugal and Slovakia, there is a "patent linkage system" (Pharmaceutical Sector Inquiry Report, 2008). Despite the lack of correlation of the procedure for registration of a medicine in the European Medicine Agency with the effect of a patent, the EU has established a sufficiently long validity period for the data exclusivity.

As part of the implementation of the patent clearance mechanism for pharmaceutical products in the US, when deciding in favor of the manufacturer of the reproduced drug that there is no patent infringement, the company is given 180 days during which the FDA is not eligible for approval of other such generics (Korn DE, Lietzan E. and Scott SW, 2009: 64).

As well as the Bolar exemption, the 180-day period is an important motivation for the manufacturing of generics, including the aim of reducing the cost of medicines for the patients.

However, the establishment of this approach has led to the fact that in practice there is an introduction into circulation of the so-called "branded generics" – branded medicines produced by the company – the developer of the original medicine, registered by submitting an application for registration of a new drug (NDA). In practice, branded generics are released within 180 days of exclusivity granted to first applicants for a reduced registration procedure (ANDA) – (FDCA, Section 505 (j) (5) (B) (iv)), which allows them to compete with the first generic for market share in terms of pricing, quality and availability. The market circulation of high-quality branded generics stimulates lower prices for generics, which would not be such a favorable consequence for the consumer if only one generic was in circulation for a certain period of time (FDA, 2005).

The impact of increased competition in the manufacturing of branded generics was fixed by the Federal Trade Commission, which found that price cuts were more than double stimulated by the introduction of branded generics to the market (Federal Trade Commission, 1999).

On the other hand, the withdrawal of branded generics when using licensing agreements (Combe, 2006: 47-62) at a reduced price may adversely affect competition, since interest for circulation of generics from other market participants may be lost (Hamdouch, Perrochon, 2000 : 46).

Considering that the patent system and the medicines registration procedure at the FDA function interdependently, it is worth to dwell on the consequences of introducing such a system, which manifests itself in the use of agreement strategies by originating companies, according to which the pharmaceutical company – the patentee pays a potential competitor – the generic manufacturer for refusal to challenge the patent or delay entry to the market at a lower cost for a period of 180 days. This is the so-called. pay-for-delay agreement (Pay-for-Delay Deals, 2013).

The US Federal Trade Commission successfully challenged the legitimacy of such agreements as part of the proceedings before the District Court of Appeals, which asserted that the agreements were illegal. However, as a result of the court's consideration of a number of cases in 2005, the "pay-for-delay" agreements were exempted from antitrust lawsuits, as a result of which the number of concluded agreements increased from three in 2005 to 19 in 2009, which cost consumers 3.5 billion US dollars per year (Pay-for-delay, 2010).

However, in 2012 the court justified the possibility of concluding such agreements to the extent that the restriction of competition is based on privileges under the current patent if, according to the agreement, the generic withdrawal is not limited after the patent expiration (Federal Trade Commission v. Watson Pharmaceuticals, Inc.).

According to the US Federal Trade Commission, agreements of this kind adversely affect competition, increase health care costs, and reduce consumer welfare (Pay For Delay, 2010). The US Federal Trade Commission has repeatedly challenged the legitimacy of such agreements in court, which resulted in conflicting decisions (Roane, 2011).

In 2012, the United States Federal District Court (In Re K-Dur Antitrust Litig.) established a generalized conclusion that any such agreement should be found to restrict trade freedom, unless the purpose of the payment is not related to the delay in entering the generic into the market or if conditions are established by agreement to facilitate competition.

However, it should be recognized that the consideration of patent infringement disputes from the point of view of antitrust laws can be permissible only to the extent that it is relevant to the question of the actual doubts of patent rights, including in relation to their scope (Ullrich, 2007).

For comparison, in the EU practice, the existence of a payment condition (Whish, 2008: 786), as well as the assumption about the final practical result of an agreement between the originator and the generic manufacturer, cannot serve as a basis for ascertaining the fact of a violation of competition (Biriukov, 2018; Holman, 2007: 489). However, in the case of an agreement between competitors that goes beyond the limits of the exclusive rights, these actions will be recognized as restricting competition on the basis of a direct ban set forth in Art. 4 (1) Guidelines for the EU Technology Transfer Treaty (Guidelines on the application of Article 101).

