Compulsory Licensing of Pharmaceutical Patents in the Russian Federation Threatens Foreign and Domestic Drug Developers

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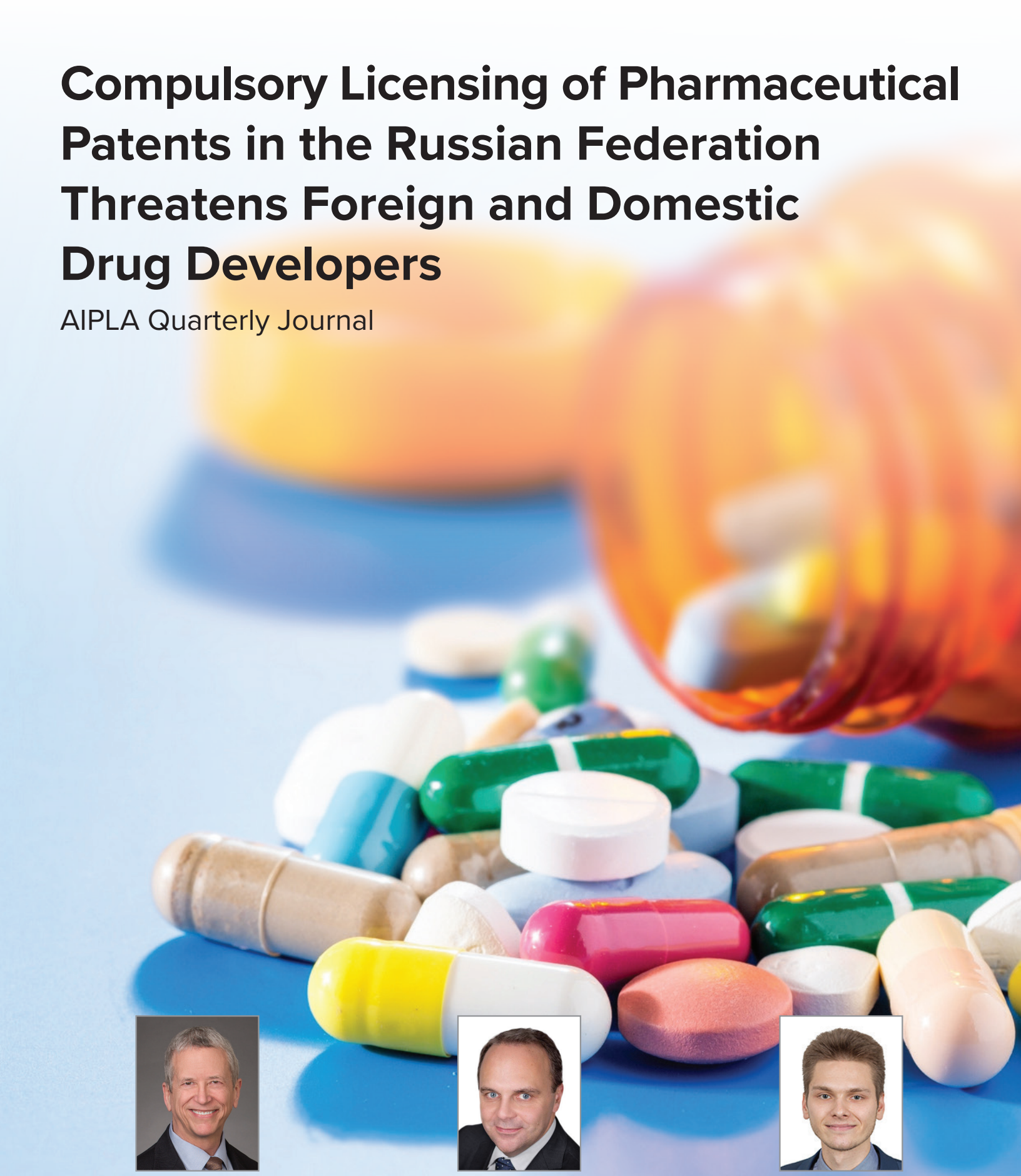

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COMPULSORY LICENSING OF PHARMACEUTICAL PATENTS IN THE RUSSIAN FEDERATION THREATENS FOREIGN & DOMESTIC DRUG DEVELOPERS*

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I. INTRODUCTION

Foreign and domestic developers of innovative drugs in the Russian Federation are bracing for the impact of anticipated amendments to intellectual property, antimonopoly, and pharmaceutical laws proposed by the Russian Federal Antimonopoly Service (the "Agency" or "FAS").[1] These amendments would eliminate antitrust immunity for intellectual property-related agreements and sharply limit patent protection for pharmaceutical products and medical devices.[2]

Among the FAS proposals is an amendment to Article 1360 of the Russian Civil Code[3] that would expand the grounds for compulsory licensing to include the protection of "public health and safety" and empower the FAS to issue a compulsory license without court approval when the Agency finds such conditions are met. Article 1360, as amended, would provide:

> The Government of the Russian Federation shall have the right, in the interest of defense, national security, *and protection of the life and health of citizens*, to allow the use of an invention, utility model or industrial design without the consent of the patent holder, upon prompt notice thereof and payment of reasonable compensation. The procedure for issuance of a [compulsory

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1 *See generally* A.C. Vorozhevich & C.B. Tret'yakov, Ob utilitarnosti intellektual"nyh prav, prinuditel"nyh licenzijah i bjurokraticheskih rentah [*The Utility of Intellectual Property Rights, Compulsory Licenses, and Bureaucratic Rents*], Aug. 2017, at 154–79 (Russ.) (describing efforts by FAS over the last five years to eliminate antitrust immunity for intellectual property agreements, and more recently to extend the basis for issuance of compulsory licenses to include antitrust violations causing a threat to life or health, and to amend Section 1360 of the Civil Code of the Russian Federation to allow for compulsory licenses in the interest of life and health). *See also* Vorozhevich, *Antitrust vs. Patent Rights; Why Interference by the Antimonopoly Service Will Harm Innovation* (January 2018), Vestnik Ekonomicheskogo Pravosudiya Rossiiskoi Federatzii No. 1/2018, pp. 72–112.

2 *See generally* A.C. Vorozhevich, *Antitrust vs. Patent Rights: Why Interference by the Antimonopoly Service Will Harm Innovations,* 1/2018 J. ECON. L. RUSS. FED. 72–112 (Jan. 2018); Vorozhevich & Tret'yakov, *supra* note 1, at 156.

3 *See generally* Vorozhevich & Tret'yakov, *supra* note 1, at 156.

license] shall be established by the Government of the Russian Federation.[4]

Another FAS proposal, which was withdrawn by the Agency in late 2017 but is still technically pending and subject to reinstatement at any time, would amend Article 1362 of the Russian Civil Code to enable the Russian government and others to file suit for a compulsory license upon a finding that the patent holder has committed an antitrust violation.[5]

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[4] Pederap'naja Antimonopod'naja Vluzhba [Fed. Antimonopoly Serv. Russ. Fed.], Letter No. AG/51550-DSP-PR/17, Pvoekt federal"nyj zakon [Draft Federal Law], O vnesenii izmenenij v federal'nyj zakon "o zashhite konkurencii" i grazhdanskij kodesks rossijskoj federacii [On the Introduction of Amendments to the Federal Law "On the Protection of Competition" and the Civil Code of the Russian Federation] art. 2, https://pharmvestnik.ru/res/dokumenty/proekt-po-prinuditeljnomu-litsenzirovaniju.pdf (Russ.); *see also* Bruce A. McDonald, *English Translation: Draft Federal Law on Amendments to Federal Law "On the Protection of Competition" and Civil Code of the Russian Federation*, Smith, Gambrell & Russell, LLP, http://www.sgrlaw.com/wp-content/uploads/2018/02/Federal-Antimonopoly-Service-Draft-Amendments-to-Antimonopoly-Law-and-Article-1360-of-the-Russian-Civil-Code.pdf [https://perma.cc/MK7L-EGF5] (last visited Mar. 1, 2018).

[5] Article 1362 currently does not provide the government a right to sue for antitrust violation. GRAZHDANSKII KODEKS ROSSIISKOI FEDERATSII [GK RF] [Civil Code of the Russian Federation], art. 1362 (Russ.), *translated in Civil Code of the Russian Federation*, WORLD TRADE ORG., https://www.wto.org/english/thewto_e/acc_e/rus_e/WTACCRUS54_LEG_1.pdf [https://perma.cc/TT8M-82JW] (last visited Mar. 1, 2018). Article 1362, as amended, *would* provide the "Federal Antimonopoly Authority" such a cause of action. *See* McDonald, *supra* note 4 ("In the case of a violation of antimonopoly legislation by the patent holder . . . the antimonopoly authority or other person desiring and prepared to use the invention . . . may file an action in court against the patent holder for issuance of a non-exclusive compulsory license for use of the invention, utility model or industrial design on the territory of the Russian Federation."); *see* O vnesenii izmenenij v federal'nyj zakon "o zashhite konkurencii" i grazhdanskij kodesks rossijskoj federacii [On the Introduction of Amendments to the Federal Law "On the Protection of Competition" and the Civil Code of the Russian Federation] art. 2, § (2)11, https://pharmvestnik.ru/res/dokumenty/proekt-po-prinuditeljnomu-litsenzirovaniju.pdf (Russ.).

In addition, FAS has proposed an amendment to the Federal Law on Circulation of Medicines that would authorize the Government to establish a procedure for government registration of medicines subject to compulsory licensing.[6] This proposal was withdrawn by FAS after an adverse assessment of the regulatory impact by the Ministry of Economic Development in April 2017, but, like the proposed amendment to Article 1362 of the Civil Code, it is subject to reinstatement at any time.[7] Regardless of whether the FAS proposals for amendment to the Law on Circulation of Medicines and Article 1362 of the Civil Code are reinstated, however, the pending proposal to amend Article 1360 of the Civil Code, combined with the anticipated removal of antitrust immunity for intellectual-property agreements, are a resounding shot across the bow of Western pharmaceutical manufacturers as well as domestic innovative-drug developers.

These measures are advocated by FAS as a means of lowering the cost of drugs and medical devices to Russian consumers, but opposed by the business community[8] and at least two government agencies — the Russian Ministry of

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6 Zakljuchenie ob Ochenke Regulirujushhego Vozdejstvija Proekta Federal'nogo Zakona O Vnesenii Izmenenij v Federal'nyj Zakon O Zashhite Knokurencii I Federal'nyj Zakon ob Obrashhenii Lekarstvennyh Sredstv [Conclusion on the Assessment of the Regulatory Impact of Draft Federal Law "On the Introduction of Amendments to Federal Law 'On the Protection of Competition' and the Federal Law 'On the Circulation of Medicines'"] BIULLETEN' NORMATIVNYKH AKTOV MINISTERSTV I VEDOMSTV ROSSIISKOI FEDERATSII [BNA] [Bulletin of Legal Acts of Ministries and Agencies of the Russian Federation], Apr. 25, 2017 (Russ.), http://regulation.gov.ru/projects#npa=46586 [https://perma.cc/UW5Y-3PQP] [hereinafter Regulatory Impact Statement on the Federal Impact of Draft Federal Law on the Protection of Competition and the Circulation of Medicines].

7 *See id*; *see also* Vorozhevich & Tret'yakov, *supra* note 1, at 156 (discussing the negative conclusions that led to the FAS surrendering its proposal).

8 *See* Ekaterina Chalova, *Igor Artemiev, Compulsory Licensing Defends Against Blackmail by Patent Holders,* PHARMVESTNIK (Oct. 31, 2016), www.pharmvestnik.ru/publs/lenta/v-rossii/igorj-artemjev-prinuditeljnaja-litsenzija-zaschitit-ot-shantazha-pravoobladatelej-patentov.html#.WPIYI_l96Uk [https://perma.cc/33BZ-5WVP] (last visited Feb. 10, 2018) (describing the government's need for compulsory licenses to enable the synthesis of pharmaceutical substances in Russian chemical laboratories "in a short period of time, to save human lives, and then settle with the right holders") (translation available with authors); Elena Kalinovskaya, *Igor Artemiev: We Will Drive Unconscionable Transational Pharmaceutical Producers Out of the Country,* Pharmvestnik (July 17, 2017),

Economic Development[9] and the Federal Service for Intellectual Property, known as the Russian Patent and Trademark Office (Rospatent).[10] Opponents of the measures point to evidence that compulsory licensing does not lead to lower drug prices or increased access to medicines, that these goals are more effectively achieved by means of direct government purchases at discounted prices, and that the proposed amendments would increase the cost and reduce the availability of innovative drugs in the Russian Federation by driving developers out of the

https://pharmvestnik.ru/publs/lenta/v-rossii/igorj-artemjev-nedobrosovestnyx-transnatsionaljnyx-farmproizvoditelej-budem-izgonjatj-iz-strany.html#.WrMcwU10zn8 [https://perma.cc/LJ69-26LJ] (reporting on the intention of Russia to join the BRICS countries in direct discussions with leaders of transnational pharmaceutical manufacturers deemed to be engaged in unfair trade practices about the future of their relationships). While advocated by the FAS, the business community staunchly opposed. PHRMA, PHRMA SPECIAL 301 SUBMISSION 2018 169 (2018) ("Further, we note that preventing potential abuses of a 'manufacturing for export' exemption would be very difficult. Such abuses could consist of illegal diversion of medicines produced pursuant to the exception within Europe, or in foreign markets where the relevant patent term has not expired.").

