PARALLEL IMPORTS OF MEDICINES (DRUGS) IN THE REPUBLIC OF MACEDONIA - COMPETITION LAW ISSUES

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I. Introduction

As from the beginning of 2012, in the Republic of Macedonian, a legal framework was created for parallel imports of medicines. This regulatory reform raised a lot of dilemmas. Namely, the government wanted to make drugs (either branded or generic) more available, affordable and accessible, for as much as of the general public with reasonable prices, by reducing at the same time the governmental spending, according to its own healthcare policy. On the other hand, authorized drug wholesalers for a long time were facing negative publicity by making huge profits on the pharmaceutical market. Finally, the parallel imports possibility deteriorated the existing producer - distributor relations on the market. Exclusive distributors feel frustrated with the possibility of an additional potential competition and they expect producers to take some remedies in order to eliminate or to restrict this competition. In this Article, we expect to clarify some of these dilemmas and give comparative view of the solutions existing in other countries.

II. What is the notion of parallel imports?

Parallel imports are legitimate goods that are placed into circulation in one market and then imported into a second market without the authorization of the patent holder, but, at the same time, allow existence of competition for a drug which is still under patent protection.[1] They are neither generic versions of a brand name drug, nor are they pirated copies that form part of the "black market". However, these drugs are sometimes referred to as "grey market goods", since parallel imports are connected to the brand-name company.[2]

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[1] See: Religioni U.*, Czerw A. , Economic impact of parallel trade on the selected pharmaceutical markets in the European Union, Prog Health Sci 2012, Vol 2 , No2 : Economic impact trade pharmaceutical markets European Union

[2] See: Brougher T. Joanna, Intellectual Property and Health Technologies Balancing Innovation and the Public's Health, Springer Science+Business Media New York 2014, pp.175 - 202

They have the same active ingredient, in the same amount and the same dosage form, as the locally sourced drugs. They might, nevertheless, differ in packaging depending on the requirement of the importing country, thus being repackaged or relabelled, and the brand name might even differ slightly.[3]

The driving force for parallel trade is the price difference between the source (exporting) and the destination (importing) country[4].

Hence, the effect of the parallel import of drugs is twofold: first, placing some branded drugs not previously subject to competition and second, increasing competition for those previously subject to it.[5]

This kind of arbitrage has been legally practiced in the EU for three decades as a part of the general rules on free movement of goods and represent instrument for creating competition for any medicine during the life of its patent.[6] But, in the US, allowing parallel trade of pharmaceuticals has for many years, since the Clinton administration, been a hot topic in debate on rising pharmaceutical costs. [7]

III. Why the patent system is important in the pharmaceutical industry?

The pharmaceutical industry is one of the most heavily regulated of all industries, and is subject to rigorous patent system. On the other hand, pharmaceutical firms earn higher than normal profits.[8]

The question that often arises is, why?

The patent system in pharmaceutical industry should serve two needs: to promote the development of innovative medicines that are important to the public's health, and to allow the public to access the medicines once they are developed. A system that only achieves one without the other is ineffective in improving the health of the general population. As a result, patent laws encourage drug companies to spend too much money on developing substantial improvements.[9]

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[3] See: Granlund David and Miyase Yesim Köksal,EU Enlargement, Parallel Trade and Price Competition in Pharmaceuticals What's to Blame? Derogation or Perception?
[4] See: Granlund David and Miyase Yesim Köksal, Ibid.
[5] See: Granlund David and Miyase Yesim Köksal, Ibid
[6] See: Miyase Yesim Köksal-Ayhan, Parallel Trade, Reference Pricing and Competition in the Pharmaceutical Market: Theory and Evidence, ECONOMIC STUDIES DEPARTMENT OF ECONOMICS SCHOOL OF BUSINESS, ECONOMICS AND LAW UNIVERSITY OF GOTHENBURG, 199, Geson Hylte Tryck 2011, p. 4
[7] See: Miyase Yesim Köksal-Ayhan, Ibid. p. 6
[8] See: Folland Sherman, Allen C. Goodman and Miron Stano, The Economics of Health and Health Care, Seventh Edition, Pearson Education, Inc, 2013 pp. 347-349
[9] See: Brougher T. Joanna, Intellectual Property and Health Technologies Balancing Innovation and the Public's Health, Springer Science+Business Media New York 2014, pp.175 - 202

On the other hand, patents certainly act to increase drug prices because of the monopoly granted by the rights. High drug prices, in turn, mean less affordability and, accordingly, less accessibility. [10]

However, the market exclusivity provisions are made in response to the declining development of pharmaceutical drugs.[11] Diminished patent protection will reduce innovative desire to develop new and potentially better drugs, which in turn could result in the use of more expensive treatments.