4. Results

It should be recognized that the measures provided for initiating the challenging of patent rights at the stage of the registration procedure stimulates a more efficient functioning of the circulation of medicines on the market in the legal field from the point of view of industrial property rights. And the provisions of the Hatch-Waxman Act provide incentives for the production of generics in terms of, for example, the use of the Bolar clause and the 180-day exclusivity priority when applying to the FDA, and the development of innovative products, for example, in connection with the possibility of extending the patent.

5. Conclusion

The unified register of patents for pharmaceutical products serves to ensure the patent protection system. At the same time, the basis of protection in terms of the circulation of medicines is the initiative of the right holders and the good faith of applicants for registration of generics. The period during which the originator and the generic company negotiate a possible threat of patent infringement may be a deterrent to the introduction of the generic into circulation. The negotiation process is a private-law element of relations in the sphere of medicines circulation.

References

The Code – The Code of Laws of the United States of America, TITLE 35 / PART III / CHAPTER 28. [Electronic resource]. URL: http://uscode.house.gov

Federal Food, Drug and Cosmetic Act – Federal Food, Drug and Cosmetic Act, As Amended Through P.L. 107–377, Dec. 19, 2002. [Electronic resource]. URL: http://www.fda.gov/regulatoryinformation/legislation/federalfooddrugandcosmeticactfdcact

FTC, 2002 – FTC (2002). Generic drug entry prior to patent expiration: An FTC study, July. [Electronic resource]. URL: https://www.ftc.gov/sites/default/files/documents/reports/generic-drug-entry-prior-patent-expiration-ftc-study/genericdrugstudy_0.pdf

Electronic orange book, 2010 – US Dept, of Health & Human Servs. Et. Al., Electronic orange book, (2010). Approved drug products with therapeutic equivalence evaluations.

Kefauver-Harris Amendments, 1962 – Kefauver-Harris Amendments Revolutionized Drug Development Drug Efficacy (1962). Amendment enacted by the 87th United States Congress, Effective October 10, 1962. [Electronic resource]. URL: http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm322856.htm

FDCA – The Federal Food, Drug and Cosmetic Act [Electronic resource]. URL: https://www.senate.gov/pagelayout/general/one_item_and_teasers/file_not_found.htm

FDA, 2005 – U.S. Food and Drug Administration (2005). FDA Talk Paper. FDA Supports Broader Access to Lower Prices Drugs. 30 March 2006. [Electronic resource]. URL: http://www.fda.gov/bbs/topics/answers/2004/ans01296.html

Comment of the Staff, 1999 – Federal Trade Commission, (1999). Comment off the Staff of the Bureau of Competition and of Policy Planning of the Federal Trade Commission. Docket № 85N-0214. 6 January 2005. [Electronic resource]. URL: http://www.ftc.gov/be/v990016.htm

Qualification Process, 2014 – Qualification Process for Drug Development Tools, (2014). U.S. Department of Health and Human Services Food and Drug Administration Center for Drug Evaluation and Research (CDER). [Electronic resource]. URL: http://www.fda.gov/forpatients/approvals/drugs/default.htm

Federal Trade Commission v. Watson Pharmaceuticals, Inc. – Federal Trade Commission v. Watson Pharmaceuticals, Inc., CPI Antitrust Chronicle June 2012 (2) WL 1427789, April 25, 2012.

Pay-for-delay, 2010 – «Pay-for-delay: How drug company pay-offs cost consumers billions» (2010). Federal Trade Commission Staff Report. A Federal Trade Commission Staff Study, January 2010. [Electronic resource]. URL: https://www.ftc.gov/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff

Peppenhausen v. Falke – *Peppenhausen v. Falke*, 19 Fed. Cas. 1048, 1049, C.C.S.D.N.Y. 1861, No. 11, 279.