9 *See* Regulatory Impact Statement on the Federal Impact of Draft Federal Law on the Protection of Competition and the Circulation of Medicines, *supra* note 6.

10 While viewing the use of compulsory licensing in the pharmaceutical sector as an effective tool in negotiating with foreign manufacturers, Rospatent believes there is no call for new legislation. *See* Elena Kalinovksaya, *Jekspert: Prinuditel'naja licenzija — instrument dlja vedenija peregovorov* [*Compulsory Licensing – Instrument for Negotiation*], PHARMACEUTICAL J., (Mar. 8, 2017) (Russ.), https://pharmvestnik.ru/publs/lenta/v-rossii/ekspert-prinuditeljnaja-litsenzija-instrument-dlja-vedenija-peregovorov.html#.Wm88CvlSyUk [https://perma.cc/KF4M-3XGA]; *see also* Sergey Ryakin, *Rospatent: c nachala goda prinjato 20 reshenij po osparivaniju patentnyh prav v oblasti farmy* [*Rospatent: 20 Decisions on Pharmaceutical Patent Disputes so Far in 2017*], PHARMACEUTICAL J. (Oct. 26, 2017) (Russ.), https://pharmvestnik.ru/publs/lenta/v-rossii/rospatent-mexanizm-prinuditeljnogo-litsenzirovanija-nuzhdaetsja-v-dorabotke.html#.Wm873_lSyUk [https://perma.cc/CJ66-9P4X] (reporting that experts from the Russian Academy of Sciences believe that Russia has all necessary tools needed to apply its compulsory licensing mechanism and so does not need to amend the current Russian legislation).

market.[11] Unlike the handful of developing countries that have issued compulsory licenses for pharmaceuticals on a case-by-case basis,[12] Russia would be the first country to institutionalize compulsory licensing in this manner.

The legislative initiatives by FAS are a matter of deep concern to foreign and domestic drug-developers doing business in Russia. Based on the experience of pharmaceutical producers in other countries, innovative-drug developers in the Russian Federation believe that these proposals would halt the prospects of growth in the Russian pharmaceutical industry, which is already struggling with restrictions on intellectual property protection by comparison to international standards.[13]

The FAS proposals are part of a broader initiative to limit patent protection for pharmaceutical products and medical devices as a means of lowering the cost of prescription drugs. The FAS is also advocating more restrictive patentability criteria for innovative medicines and the elimination of prohibitions against parallel imports.[14] In addition, the Russian Ministry of Health

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[11] *See* Regulatory Impact Statement on the Federal Impact of Draft Federal Law on the Protection of Competition and the Circulation of Medicines, *supra* note 6.

[12] *See* Satish Saroha et al., *Compulsory Licensing of Drug Products in Developing Countries*, 12 J. GENERIC MEDS. 89, 89 (2013) (exemplifying that countries including Brazil, India, Indonesia, Malaysia, Mozambique, Rwanda, Thailand, Zambia, Zimbabwe have been given compulsory licenses).

[13] *See PhRMA Reports Highlight Increased Risks for Innovative Drugmakers,* BUS. MONITOR ONLINE (Mar. 8, 2017) ("Russia's pharmaceutical legislation bans foreign participation in tenders where two or more companies from the Eurasian Economic Union (EAEU) have bid to supply medicines on the Essential Drugs List."). In Russia, for example, unlike Western countries, the manufacturer of a generic or biosimilar copy of a competitor's patented drug may apply for and obtain marketing approval while the competitor's patent is still in effect. *Id.* It is therefore impossible to resolve an infringement dispute in Russia prior to the registration and marketing of a generic or biosimilar copy. *Id.* (finding that in Russia "there is no effective mechanism to enforce patents; generic products of an innovative drug are able to apply for and receive marketing approval while the innovative drug's patent is still active").

[14] *See* Maria Dranishnikova, *FAS: Vydachu patentov na lekarstva nado ogranichit'* [*FAS: Issuing Patents for Medicines Must Be Limited*], VEDOMOSTI (Mar. 14, 2014, 15:17) (Russ.), https://www.vedomosti.ru/business/articles/2014/03/14/fas-vydachu-patentov-na-lekarstva-nado-ogranichit [https://perma.cc/8YQ6-HSED];

is advocating limitations on the criteria for state procurement of medicines.[15] Domestically produced medicines already enjoy a 15% price preference in state tenders; further discriminatory measures in tenders have been proposed and the government has isolated segments of the market for sole-supply contracts to Russian companies.[16]

Although FAS disclaims an intent to fundamentally alter the compulsory-license procedure,[17] the Agency's proposals would subject patent holders to increased antitrust liability and alter the procedure for drug registration to provide for the availability of compulsory licensing.[18] Furthermore, the FAS continues to engage in a high-profile public campaign to institutionalize compulsory licensing

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Parallel'nyj import obespechivaet scobodnyj oborot tovarov mezhdu EAJeS i mirovymi jekonomikami [*Parallel Import Guarantees Free Circulation of Goods between EEU and World's Economies*], FED. ANTIMONOPOLY SERV. (Sept. 19, 2017, 11:48) (Russ.), https://fas.gov.ru/news/23163 [https://perma.cc/6JBP-PTFP] PowerPoint Presentation: Parallel'nyj Import (Import bez Soglasja Pravoobladatelja), Za i Protiv [Parallel Imports (Imports Without Consent of the Rights Holder), the Pros and Cons], Fed. Antimonopoly Serv., 2016 (Russ.) (translated by and available with the author).

15 *See* O Vnesenii Izmenenij v Postanovlenie Pravitep'stva Rossijskoj Federatsii ot 30 Noiabria 2015 [On Limitations and Conditions of Access of Producers from Foreign countries of Pharmaceuticals Included on the List of Lifesaving and Essential Medicines, for the Purposes of Exercising Orders for the Securing of Government and Municipal Requirements] 2015, No. 1289; *see also Russian government to change tender conditions for public procurement of high-priced drugs*, Pharma Letter (Sept. 15, 2016), https://www.thepharmaletter.com/article/russian-government-to-change-tender-conditions-for-public-procurement-of-high-priced-drugs [https://perma.cc/DDD3-HS8G] [hereinafter On Limitations and Conditions of Access of Producers from Foreign countries of Pharmaceuticals].

16 *See PhRMA Reports Highlight Increased Risks for Innovative Drugmakers*, *supra* note 13; On Limitations and Conditions of Access of Producers from Foreign countries of Pharmaceuticals, *supra* note 15, Nov. 30, 2015, No. 1289.

17 *See* Valery Narezhny, *Current Practice and FAS Further Plans*, MONDAQ, Mar. 23, 2017, 2017 WLNR 9061871 (comparing the contents regarding the compulsory license in the current law with the proposed provisions in the draft law).

18 *See* On Limitations and Conditions of Access of Producers from Foreign countries of Pharmaceuticals Included on the List of Lifesaving and Essential Medicines, for the Purposes of Exercising Orders for the Securing of Government and Municipal Requirements, 2015, No. 1289, *supra* note 15.

in the pharmaceutical sector.[19] Although FAS has suspended its initiative to amend Article 1362 of the Civil Code, this fact should not be misconstrued as an indication that the agency has decided to limit the scope of its "creativity" in the pharmaceutical sector.[20] As it is, "[t]here is a risk that most licensing agreements will be declared illegal by FAS."[21]

As support for these legislative proposals, FAS argues that they are authorized by the Agreement on Trade Related Aspects of Intellectual Property (the "TRIPS Agreement" or "TRIPS"), consistent with international practice, and substantially no different from legislation in the United States that supposedly allows for compulsory licensing under a variety of circumstances.[22] This Article explains why those assertions are incorrect, and argues that the direct purchase of medicines and medical devices by the Russian government at discounted prices is a more effective means to increase the availability of life-saving pharmaceutical products and medical devices to Russian consumers.

II. WHAT IS A COMPULSORY LICENSE?

A *compulsory license* in this context is the grant of permission by a government to a manufacturer seeking to use another party's intellectual property without consent.[23] Compulsory licenses have been imposed on pharmaceutical manufacturers by some developing countries on the asserted grounds of public health and safety,[24] but they potentially apply to any patented invention. Grounds

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19 *PhRMA Reports Highlight Increased Risks for Innovative Drugmakers*, *supra* note 13.

20 Vorozhevich & Tret'yakov, *supra* note 1, at 155.

21 Vorozhevich, *supra* note 2, at 73 (translation available with authors).

22 *See, e.g.*, *Parallel Import Guarantees Free Circulation of Goods between EEU and World's Economies*, *supra* note 14 (describing the legislative basis for the FAS's activity to issue a new legal framework for regulating unfair competition and how it implements fundamental WTO requirements).

23 *See* JOHN R. THOMAS, CONG. RESEARCH SERV., R43266, COMPULSORY LICENSING OF PATENTED INVENTIONS 1 (2014).

24 *See generally* Caroline Manne, Note, *Pharmaceutical Patent Protection and TRIPS: The Countries That Cried Wolf and Why Defining "National Emergency" Will Save Them from Themselves*, 42 GEO. WASH. INT'L L. REV. 349, 361–64 (2010) (providing as an example the Brazilian's government success at receiving low-cost drugs by "threaten[ing] to use the compulsory licensing and 'national emergency' provisions of the TRIPS Agreement against the pharmaceutical companies").

that have been proposed or asserted, mostly by developing countries, to support the imposition of a license have included:

- Circumstance of national emergency or extreme urgency.
- Where the invention serves vital public health needs.
- A strong societal interest has arisen in access to the patented invention.
- The patent owner has failed to practice the patented invention in the jurisdiction that granted the patent within a reasonable period of time.
- The patent owner has abused its economic power in such a manner as to violate the antitrust laws.
- In circumstances where multiple patents held by different owners cover a particular technology. For example, combination therapies — such as triple antiretroviral drugs — may be subject to more than one patent. In such cases, if one patent owner refuses to license, then the technology may not be marketed absent a compulsory licens[e].[25]

III. VULNERABILITY OF INNOVATIVE-DRUG DEVELOPERS TO COMPULSORY LICENSING

While restrictions on pharmaceutical-patent protection may appear to Russian antimonopoly regulators as a quick fix to shortages of affordable medicine, experience shows that compulsory licensing is an impediment to growth in the domestic pharmaceutical industry. This is because innovation in the United States depends on patent protection to a greater extent than in other areas of manufacturing.[26]

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[25] COMPULSORY LICENSING OF PATENTED INVENTIONS, *supra* note 23, at 3–4 (internal citation omitted). Each of the quoted bullet points is currently a "ground[] for government award of compulsory license;" whether a particular ground applies in given country "[d]epend[s] upon particular national laws." *Id.* at 3.

[26] *See generally* Richard A. Epstein & F. Scott Kieff, *Questioning the Frequency and Wisdom of Compulsory Licensing for Pharmaceutical Patents*, 78 U. CHI. L.

The vulnerability of innovative-drug developers to restrictions on patent protection has increased over the last decade with surging investment in pharmaceutical research and development. By 2003, the cost to develop and win marketing approval for a new drug in the United States was $802 million.[27] By 2014, that number reached an astonishing $2.6 billion, including marketing, capital costs, research and development, and recovery of losses from unsuccessful drugs.[28]

The development of innovative medicines in the United States and elsewhere is exceptionally lengthy, expensive, and risky. A company seeking approval of a new drug in the United States must begin with an investigational new-drug application,[29] including detailed data and reports of all animal and non-clinical testing performed on the drug.[30] Physicians, pharmacologists, chemists,

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REV. 71, 80 (2011) (arguing that compulsory licensing impairs incentives to develop new drugs as its allowance reduces some key revenue streams); Dina Halajian, Note, *Inadequacy of TRIPS & the Compulsory License: Why Broad Compulsory Licensing Is Not a Viable Solution to the Access to Medicine Problem*, 38 BROOK. J. INT'L L. 1191, 1219 (2013) ("The shortcomings of TRIPS reveal that compulsory licensing is an ineffective solution to the problem of access to essential medicines. . . . [B]road-range compulsory license use is not a viable solution because it jeopardizes the research and development structure of pharmaceutical companies.").