Hence, patent protection for pharmaceutical products has increased substantially since the 1980s. In fact, the EU currently boasts the highest level of market protection for pharmaceuticals in the world.[12]

IV. Some statistical data related to parallel imports

Parallel trade in the European pharmaceutical sector is widespread. In its 2009 Final Report following its inquiry into the pharmaceuticals sector,[13] the European Commission noted that the turnover of parallel traders was between EUR3.5 billion and EUR5 billion in Europe, that is, between 2% and 3% of the overall market. It also noted that there were about 100 companies engaged in parallel trade in the EU, which employed between 10,000 and 15,000 people.

Comparatively, the lowest-priced drug countries are Poland, Turkey, the Slovak Republic, the Czech Republic, Korea, Greece, Hungary, Spain and Australia, all of which, had retail pharmaceutical price levels between 68% and 81% of the OECD average.[14] In addition, Greece is one of the main EU countries from which parallel traders source drugs.[15]

Drugs facing competition from parallel imports are found to have on average 17% to 21% lower prices than they would have had if they had never faced such competition.[16]

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[10] See: Brougher T. Joanna, Ibid
[11] See: Brougher T. Joanna, Ibid
[12] See: Patent-related Barriers to Market Entry for Generic Medicines in the European Union, A review of weaknesses in the current European patent system and their impact on market access of generic medicines in Kristof Roox ed., European Generic medicines Association, May 2008, available at: http://www.ieis.org.tr/ieis/assets/media/EGA%20-%20IP_Barriers_web.pdf (accessed on December 19th, 2015).
[13] See: http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/ (accessed on December 19th, 2015).
[14] See: Pharmaceutical Pricing Policies in a Global Market, OECD 2008
[15] See: Granlund David and Miyase Yesim Köksal, EU Enlargement, Parallel Trade and Price Competition in Pharmaceuticals, What's to Blame? Derogation or Perception?
[16] See: Granlund David and Miyase Yesim Köksal, Ibid

Although in the OECD study, related to pharmaceutical pricing policies in a global market there is a solid inference that most sales revenues derive from on-patent products rather than generics[17], beginning in 2010, the pharmaceutical industry faced one of the biggest waves of drug patent expirations in history, a phenomenon referred to as the "patent cliff". A significant number of top-selling drugs in the history of the pharmaceutical industry will experience patent expirations over the next 5 years, paving the way for lower-priced generics.[18]

V. Negative effects of parallel imports

Besides, the unquestionable benefits from parallel imports, they may cause negative effects as well. One of them is the problem of drug shortage in the countries with smaller prices of medicinal products. Medications imported on other markets come mainly from these countries. They are exported from those particular countries in large numbers, thus hampering the access to drugs for the local patients. Therefore, many European countries, such as Belgium, Finland, France, Greece, Italy, Portugal or Spain, imposed on wholesalers the obligation to have in stock a big amount of all medicinal products and to provide them to all purchasers on the area of a given country in order to evade the drug shortage.[19]

The drug quality may, as well, be impaired during transportation between many entities or in the process of drug storage or repacking. Drugs from parallel import may be to some extent defective or even damaged because importers pay less attention to the control and the maintenance of drug quality in the postproduction processes. [20]

Parallel import may also disrupt the marketing arrangements established by the producer - distributor relations on a particular market. Exclusive distributors feel frustrated with the existence of an additional potential strong competition.[21] If producers cannot offer a distributor territorial protection, the incentive to export might be reduced.[22]

By forcing lower prices throughout different governmental policies, the income of pharmaceutical companies decreases, whereas a part of this income could be as an incentive to promote activities in the area of R&D in order to create new pharmaceutical products and

[17] See: Pharmaceutical Pricing Policies in a Global Market© OECD 2008
[18] See: DeRuiter Jack, PhD, Pamela L. Holston, RPh, BS, BA, Drug Patent Expirations and the "Patent Cliff", U.S. Pharm. 2012;37(6)(Generic suppl): pp. 12-20
[19] See: Religioni U.*, Czerw A. , Economic impact of parallel trade on the selected pharmaceutical markets in the European Union, Prog Health Sci 2012, Vol 2 , No2 : Economic impact trade pharmaceutical markets European Union
[20] See: Religioni U.*, Czerw A., Ibid
[21] See: Religioni U.*, Czerw A., Ibid
[22] See: Monti Giorgio, EC Competition Law, Cambridge University Press, 2007 pp. 41

provide support for future pharmaceutical innovation.[23] The literature is quite clear on the adverse effects of price regulation on R&D investment, innovation, access to new drugs, and delays in availability.[24]

Consumers might consider parallel imports to be imperfect substitutes for the locally-sourced drugs. This is due to: poor information; risk aversion about the quality of low priced generics; mistrust of regulatory enforcement; responsiveness to advertising; reliance on the advice of imperfect agents (pharmacists, doctors) influenced by company detailing or profit margins on higher priced medicine sales, etc.[25]

In addition, in order to measure the effects of the parallel imports, testing should be made in correlation with the existing health insurance coverage in the respective country, the active pricing system in the pharmaceutical sector (price regulation vs. "free" pricing i.e. over-the-counter (OTC), etc.[26]

VI. Barriers for new entrants on the pharmaceutical market

To gain further protection, pharmaceutical firms adopt different business strategies.

