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INTRODUCING PATENT LINKAGE IN RUSSIA: AN ODD CHOICE AT ODD TIMES

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This paper critically reviews the draft proposal that would introduce patent linkage to Russia's drug approval system. The paper looks at the emergence and spread of patent linkage in the USA and further in several jurisdictions. This research concludes that patent linkage and the interests it protects are far from the goals that the state should set in the post-pandemic period. Even if adopted, the proposed changes will be unable to incorporate the best practices of mitigating the effect of patent linkage on the pharmaceutical market demonstrated by the experience of jurisdictions that employ this mechanism. The new initiative reveals its total incompatibility with the new priorities of public policy in the field of intellectual property and health care that came to light thanks to the COVID-19 pandemic.

Key words: patent linkage, competition law, intellectual property, pharmaceutical market, drug approval

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Ensuring access to safe and effective medicines has become a new focus for regulators due to the COVID-19 pandemic. Maintaining a relative balance in the markets of pharmaceuticals and medical devices is, as well as these markets themselves, strongly dependent on intellectual property rights. Therefore, access to affordable and effective medicines remains illusory if the state gives absolute protection and priority over the public interest to certain exclusive rights. The pharmaceutical market approached the pandemic in a strongly monopolized, but not well-equipped state. R&D priorities were given to more lucrative drugs, despite the fact that the 21st century has already seen large-scale epidemics[1].

Nevertheless, a change in the current exploitative model is more than possible if allowed politically[2]. In the course of the pandemic, several countries corrected their national legislation putting an emphasis on the public interest when using intellectual property rights. Israel became the first country to issue a compulsory license for the antiviral drug Kaletra[3]. Canadian compulsory licensing legislation was also simplified during the pandemic[4]. Russia and Hungary issues compulsory licenses for remdesivir, an antiviral used to treat the new coronavirus infection.[5] Antitrust control over socially significant markets including the pharmaceutical market has been strengthened in several jurisdictions[6].

Meanwhile, businesses in Russia continue to push a draft law that bears a potential and serious damage not only to the Russian pharmaceutical market but also to the individual right to affordable treatment.

Russia's Ministry of Health and the state's patent office (Rospatent) proposed jointly to create the Unified Register of Pharmacologically Active Substances Protected by a Patent for an Invention. In September 2019, the Ministry of Health updated the draft amendments to the Law

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[1] Amin T., Malpani R., Covid-19 Has Exposed the Limits of the Pharmaceutical Market Model // STAT News. May 19, 2020. URL: https://www.statnews.com/2020/05/19/covid-19-exposed-limits-drug-development-model/

[2] Stiglitz J. E., Jayadev A., Prabhala A., Patents v. the Pandemic // Project Syndicate. April 23, 2020. URL: https://www.project-syndicate.org/commentary/covid19-drugs-and-vaccine-demand-patent-reform-by-joseph-e-stiglitz-et-al-2020-04

[3] Israel Issuing Compulsory License During The Time Of Covid 19 Pandemic // Mondaq. April 16, 2020. URL: https://www.mondaq.com/india/operational-impacts-and-strategy/917898/israel-issuing-compulsory-license-during-the-time-of-covid-19-pandemic

[4] A Canadian bill would make it easier to issue compulsory licenses for Covid-19 products // STAT News. March 25, 2020. URL: https://www.statnews.com/pharmalot/2020/03/25/canada-compulsory-license-coronavirus-covid19/

[5] COVID-19 and trade – Hungary // World Trade Organization. URL: https://www.wto.org/english/tratop_e/covid19_e/covid_details_by_country_e.htm?country=HUN. A Decree of the Government of the Russian Federation №3718-p of 31.12.2020 // Pharmvestnik. URL: https://pharmvestnik.ru/documents/3718-r-ot-31-12-2020.htm.

[6] The impact of COVID-19 on competition law in the pharmaceutical sector // Lexology. March 30, 2020. URL: https://www.lexology.com/library/detail.aspx?g=e71c163e-5d24-4b84-8b97-f6384cd8f43

No. 61-FZ "On the Circulation of Medicines", adding several clauses on the Unified Register. The Register is the first step to introduce patent linkage into the market approval system. At the time of writing, these draft amendments to the Law No. 61-FZ "On the Circulation of Medicines" regarding the creation of a unified register are under consideration at the Government of the Russian Federation. This draft law, if adopted, will transplant into Russian patent law a new regulatory obstacle closely related to the mechanism of patent linkage that exists in some jurisdictions.