27 *See* Joseph A. DiMasi et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151, 166 (2003); Christopher P. Adams & Van V. Brantner, *Estimating the Cost of New Drug Development: Is it Really $802 Million?*, 25 HEALTH AFF. 420, 427 (2006) (responding in the affirmative).

28 *See Cost to Develop and Win Marketing Approval for a New Drug is $2.6 Billion*, TUFTS CTR. FOR STUDY DRUG DEV. (Nov. 18, 2014), http://csdd.tufts.edu/news/complete_story/pr_tufts_csdd_2014_cost_study [https://perma.cc/9H3T-C9AX]; Joseph A. DiMasi et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. HEALTH ECON. 20, 31 (2016); Jerry Avorn, *The $2.6 Billion Pill — Methodologic and Policy Considerations*, 372 NEW ENG. J. MED. 1877, 1877–78 (2015).

29 *The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective*, FDA, http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143534.htm [https://perma.cc/SA24-PPSP] (last updated Nov. 24, 2017).

30 21 U.S.C. § 355(b)(1) (2012) (requiring an applicant to submit, among other things, "full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use"); *Investigational New Drug (IND) Application*, FDA, http://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevel

microbiologists, and statisticians must review all laboratory testing, including pharmacology and toxicology reports.[31] Only after the U.S. Government has seen and approved these reports can clinical trials begin on humans.[32] "Even attaining this step in the approval process is extremely difficult; estimates suggest that for every [5,000] [active pharmaceutical ingredients] screened, [in the United States], only [5] will proceed to clinical testing, and only [1] will eventually be approved by the FDA."[33]

After trials on humans begin, the time and costs of drug development escalate. In the United States, clinical testing goes through three phases, each taking several years.[34] Each phase involves an increased number of human subjects, and only after all phases are completed can a new drug application be submitted to the Government for final review.[35] The final review process can take another several years, and the approval of new drugs is often denied at this stage.[36] Even when approval is granted, the developer's costs continue, as information about safety and efficacy is inevitably incomplete, and some adverse reactions are discovered only after a drug has been marketed for years.[37] Drug manufacturers

opedandapproved/approvalapplications/investigationalnewdrugindapplication/default.htm [https://perma.cc/FC55-8A4X] (last updated Oct. 5, 2017).

31 21 U.S.C. § 355(n)(3)(b); 21 C.F.R. § 56.107 (2017). *See generally* SUSAN THAUL, CONG. RESEARCH SERV., R41983, HOW FDA APPROVES DRUGS AND REGULATES THEIR SAFETY AND EFFECTIVENESS 5 (2012) (explaining that the FDA "prepare[s] written assessments in several categories including . . . Pharmacology . . . [and] *Risk Assessment and Risk Mitigation*") (emphasis added).

32 *See generally* Veronica S. Jae, Comment, *Simplifying FDASIA: The "Fast Track" to Expedited Drug Approval Efficiency*, 66 ADMIN. L. REV. 173, 177 (2014) (citing 21 U.S.C § 335(i)(2)) ("Thirty days after the FDA receives a satisfactory [investigational new drug application] with adequate information to determine the safety of the drug, clinical trials may begin.").

33 Jae, *supra* note 32, at 178.

34 *Id.*; *see also The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective*, *supra* note 29 (listing and describing the stages of drug development and review).

35 Jae, *supra* note 32, at 178–79; *The FDA's Drug Review Process: Ensuring Drugs are Safe and Effective*, *supra* note 29.

36 *E.g.*, David S. Torborg, Note, *Design Defect Liability and Prescription Drugs: Who's in Charge?*, 59 OHIO ST. L.J. 633, 652 (1998).

37 *See, e.g.*, Bruce N. Kuhlik & Richard F. Kingham, *The Adverse Effects of Standardless Punitive Damage Awards on Pharmaceutical Development and*

must report all instances of adverse drug reactions regardless of whether the physician, the manufacturer, or others believe the reaction to be drug related.[38] The Government retains "the ability to revoke approval upon new evidence of risks, to request changes in labeling, and to issue a risk-evaluation[-]and[-]mitigation strategy, all in the interest of consumer safety."[39] Innovative-drug developers thus have substantial regulatory costs even after approval.[40]

In contrast to the average $2.6 billion investment needed for research, development, and regulatory approval of an *innovative* drug, a *generic* copy of a drug can be manufactured with an investment of only $2–$3 million with reverse engineering and marketing approval.[41] Consequently, producers of generic copies of an innovative drug can push the original developer out of the market within several months following expiration of the patent.[42]

Given these realities, the temporary exclusivity of patent protection for pharmaceuticals is fleeting. Upon expiration of the patent term, even if the term is extended by a period of regulatory data protection (which is also under attack by regulators and courts in the Russian Federation),[43] innovative medicines go into

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Availability, 45 FOOD DRUG COSM. L.J. 693, 696 (1990) (discussing how, through clinical testing alone, adverse reactions rarely come to light, and may only do so once placed in the market).

38 Applicants must report any "adverse drug experience information." 21 C.F.R. § 314.80(c) (2017). An *adverse drug experience* is "[a]ny adverse event associated with the use of a drug . . . whether or not considered drug related." 21 C.F.R. § 314.80(a).

39 Jae, *supra* note 32, at 179 (citing 21 U.S.C. § 355(e), (o)).

40 *See id.*; *see also* THAUL, *supra* note 31, at 8 (describing the FDA's role in monitoring drug safety and efficacy after approval).

41 Adi Gillat, *Compulsory Licensing to Regulated Licensing: Effects on the Conflict Between Innovation and Access in the Pharmaceutical Industry*, 58 FOOD & DRUG L.J. 711, 724, 724 n.77 (2003).

42 *See, e.g.*, Martha M. Rumore, *The Hatch–Waxman Act—25 Years Later: Keeping the Pharmaceutical Scales Balanced*, PHARMACY TIMES (Aug. 15, 2009), http://www.pharmacytimes.com/publications/supplement/2009/genericsupplement0809/generic-hatchwaxman-0809 [https://perma.cc/XE5V-PC9C] (informing that today 70% of prescriptions are for generics; whereas, before Hatch–Waxman, generics only occupied 15% of the prescription market).

43 In *Novartis AG v. BioIntegrator*, the Russian Intellectual Property Court limited the scope of regulatory protection for investigative data filed in support of an application for marketing approval of a new drug, holding that such protection is limited to undisclosed data, and does not include

the public domain, allowing competitors to create and market generic- and biosimilar-copies of them at dramatically lower prices.[44]

Patent protection is especially fleeting in the case of innovative-drug development, where the time between the first identification of a new chemical compound and the marketing of the final product is 10–15 years,[45] and the average period of protection for an innovative drug following the receipt of marketing approval is less than 12.[46] The 20-year patent term provided by international treaty[47] is barely sufficient to recoup the investment in development, even after statutory extension of the patent term to account for time consumed in the regulatory approval process.

Adding to their challenges, innovative-drug developers are uniquely required to file for patent protection at the earliest stages of development because of unparalleled competition among innovative-drug companies.[48] In contrast to

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data that was filed by the developer in support of its application and published in medical journals. *See* Postanovleniye ot 14 Avgusta 2015 [Novartis AG v. BioIntegrator], Ninth Arbitration Appeals Court of the Russian Federation, Aug. 14, 2015, No. 09AP-20782/2015-GK (Russ.). The IPC holding significantly curtailed the ability of drug developers to prohibit the manufacturers of a generic or biosimilar copy of the innovative drug from using their data to support its own competing application. *Id.* In October 2016, the Russian Ministry of Health proposed amendments to the Law on Circulation of Medicines that would codify the ruling.

44 *See generally* Rumore, *supra* note 42 (explaining that generic prices are approximately 60% or less than brand).

45 PHRMA, DRUG DISCOVERY AND DEVELOPMENT: UNDERSTANDING THE R&D PROCESS 2–3 (2007), http://cmidd.northwestern.edu/files/2015/10/Drug_RD_Brochure-12e7vs6.pdf [https://perma.cc/3UQG-TTJR].

46 Aaron S. Kesselheim & Jonathan J. Darrow, *Hatch–Waxman Turns 30: Do We Need a Re-Designed Approach for the Modern Era?*, 15 YALE J. HEALTH POL'Y L. & ETHICS 293, 308 (2015) ("[A]ctual average pharmaceutical market exclusivity periods . . . are approximately twelve years."); Henry G. Grabowski & John M. Vernon, *Effective Patent Life in Pharmaceuticals*, 19 INT'L J. TECH. MGMT. 98, 116 (2000) (reporting that the effective patent life of pharmaceuticals was 11.7 years in the period from 1990–1995).

47 Agreement on Trade-Related Aspects of Intellectual Property Rights, Dec. 15, 1993, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 333–34, art. 30(a) [hereinafter TRIPS].

48 *See, e.g.*, Stephanie E. Piatt, *Regaining the Balance of Hatch–Waxman in the FDA Generic Approval Process: An Equitable Remedy to the Thirty-Month Stay*, 59

other fields of manufacturing, competitors in the pharmaceutical industry can easily copy innovative medicines with far less expense and shorter periods of time.

IV. VULNERABILITY OF CONSUMERS TO COMPULSORY LICENSING

Drug developers are not the only ones adversely affected by compulsory licensing. Consumers have been harmed even more than drug developers in situations where compulsory licensing leads to damaging delays and excessive costs. In Thailand, for example, following the issuance of a compulsory license, the Taiwanese government reneged on its promise to lower the price of the original drug by 20%.[49] Instead, the generic drug was sold in some instances at a 1,000% mark-up.[50] India provides another example, as compulsory licensing there stimulated the generic-drug industry but dramatically diminished the market share of domestic innovative-drug developers.[51]

V. THE AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY

Access to medicines in developing countries has always been a controversial issue, and became more so with the advent of the HIV/AIDS pandemic. In the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) negotiations in 1994, the member states of the newly created World

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N.Y.U. ANN. SURV. AM. L. 163, 166 n.11 (2003) ("Patent applications for pharmaceutical drugs are often filed as soon as possible . . . . to establish priority, and in the case of pioneer drugs or drug methods, at a time usually preceding clinical testing and clinical trials.").

49 *See* Kristina M. Lybecker & Elisabeth Fowler, *Compulsory Licensing in Canada and Thailand: Comparing Regimes to Ensure Legitimate Use of the WTO Rules*, 37 J. L. MED. & ETHICS 222, 228 (2009) ("Ultimately the Thai government hopes to reduce the price of [the drug] to about 20% . . . , current prices have not reached this level.").

50 *See id.* ("[T]he [Thai government] sold about 60% of its medical products to government agenceies at above market prices. In some cases, products were marked up 1,000 percent.") (citation omitted).

51 *See* Andrew Q. Leba, Note, *Lowering the "Efficacy" Threshold for Section 3(d) of the Indian Patents (Amendment) Act 2005: A Case for a Broader Scope*, 28 EMORY INT'L L. REV. 649, 674 (2014) ("From the outcomes of the legal battles between the generics industry and Pfizer, Bayer, Hoffman-La Roche, and Boehringer Ingelheim, India has made clear to the world that it will aggressively protect its domestic generics industry.").

Trade Organization (WTO) established minimal standards for the protection of intellectual-property rights.[52] These standards were codified in the TRIPS Agreement, which went into force on January 1, 1995.[53] The standards, however, were not self-executing.[54]

In the face of opposition from developing countries that did not provide patent protection for pharmaceutical-products and -processes prior to joining the WTO, the adoption of TRIPS represented a compromise between them and the developed countries already providing some level of protection.[55] This compromise became a successful inducement to the development of international trade, as it facilitated the transfer of technology from the developed countries to the developing ones. The foundation of this compromise is found in Article 30 of the TRIPS Agreement, which provides for the availability of compulsory licensing and other exceptions to intellectual property rights only when "such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not

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[52] *Intellectual Property: Protection and Enforcement,* WORLD TRADE ORG., https://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm [https://perma.cc/ZK4W-59Y2] (last visited Feb. 21, 2018).

[53] *See generally* TRIPS, *supra* note 47.

[54] A *self-executing treaty* is a treaty that becomes judicially enforceable upon ratification. As opposed to a *non-self-executing treaty*, which becomes judicially enforceable through the implementation of legislation. A treaty could be identified as either self-executing or non-self-executing by looking to various indicators, including statements that are made by Congress or the Executive regarding the treaty, indeterminate language of the treaty, or if the treaty deals with a matter within the exclusive law-making power of Congress, indicating that Congress must create implementing legislation.