In the US for example, one of the possible paths for extending the exclusivity period of a product is through gaining additional patent exclusivities via compensation for time lost during the patent administrative prosecution and regulatory processes (delays due to regulatory approval).

The exclusivity period of a product on the market can also be extended through non-patent exclusivities[27], authorized generics[28], new drug application, new formulations**,** patents directed to new uses and treatment indications**,** combining two or more successful drugs into one

[23] See: Religioni U.*, Czerw A. , Economic impact of parallel trade on the selected pharmaceutical markets in the European Union, Prog Health Sci 2012, Vol 2 , No2 : Economic impact trade pharmaceutical markets European Union

[24] See: Folland Sherman, Allen C. Goodman and Miron Stano, The Economics of Health and Health Care, Seventh Edition, Pearson Education, Inc, 2013 pp. 361 and Pharmaceutical Pricing Policies in a Global Market © OECD 2008

[25] See: Hawkins Loraine, WHO/HAI Project on Medicine Prices and Availability , Review Series on Pharmaceutical Pricing Policies and Interventions Working Paper 4: Competition Policy, May 2011

[26] In France, for example, specific agreements are signed for some products with high risk of overuse or misuse, under which the pharmaceutical company will pay rebates when the agreed volume of consumption is exceeded or when drugs have been misused. See: Pharmaceutical Pricing Policies in a Global Market © OECD 2008

[27] About the five available different types of non-patent exclusivities in the US see: Brougher T. Joanna, Intellectual Property and Health Technologies Balancing Innovation and the Public's Health, Springer Science+Business Media New York 2014, pp. 117-129, 145-159

[28] See: Brougher T. Joanna, Intellectual Property and Health Technologies Balancing Innovation and the Public's Health, Springer Science+Business Media New York 2014, pp.145 - 159

tablet and marketing it as a whole new product**,** synergies drug combinations under development[29], etc.

Similarly, in response to external price referencing, pharmaceutical companies may maintain artificially high prices by launching their products first in countries where they can set prices freely or can negotiate relatively high prices and afterwards to delay or refrain from launching in relatively lower-price countries.[30]

The notion of "misuse of exclusivities" is known as well. In includes practices known as evergreening[31], patenting of obvious inventions, so-called ''pay for delay'' settlements, continuation application practice,[32] strategic patenting[33], etc. Such misuse of exclusivities is frequent and can result in improper financial gains by the drug manufactures at the expense of the public and insurers.[34]

In this respect, there is a case law existing related to the violation of the so called "double patenting" doctrine. This doctrine prevents getting claims in a later patent that are not distinct from those in an earlier patent. One of the famous cases in this respect was Eli Lilly, losing the exclusive right to market Prozac, after patent expired.[35]

Practices, such as dual pricing schemes and allocation systems are recognized as well. However, these practices are subject to EU company law scrutiny as we will illustrate *infra* in section 7.1. of this Article.

As a result of the approaching "patent cliff" some companies already are entering into agreements with generic manufacturers, licensing them the right to sell "authorized generics" identical to branded drugs that have gone or will go off patent. Others have established their own generic manufacturing companies or subsidiaries.[36]

Advertising and promotion can also create economic barriers when they successfully increase brand loyalty, allowing by that trade names still retaining a monopoly premium. One of

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[29] See: Gupta Himanshu , Suresh Kumar, Saroj Kumar Roy, and R. S. Gaud, Patent protection strategies, Journal of Pharmacy and Bioallied Sciences 2010 Jan-Mar; 2(1): 2–7

[30] See: Pharmaceutical Pricing Policies in a Global Market, OECD 2008

[31] See: Brougher T. Joanna, Intellectual Property and Health Technologies Balancing Innovation and the Public's Health, Springer Science+Business Media New York 2014, pp.145 - 147

[32] See: Brougher T. Joanna, Ibid., pp.145 - 159

[33] See: Pharmaceutical Patents, Patents & Lifecyle Maximisation, European Generic Medicines Association, From a text prepared by Veronica Lowe, EGA Board Member (Mayne Pharma)

[34] See: Brougher T. Joanna, Intellectual Property and Health Technologies Balancing Innovation and the Public's Health, Springer Science+Business Media New York 2014, pp.129 - 133

[35] See: http://www.nytimes.com/2000/08/10/business/lilly-set-back-in-patent-case-over-prozac.html (accessed on December 21st, 2015)