Patent linkage conditions the market approval of a generic drug upon the patent status of its branded equivalent. Following this model in different variations, patent linkage exists in some foreign jurisdictions, a brief overview of them is given below. Thus, if a patent for an active substance is in the register then market approval for the generic drug can either be postponed until the expiration of the patent, or suspended for the litigation period in case an infringement claim is filed.

The applicant will have to indicate whether the active ingredient in the product under approval is protected by patents and confirm that the market approval of the generic will not infringe the valid patent[7]. If there is a patent in the register, a drug can be approved but the approval certificate will only become active once the patent expires which poses significant risks to the generic manufacturer due to an abundance of abusive practices that may easily prolong the patent protection period.

The initiators of the bill justify the proposed amendments by the need to harmonize Russia's legislation with that of the Eurasian Economic Union (EAEU)[8]. EAEU has its own market approval rules that apply to the internal market of the Union. According to these Rules, the application must contain information about the patent for the reference drug, its validity in the territory of the Member State, date of issue, the validity period and the owner of the patent[9]. In addition, the applicant must provide written confirmation that market approval does not infringe the intellectual property rights of third parties[10].

At the same time, within the framework of the EAEU, the patent linkage regime is not established in the form in which it is proposed to be introduced in Russia. Therefore, there is no need to create a single Register as part of the patent linkage mechanism to just comply with the Union obligations.

Another common argument in support of the amendments states that investments go exclusively to countries where "proper" protection of intellectual property rights is guaranteed. It is claimed that "there will be no investment if intellectual property rights are violated. There will be no cutting-edge treatment technologies and there will be no quality generics either, because

[7] Draft Law on Amendments to the Federal Law "On the Circulation of Medicines" in terms of creating a unified register of pharmacologically active substances protected by a patent for an invention. ID 02/04/02-19/00088523. URL: https://regulation.gov.ru/p/88523

[8] Draft Law on Amendments to the Federal Law "On the Circulation of Medicines" in terms of creating a unified register of pharmacologically active substances protected by a patent for an invention. ID 02/04/02-19/00088523. URL: https://regulation.gov.ru/p/88523

[9] Rules for registration and examination of medicines for medical use. November 3, 2016, No. 78. Clause 3, app. N. 2. URL: http://docs.cntd.ru/document/456026097

[10] Rules for registration and examination of medicines for medical use. November 3, 2016, No. 78. Clause 4, app. N. 2. URL: http://docs.cntd.ru/document/456026097

branded products will not be introduced to the Russian market"[11]. However, generic manufacturers strongly emphasize the potential negative impact that patent linkage will have on the industry, in particular, due to the lack of affordable drugs available to consumers and the state[12].

In the current situation, patent linkage is a mechanism without any clear necessity that brings with it a shift in the regulatory focus from ensuring the availability of medicines to protecting large pharmaceutical companies.

At the same time, Russian intellectual property law offers to patent owners sufficient tools to seek redress for the infringement of their rights without having to resort to administrative mechanisms.

This article takes a critical look at the emergence and spread of patent linkage and demonstrates its total incompatibility with the new priorities of public policy in the field of intellectual property and health care that came to light thanks to the COVID-19 pandemic.

National Experience of Implementing Patent Linkage

Patent linkage originated in the the American political, legal and economic context with the adoption of the Hatch-Waxman Act in 1984.

Patent linkage in its classic form laid down by the Hatch-Waxman Act offers the following set of tools:

a) a right of a generic manufacturer to submit an abbreviated market approval application before the patent expires that indicates that the generic is similar to the original drug in terms of safety and efficacy;
b) an obligation to indicate whether any patents are associated with the generic product and, if so, an explanation of why the approval does not infringe patent rights (the patent will expire by the time it is placed on the market, is invalid, or the generic will not infringe a valid patent);
c) the obligation of the generic manufacturer to notify the holder of the registration certificate for the original drug of the application for accelerated release of the drug;
d) the right to 180 days of market exclusivity, i.e. the first applicant to submit an expedited application is entitled to 180 days of exclusive market exposure, often in parallel with the originator.

The system invites the patent owner to initiate patent infringement proceedings within 45 days of receipt of notification from the generic manufacturer. During the trial, registration process at the FDA is suspended for a period of 30 months. If the dispute is not resolved within this timeframe, the FDA can issue a preliminary approval. However, most generic manufacturers prefer to wait for the end of litigation to avoid future lawsuits[13].