Self Executing Treaty, CORNELL LAW SCHOOL: WEX, https://www.law.cornell.edu/wex/self_executing_treaty (last visited Feb. 26, 2018).

[55] "There are no WTO definitions of 'developed' and 'developing' countries. Members announce for themselves whether they are 'developed' or 'developing' countries. However, other members can challenge the decision of a member to make use of provisions available to developing countries." *Who are the developing countries in the WTO,* WORLD TRADE ORG., https://www.wto.org/english/tratop_e/devel_e/d1who_e.htm [https://perma.cc/RQ2K-W6CB] (last visited Feb. 21, 2018).

unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties."[56]

Article 31 of TRIPS lists multiple conditions for the issuance of compulsory licenses, none of which appear in any of the legislative initiatives advocated by FAS. These include the following requirements:

> (a) authorization of such use shall be considered on its individual merits;
>
> (b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;
>
> (c) the scope and duration of such use shall be limited to the purpose for which it was authorized . . . ;
>
> (d) such use shall be non-exclusive;
>
> (e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;
>
> (f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;
>
> (g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it

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[56] *See* TRIPS, *supra* note 47, 1869 U.N.T.S. at 332, art. 30.

cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;

(h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;

(i) the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(j) any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur;

(*l*) where such use is authorized to permit the exploitation of a patent ("the second patent") which cannot be exploited without infringing another patent ("the first patent"), the following additional conditions shall apply:

> (i) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;
>
> (ii) the owner of the first patent shall be entitled to a cross-licence on reasonable terms to use the invention claimed in the second patent; and

> (iii) the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.[57]

Of the criteria enumerated above, Article 31(b) is the most contentious, as it requires a showing that the prospective licensee has made efforts to obtain a voluntary license from the right holder "on reasonable commercial terms," and that such efforts were unsuccessful within a "reasonable period of time."[58] Article 31(b), however, offers no guidance on the meaning of "reasonable commercial terms" or a "reasonable period of time," leaving those standards to the discretion of national legislatures.[59] Nor does TRIPS define the "national emergency or other circumstances of extreme urgency" that would justify a waiver of the requirement for negotiations with the right holder.[60] However, there is a limit to the discretion of member states to allow for compulsory licensing, because Article 31(b) must be construed consistently with Article 30, which requires participating countries to ensure that a compulsory license does not "unreasonably conflict with a normal exploitation of the patent" or "unreasonably prejudice the legitimate interests of the patent owner."[61]

VI. THE DOHA DECLARATION

In 2001, WTO members adopted the Declaration on the TRIPS Agreement and Public Health (the "Doha Declaration" or "Declaration").[62] The Declaration provides that TRIPS "does not and should not" prevent WTO members from

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57 TRIPS, *supra* note 47, 1869 U.N.T.S. at 333–34, art. 31.

58 In the case of a "national emergency or other circumstances of extreme urgency," the requirement of negotiation with the right holder may be waived. TRIPS, *supra* note 47, 1869 U.N.T.S. at 333; *see also TRIPS and Pharmaceutical Patents: Obligations and Exceptions,* WORLD TRADE ORG., https://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm [https://perma.cc/NL4Y-XKYB] (last visited Feb. 21, 2018).

59 *See* TRIPS, *supra* note 47, 1869 U.N.T.S. at 333, art. 31; *see also* Jamie Feldman, Note, *Compulsory Licenses: The Dangers behind the Current Practice,* 8 J. INT'L BUS. & L. 137, 165 (2009).

60 *See* TRIPS, *supra* note 47, 1869 U.N.T.S. at 333, art. 31.

61 *See id.* at 332, art. 31.

62 World Trade Organization, Ministerial Declaration of 14 November 2001, WTO Doc. WT/MIN(01)/DEC/1, 41 ILM 746 (2002) [hereinafter Doha Declaration].

"taking measures to protect public health."[63] It further provides that the TRIPS Agreement "should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all."[64] Paragraph 5 of the Declaration, which is cited by developing countries as a basis for expanding the use of compulsory licensing, states in relevant part:

> (b) Each Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.
>
> (c) Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.[65]

Advocates for compulsory licensing have cited Paragraph 5 of the Doha Declaration, specifically subparagraphs (b) and (c) quoted above, as grounds for a liberal interpretation of their right to issue compulsory licenses for pharmaceutical products.[66] Paragraph 5(a), however, emphasizes the importance of the objectives and principles of the TRIPS Agreement to the interpretation of its provisions, stating: "In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be *read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles*."[67]

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63 *Id.*

64 *Id*.

65 *Id.*

66 *See* Reed Beall & Randall Kuhn, *Trends in Compulsory Licensing of Pharmaceuticals Since the Doha Declaration: A Database Analysis*, 9 PLOS MED. J. 1, 2 (2012).

67 Doha Declaration, *supra* note 62, WTO Doc. WT/MIN(01)/DEC/2 (emphasis added); *cf.* TRIPS, *supra* note 47, 1869 U.N.T.S. at 323, art. 7 ("Objectives"); TRIPS, *supra* note 47, 1869 U.N.T.S. at 323, art. 8 ("Principles").

A. PARAGRAPH 6 OF THE DOHA DECLARATION

The Doha Declaration contains no express guidelines for the interpretation of Articles 30 or 31(b) of TRIPS.[68] The Declaration merely asserts that member states have the right to independently establish criteria for the issuance of compulsory licenses, and that AIDS/HIV, tuberculosis, malaria and other epidemics may be recognized as a "national emergencies" or "other circumstance of extreme urgency."[69]

Paragraph 6 of the Doha Declaration therefore instructed the Council for TRIPS to address the "delicate issue" of how WTO members with insufficient manufacturing capacity are to make use of compulsory licensing.[70] The developing countries sought an interpretation of Article 30 of the TRIPS Agreement to permit the manufacture and export of patented medicines by third parties to countries

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[68] *See generally* Doha Declaration, WTO Doc. WT/MIN(01)/DEC/2.

[69] Eric M. Solovy & Pavan S. Krishnamurthy, *TRIPS Agreement Flexibilities and Their Limitations: A Response to the UN Secretary-General's High-Level Panel Report on Access to Medicines*, 50 GEO. WASH. INT'L L. REV. 69, 95–96 (2017) ("[T]he Doha Declaration does not, itself, purport to add any TRIPS flexibilities that are not already evident in the TRIPS Agreement; rather, Paragraph 4 makes it clear that the Doha Declaration is merely a 'reaffirm[ation]' of rights already provided by the TRIPS Agreement.") (alteration in original).

[70] Carlos M. Correa, *Implications of the Doha Declaration on the TRIPS Agreement and Public Health, in* HEALTH ECONOMICS & DRUGS 1, 19 (World Health Org., Essential Drugs & Med. Pol'y Ser. No. 12, 2002), http://apps.who.int/medicinedocs/pdf/s2301e/s2301e.pdf [https://perma.cc/A24J-DNLY]. The Council for TRIPS is the body responsible for administering the TRIPS Agreement and monitors the operation of the Agreement. *See* TRIPS, Dec. 15, 1993, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 349 art. 68. In its regular sessions, the TRIPS Council serves as a forum for discussion among members on key issues and is open to all WTO members and observers. *See Council for TRIPS*, WORLD TRADE ORG., https://www.wto.org/english/tratop_e/trips_e/intel6_e.htm [https://perma.cc/8UGD-PCYB] (last visited Feb. 21, 2018).

lacking the capacity to manufacture such products.[71] Thus, Paragraph 6 instructed the TRIPS Council to find a "solution" to the problem, stating:

> We recognize that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. *We instruct the Council for TRIPS to find an expeditious solution* to this problem and to report to the General Council before the end of 2002.[72]

B. THE PARAGRAPH 6 "SOLUTION"

Paragraph 6 of the Doha Declaration became a controversial issue because the "solution" — announced by the TRIPS Council in 2003,[73] and codified in Article 31*bis* of TRIPS by means of a Protocol dated December 6, 2005 (the "2005 Protocol")[74] — was perceived as changing the basic features of the Agreement.[75]

TRIPS Agreement relating to pharmaceutical products and prescribing the conditions for exporting and importing countries.[76] Under the Paragraph 6 Mechanism, the exporting country can export such drugs upon notification to the TRIPS Council that:

a) Specifies the name and expected quantity of the product needed;

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71 Daya Shanker, *Access to Medicines, Article 30 of TRIPS in the Doha Declaration and an Anthropological Critique of International Treaty Negotiations* 20 (2003), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=391540.

72 Doha Declaration, *supra* note 62, WTO Doc. WT/MIN(01)/DEC/2 (emphasis added); *see also* Correa, *supra* note 70, at 19.

73 General Council Decision, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WTO Doc. WT/L/540 (Sept. 1, 2003) [hereinafter *Implementation of Paragraph 6*].

74 General Council Decision, *Amendment of the TRIPS Agreement*, WTO Doc. WT/L/641 (Dec. 6, 2005).

75 Shanker, *supra* note 71, at 8.

76 *Implementation of Paragraph 6*, *supra* note 73, WTO Doc. WT/L/540. TRIPS Article 31(f) requires compulsory licenses to be "authorized predominantly for the supply of the domestic market;" and Article 31(h) calls for "adequate remuneration." TRIPS, *supra* note 47, 1869 U.N.T.S. at 333, art. 31.

b) Certifies that the importing Member does not have the manufacturing capacity or has insufficient manufacturing capacities in the pharmaceutical sector for the product; and

c) Confirms that a compulsory license has been issued in its territory under Article 31 of the TRIPS Agreement.[77]

On July 24, 2017, the Russian Parliament adopted legislation to execute the 2005 Protocol's addition of 31*bis* in its own system.[78] To the dismay of international observers, however, the Russian Government intends to use the Paragraph 6 Mechanism both as an *exporting* country on the basis of its existing pharmaceutical manufacturing capabilities, and as an *importing* country on the basis of insufficiencies in its pharmaceutical manufacturing capabilities. An explanatory note to the law, states:

> Using Article 31*bis*, the Russian Federation might arrange production of generic medicinal products to supply to the former Soviet countries at a reasonable price to fight epidemics in case of compliance with the relevant provisions of the Protocol.
>
> At the same time, the Russian Federation may use the mechanism to import costly medicinal products which would be

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[77] *See* Agreement on Trade-Related Aspects of Intellectual Property Rights, Jan. 23, 2017, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Annex to the TRIPS Agreement, art. 31*bis*, ¶ 2, https://www.wto.org/english/docs_e/legal_e/31bis_trips_e.pdf [https://perma.cc/GMC6-4332] [hereinafter TRIPS (as amended Jan. 23, 2017)].

[78] *See* [On Approval of Protocol of Amendments to the Agreement on Trade-Related Aspects of Intellectual Property Rights], Draft Law No. 179671-7, May 19, 2017 (Russ.); *see also Russia Accepts TRIPS Amendment to Ease Poor Countries' Access to Affordable Medicines*, WORLD TRADE ORG. (Sept. 22, 2017), https://www.wto.org/english/news_e/news17_e/trip_25sep17_e.htm [https://perma.cc/NU7S-E4BZ]. A self-executing treaty is one that may be enforced in the courts without prior legislation, and a non-self-executing treaty, such as TRIPS article 31*bis*, may not be enforced in the courts without prior legislative implementation. *See* Carlo Manuel Vázquez, *The Four Doctrines of Self-Executing Treaties*, 89 AM. J. INT'L L. 695, 695 (1995).

> produced by another member of the WTO under a compulsory license while fighting epidemics.[79]

While countries are not expressly prohibited from using the Paragraph 6 Mechanism for purposes of both exporting and importing,[80] the mechanism was expressly intended for the benefit of the "least-developed countries and countries that do not have production capacity."[81] As such, 23 developed countries have announced that they will not use the mechanism to import,[82] and 11 other WTO members (developing and developed) have announced that they will only use the system as importers in situations of national emergency or other "circumstances

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79 Draft Law No. 179671-7, *supra* note 78.

80 *See Compulsory Licensing of Pharmaceuticals and TRIPS*, WORLD TRADE ORG. (Sept. 2006), https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm [https://perma.cc/L5U5-FNVA] ("All WTO member countries are eligible to import under this decision . . . .").