[36] See: DeRuiter Jack, PhD, Pamela L. Holston, RPh, BS, BA, Ibid.,

the most controversial and visible practice of the pharmaceutical industry is the advertising approach known in the US as "Direct-to-Consumer (DTC) Advertising".[37]

VII. Governmental policies to increase competition on the market

Generic drugs, differential pricing,[38] parallel imports, compulsory licensing, reference pricing, and corporate donations[39] are all mechanisms used to increase competition and at the same time reduce drug prices and make them more accessible.[40]

For example, in the US the Hatch-Waxman Act, also known as the Drug Price Competition and Patent Term Restoration Act, was enacted in 1984 to establish abbreviated approval pathway for generic drugs.[41][42]

VIII. EU competition law rules related to pharmaceutical industry

The objective of the Community's competition provisions is set out in Art 3(g) of the EC Treaty. The Community is to set up 'a system ensuring that competition in the internal market is not distorted'. However, this fundamental provision of the EC Treaty (Article 3(1)(g) EC) was suppressed by the final version of the Lisbon Treaty. Since the Lisbon Treaty entered into force in December 2009, there has been no Treaty provision proclaiming adherence to the principle of undistorted competition. The substantive content of Article 3(1)(g) EC has been transferred to a Protocol (No 27) on the Internal Market and Competition, annexed to the Treaties.[43]

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[37] See: Folland Sherman, Allen C. Goodman and Miron Stano, The Economics of Health and Health Care, Seventh Edition, Pearson Education, Inc, 2013 pp. 348, 365.

[38] Price differentiation, also known as price discrimination, is the practice of charging consumers different prices for the same product. Theoretically, drug prices would be the highest in the countries that are able to pay the higher costs and lowest in the countries that are not able to pay the high costs. Through this mechanism, the poorest countries should be able to afford the drugs. See: Brougher T. Joanna, Intellectual Property and Health Technologies Balancing Innovation and the Public's Health, Springer Science+Business Media New York 2014, pp.175 – 202; See: Granlund David and Miyase Yesim Köksal,EU Enlargement, Parallel Trade and Price Competition in Pharmaceuticals What's to Blame? Derogation or Perception?

[39] These are philanthropic donations made by pharmaceutical companies to supply their drugs at little to no cost to people in need. Such donations provide access to brand-name drugs at little cost. The concept of donations played an important role in famous Novartis Glivec case. See: Brougher T. Joanna, Intellectual Property and Health Technologies Balancing Innovation and the Public's Health, Springer Science+Business Media New York 2014, pp.175 - 202

[40] See: Brougher T. Joanna, Ibid., pp.175 – 202 and See: Miyase Yesim Köksal-Ayhan, Parallel Trade, Reference Pricing and Competition in the Pharmaceutical Market: Theory and Evidence, ECONOMIC STUDIES DEPARTMENT OF ECONOMICS SCHOOL OF BUSINESS, ECONOMICS AND LAW UNIVERSITY OF GOTHENBURG, 199, Geson Hylte Tryck 2011, p. v

[41] See: Brougher T. Joanna, Ibid., pp.135 - 137

[42] See: Brougher T. Joanna, Ibid.,

[43] See: Van Rompuy, Ben, The Impact of the Lisbon Treaty on EU Competition Law: A Review of Recent Case Law of the EU Courts (December 8, 2011). CPI Antitrust Chronicle, Vol. 1, December 2011.

Parallel trade of medicinal products itself is regulated only by common norms of the primary EU law i.e. the parallel import is based on Article 34 (ex. 28) of the Treaty on the Functioning of the European Union (hereinafter – TFEU). However, it is subject to the derogations regarding the protection of human health and life and the protection of industrial and commercial property, as defined by Article 36 (ex. 30) of the TFEU.

Any other restrictions are appraised in accordance with the rules on competition in Articles 101 (ex. 81) and 102 (ex. 82) of the TFEU. [44]

In this context, the Commission Communication on parallel imports of proprietary medicinal products for which marketing authorisations have already been granted, COM(2003) should be mentioned. This communication aims at giving some guidance on the practical application of the jurisprudence of the European Court of Justice to national measures relating to parallel imports, from one Member State to another, of proprietary medicinal products for which marketing authorisations have already been granted in the Member State of destination.[45]

Since out the scope of this Paper, simple reference should be made to the following EU legal acts related to medicinal products: Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products; Directive 2009/53/EC of the European Parliament and of the Council of 18 June 2009 amending Directive 2001/82/EC and Directive 2001/83/EC, as regards variations to the terms of marketing authorisations for medicinal products. (Official Journal L 168, 30/6/2009) and Commission Regulation (EC) No 1084/2003 of 3 June 2003 concerning the examination of variations to the terms of a marketing authorisation for medicinal products for human use and veterinary medicinal products granted by a competent authority of a Member State.[46]