After the adoption of the Hatch-Waxman Act and the strengthening of patent linkages in the US, patent linkage gradually began its spread to several other jurisdictions.

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[11] Rospatent proposes to create a unified register of medicines // Intellectual property of medicines as a factor in achieving socially significant indicators and a tool for entering the international pharmaceutical market. Gaidar Forum. 17.01.2019. URL: https://gaidarforum.ru/news/rospatent-predlagaet-sozdat-edinyy-reestr-lekarstv-/

[12] Generic manufacturers against linking patent protection with the drug registration procedure // GMP News. 09.04.2020. URL: https://gmpnews.ru/2020/04/proizvoditeli-dzhenerikov-protiv-uvyazki-zashhity-patentnyx-prav-s-proceduroj-registracii-lekarstv/

[13] Global Guide to Patent Linkage. Baker & McKenzie (2019), p. 157–158. URL: https://www.bakermckenzie.com/en/insight/publications/guides/global-guide-to-patent-linkage

It is noteworthy that in some cases this mechanism was transferred to the legislation of other countries somewhat involuntarily – the implementation of patent linkage often is one of the mandatory conditions of Free Trade Agreements (FTA) concluded by these countries with the United States[14]. The need to introduce patent linkage in the legislation on patent protection and market approval is explained solely by the positive impact of this amendment on the pharmaceutical market and innovation. At the same time, in fact, these FTAs are asymmetric, since they are intended primarily to protect the interests of those who export intellectual property rights as a result, they pose an extremely heavy burden on countries dependent on foreign intellectual property. In many instances, these stiff provisions appear in national laws due to certain degree of economic and political pressure. This is particularly true for developing countries that had to agree to patent linkage to be able to join to trade agreements. Various studies attempted to assess the impact of FTA and TRIPS-plus provisions on public health in developing countries. Many of them shown that these provisions have a negative impact on the price and availability of medicines[15]. Moreover, even in developed countries these provisions have a negative impact on ensuring access to affordable medicines. For example, research notes the negative impact of the FTA between Australia and the United States (AUSTFA). Several of its provisions weaken the Australian Pharmaceutical Benefits System (PBS), which was created to provide universal access to most essential medicines[16].

Nowadays patent linkage exists in many Pacific Rim countries that actively trade with the United States. In several of them (Singapore, Australia, South Korea), this mechanism emerged from FTAs with the United States, and in some – from the corresponding provisions of the Trans-Pacific Partnership Agreement, in which the patent linkage remained after the US withdrew from the Agreement.

This may explain why in some jurisdictions patent linkage has features that attempt to balance the interests of patent owners and generic producers. Research conducted in South Korea in 2018 shows that South Korea, Canada, and Australia modeled patent linkage to provide generic manufacturers with additional safeguards[17].

Thus, Australia introduced patent linkage into its law with significant restrictions. According to the Therapeutic Goods Act, during the market approval process an applicant must fulfill one of two mandatory requirements to confirm its safety and effectiveness. One is to declare that the applicant undertakes not to launch the drug in a way that would lead to an infringement of a valid patent. Another is to declare the applicant's intention to launch the drug before the expiry date of the patent and confirm patent owner was notified[18].

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[14] Cynthia Ho, Access to Medicine in the Global Economy: International Agreements on Patents and Related Rights, P. 278-279.

[15] Ibid, p. 226.

[16] Akaleephan C, Wibulpolprasert S, Sakulbumrungsil R; Extension of market exclusivity and its impact on the accessibility to essential medicines, and drug expense in Thailand: Analysis of the effect of TRIPS-Plus proposal. // Health Policy. 2009.; Moir H.V, Tenni B, Gleeson D, Lopert R; assessing the impact of alternative patent systems on the cost of health care: the TPPA and HIV treatment in Vietnam. Presented at Asia-Pacific Innovation Conference, University of Technology Sydney. 2014.

[17] Son, K. B., Lopert, R., Gleeson, D., & Lee, T. J. (2018). Moderating the impact of patent linkage on access to medicines: lessons from variations in South Korea, Australia, Canada, and the United States. Globalization and health, 14(1), 101.