81 *Id.* In assessing the manufacturing capacity of an importing WTO member, the Appendix to Article 31*bis* of the TRIPS Agreement states:

> Least-developed country Members are deemed to have insufficient or no manufacturing capacities in the pharmaceutical sector.
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> For other eligible importing Members insufficient or no manufacturing capacities for the product(s) in question may be established in either of the following ways:
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> (i) the Member in question has established that it has no manufacturing capacity in the pharmaceutical sector; or
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> (ii) where the Member has some manufacturing capacity in this sector, it has examined this capacity and found that, excluding any capacity owned or controlled by the patent owner, it is currently insufficient for the purposes of meeting its needs. When it is established that such capacity has become sufficient to meet the Member's needs, the system shall no longer apply.

TRIPS (as amended Jan. 23, 2017), *supra* note 77, app.

82 Namely, Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom and the U.S. *See Compulsory Licensing of Pharmaceuticals and TRIPS*, *supra* note 80.

of extreme urgency."[83] The Russian Government, however, judging from its explanatory note to the May 2017 draft legislation, does not intend to conform to the practice and understanding of the other developed WTO members in regard to compulsory licenses for the importation of pharmaceutical products and medical devices.

Under the Paragraph 6 Mechanism, in addition to the requirements of TRIPS Article 31 (other than paragraphs (f) and (h), which are waived by the Declaration),[84] the compulsory license granted by the exporting member must contain additional conditions that: (1) "only the amount necessary to meet the needs of the eligible importing Member(s)" may be produced under the license; and (2) "the entirety of [the] production shall be exported to the Member(s)" which has notified the TRIPS Council of its need for the product.[85] The product must be clearly identified as produced pursuant to Paragraph 6 of the Doha Declaration by means of specific labeling or marking.[86] Suppliers must also identify such products by means of special packaging, color, or product-configuration, provided that such form of identification is feasible and has no significant impact on the price.[87] These conditions were adopted "to provide comfort to those who feared that the decision might be abused and undermine patent protection."[88]

To comply with the Paragraph 6 Mechanism, the measures described above must be taken under the supervision of the TRIPS Council, which must be informed of: "the name and address of the licensee[;] the product(s) for which the licence has been granted[;] the quantity(ies) of the product(s) for which it has been granted[;] the country(ies) . . . to be supplied . . . [;] and the duration of the

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83 *Id.* (exemplifying Hong Kong China, Israel, Korea, Kuwait, Macao China, Mexico, Qatar, Singapore, Chinese Taipei, Turkey, and United Arab Emirates).

84 *Implementation of Paragraph 6*, *supra* note 73, WTO Doc. WT/L/540 (Sept. 1, 2003).

85 *Id.*

86 *Id.*

87 *See id.*; Jennifer A. Lazo, *The Life-Saving Medicines Export Act: Why the Proposed U.S. Compulsory Licensing Scheme Will Fail to Export Any Medicines or Save Any Lives*, 33 BROOK. J. INT'L L. 237, 247 (2007).

88 *See General Council Chairperson's Statement*, WORLD TRADE ORG. (Aug. 30, 2003), https://www.wto.org/english/news_e/news03_e/trips_stat_28aug03_e.htm [https://perma.cc/F6KU-CTK5].

licence."[89] Further, Paragraph 3 of the Paragraph 6 Mechanism requires that the supplier from the exporting country must remunerate the patent holder but that payment by the receiver is waived.[90]

Of the developing countries that allow for compulsory licensing in one form or another, approximately a dozen have issued compulsory licenses for the use of patented pharmaceuticals, including: Brazil, Ecuador, Egypt, Ghana, India, Indonesia, Malaysia, Mozambique, Rwanda, Thailand, Zambia, and Zimbabwe.[91] Of the developed countries, the only one to invoke the Paragraph 6 Mechanism was Canada, and with limited success.[92]

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[89] *Implementation of Paragraph 6*, *supra* note 73, WTO Doc. WT/L/540 (Sept. 1, 2003).

[90] Paragraph 3 of the Mechanism states:

> Where a compulsory licence is granted by an exporting Member under the system set out in this Decision, adequate remuneration pursuant to Article 31(h) of the TRIPS Agreement shall be paid in that Member taking into account the economic value to the importing Member of the use that has been authorized in the exporting Member. Where a compulsory licence is granted for the same products in the eligible importing Member, the obligation of that Member under Article 31(h) shall be waived in respect of those products for which remuneration in accordance with the first sentence of this paragraph is paid in the exporting Member.

Implementation of Paragraph 6, *supra* note 73, WTO Doc. WT/L/540 (Sept. 1, 2003).

[91] *See* Beall & Kuhn, *supra* note 66, at 4, 4 tbl.1. As of 2012, researchers have identified 24 compulsory license disputes in 17 countries between 1995 and 2011. *Id.* Half of these resulting from compulsory license issuances. *Id.* Sixteen of the disputes involved HIV drugs, four involved drugs for other communicable diseases, and four involved drugs for non-communicable diseases such as cancer. *Id.* More than half of these episodes occurred in upper-middle-income countries such as Brazil and Thailand. *Id.* at 5 fig.5 Most of them occurred between 2003 and 2005, and after 2006 activity declined substantially. *Id.* at 4. One of the few recent examples was in Malaysia. *See* Catherine Saez, *Malaysia Grants Compulsory License for Generic Sofosbuvir Despite Gilead License,* INTELL. PROP. WATCH (Sept. 15, 2017), www.ip-watch.org/2017/09/15/malaysia-grants-compulsory-licence-generic-sofosbuvir-despite-gilead-licence [https://perma.cc/TD5K-PWMT].

[92] *See* Lybecker & Fowler, *supra* note 49, at 231. Prior to 2004, compulsory licensing was prohibited in Canada. *See id.* at 226, 230. In 2004, Canada

At the time of the Doha Declaration, Japan proposed the establishment of a universal source of funding for the treatment of HIV/AIDS, tuberculosis, and malaria. This let to establishment of the Global Fund in 2003.[93] Today the Global Fund operates as "a partnership of governments, civil society, the private sector[,] and people affected by the diseases."[94] The Global Fund raises and invests nearly $4 billion a year to support programs run by local experts in countries and communities most in need.[95]

Although the Doha Declaration references only HIV/AIDS, tuberculosis, and malaria, licenses have been granted for other afflictions not listed. For example, a compulsory license was granted by Thailand in 2007 for the heart-disease medication clopidogrel.[96] Thailand has also granted compulsory licenses for four cancer drugs.[97] "In 2012, India granted a compulsory license for kidney[-]

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enacted the Jean Chretien Pledge to Africa: Access to Medicines Act to enable Canada to participate in the Doha export regime. *Id.* at 226. "While the Act was applauded by civil society advocates and generic drug manufacturers at its inception . . . the process was revealed to be greatly flawed." *Id.* Industry Canada, the responsible agency, later acknowledged that the law "mistakenly assumed drug makers will seek to export drugs for humanitarian reasons." *Id.* (citation omitted). "The problem . . . is that generic drug makers are not charities." *Id.* (quoting Dennis Bueckert, *Drug Aid for Africa Political Illusion*, CANADIAN PRESS (May 1, 2005), https://www.theglobeandmail.com/news/national/drug-aid-for-africa-political-illusion/article1118283/lib/core/?).

93 *See* Sam F. Halabi, *International Intellectual Property Shelters,* 90 TUL. L. REV. 903, 940 (2016).

94 *Global Fund Overview*, THE GLOBAL FUND, https://www.theglobalfund.org/en/overview/ (last visited March 21, 2018).

95 THE GLOBAL FUND, https://www.theglobalfund.org/en [https://perma.cc/83ER-AVCK] (last visited Feb. 22, 2018).

96 *See generally* Halabi, *supra* note 93, at 941; Jakkrit Kuanpoth, *Compulsory Licenses: Law and Practice in Thailand, in* 22 COMPULSORY LICENSING, PRACTICAL EXPERIENCES AND WAYS FORWARD 61, 64 (Reto M. Hilty & Kung-Chung Liu eds., 2014).

97 Halabi, *supra* note 93, at 941. The owners of the affected drugs objected unsuccessfully on the grounds that the government failed to negotiate with the patent holders or to declare an emergency before announcing the license; that the licenses failed the "public non-commercial use" test because they were issued to a state enterprise operating on a for-profit basis; and that the 0.5% royalty rate was arbitrary insufficient. *See* Kuanpoth, *supra* note 96, at 66. In response, the U.S. Trade Representative (USTR) placed Thailand on

and liver[-]cancer medications, but refused to grant several recent compulsory license applications."[98] On the whole, there has been "[n]o substantial wave of compulsory licensing activity" since the Doha Declaration.[99]

It is difficult to evaluate the impact of the Doha Declaration and its Paragraph 6 Mechanism without accounting for the impact of the dramatic growth in global-funding institutions that accompanied it.[100] At a minimum, the Doha Declaration brought patent holders "to the negotiating table with middle-income countries that possessed the manufacturing capacity to make compulsory licensing threats credible and gave those countries . . . negotiating leverage" in the specific diseases identified in the Declaration — i.e., HIV/AIDS, tuberculosis, and malaria.[101]

The Doha Declaration, however, has been largely eclipsed by the establishment of international financing institutions such as the Global Fund and Gavi,[102] and by the increase in health aid, both directly to ministries of health and

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the Special 301 Priority Watch List issued annually by the USTR, threatened to revoke the trade privileges granted to Thailand under the Generalized System of Preferences, and set about to limit the compulsory licensing procedure in the Free Trade Agreement that it had been negotiating with Thailand since 2003. *Id.* at 66–67; *see also*, Toni Johnson, *The Debate Over Generic-Drug Trade*, COUNCIL FOREIGN RELS. (Aug. 3, 2011), http://www.cfr.org/drugs/debate-over-generic-drug-trade/p18055 [https://perma.cc/4YTH-4DYY]; PROGRAM INFO. JUST. & INTELL. PROP., TIMELINE FOR U.S.–THAILAND COMPULSORY LICENSE DISPUTE *13 (Apr. 2, 2009), http://infojustice.org/wp-content/uploads/2012/11/pijip-thailand-timeline.pdf [https://perma.cc/X2YB-K9TB].

98 Halabi, *supra* note 93, at 941 (citation omitted).

99 *Id.* at 941, 942 n.226 (citing Peter Leung, *India Rejects Another Compulsory License*, MANAGING INTELL. PROP. (Nov. 1, 2013), http://www.managingip.com/Blog/3273950/India-rejects-another-compulsory-licence.html [https://perma.cc/9RBT-5FSB]).

100 *See id.* at 942.

101 *Id*.

102 "Created in 2000, Gavi is an international organi[z]ation — a global Vaccine Alliance, bringing together public and private sectors with the shared goal of creating equal access to new and underused vaccines for children living in the world's poorest countries." *About Gavi, the Vaccine Alliance*, GAVI: VACCINE ALLIANCE, http://www.gavi.org/about [https://perma.cc/G6Y3-E56K] (last visited Jan. 23, 2018).

indirectly through organizations like the Global Fund.[103] As a result of these programs, affordable access to life-saving medicines does not require compulsory licensing. Instead, pharmaceutical manufacturers have an incentive to win opportunities through international funding mechanisms and develop relationships with ministries of health in the countries where they are doing business.[104] Because of such incentives, collaboration between governments and pharmaceutical producers has proven to be a more effective means of providing increased access to life-saving medicines at affordable prices around the world.

VII. COMPULSORY LICENSING IN THE RUSSIAN FEDERATION

On August 22, 2012, Russia joined the WTO.[105] To conform Russian patent law to TRIPS requirements, the Russian Parliament had already amended Articles 1360 and 1362 of the Russian Civil Code.[106] Article 1360 allows for the use of an invention without the consent of the right owner in the interest of "national security,"[107] and Article 1362 authorizes the issuance of compulsory licenses.[108] However, no compulsory license has ever been granted under this provision.

The foremost requirement for issuance of a compulsory license under international standards is the non-use of the invention by the patent holder.[109]

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103 Halabi, *supra* note 93, at 942; *see also About Us,* U.S. PRESIDENT'S EMERGENCY PLAN FOR AIDS RELIEF, http://www.pepfar.gov/about/270968.htm [https://perma.cc/P7UM-28VW] (last visited Jan. 23, 2018) [hereinafter PEPFAR].

104 *See* Halabi, *supra* note 93, at 942.

105 *See Russian Federation and the WTO,* WORLD TRADE ORG., https://www.wto.org/english/thewto_e/countries_e/russia_e.htm [https://perma.cc/CNQ8-4GJW] (last visited Feb. 4, 2018).

106 *See* GRAZHDANSKII KODEKS ROSSIISKOI FEDERATSII [GK RF] [Civil Code] art. 1360 (Russ.); GRAZHDANSKII KODEKS ROSSIISKOI FEDERATSII [GK RF] [Civil Code], art. 1362 (Russ.).

107 [GK RF] [Civil Code] art. 1360.