The legality of parallel imports stems from the territorial exhaustion of intellectual property rights (IPRs).[47] Regional exhaustion applies in the EU, meaning that IPRs are exhausted

[44] See: Granlund David and Miyase Yesim Köksal,EU Enlargement, Parallel Trade and Price Competition in Pharmaceuticals What's to Blame? Derogation or Perception?
[45] The Communication is avalible at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2003:0839:FIN:EN:PDF (accessed on December 21st, 2015)
[46] More about Pharmaceutical Legislation See: http://ec.europa.eu/health/documents/eudralex/vol-1/index_en.htm
[47] For exhaustion of intellectual property rights options see more *infra* in Section 8. of this Article.

upon first sale anywhere in the EU. So pharmaceuticals can be freely circulated without the consent of the intellectual property right holder.[48]

According to the EU Competition Law rules, any attempt by a dominant undertaking to impose export bans on its purchasers, will be considered abusive. Obviously, this forms part of the Community's attempt to stop undertakings re-erecting trade barriers which have been dismantled at state level. Such bans distort the intra-brand competition, i.e. competition between same brand products. The absolute territorial protection is per se prohibited under the EU competition rules.

a. EC competition law cases on parallel imports and other export bans in pharmaceutical industry

In continuation, we would like to chronicle some of the most referential competition law cases related to pharmaceutical industry practices in the EU:

1. The Istituto Chemioterapico Italiano S.p.A. and Commercial Solvents Corporation v Commission of the European Communities in context of abuse of dominant position on refusal to supply grounds;[49]
2. The Bayer AG v Commission of the European Communities on the grounds of competition, parallel imports, meaning of "agreement between undertakings", proof of the existence of an agreement, refusal to supply, market in pharmaceutical products;[50]
3. The GlaxoSmithKline Services Unlimited case in Spain dealt with dual pricing schemes in relation to Article 81 of the EC Treaty (new Article 101 of the TFEU);[51]

[48] See: Granlund David and Miyase Yesim Köksal,EU Enlargement, Parallel Trade and Price Competition in Pharmaceuticals What's to Blame? Derogation or Perception?

[49] ECR 223, [1974] 1 CMLR 309, Joined cases 6 and 7-73, Judgment of the Court of 6 March 1974. See more: Jones Alison and Brenda Sufrin, EC Competition Law (text, cases, and materials), third edition, Oxford University Press, 2008, pp. 529-530

[50] Judgment of the Court of First Instance of 26 October 2000, Case T-41/96. See more: Jones Alison and Brenda Sufrin, EC Competition Law (text, cases, and materials), third edition, Oxford University Press, 2008, p. 529-530 and http://curia.europa.eu/juris/document/document.jsf?docid=48819&doclang=en

[51] Cases C-501/06, C-213/06, C-515/06 and C-519/06 - the Spanish GSK case. Decision 2001/791/EC, 8 May 2001. See more: http://curia.europa.eu/juris/liste.jsf?language=en&num=C-501/06 (accessed on December 21st, 2015). It should be noted that since this case, issues surrounding dual pricing schemes might continue to arise. In addition to the Spanish law still in force, the possibility to adopt dual pricing schemes has been recently authorised in France through Law no. 2011-2012 of 29 December 2011 on strengthening the safety of medicinal and health products in France. See: Parallel trade and pharmaceuticals in the EU: current issues, available at: http://us.practicallaw.com/5-518-2417?q=&qp=&qo=&qe=#a935666 (accessed on December 26th, 2015).

4. Syfait and others v Glaxosmithkline in context of abuse of dominant position on refusal to supply grounds, limitation of parallel imports, export bans and other conducts hindering inter-member state trade;[52]
5. Sot. Lelos kai Sia EE and others v GlaxoSmithKline AEVE Farmakeftikon Proionton on the grounds of abuse of dominant position, where the ECJ confirmed that the single-market objective remains relevant;[53]
6. AstraZeneca v Commission on the grounds of misuse of intellectual property rights by preventing the marketing of generic versions of one of its medicinal products;[54]
7. Hoffmann-La Roche & Co. AG v Commission of the European Communities Court of Justice of the European Communities on the grounds in context of abuse of dominant position by entering into exclusive purchasing agreements with some customers in return for loyalty rebates;[55]
8. As per excessive prices under Article 82 (new Article 102 of TFEU) it is obvious that competition authorities have attacked excessive prices very rarely. However, some national competition authorities were more eager than the Commission to regulate high prices. That was the case with the Napp Pharmaceutical Holdings Ltd in the UK competition law practice;[56]
9. As to how the Commission interprets the criteria laid down in Article 81(3) EC, the best way to illustrate its approach is by considering an example where the Commission granted an individual exemption. In Re Bayer & Gist-Brocades a series of specialisation

[52] Case C-53/03, 28 October 2004. See: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:62003CC0053:EN:HTML (accessed on December 21st, 2015) and Jones Alison and Brenda Sufrin, EC Competition Law (text, cases, and materials), third edition, Oxford University Press, 2008, pp. 607-608.