[18] Therapeutic Goods Act 1989. 26B

Therefore, in Australia there are no administrative measures by which a generic product can be prohibited from being placed in the market[19]. The Therapeutic Goods Administration (TGA) can proceed with the market approval of the generic drug whether the patent has expired or not, and the patent owner can go to court for an injunction to prevent it from entering the market. At the same time, in accordance with section 26C of the Therapeutic Goods Act, the patent owner is obliged to send to the Secretary and the potential infringer of the patent an assurance that the proceedings are to be commenced in good faith, have reasonable prospects of success and will be conducted without unreasonable delay[20]. If the generic company wins the lawsuit, the patent holder must compensate for any damage caused by delays in the introduction of the generic to the market[21].

In that way, Australia has fulfilled its obligation under the FTA to include patent linkage in its legislation and grant several additional rights and guarantees to generic manufacturers. They have the right to choose one of two paths – to undertake an obligation not to infringe a valid patent or to notify the patent owner of their intention to distribute the drug before the expiration of the patent. At the same time, only a court can prohibit a generic drug from entering the market, which gives generic manufacturers the opportunity to prove the legality of their actions in an adversarial process. Moreover, they have additional guarantees – the patent owner must conduct the dispute in good faith, not delay consideration, and pay compensation to the generic company in case it wins the lawsuit.

Similar amendments aimed at protecting the rights of generic companies were introduced to Canadian legislation in 2017. All disputes are now resolved through legal actions – the owner of the patent for the branded drug receives notice of an attempt to get the market approval for the generic (NOA – notice of allegation) and files a claim for infringement of exclusive rights, which will cause market approval. Generic manufacturers can use counter-claims to challenge a patent. In addition, the generic company can claim compensation for the losses incurred during the period when the drug was out of the market as a result of a lawsuit initiated and lost by the patent owner. The new rules have further expanded the scope of responsibility of the patent owner. The generic manufacturer may seek reimbursement from all plaintiffs for any losses incurred because of delays in the market entry[22].

In South Korea, an applicant wishing to obtain market approval must prove that the rights of the patent owner of the branded drug will not be violated. At the same time, a generic manufacturer can obtain a confirmation from the Korean Patent Authority before market approval that a future generic patent does not infringe a patent for the branded drug, and thus avoid potentially costly and time-consuming legal proceedings[23]. Such a certificate is one of the grounds for marker approval of the generic along with the expiration of the original patent, obtaining

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[19] Therapeutic Goods Act 1989. 26C, 26D. URL: https://www.tga.gov.au/therapeutic-goods-act-1989-poisons-standard

[20] Ibid, 26C.

[21] Son, K., Lopert, R., Gleeson, D. Moderating the impact of patent linkage on access to medicines: lessons from variations in South Korea, Australia, Canada, and the United States. // Global Health. 2018. URL: https://globalizationandhealth.biomedcentral.com/articles/10.1186/s12992-018-0423-0.

[22] Mowatt G.D. Amendments to Canada's patent linkage provisions relating to generic and biosimilar market approval // DLA paper. 2017. URL: https://www.dlapiper.com/en/canada/insights/publications/2017/07/amendments-to-canada-patent-linkage-provisions/

[23] Raley K.T. The South Korean Patent Linkage System: A Model for Reforming the United States Hatch – Waxman Act. // Emory International Law Review. Vol. 33. 2019. URL: https://law.emory.edu /eilr/_documents/volumes/33/3/raley.pdf

permission from the owner of the patent, invalidating the patent, and others. In addition, the legislation provides incentives for generic companies to challenge the original patents. The applicant may be granted a 9-month exclusivity period starting from the date the generic is marketed if it is the first applicant, which challenge the patent and receive a positive decision[24]. Thus, in Korea generic manufacturers can challenge a patent in court and obtain a longer exclusivity period compared to that established in the United States (630 days in Korea versus 180 days in the United States).

Finally, the experience of the European Union, where the institution of patent linkage is absent at the level of both Union and national legislation, is very significant for Russia. A sectorial study of the pharmaceutical market done by the European Commission in 2009 noted that the main function of public authorities issuing certificates of the market approval is to ensure the quality, safety and efficacy of drugs entering the market, and patent status should not matter when conducting such drug evaluation[25].

Failed Patent Linkage Attempt in India

The example of India is a good illustration of why patent linkage is a bad choice the national patent legislation.

India, with the largest generic industry, is still (along with Russia) on the priority list of countries that, according to the US Trade Representation, do not provide an adequate level of protection of intellectual rights[26]. Obviously, this is facilitated by the unwillingness of the Indian government to infringe on the interests of its pharmaceutical manufacturers, obliging them to notify the patent owners about the preparation for market approval of the generic.