108 [GK RF] [Civil Code] art. 1362.

109 *See generally* Neil S. Tyler, Note, *Patent Nonuse and Technology Suppression: The Use of Compulsory Licensing to Promote Progress,* 162 U. PENN. L. REV. 451, 460–61 (2014) (discussing the non-use standard for granting compulsory licenses under TRIPS and other treaties); *see also* Paris Convention for the Protection of Industrial Property art. 5A, Sept. 28, 1979, 21 U.S.T. 828 U.N.T.S. 305, 321 ("Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to

Article 1362 of the Russian Civil Code is consistent with these standards in providing that a compulsory license may be issued upon the "unjustified" (literally translated, "unrespectable") non-use or insufficient use of an invention by the right holder for a period of four years from the date the patent is issued, if such non-use causes an insufficiency of goods in the market.[110]

It is doubtful, however, that the threat of compulsory licensing is necessary to stimulate the actual use of pharmaceutical patents in the Russian Federation by foreign pharmaceutical manufacturers. Due to the existing and potential market for pharmaceutical products in the Russian Federation, the international pharmaceutical companies who have been targeted by the FAS proposals would not have patents for their products in Russia if they did not intend to market them in Russia. In cases where drug and device developers do not use an innovative medicine or pharmaceutical product for more than four years from the issuance of the patent, the reason for the non-use is typically the need for lengthy preclinical investigation and clinical trials, followed by the application for marketing approval. Such actions, being necessary to the use of the patent, are universally accepted reasons for non-use within the meaning of Article 1362 of the Civil Code.

A. STATUS OF CURRENT INITIATIVE

As discussed above, the FAS is engaged in a high-visibility legislative and public relations campaign to institutionalize the use of compulsory licensing for pharmaceuticals and medical devices.[111] According to the FAS, compulsory licenses are a means of curtailing the abuse of exclusive patent rights and instruments for governments to provide for national security and react to emergencies.[112]

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prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work.").

110 [GK RF] [Civil Code] art. 1362.

111 Increases in the availability of compulsory licensing are also actively advocated by the producers of generics. *See Vikram Punia Proposed that the President Introduce a Compulsory Licensing Scheme*, GMP NEWS (Feb. 3, 2016), http://gmpnews.ru/2016/02/vikram-puniya-predlozhil-prezidentu-vnedrit-sxemu-prinuditelnogo-licenzirovaniya [https://perma.cc/WTE3-SMYT].

112 *See* Chalova, *supra* note 8 (emphasizing the need to "save human lives, and then settle with the rights holders) (translation available with author); Kalinovskaya, *supra* note 8 (stating that the U.S. "has adopted this practice hundreds of times") (translation available with author).

The FAS claims that western pharmaceutical companies are abusing their exclusive patent rights by refusing to supply life-saving medicines to the Russian market,[113] a claim denied by both Western and Russian drug developers. The Agency also claims that the excessive price of a pharmaceutical without more can justify the imposition of a compulsory license,[114] although it has offered no basis for calculation of what is excessive in the case of an innovative drug for which there is no analogue.

These compulsory licensing proposals are part of a larger comprehensive and coordinated effort by the Russian Government, the particulars of which were revealed in a document entitled "Roadmap for Development of Competition in Healthcare," released on January 12, 2018.[115] The Roadmap designates measures, anticipated results and corresponding timelines in the markets for medicines,[116]

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113 *See, e.g.* Ekateria Chalova, *Igor Artemiev: Compulsory License Defendants Against Blackmail by Patent Holders,* PHARMVESTNIK (Oct. 31, 2016), www.pharmvestnik.ru/publs/lenta/v-rossii/igorj-artemjev-prinuditeljnaja-litsenzija-zaschitit-ot-shantazha-pravoobladatelej-patentov.html#.WPIYI_l96Uk [https://perma.cc/NSV7-3X55].

114 *Association of Eurasian Businesses Discusses New Legislative Initiatives by FAC*, FED. ANTIMONOPOLY SERV. (Oct. 5, 2016, 12:55 PM), http://en.fas.gov.ru/press-center/news/detail.html?id=47380 [https://perma.cc/SSE7-JVGQ].

115 Utverdit' prilagaemyj plan meroprijatij ("dorozhnuju kartu") "Razvitie konkurencii v zdravoohranenii" (dalee – plan) [To Ratify the Attached Plan of Action ("Roadmap"), "Development of Competition in Healthcare"], Pravitel"stvo rossijskoj federacii rasporjazhenie [Government of the Russian Federation Order], Jan. 12, 2018, No. 9-r.

116 In the market for pharmaceuticals, the Roadmap identifies measures in respect to (1) government registration of pharmaceutical products; (2) interchangeability of products; (3) establishment of prices for products on a list of lifesaving and essential medicines; (4) government procurement; and (5) intellectual property; and (6) competition among pharmacies. *Id.*

medical devices,[117] medical services[118] and biologically active additives.[119] As relates to intellectual property protection the Roadmap identifies the following three areas of focus:

(1) Clarification of conditions on patentability of new properties and applications of previously known pharmaceutical substances;

(2) Establishment of periods for examination of patent applications by Rospatent; and

(3) Development of procedures for implementation of the compulsory licensing provisions proposed by FAS by way of amendments to Article 1360 of the Russian Civil Code.

In addition to FAS, the agencies enlisted in this ambitious program include the Federal Service for Oversight of Consumer Protection and Welfare; the Federal Service for Supervision of Communications, Information Technology and Mass Media; the Federal Service for Surveillance in Healthcare; the Ministry of Economic Development; the Ministry of Education and Science; the Ministry of Finance; the Ministry of Health; the Ministry of Industry and Trade; and Rospatent.

B. Opposition to Russian Federal Antimonopoly Service Initiatives

Industry observers are surprised at the determination of the FAS to institutionalize compulsory licenses in the absence of any real threat of refusal by any foreign patent holder to license an innovative medicine or supply patented

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[117] In the medical device market, the Roadmap calls for the development of a regulatory framework in relation to (1) medical devices generally; and (2) government procurement. *Id.*

[118] In connection with the market for medical services, the Roadmap calls for regulatory actions in respect to (1) unpaid medical benefits; (2) licensing; (3) treatment protocols; (4) conditions under which government organizations may render paid medical services; and (5) territorial programs involving government guarantees for unpaid assistance. *Id.*

[119] Regarding biologically active additives, the Roadmap calls for the development of regulations including a prohibition on government registration of identically named or confusingly similar biologically active additives. *Id.*

pharmaceutical products in the Russian Federation over the protests of Russian industry.[120] The explanation is believed to inhere in the agency's drive to expand its authority in the area of intellectual property rights.[121]

These legislative proposals by FAS have been publicly opposed by the Russian Patent and Trademark Office (Rospatent), and even more vocally opposed by the Russian Ministry of Economic Development.[122] In April 2017, the Ministry of Economic Development issued a regulatory impact statement disputing the basis for the FAS's proposed amendments to the antimonopoly law,[123] and the law on the circulation of medicines.[124]

The FAS's proposed amendment to the antimonopoly law would expand both prohibitions against the abuse of a dominating market position and agreements in restraint of competition to include the exercise of patent and intellectual property rights.[125] The proposed amendment to the Federal Law on

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120 At a meeting of the Ministry of Economic Development in the course of preparation of opinions about the evaluation of the regulatory impact of the draft law of the FAS on April 10, 2017, representatives of the pharmaceutical industry again came out against the FAS initiative. *See* Oksana Baranova, *Ministry of Economic Development is Preparing an Opinion on the FAS Bill on Introducing a Mechanism for Compulsory Licensing*, PHARMACEUTICAL BULL. (Apr. 11, 2017), http://www.pharmvestnik.ru/publs/lenta/v-rossii/minekonomrazvitija-gotovit-zakljuchenie-na-zakonoproekt-fas-o-vvedenii-mexanizma.html#.WPIKJPl96Um [https://perma.cc/QEZ8-BT2C].

121 *See, e.g.*, Ekaterina Mereminskaia, *Pravitel'tvo reshpt, kak otbirat' lichenzii na lekarstva* [*The Government Will Decide how to Select Licenses for Medicines*], VEDOMOSTI (Nov. 1, 2016, 12:02 AM), http://www.vedomosti.ru/economics/articles/2016/11/01/663155-pravitelstvo-reshit-kak-otbirat-litsenzii [https://perma.cc/33KL-LVZF] (describing the Federal Antimonopoly Services proposed role in issuing compulsory licenses).

122 O vnesenii izmeneniī v federal'nyī zakon "O zashchite konkrrentsii" i federal'nyi zakon "Ob obrashchenii lekarstvennykh sredstv" [The Federal Law On Amending the Federal Law "On Protection of Competition" and the Federal Law "On the circulation of medicines"], MINISTRY ECON. DEV. (Russ.), http://regulation.gov.ru/projects#npa=46586 [http://perma.cc/KZ47-3M5U] (last visited Feb. 15, 2018) (providing a timeline on amending "The Federal Law on Protection of Competition").

123 *See id*.

124 *See id*.

125 *See The Ministry of Economic Development Will Prepare an Opinion on Compulsory Licensing of Pharmaceuticals,* GMP NEWS (April 11, 2017),

Circulation of Medicines would authorize the Ministry of Health to establish a separate procedure for approval and registration of designated drugs amenable to compulsory licensing.[126] Following a meeting on April 10, 2017, which the FAS conspicuously declined to attend,[127] the Ministry issued a forceful repudiation of both proposed amendments.[128]

C. PROPOSED AMENDMENTS TO THE ANTIMONOPOLY LAW

Addressing the FAS's proposed amendment to the antimonopoly law, the Ministry in its regulatory impact statement rejected the FAS's citations to "the international practice of compulsory licensing by foreign countries . . . which in the opinion of [the FAS] [is] not exercised in the Russian Federation."[129] The Ministry responded that, "at the present time, the law of the Russian Federation on compulsory licensing does not require correction to comport with international standards."[130]

The Ministry concluded that the necessary authority for compulsory licensing was already found in Article 1360 of the Russian Civil Code on the "use of inventions, utility models and industrial designs in the interest of national security," and Article 1362 on "compulsory licensing of inventions, utility models and industrial designs."[131] The Ministry found that the proposed amendment would "significantly widen the scope of contractual relationships at which it is

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http://gmpnews.ru/2017/04/minekonomrazvitiya-podgotovit-zaklyuchenie-na-prinuditelnoe-licenzirovanie-lekarstv [https://perma.cc/X8LR-27H4] [hereinafter *MED Will Prepare Opinion*].

126 *See* Regulatory Impact Statement on the Federal Impact of Draft Federal Law on the Protection of Competition and the Circulation of Medicines, *supra* note 6, at 2.

127 *Id.* at 1–2. Referring to the FAS, the Ministry stated, "The drafter, to whom an invitation was sent by Letter No. D26i-212, dated April 5, 2017, did not send its representative to participate in the meeting." *Id.* at 2 (translation available with the author).

128 The Federal Law On Amending the Federal Law "On Protection of Competition" and the Federal Law "On the circulation of medicines", *supra* note 122.

129 Regulatory Impact Statement on the Federal Impact of Draft Federal Law on the Protection of Competition and the Circulation of Medicines, *supra* note 6 (Bruce McDonald, translating).

130 *Id.* at 2 (Bruce McDonald, translating).

131 *See id.* at 3 (Bruce McDonald, translating).

directed, affecting not only compulsory licensing of medicines but other relationships involving intellectual property rights in any goods."[132]

The Ministry credited the data submitted by the Pharmaceutical Research and Manufacturers of America (PhRMA) — attesting to the average cost of $2.6 billion to bring a new drug to the market and the losses suffered by pharmaceutical companies from the premature expiration of patent terms — and concluded that the measures proposed by the FAS would create a mechanism for alienating intellectual property rights and cause economic harm in the marketplace.[133]

The Ministry found that the measures proposed by the FAS had been proven ineffective in the pharmaceutical market, which depends on manufacturing capability and access to technology by local producers, citing evidence submitted by the Russian Association of Innovative Drug Developers (InPharma).[134] The Ministry observed that "the transfer of technology is an extended process and that the joint activity of developers, training of personnel and acquisition of manufacturing capability demands a significant amount of time," stating:

> [T]he marketing of medicines under a compulsory license can result in significant delays arising from the need for additional investigation of the quality, safety and efficacy of the products, resulting in the denial of fast and effective access to such medicines. At the same time, compulsory licensing it is likely to result in a reduction in importation of innovative medicines and a deficit in life-saving medicines.[135]

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132 *Id.* (Bruce McDonald, translating).