[53] Joined Cases C-468/06 to C-478/06, 16 September 2008. GORMSEN LIZA LOVDAHL, A PRINCIPLED APPROACH TO ABUSE OF DOMINANCE IN EUROPEAN COMPETITION LAW, Cambridge University Press, 2010, pp. 67-69, 137-146

[54] Judgment of 1 July 2010 (Case: T-321/05). See: Jones Alison and Brenda Sufrin, EC Competition Law (text, cases, and materials), third edition, Oxford University Press, 2008, pp. 529-530, 581-582 and http://curia.europa.eu/juris/liste.jsf?num=T-321/05&language=en (accessed on December 21st, 2015).

[55] Case 85/76, Judgment of the Court of 13 February 1979, available at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:61976CJ0085:EN:PDF (accessed on December 21st, 2015) and GORMSEN LIZA LOVDAHL, A PRINCIPLED APPROACH TO ABUSE OF DOMINANCE IN EUROPEAN COMPETITION LAW, Cambridge University Press, 2010, pp. 80-81 and Jones Alison and Brenda Sufrin, EC Competition Law (text, cases, and materials), third edition, Oxford University Press, 2008, pp. 410, 486-487

[56] See: CA98/2/2001 [2001] UKCLR 597. See: Rodger, BJ and MacCulloch, A, COMPETITION LAW AND POLICY IN THE EC AND UK, Second Edition, Cavendish Publishing Limited, 2001, pp. 124 – 125 and Monti Giorgio, EC Competition Law, Cambridge University Press, 2007, pp. 218-220.

agreements concluded between Bayer, a German pharmaceutical company, and Gist-Brocades, a Dutch company, were notified to the Commission.[57]

There is a strong observation that from an economic perspective, the Commission's market integration policy may be called into question, since the pharmaceutical market works slightly differently from the other markets. Hence, the Commission's pursuit of market integration via competition law in this context appears counterproductive. The caution displayed by the Court runs against the Commission's policy, and evidences how policy can guide the evolution of the law, but with limits – legal language can be stretched to accommodate policy ambitions but cannot be deprived of meaning simply to achieve a desired goal. In other words in the pharmaceutical sector the Commission's policy of market integration can be characterized as misguided from an economic perspective.[58]

b. Cases related to repackaging, rebranding, co-branding[59]

Parallel imports might differ from locally-sourced drugs in colour, taste, or shape in which case the outer package should have information making that clear. Due also to differences in country-specific labelling requirements or standard package sizes, parallel imports might thus be repackaged or relabelled.

The ECJ, in the past, has adopted decisions related to this issue: Bristol-Myers Squibb[60]; Upjohn[61]; Merck[62]; Boehringer Ingelheim I[63]; and Boehringer Ingelheim II[64]. Two recent cases on the repackaging of pharmaceutical goods by parallel importers reconsider the exhaustion of rights principle in the context of free movement of pharmaceuticals: the Wellcome Foundation

[57] Albertina Albors-Llorens, EC Competition Law and Policy,Willan Publishing, 2002, pp. 48-49
[58] See: Monti Giorgio, EC Competition Law, Cambridge University Press, 2007 pp. 43, 51
[59] See: Parallel trade and pharmaceuticals in the EU: current issues, available at: http://us.practicallaw.com/5-518-2417?q=&qp=&qo=&qe= (accessed on December 1st, 2015).
[60] Joint Cases C-427/93, C-429/93 and C-436/93. This was the leading case concerning repacking of pharmaceutical products is Bristol-Myers Squibb v Paranova AS. It was in this case that the European Court of Justice (ECJ) first comprehensively formulated the five general conditions with which a parallel trader of repackaged drugs must comply (collectively, "the BMS Conditions") to avoid infringing the re-applied trade mark. See: Armengod Héctor and Laura Melusine Baudenbacher, The Repackaging of Pharmaceutical Products and Parallel Trade in the EU, RAJ Pharma, December 2009
[61] Case C-379/97
[62] Case C-443/99
[63] Case C-143/00
[64] Case C-348/04

Ltd v Paranova Pharmazeutika Handels GmbH [65] and Orifarm and Paranova v Merck Sharp and Dohme[66].

IX. Access to drugs in the context of international patent law[67]

Patent law is territorial by nature. As a result, a patent holders right to his invention are only protected in those countries that grant him a patent. As a result of globalization, however, the barriers between economic markets are continuously lessening. Thus, companies are faced with the challenge of protecting and managing patent rights worldwide. Those rights are governed by two main organizations: the World International Patent Organization (WIPO) and the World Trade Organization (WTO). WIPO currently administers 24 treaties, one of which is the Patent Cooperation Treaty (PCT).