Currently, an application for the market approval of a generic drug in India can be filed even if the patent for the originator drug is valid, but this drug will not enter the market until the expiration of this patent[27]. The Regulator (DCGI) is not obliged to check the patent status of the originator product while reviewing an application.

Attempts of branded drugs manufacturers to prevent the registration of generics with reference to a valid patent were twice considered by the courts. In the first case, Bristol-Myers Squibb filed a lawsuit against the generic manufacturer Hetero to prevent a generic competitor from entering the market. Hetero's court order prohibited the manufacture, sale, and distribution of the drug in violation of the patentee's patent rights, and the registration authority was charged with monitoring potential intellectual property rights violations during the market approval

[24] Son, K., Lopert, R., Gleeson, D. Moderating the impact of patent linkage on access to medicines: lessons from variations in South Korea, Australia, Canada, and the United States. // Global Health. 2018. URL: https://globalizationandhealth.biomedcentral.com/articles/10.1186/s12992-018-0423-0

[25] Pharmaceutical Sector Inquiry, Final Report. European Commission, Competition DG (2009), p. 871-873. URL:https://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf

[26] USTR Releases Annual Special 301 Report on Intellectual Property Protection and Review of Notorious Markets for Counterfeiting and Piracy // USTR. April 29, 2020. URL: https://ustr.gov/about-us/policy-offices/press-office/press-releases/2020/april/ustr-releases-annual-special-301-report-intellectual-property-protection-and-review-notorious

[27] India Drugs Act. URL: https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/acts_rules/2016DrugsandCosmeticsAct1940Rules1945.pdf

process[28]. The expert community criticized this decision not only because it contradicted the law, but also because it confused two completely different areas of regulation – patent protection and market approval of drugs.

The following year, the same court delivered an opposite decision on Bayer's complaint against the Indian government, the DCGI and Cipla. Bayer argued that the DCGI must review the patent status of the branded drug when reviewing Cipla's application for market approval and refuse market approval because of an infringement of an existing patent. In doing so, Bayer referred to the provision that the law on market approval of drugs must not violate any other applicable law, including the 1970 Patent Act and its intellectual property exclusivity provisions. In addition, the DCGI would be guilty of infringing of the Bayer patent if it approved the Cipla's application.

By rejecting Bayer's claim, the court provided several significant explanations that sheds light on the problematic aspects of patent linkage. To begin with, the legislation on market approval and patent legislation are not only different in nature, but also based on different goals – public interest and efficacy of drugs and private interest in the protection of intellectual property rights. This determines the different expertise of the regulators, which cannot be mixed without going beyond the law[29]. Secondly, infringement of patent law cannot be established by an administrative body based on the words of the patent owner[30]. Infringement of the patent should be established only by a court decision, any other way of doing this would be a violation of the statutory powers and competences of those state bodies that are endowed with an examination of patents by the patent law (in this case, this is the patent office and the courts). Thirdly, prioritizing patent law and extending it to the DCGI would mean to overstretch the boundaries of patent law, requiring industry agencies to sacrifice security and efficiency concerns for the ultimate protection of intellectual property rights[31]. Finally, the court points out the ambiguity of patent linkage, noting that in the European Union and in many developing countries this institute is absent and is considered undesirable due to the negative effect it has on the pharmaceutical market[32].

What Is Wrong With Patent Linkage?

The experience of the jurisdictions outside of the United States indicates three important things. Most notably, patent linkage exists not only in the rather harsh form in which it was established by the Hatch-Waxman Act, moreover, it often includes serious legal guarantees for each of the interested parties. Secondly, more flexible variations of patent linkage are justified, among other things, by the need to stimulate the production of generic drugs, and not only by the need to protect patent owners, as, unfortunately, it is increasingly heard in the discussion about the initiative of Russia's Ministry of Health and the state's patent office (Rospatent)[33]. Thirdly, in the vast majority of jurisdictions where patent linkage exists, it was introduced to adjust national

[28] Global Guide to Patent Linkage. Baker & McKenzie (2019), p. 73. URL: https://www.bakermckenzie.com/en/insight/publications/guides/global-guide-to-patent-linkage

[29] Bayer Corporation & Ors. vs U & Ors. on 18 August, 2009, 37.

[30] Ibid, 39.

[31] Ibid, 40.

[32] Ibid, 44.

[33] The Unified Register will protect // Rossiyskaya Gazeta. 04.06.2019. URL: https://rg.ru/2019/06/04/dlia-zashchity-patentoobladatelej-nuzhno-meniat-zakon-ob-obrashchenii-lekarstv.html

legislation in accordance with bilateral or multilateral FTAs drafted with the participation of the United States, the homeland of the patent linkage.