133 *Id.* (citing Fedorov, *Pharmaceutical Companies Spend Billions on Development of Drugs for Rare Diseases,* VEDEMOSTI, Nov. 9, 2015, https://www.vedomosti.ru/business/articles/2015/11/10/616116-farmkompanii-tratyat-milliardi-dollarov-razrabotku-lekarstv-dlya-lecheniya-redkih-zabolevanii [https://perma.cc/78JW-YL6M]).

134 *Id.*; *see also* PHARMACEUTICAL RES. & MANUFACTURERS AM., BIOPHARMACEUTICAL RESEARCH AND DEVELOPMENT: THE PROCESS BEHIND NEW MEDICINES 1, http://phrma-docs.phrma.org/sites/default/files/pdf/rd_brochure_022307.pdf [https://perma.cc/THS3-3SMS] (Discussing the high costs of developing new pharmaceuticals and the entire development process).

135 Regulatory Impact Statement on the Federal Impact of Draft Federal Law on the Protection of Competition and the Circulation of Medicines, *supra* note 6; *see also* Reed F. Beall et al., *Compulsory Licensing Often Did Not Produce Lower*

Looking to the experience of other countries, the Ministry cited the example of Brazil, which enacted a law in May 2007 granting a compulsory license for the distribution of HIV/AIDS drugs to a Brazilian state-owned enterprise.[136] This grant resulted in a delay of two years during which the local producer was required to conduct its own investigations of safety, efficacy, and quality prior to marketing the medicine.[137] The Ministry also cited research published in 2015 showing that in 30 cases of compulsory licensing, 19 of them (more than 63%) resulted in prices that exceeded the average price available through the Global Fund,[138] UNICEF, and other international channels, by more than 25%.[139]

The Ministry rejected the FAS's interpretation of previous court decisions, beginning with Supreme Commercial Court Order No. 30, dated June 30, 2008,[140] where the court held that entities entering into contractual relationships must comply not only with the Civil Code but also the antimonopoly law.[141] The Ministry cited *Teva Pharmaceutical Industries Limited,* where the appellate courts

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Prices for Antiretrovirals Compared to International Procurement, 34 HEALTH AFF. 493, 493 (2015), http://content.healthaffairs.org/content/34/3/493.abstract?rss=1 [https://perma.cc/HQ7C-V77X] (noting that compulsory license exceeded median international procurement prices by more than 25 percent in over half of the case studies).

136 Regulatory Impact Statement on the Federal Impact of Draft Federal Law on the Protection of Competition and the Circulation of Medicines, *supra* note 6.

137 *Id.* at 4.

138 *See generally* THE GLOBAL FUND, *supra* note 95 (describing, briefly, the Global Fund Program).

139 Regulatory Impact Statement on the Federal Impact of Draft Federal Law on the Protection of Competition and the Circulation of Medicines, *supra* note 6; *see also* Beall et al., *supra* note 135, at 493.

140 Regulatory Impact Statement on the Federal Impact of Draft Federal Law on the Protection of Competition and the Circulation of Medicines, *supra* note 6 (citing Order No. 30, June 30, 2008, "On questions arising in connection with the application of the antimonopoly law").

141 *See generally* Valentina Rucker & German Zakharaov, *Gold Mine or Minefield: Understanding Russian Law on Verticle Restraints*, 2 RUSS. L.J. 96, 104 (2014) (citing Decision of the Presidium of the Supreme Commercial Court, Nov. 29, 2011, No. 6577/11) (discussing the *Angstrem* case and the Federal Antimonopoly Service's upholding the application of the antimonopoly law to anticompetitive conduct in the imposition of conditions for distribution of goods protected by intellectual property rights).

concluded that companies marketing goods in Russia have no right to disregard limitations established by the antimonopoly law. [142] The Ministry concluded instead that the antimonopoly law already prohibits actions and omissions that restrain competition, including those involving the exercise of intellectual property rights.[143] The Ministry stated:

> [E]xclusive rights to intellectual property by their very nature confer a monopoly on the holder, allowing for competitive advantages based on the use, for example, of more highly developed technology, and for the opportunity, by reason of such advantages, to recoup their investment in development of the intellectual property, to earn profits and to finance the development of new innovations. This right is fundamental to scientific and technical progress, and its efficacy exerts an influence on the development of the high technology sector, the quality of the business climate in the country, and the attractiveness of the government for foreign investment.[144]

The Ministry added, "the proposed amendments could negatively influence the protection of intellectual property rights inasmuch as contracts between economic entities only rarely omit the conditions under which goods protected by intellectual property are distributed."[145] The Ministry found that the proposed amendments were "in conflict with the protection of intellectual property rights," citing Articles 129, 1356, 1357 and 1358 of the Russian Civil Code,[146] and would likely "reduce innovation and patenting activity in Russia and limit the transfer of technology.[147] The Ministry stated:

> A high level of intellectual property protection is one of the key conditions for the successful development of the innovation

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142 Teva Pharmaceutical Indus. Ltd., Decision of Ninth Commercial Appellate Court, Oct. 6, 2014, Case No. A40-42997/14, Decision of Commercial Court of Moscow District, Mar. 18, 2015, Decision of Russian Federation Supreme Court, Nov. 9, 2015, No. 305-KG15-7123.

143 *Id.* at 4.

144 *Id.* at 5.

145 *Id*.

146 *Id.*

147 *Id*.

> economy and attraction of foreign direct investment. The potential in the areas of research development and commercialization is clearly tied to the level of intellectual property protection.
>
> Conversely, a low level of intellectual property protection will result in an absence of incentive for researchers and developers, depriving the domestic industry of innovation as a vector to development. [148]

Citing research by the Russian Association of Pharmaceutical Marketing (RAFM), the Ministry emphasized the existence of a direct relationship between the level of intellectual property protection and the attraction of venture capital and direct investment in the country.[149] "Where intellectual property protection is reduced," the Ministry stated, "the volume of direct investment also falls, as confirmed by a multiplicity of international examples."[150]

The Ministry found that the FAS had failed to establish that there was any deficiency in the existing law. "In the event of a need for corrective antimonopoly legislation in specific areas of commerce," the Ministry recommended that the FAS "examine concrete practical examples and cases of unfair competition attesting to difficulty in application of the law."[151]

The Ministry concluded that even if the problems cited by the FAS existed, the proposed amendments were defective because they were at cross purposes with joint orders from the Ministry of Industry and Trade and the Ministry of Health on the formation of an Interdepartmental Commission on the Conduct of

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148 *Id.* at 5–6 (citing Pugatch Consilium, *Separating Fact From Fiction: How Localization Barriers Undermine Non-Discriminatory Incentives* (2016)) (demonstrating that countries where compulsory licensing is employed suffer from the absence of development and employment in the sphere of clinical trials and scientific enterprises).

149 *Id.* at 6.

150 *Id*. (citing Marina Veldanova, *Mezhdunarodnaia Farmatsevticheskaia Industriia v Rossii I Mire: Sotsial'naia Rol' I imidzh* [*The International Pharmaceutical Industry in Russia and the World: Social Role and Image*] (2016), http://www.rafm.ru/uploads/ppt/26102016Veldanova.pdf [https://perma.cc/E8GM-WF4B].

151 Regulatory Impact Statement on the Federal Impact of Draft Federal Law on the Protection of Competition and the Circulation of Medicines, *supra* note 6, at 6.

Direct Negotiations With Pharmaceutical Manufacturers (the "Interdepartmental Commission").[152] The Interdepartmental Commission is a coordinating body formed for the purpose of conducting negotiations aimed at the "localization of production and the determination of mutually profitable conditions for the purchase of pharmaceutical products for national and municipal needs, including the framework of specialized investment contracts."[153]

The main tasks of the Interdepartmental Commission are to cooperate in: (a) negotiations with pharmaceutical manufacturers; (b) the determination of conditions for government procurement of pharmaceuticals; (c) the development of positions on the price of pharmaceutical products; and (d) collaboration with pharmaceutical manufacturers.[154] The Ministry observed that there is a consensus in the business community that the mechanism of the Interdepartmental Commission is the optimal means to achieve the desired goals, and that the conduct of negotiations between the government and pharmaceutical producers is "consistent with the main principles and approaches worked out in international practice."[155]

In light of the above, the Ministry determined that the FAS's proposed amendment to the antimonopoly law was "excessive, risky, contrary to the Civil Code provisions on protection of intellectual property, and inconsistent with the aims of development in the national innovation sector and localization of manufacturing facilities by foreign producers."[156]

D. PROPOSED AMENDMENT TO THE LAW ON THE CIRCULATION OF MEDICINES

The Ministry also disputed the FAS's proposal to amend the law on the circulation of medicines by designating certain drugs as amenable to compulsory licensing pursuant to Article 1360 of the Civil Code, and establishing a separate procedure for the approval of such drugs.[157] The Ministry found that the proposed

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152 *Id.; see also* Order on the formation of the Interdepartmental Commission, No. 3684/780/1484/16, Oct. 14, 2016 (Russ).

153 Regulatory Impact Statement on the Federal Impact of Draft Federal Law on the Protection of Competition and the Circulation of Medicines, *supra* note 6, at 6.

154 *Id.*

155 *Id.* at 7.

156 *Id.*

157 *Id*.

amendment was unnecessary because the procedure for compulsory licenses is already established by Article 1360 of the Russian Civil Code. The Ministry stated: "The [FAS] has not established a need for the establishment of new procedures for government registration of medicines."[158]

The Ministry also found that the FAS's proposal would interfere with the Agreement on Unified Principles and Rules for the Circulation of Medicines in the Eurasian Economic Union, signed in Moscow on December 23, 2014.[159] The FAS's proposed amendment to the law on circulation of medicines, the Ministry found, would be in conflict with the EAEU's "supranational" legislation.[160]

The Ministry additionally found that the FAS's proposed amendment would result in market discrepancies between pharmaceuticals registered pursuant to preexisting procedures, and those registered under the procedure advocated by the FAS. The Ministry found that such an anomaly would "lead directly" to discrepancies in competitive conditions for entrepreneurs, including: differences in the timing of pharmaceutical regulatory approval; differences in

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158 *Id.*

159 *Compare generally* Agreement on Common Principles and Rules of Circulation of Medicinal Products Within the Eurasian Economic Union, Eurasian Econ. Union, arts. 1–21 Dec. 23, 2014, https://docs.eaeunion.org/docs/en-us/01213250/itia_24122014_doc.pdf [https://perma.cc/XG4G-QJ3B], *with* Ob ocenke regulirujushhego vozdejstvija proekta federal'nogo zakona "O vnesenii izmenenij v Federal'nyj zakon 'O zashhite konkurencii' i Federal'nyj zakon 'Ob obrashhenii lekarstvennyh sredstv'" [On the Assessment of the Regulatory Impact of Draft Federal Law "On the Introduction of Amendments to Federal Law 'On the Protection of Competition' and the Federal Law 'On the Circulation of Medicines'"], Ministry of Econ. Dev., Apr. 25, 2017 (Russ.) (providing that using compulsory licenses during the transition phase may undermine the basic postulates of the creation of a common market for pharmaceutical substances in the EAEU).

160 On the Assessment of the Regulatory Impact of Draft Federal Law "On the Introduction of Amendments to Federal Law 'On the Protection of Competition' and the Federal Law 'On the Circulation of Medicines'", *supra* note 159 (Bruce McDonald, translating) ("In connection with [the plan to introduce harmonized rules for best manufacturing practices and pharmaceutical monitory], the use of compulsory licensing in the transition period . . . may undermine the basic postulates of the creation of a common market for pharmaceutical substances in the EAEU and destabilize the balance which is necessary for formation of a common legal and economic space for the country-participants of the EAEU.").

pricing; the arbitrary loss of product exclusivity by one person in favor of the other; and a risk of negative impact on the quality of pharmaceutical products.[161]

The Ministry further noted that the EAEU is in the process of introducing harmonized rules for good manufacturing practices (GMP) and oversight of pharmaceuticals aimed at the establishment of a "common denominator."[162] The Ministry found that the use of compulsory licensing during this transitional period, by introducing "cardinally new norms" for the Russian Federation, would "subvert the basic postulates of a common market for medicines in the EAES and destabilize the balance necessary for the formulation of common rules and economic space in the EAEU member countries."[163] The Ministry also emphasized the risk that the FAS proposal would result in a discrepancy between the quality of pharmaceuticals produced by the patent holder and those resulting from a compulsory license.[164]

In short, the Ministry has declared its public opposition to the FAS's attempt to institutionalize the compulsory licensing of pharmaceutical patents in the Russian Federation, finding that there is insufficient evidence of an existing problem in the existing legislative framework, and that the proposals would lead to "excessive obligations, prohibitions and limitations" on economic activity and "result in unjustified expenses to private companies and government bodies alike."[165]

E. CONTINUING EFFORTS BY THE RUSSIAN FEDERAL ANTIMONOPOLY SERVICE

Despite opposition from other agencies in the Russian government, the FAS continues to claim that its proposed amendments are consistent with international law and practice — in particular, law and practice in the United States.[166]

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161 *Id.*

162 *Id.*

163 *Id.*

164 *Id.*

165 *Id.* (observing, in a closing remark, that previous efforts by the FAS to "relieve patent holders from their immunities" in earlier versions of the proposed amendments were rejected by the Ministry in Statement Nos. 19967OF/D26, Sept. 19, 2013, 6393-OF/D26, Mar. 28, 2014).