The WTO is an organization that oversees and regulates trade between participating countries and has two primary functions: first, it oversees the development and administration of its agreements, and second, it enforces adherence to the agreements by providing a forum for negotiating and settling disputes.

One of the agreements that countries must ratify upon joining the WTO is the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS).

While the TRIPS Agreement provides the basic foundation for patentability, it also allows its member countries to exclude certain inventions from being patentable.

In particular, members are allowed to exclude inventions in order to protect "order public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment".

There are several provisions under TRIPS that allow governments to provide for exceptions, exclusions, and limitations to intellectual property rights. In Article 31, for instance, TRIPS allows governments to order domestic manufacturers to make a patented product without permission from the patent holder. This practice is known as "compulsory licensing".

Concerned that many developing countries would not be able to satisfy the compulsory licensing requirements under TRIPS, developing countries initiated a round of talks in 2001, to discuss a possible solution for those countries unable to manufacture a product ''predominantly

[65] Case C-276/05
[66] Cases 400/09 and C-207/10
[67] See: Brougher T. Joanna, Intellectual Property and Health Technologies Balancing Innovation and the Public's Health, Springer Science+Business Media New York 2014, pp.175 - 202

for supply of domestic market.'' The talks resulted in the Doha Declaration, which is a WTO statement that clarifies the scope of the TRIPS Agreement.

Overall, the Doha Declaration reaffirms the flexibility of TRIPS, saying it should be interpreted in light of the goal "to promote access to medicines for all".

In Paragraph 4, the Doha Declaration emphasizes the right of member states to establish procedures that circumvent patent rights for better access to essential medicines.

In the light of the Doha Declaration's reaffirmation of compulsory licensing, a new amendment was made to the TRIPS Agreement. The amendment, known as Article 31bis, allows developed countries to issue compulsory licenses to its domestic generic pharmaceutical manufacturers, permitting the domestic manufacturers to export. To import pharmaceuticals under this amendment, both the importing country and the exporting country must satisfy certain criteria.

Parallel imports are allowed under the TRIPS Agreement. Article 6 of the TRIPS Agreement, provides that the issue of exhaustion of rights shall not be a matter of dispute settlement. Hence, TRIPS leaves it to Members to decide how the principle should be applied within their national territory. Most countries have selected one of three possible options: "national exhaustion" (US), "regional exhaustion"(EU), and "international exhaustion".

However, in the EU intellectual property rights context attention should be paid to the provisions of the Commission Regulation (EC) No 1172/2007 of 5 October 2007, amending Commission Regulation (EC) No 1891/2004 of 21 October 2004, laying down provisions for the implementation of Council Regulation (EC) No 1383/2003, concerning customs action against goods suspected of infringing certain intellectual property rights and the measures to be taken against goods found to have infringed such rights.[68]

X. The Case of the Republic of Macedonia

The Macedonian Constitutional principle on freedom of market and entrepreneurship is embodied in three pivotal legal acts: the 2004 Law on Trading Companies, the 2001 Law on Obligations and the 2010 Law on Protection of Competition.

[68]The Regulation is available at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:261:0012:0023:EN:PDF (accessed on December 23rd, 2015)

Republic of Macedonia signed the Stabilization and Association Agreement with the European Communities and their Member States ("SAA") in March 2001[69]. According to Article 68(3) of the SAA, competition legislation was seen as one of the legal areas that should have had priority in approximation with the EU legislation.

Secondary legislation was enacted for block exemptions. All of the above regulations were enacted during 2012. The primary and secondary competition legislation and their amendments in Macedonia result primarily from the transposition of the relevant regulations and directives that give effect to the principles and competition rules set out in Articles 101 (ex Article 81) and 102 (ex Article 82) of the 2009 Treaty on the Functioning of the European Union – TFEU.

a. Relevant Macedonian legislation regarding drug distribution

Medical and pharmaceutical sector in the Republic of Macedonia are regulated by the 2000 Compulsory Health Insurance Law,[70] 2012 Health Protection Law[71], 2007 Law on Drugs and Medical Devices[72], 2009 Law on Industrial Property[73], 2004 Consumer Protection Law[74], 2012 Non-compulsory Health Insurance Law[75], etc.