Russian expert community quite widely discussed the possible introduction of patent linkage to the national law. For example, Andrei Kolesnikov, Director for Government Relations and Market Access for Russia and Eurasia at Teva, concluded that the proposed amendments created the basis for introducing patent linkage to the EAEU law. Ivan Glushko, Director of the Department of External Relations of STADA in Russia, commented that the proposed norms could only be assessed as "efficient action of the lobbyists of several pharmaceutical companies who put the interests of their shareholders above the interests of patients".[34] According to Pyotr Rodionov, board member of the EAEU Association of Pharmaceutical Manufacturers, amendments, both at the national and at the Eurasian level, will lead to an increase in the time to market drugs by at least six months, which will increase the burden on the budget and on patients.[35].

Meanwhile, the only argument in support of patent linkage has not changed since the discussion of the Hatch-Waxman Act in the US Congress – the need to protect the economic interests of the patent owner and maximize the patent protection period by all possible means. The arguments against are much more varied and provide a look far beyond the horizon of economic efficiency.

i. Turning to the origins of patent linkage, one can observe that it was adopted together with "Bolar exemption" – another significant provision that allows to conduct research on a generic drug before the patent has expired in preparation for filing a market approval application. This was an important balancing element – the resulting law took into account not only the economic interests of the originator, but also the concerns of the generics manufacturers. However, the existence of a patent linkage devalues this exception. The Bolar provision is designed to speed up the process of launching a generic to the market. Patent linkage, on the contrary, artificially postpones this moment either by the fact of a valid patent or by the disputes that follow after the market approval application has been filed. Such a logical paradox justifies, for example, the lack of patent linkage in the European Union, which clearly states (both in Directive 2001/83/ EC and in the national legislation) that the exclusion from patent protection includes steps to prepare for filing an application for market approval of drugs[36]. Russian law provides no clear explanations of whether preparation for market approval of a medicinal product is included into the exception provided for in paragraph 2 of Art. 1359 of the Civil Code. The trend in case law illustrated by the litigation between Novartis and Nativa, AstraZeneka and Jodas Expoim only supports the initiative of the Ministry of Health to prohibit the market approval of a generic drug until the patent expires. At the same time, the initiative discussed in this article is not balanced even by the introduction of a clear exception to prepare for market approval, which means that generic manufacturers, even without applying for marketing authorization, but only doing research using the branded drug to, for instance, create a new dosage form, may violate intellectual property rights.

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[34] Generic drug manufacturers have warned of delayed drug-to-market / Pharmvestnik, 20 April, 2020. URL: https://pharmvestnik.ru/content/news/Proizvoditeli-djenerikov-predupredili-o-zaderjke-vyhoda-lekarstv-na-rynok.html (in Russian).

[35] Generic drug manufacturers have warned of delayed drug-to-market / Pharmvestnik, 20 April, 2020. URL: https://pharmvestnik.ru/content/news/Proizvoditeli-djenerikov-predupredili-o-zaderjke-vyhoda-lekarstv-na-rynok.html (in Russian).

[36] See, for example: Global Guide to Patent Linkage. Baker & McKenzie (2019), p. 73. URL: https://www.bakermckenzie.com/en/insight/publications/guides/global-guide-to-patent-linkage

ii. Having enough "checks and balances" does not yet guarantee that patent linkage will not lead to further abuse of intellectual rights by patent owners. This can be illustrated by the so-called pay-for-delay agreements that blossomed in the United States just after the Hatch-Waxman Act had been passed.[37] These agreements establish the obligation of the generic producer to refrain from launching the market approval process for a certain period. The generic manufacturer receives payments in turn.

Patent holders feared a possible duopoly that would arise in the market if the generic company won a dispute over the validity of an existing patent and the release of a generic drug to the market[38]. Thus, negotiating a pay-for-delay agreement could benefit both the generic manufacturer – it still does not lose its 180 days of first-to-file market exclusivity – and, of course, the originator. However, consumers, who often need less expensive analogs of medicines, become unwitting victims of such agreements. US FTC estimates that consumers lose an average of $ 3.5 billion annually to competition from generic delay-to-market agreements[39]. The FTC is now monitoring such agreements between pharmaceutical companies for their possible anti-competitive effect – this became possible after the landmark decision of the Supreme Court in *FTC v. Actavis.*