In re Cardizem CD litigation – U.S. Court of Appeals for the Sixth Circuit. *In re Cardizem CD litigation*, 332 F.3d 896, 6th Cir. 2003.

In re K-Dur Antitrust Litig – United States Court of Appeals for the Third Circuit. *In re K-Dur Antitrust Litig*., No. 10-2078, slip op. 3d Cir. July 16, 2012.

Guidelines on the application of Article 101 – Communication from the Commission — Guidelines on the application of Article 101 of the Treaty on the Functioning of the European Union to technology transfer agreements [Electronic resource]. URL: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52014XC0328(01)

Pharmaceutical Sector Inquiry Report, 2008 – Pharmaceutical Sector Inquiry Report, 2008, European Commission.

Biriukov, 2018 – *Biriukov, P.* (2018). On the Legal Status of Medicinal Products in the EU and the UK. *Russian Journal of Legal Studies*, 2018, 5(1): 3-9.

Bhardwaj et al., 2013 – *Bhardwaj, R., Raju, K.D., Padmavati, M.* (2013). The impact of patent linkage on marketing of generic drugs. *Journal of Intellectual Property Rights,* Vol 18, July.

Combe, 2006 – *Combe, E.* (2006). Les laboratoires pharmaceutiques face à la concurrence des génériques: quells enjeux pour l‟antitrust? *Concurrences. Revue des droits de la concurrence,* № 1.

Engelberg, 1999 – *Engelberg, A.* (1999). Special patent provisions for pharmaceuticals: Have thay outlived their usefulness? IDEA.

Guideline, 2005 – Guideline on experimental (preclinical) research of new pharmaceutical substance, (2005). M.

Hamdouch, Perrochon, 2000 – *Hamdouch A., Perrochon D.* (2000). Formes d'engagement en R&D, processus d'innovation et modalités d'interaction entre firmes dans l'industrie pharmaceutique. *Revue d'économie industrielle,* Vol. 93,

Holman, 2007 – *Holman, C.M.* (2007). Do Reverse Payment Settlements Violate the Antitrust Laws? Vol. 23, Santa Clara Computer & High Tech. L.J. P. 489. [Electronic resource]. URL: http://papers.ssrn.com/sol3/papers.cfm?abstract_id=989611

Korn et al., 2009 – *Korn, D.E., Lietzan, E., Scott, S.W.* (2009). A new history and discussion of 180-day exclusivity, Food & Drug L.J.

Kucukarslan, Cole, 1994 – *Kucukarslan, S., Cole, J.* (1994). Patent extension under the drug price competition and Patent Term Restoration Act of 1984, Food & Drug L.J.

Merck KGaa v. Integra Lifesciences I, Ltd. – Supreme Court of the United States, Merck KGaa v. Integra Lifesciences I, Ltd. (2005). № 03—1237, 545 U.S. 193.

Roche Products, Inc. v. Bolar Pharmaceuticals Co., Inc. – *Roche Products, Inc. v. Bolar Pharmaceuticals Co., Inc.* (1984). U.S. Court of Appeals for the Federal Circuit, Roche Products, Inc. v. Bolar Pharmaceuticals Co., Inc., 733 F.2d 858, Fed. Cir. 1984, April 23. [Electronic resource]. URL: http://law.justia.com/cases/federal/appellate-courts/F2/733/858/459501

Roane, 2011 – *Roane, K.R.* (2011). Generics' new legal attack: Big pharma's aging patents, Fortune.

Ullrich, 2007 – *Ullrich, H.* (2007). VI Abschnitt. Kartellverfahrensverordnung in Ulrich Immenga, Ernst-Joachim Mestmäcker, Wettbewerbsrecht Kommentar zum Europäischen Kartellrecht, 4. Auflage, München, Verlag C.H. Beck.

Voet, 2008 – *Voet, M.* (2008). The Generic Challenge: Understanding Patents, FDA & Pharmaceutical Life-Cycle Management, 2nd Edition, Brown Walker Press, Boca Raton.

Whish, 2008 – *Whish, R.* (2008). Competition Law, Oxford, Oxford University Press. 786 p.