At the moment in Macedonia there are 269 drug wholesalers ("veledrogerii")[76] and 1019 retail drug sellers (pharmacies – "apteki")[77]. Few of the wholesalers supposedly have dominant

[69] Available at: http://ec.europa.eu/enlargement/pdf/the_former_yugoslav_republic_of_macedonia/saa03_01_en.pdf (accessed on December 23rd, 2015)
[70] See: "Official Gazette of the Republic of Macedonia" no. 25/2000, 96/2000, 50/2001, 11/2002, 31/2003, 84/2005, 37/2006, 18/2007, 36/2007, 82/2008, 98/2008, 6/2009, 67/2009, 50/10, 156/10, 53/11, 26/12, 16/13, 91/13, 187/13, 43/14, 44/14, 97/14, 112/14, 113/14, 188/14, 20/15, 61/15, 98/15, 129/15, 192/15 and 217/15.
[71] See: "Official Gazette of the Republic of Macedonia" no. 43/12, 145/12, 87/13, 164/13, 39/14, 43/14, 132/14, 188/14, 10/15, 61/15,154/15 and 192/15.
[72] See: "Official Gazette of the Republic of Macedonia" no.106/2007, 88/2010, 36/11, 53/11, 136/11, 11/12, 147/13, 164/13, 27/14, 43/14, 88/15, 154/15 and 228/15.
[73] See: "Official Gazette of the Republic of Macedonia" no. 21/2009, 24/11, 12/14, 41/14 and 152/15.
[74] See: "Official Gazette of the Republic of Macedonia" no. 38/2004, 77/2007, 103/2008, 24/11, 164/13, 97/15 and 152/15.
[75] See: "Official Gazette of the Republic of Macedonia" no. 145/12 and 192/15.
[76] Data available on: http://www.veledrogerii.reglek.com.mk/ (in Macedonian language) (accessed on January 23rd, 2016)
[77] Data available on: https://lekovi.zdravstvo.gov.mk/pharmacies (in Macedonian language) http://www.veledrogerii.reglek.com.mk/ (in Macedonian language) (accessed on January 23rd, 2016)

position, but there is no data available in terms of their market share and market power. There are two main drug manufacturers in the country: Alkaloid AD Skopje and Replek AD Skopje.

The concept of parallel imports is not defined by the 2010 Law on Protection of Competition[78]. However, the 2007 Law on Drugs and Medical Devices was amended in January 2012, when the procedures for parallel imports of drugs were introduced for a first time in Macedonia.

"Parallel import of drugs is import of drugs for which there is already an authorization to be marketed issued and are already in use in a Member State of the EU, in Switzerland, Norway, Canada, Japan, Israel or in the USA, and are manufactured by the same manufacturer who has already been granted with authorization to market the drugs in the Republic of Macedonia with the same pharmaceutical form, dosage and packing, and who is issued with special authorization for parallel imports by the Drug Agency on the basis of substantial similarities of the both drugs. The importer of the drugs who is subject to parallel imports can be neither commercially nor capitally related to the person who is granted with authorization to market the drug in the Republic of Macedonia." (Article 2, paragraph 1, subparagraph 56 of the Law).

So far (December 2013 – December 2014), 164 approvals have been issued for parallel imports by the Drug Agency in Macedonia. Turkey emerges as the only exporting country in all imports. Four drug wholesalers are engaged in parallel imports.[79] However, there is still no significant official evaluation as regards the economic effects of these parallel imports.

From the price regulation prospective, it should be noted that since March 2007 external reference pricing was introduced in Macedonia and positive list of drugs reimbursable under the Macedonian Health Insurance Fund is continuously updated. Separate Methodology for the Modes on Calculating the Drug Prices was enacted in October 2011. This Methodology maximizes the wholesale and retail prices on prescribed drugs with marketing authorization issued by the Drug Agency and refers to both patented and generic drugs.

National exhaustion approach was introduced for trademarks with the Law on Industrial Property. However, this approach should not interfere with the obligations undertaken with the WTO membership in 2003. This means that parallel imports are allowed under the TRIPS Agreement.

[78] See: "Official Gazette of the Republic of Macedonia" no. 145/10, 136/11 and 41/14.

[79] Data available on http://zdravstvo.gov.mk/azhurirana-lista-na-lekovi-od-paralelen-uvoz/ (in Macedonian language) (accessed on January 25th, 2016).

XI. Conclusion

As to whether the current Macedonian legislation is well founded to support the officially declared goals of national pharmaceutical policy, it can be concluded that the situation is "healthy". The transposition of EU legislation into the national legislation was made diligently.

Parallel imports represent just one of the tools to achieve the laid down goals. However, at the same time with the parallel imports, the Macedonian government should develop additional policies and take further measures: to increase the availability of lower-priced generic products primarily via institutional purchasers; some core forms of regulation need to be in place and adequately enforced to foster stronger competition; strict application of border measures in coverage practical aspects of problems involving multi-state abuses of intellectual property rights; strengthening the institutional capacities of authorities dealing with increasingly prevalent criminal issue in counterfeiting networks; competition authorities should provide health authorities with expert advice on the potential risks involved in pharmaceutical regulation and its implementation including unintended anti-competitive effects, etc.

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