The example of pay-for-delay agreements is noteworthy in that, despite efficiency considerations (the generic company decides whether to file a market approval application risking patent litigation) and the existence of various dispute resolution mechanisms under the Hatch-Waxman Act, the patent linkage system can negatively affect the consumer. In the case of pay-for-delay agreements, consumers are deprived of more affordable analogs of branded drugs. To smooth out such risks, the antitrust authority is also included into the complex system of relations between patent owners, the generic companies, the patent office and the industry regulator. For Russia, however, this situation is more complex due to the exceptions from antitrust control that intellectual property rights enjoy. Even if such an agreement is takes place on the Russian pharmaceutical market, it will be quite difficult for the Federal antitrust service (FAS of Russia) to effectively investigate it.

iii. In addition to the above arguments, the institutional effect that patent linkage gives also violates the logic of how the market approval system functions.

It is appropriate here to return to the line of reasoning presented by the court in the Indian case of *Bayer Corporation v. Union of India and Others*. The market approval system established in Russia, including by the Federal Law "On the Circulation of Medicines"[40], aims at state regulation of "safety, quality and efficacy of drugs". This system includes no competence for control over the observance of intellectual property rights. Russian Ministry of Health is the guarantor of public interest in the efficacy and safety of medicines, but it has never been empowered to monitor how individual intellectual property rights are protected. This competence

[37] Robin C. Feldman & Prianka Misra, The Fatal Attraction of Pay-for-Delay, 18 Chi. -Kent J. Intell. Prop. 249 (2019), p. 250.

[38] Ibid, p. 255.

[39] Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions, FTC (2010), p. 8. URL: https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf

[40] Federal Law of 12.04.2010 N 61-FZ (as amended on 03.04.2020) "On the Circulation of Medicines", Article 1.

is not established in the new draft law presented by the Russia's Ministry of Health[41], just as it cannot be replaced by interagency cooperation between the Ministry of Health and the state's patent office (Rospatent)[42]. As noted above, a similar argument blocks the introduction of patent linkage into the European Union law.

Such artificial expansion of competence means that the patent linkage system makes the approval certificate dependent solely on the discretion of Russia's Ministry of Health. Moreover, in its current form, it does not offer the generic manufacturer to preliminarily indicate, for example, that the current patent is defective or is not violated by the market approval of a new drug, as is done in the Hatch-Waxman Act, which increases the risks of abuse of evergreen patents. Such an administrative mechanism is incompatible with the essence of intellectual rights, which always enjoy a special regulatory regime, largely based on judicial protection[43]. Finally, it is also unfair to shift the burden of proof from the patent owner to the manufacturer of the generic drug. In the proposed version of the patent linkage draft, the applicant himself declares (and, obviously, proves for himself) the absence of infringement of intellectual property rights, whereas, for example, in the USA and Australia, the task of proving the fact of patent infringement rests on the manufacturer of the branded drug.

Conclusion

Patent linkage and the interests protected by it are far from the goals that the public health regulator should set for itself in the post-pandemic period. The authors of the initiative do not hide the fact that the amendments are aimed solely at protecting the interests of large pharmaceutical manufacturers, who normally own patents for branded medicines. Literature has documented the ambiguity of arguments that patent protection measures would obviously lead to an increase in the rate of innovation[44]. Likewise, it has been suggested that considering the current socio-economic, political, and legal landscape, the introduction of patent linkage in Russia seems inappropriate and untimely since the exclusive rights of patent holders can be secured in court[45].

Finally, adding to the generally problematic nature of patent linkage, the changes proposed by Russia's Ministry of Health were unable to incorporate the best practices of mitigating the effect of patent linkage on the pharmaceutical market, which foreign experience offers. Russian version of patent linkage risks remaining "naked", containing no legal guarantees to balance the interests of patent owners and generic drug manufacturers; it is not proposed to adopt additional amendments to secure such balance (for example, the introduction of market exclusivity for the first applicant). The desire to copy a mechanism that came from the common law system, even

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[41] Draft Law on Amendments to the Federal Law "On the Circulation of Medicines" in terms of creating a unified register of pharmacologically active substances protected by a patent. ID 02/04/02-19/00088523. URL: https://regulation.gov.ru/p/88523

[42] The Unified Register will protect // Rossiyskaya Gazeta. 04.06.2019. URL: https://rg.ru/2019/06/04/dlia-zashchity-patentoobladatelej-nuzhno-meniat-zakon-ob-obrashchenii-lekarstv.html

[43] Bayer Corporation & Ors. vs U & Ors. on 18 August, 2009, at 39.

[44] For Example: Hall, Bronwyn H. and Christian Helmers, The Role of Patent Protection in (Clean/Green) Technology Transfer, Santa Clara Computer and High Technology Law Journal 26: 487–532; Gregory Day & Steven Udick, Patent Law and the Emigration of Innovation, 94 Wash. L. Rev. 119 (2019); Gubby, Helen. (2019). Is the Patent System a Barrier to Inclusive Prosperity? The Biomedical Perspective. Global Policy.

[45] Tsomartova F.V. State guarantees of the availability of medicines in Russia and abroad // Journal of Foreign Legislation and Comparative Law. 2018. No. 4. P. 161–170.

though European countries, whose legal systems are much closer to the one in Russia, do not contain such an institution, is also not entirely clear.

In this form, the initiative to introduce patent linkage in Russia looks more like an intentional move in favor of (which is specific for Russia) foreign pharmaceutical manufacturers, but not as a well-thought-out measure that meets the general economic and, even more significant, social context.

References

Akaleephan C, Wibulpolprasert S, Sakulbumrungsil R; Extension of market exclusivity and its impact on the accessibility to essential medicines, and drug expense in Thailand: Analysis of the effect of TRIPS-Plus proposal // Health Policy. 2009.

Amin T., Malpani R., Covid-19 Has Exposed the Limits of the Pharmaceutical Market Model // STAT News. May 19, 2020. URL: https://www.statnews.com/2020/05/19/covid-19-exposed-limits-drug-development-model/

Cynthia Ho, Access to Medicine in the Global Economy: International Agreements on Patents and Related Rights. P. 278–279.

Moir H.V, Tenni B, Gleeson D, Lopert R; assessing the impact of alternative patent systems on the cost of health care: the TPPA and HIV treatment in Vietnam. Presented at Asia-Pacific Innovation Conference. University of Technology Sydney, 2014.

Mowatt G.D. Amendments to Canada's patent linkage provisions relating to generic and biosimilar market approval // DLA paper. 2017. URL: https://www.dlapiper.com/en/canada/insights/publications/2017/07/amendments-to-canada-patent-linkage-provisions/

Raley K.T. The South Korean Patent Linkage System: A Model for Reforming the United States Hatch-Waxman Act. // Emory International Law Review. 2019. Vol. 33. URL: https://law.emory.edu/eilr/_documents/volumes/33/3/raley.pdf

Robin C. Feldman & Prianka Misra. The Fatal Attraction of Pay-for-Delay, 18 Chi.-Kent J. Intell. Prop. 249 (2019), p. 250.

Son, K., Lopert, R., Gleeson, D. Moderating the impact of patent linkage on access to medicines: lessons from variations in South Korea, Australia, Canada, and the United States. // Global Health. 2018. URL: https://globalizationandhealth.biomedcentral.com/articles/10.1186/s12992-018-0423-0.

Stiglitz J.E., Jayadev A., Prabhala A., Patents v. the Pandemic // Project Syndicate. April 23, 2020. URL: https://www.project-syndicate.org/commentary/covid19-drugs-and-vaccine-demand-patent-reform-by-joseph-e-stiglitz-et-al-2020-04

Tsomartova F.V. State guarantees of the availability of medicines in Russia and abroad // Journal of Foreign Legislation and Comparative Law. 2018. No. 4. P. 161–170.

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В настоящем исследовании анализируются положения законопроекта, которые вводят институт патентной увязки в российскую систему государственной регистрации лекарственных средств. Авторы рассматривают возникновение и распространение патентной увязки в США, а также в ряде других юрисдикций. В рамках исследования сделан вывод о том, что патентная увязка и интересы, которые защищает данный институт, далеки от целей, которые государство должно ставить в постпандемический период. В случае, если рассматриваемые изменения будут приняты, не будет учтен передовой опыт смягчения воздействия патентной увязки на фармацевтический рынок. Нормы предлагаемых изменений несовместимы с новыми приоритетами государственной политики в области интеллектуальной собственности и здравоохранения, выявленными в результате пандемии COVID-19.

Ключевые слова: патентная увязка, конкурентное право, интеллектуальная собственность, фармацевтический рынок, выдача регистрационного удостоверения на лекарственный препарат

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Дарья Александровна Котова, Ольга Андреевна Гаврилова

Патентная увязка в России:
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(*на английском языке*)

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