166 *See, e.g.*, Aleksey Y. Ivanov, *Prinuditel'noe Litsenzirovanie Diiainnovatsionnogo*

To that end, the FAS cites consistency with: 28 USC § 1498;[167] two court opinions of questionable relevance — *Carter-Wallace, Inc. v. United States*[168] and

Razvitiia: Oneobxodimosti Balansirovki Rezhima Intellektual'nyx Prav [*Compulsory Licensing for Innovative Development: The Need to Balance the Intellectual Property Regime*], ZAKON RU, May 16–20, 2017, at 80–95 (Russ.), https://rucont.ru/efd/607130 [https://perma.cc/FN6G-SVWN] (implying that commentators from United States have no grounds to criticize Russia for alleged deficiencies in Russian legislation).

167 28 U.S.C. § 1498(a) (2012) ("Whenever an invention . . . is used . . . by or for the United States without license of the owner thereof or lawful right to use or manufacture the same, the owner's remedy shall be by action against the United States in the United States Court of Federal Claims for the recovery of his reasonable and entire compensation for such use and manufacture. Reasonable and entire compensation shall include the owner's reasonable costs, including reasonable fees for expert witnesses and attorneys, in pursuing the action if the owner is an independent inventor, a nonprofit organization, or an entity that had no more than 500 employees at any time during the 5-year period preceding the use or manufacture of the patented invention by or for the United States. Notwithstanding the preceding sentences, unless the action has been pending for more than 10 years from the time of filing to the time that the owner applies for such costs and fees, reasonable and entire compensation shall not include such costs and fees if the court finds that the position of the United States was substantially justified or that special circumstances make an award unjust.").

168 496 F.2d 535, 542 (Ct. Cl. 1974) (granting summary judgment to the government in a patent infringement action and holding that the patentee was estopped from asserting the validity of a patent that had been declared invalid in a prior suit against a different defendant); *see* Ivanov, *supra* note 166, at 86 n.23 (characterizing *Carter-Wallace* as "one of the key precedents" involving the establishment of fair compensation in cases of compulsory licensing).

Leesona Corp. v. United States;[169] a 1966 law review article;[170] and a handful of decisions from the 1990's declining to award lost profits as a remedy in suits for patent infringement against the Government,[171] including a case that was subsequently vacated on appeal to the U.S. Supreme Court.[172] The FAS also cites the Bayh–Dole Act, which provides the U.S. Government with *march-in rights*.[173]

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169 530 F.2d 896, 899–900, 905 (Ct. Cl. 1976). *See generally* Ivanov, *supra* note 166, at 86 n.24 ("The final principles for calculation of compensation under Section 1498 were formulated in the precedential 1976 decision in *Leesona Corp. v. United States*."). In *Leesona Corp.*, the holder of patents covering electrochemical devices brought an action against the U.S. Government to recover for alleged patent infringement. 530 F.2d at 899, 903 n.6. The court held that a misstatement to the United States Patent and Trademark Office regarding one of the applicant's educational qualifications was immaterial since: it was the substance of test results rather than the affiants' degrees that resulted in allowance of the subject claim; more than a literal response to the terms of the claims must be shown to make out a case of infringement; certain claims were valid and infringed, other claims were invalid, and some claims were not infringed; and the Government had a license to the remaining claims. *Id.* at 905. The holding had nothing to do with the criteria for calculation of compensation in the case of a compulsory license.

170 *See* Ivanov, *supra* note 166, at 86 n.20 (citing Gerald J. Mossinghoff & Robert F. Allnutt, *Patent Infringement in Government Procurement: A Remedy Without a Right?*, 42 NOTRE DAME LAW. 5, 10 (1966)).

171 *See* Gargoyles, Inc. v. United States, 113 F.3d 1572, 1579, 1582 (Fed. Cir. 1997) (holding that the remedy in a suit for patent infringement against the Government was limited to a reasonable royalty and did not include lost profits); *accord* Brunswick Corp. v. United States, 36 Fed. Cl. 204, 220 (1996), *aff'd*, 152 F.3d 946 (Fed. Cir. 1998).

172 Hughes Aircraft Co. v. United States, 86 F.3d 1566, 1571–72 (Fed. Cir. 1996); *see* Ivanov, *supra* note 166, at 86–87 n.25 (citing *Hughes Aircraft* limiting damages to "what the owner has lost, not what the taker has gained"). The decision in *Hughes Aircraft* was vacated by the U.S. Supreme Court. *See* Hughes Aircraft Co. v. United States, 520 U.S. 1183, 1183 (1997) (remanding for further consideration in light of Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17 (1997)).

173 *See* 35 U.S.C. § 203(a) (2012). *March-in rights* allow the U.S. Government, in narrow circumstances, to require the contractor or successors-in-title to a patent to grant a "nonexclusive, partially exclusive, or exclusive license" to a "responsible applicant or applicants." *Id.* If the patent owner refuses to do so, the Government may grant the license itself. *Id.* However, no federal agency has ever exercised its power to march in and license patent rights to

The Bayh–Dole Act, however, has no relationship to compulsory licensing, because *march-in rights* are a condition to the receipt of financing and are therefore not compulsory.[174] In addition, the FAS claims that its position is consistent with the practice of U.S. courts in denying injunctive relief where a plaintiff cannot establish irreparable harm under *eBay Inc. v. MercExchange, L.L.C.*,[175] and argues that compulsory licenses are frequently imposed in the United States as a remedy for antitrust violations.[176]

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others. *See* JOHN R. THOMAS, CONG. RESEARCH SERV., R44597, MARCH-IN RIGHTS UNDER THE BAYH–DOLE ACT 8 (2016). The National Institutes of Health (NIH) has decided six march-in petitions and has denied each one. *Id.*

174 Unlike compulsory licensing, licensing compelled under the Bayh–Dole Act does not grant the contractor the right to seek compensation in the U.S. Court of Federal Claims, although under § 203(b) contractors may challenge the exercise of march-in rights in the U.S. Court of Federal Claims. Brice Lauer Biggins, *Keep it American: Preventing Foreign Acquisition of Federally Funded Intellectual Property*, 96 J. PAT. & TRADEMARK OFF. SOC'Y 76, 88 n.110 (2014).

175 547 U.S. 388, 391, 394 (2006). In *eBay,* the owner of a patent for a method of conducting on-line sales sued auction website operators for infringement. *Id.* at 390. The trial court found that the patent was valid and infringed, and awarded damages, but denied permanent injunctive relief. *Id.* at 391. The U.S. Court of Appeals for the Federal Circuit reversed in part, finding that the district court had abused its discretion by denying permanent injunction. *Id.* The Supreme Court vacated and remanded the appellate court decision, holding that (1) the traditional test for permanent injunctive relief applies to disputes arising under the Patent Act (i.e., whether damages would be adequate to provide relief to the patent holder absent also granting a permanent injunction), and (2) in a successful patent infringement action, the patent holder's willingness to license its patents and lack of commercial activity in practicing the patents do not preclude permanent injunction. *Id.* at 393.

176 *See* Ivanov, *supra* note 166, at 90 n.33; *Russia May Authorize Compulsory Licensing of Medicinal Products This Year*, GMP NEWS (Nov. 11, 2017), https://gmpnews.net/2017/07/russia-may-authorize-compulsory-licensing-of-medicinal-products-this-year ("We will use [compulsory licensing]. The USA used this procedure thousands of times and did it unceremoniously no matter who they were dealing with."). *See generally* Walker Process Equip., Inc. v. Food Mach. & Chem. Corp., 382 U.S. 172, 173–74 (finding the patent procured through fraud on the USPTO and that its enforcement may violate American antitrust law).

It is true that U.S. law provides for the availability of compulsory licenses in limited circumstances. Specifically, the Atomic Energy Act, Clean Air Act, and Plant Variety Protection Act provide for compulsory licensing,[177] although these provisions have rarely been invoked[178] and have only been applied narrowly to specific types of technologies.[179] Moreover, no compulsory license has been granted under these Acts. It is also true that patent rights can be stripped away in the United States as a remedy for violation of antitrust law,[180] and that U.S. courts

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[177] *See* 7 U.S.C. § 2404 (2012) ("The Secretary may declare **a** protected variety open to use on a basis of equitable remuneration to the owner, not less than a reasonable royalty, when the Secretary determines that such declaration is necessary in order to insure an adequate supply of fiber, food, or feed in this country and that the owner is unwilling or unable to supply the public needs for the variety at a price which may reasonably be deemed fair."); 42 U.S.C. § 2183(a) (2012) ("The Commission may, after giving the patent owner an opportunity for a hearing, declare any patent to be affected with the public interest if (1) the invention or discovery covered by the patent is of primary importance in the production or utilization of special nuclear material or atomic energy; and (2) the licensing of such invention or discovery under this section is of primary importance to effectuate the policies and purposes of this chapter."); 42 U.S.C. § 7608 ("Whenever the Attorney General determines, upon application of the Administrator . . . that . . . a right under any United States letters patent, which is being used or intended for public or commercial use and not otherwise reasonably available, is necessary to enable any person required to comply with such limitation to so comply, and . . . there are no reasonable alternative methods to accomplish such purpose, and . . . that the unavailability of such right may result in a substantial lessening of competition or tendency to create a monopoly in any line of commerce in any section of the country, the Attorney General may so certify to a district court of the United States, which may issue an order requiring the person who owns such patent to license it on such reasonable terms and conditions as the court, after hearing, may determine.").

[178] *See, e.g.*, Samuel Mark Borowski, *Saving Tomorrow from Today: Preserving Innovation in the Face of Compulsory Licensing*, 36 FLA. ST. L. REV. 275, 282 (2009) ("[I]n the United States, while the government is free to issue compulsory licenses, it is rare that it will.").

[179] *See id.* at 282 n.52 (citing the Atomic Energy Act, Clean Air Act, and Plant Variety Protection Act as triggering legislations for the U.S. Government to invoke its right to issue compulsory licenses).

[180] *See, e.g.*, B. Braun Med., Inc. v. Abbott Labs., 124 F.3d 1419, 1426 (Fed. Cir. 1997) ("[T]he patent misuse doctrine is an extension of the equitable doctrine

may decline to grant a preliminary injunction in a patent-infringement case where irreparable harm to the patent holder cannot be established.[181] Nonetheless, these practices are not analogous to, nor do they justify the FAS's proposed expansion of, compulsory licensing of pharmaceuticals.

The reliance on U.S. law and practice as justification for compulsory licensing of pharmaceuticals was the subject of much debate after Thailand asserted it as a basis for issuing compulsory licenses on patents for essential medicines.[182] Like the FAS, advocates for compulsory licensing of pharmaceuticals in Thailand pointed to the purported frequency of compulsory licenses in the United States.[183] As evidence of widespread compulsory licensing, the Thai government cited U.S. statutory exemptions from patent-infringement liability in the case of pharmaceuticals and medical procedures.[184]

Like the FAS, Thailand cited: U.S. court cases denying injunctive relief to patent-infringement plaintiffs who cannot establish irreparable harm; the immunity of the U.S. Government for compensation claims based on the "taking" of intellectual property under the Fifth Amendment to the U.S. Constitution; and the availability of licensing as a remedy in cases of U.S. antitrust violation.[185] The

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of unclean hands, whereby a court of equity will not lend its support to enforcement of a patent . . . . When used successfully, this defense results in rendering the patent unenforceable until the misuse is purged."); Mallinckrodt, Inc. v. Medipart, Inc., 976 F.2d 700, 706 (Fed. Cir. 1992) (finding a patent unenforceable for antitrust violation and holding that it remains unenforceable until such time as the patent owner cures the antitrust).

181 *See* Matthew C. Darch, *The Presumption of Irreparable Harm in Patent Infringement Litigation: A Critique of* Robert Bosch LLC v. Pylon Manufacturing Corp., 11 NW. J. TECH. & INTELL. PROP. 103, 103 (2013).

182 *See* Epstein & Kieff, *supra* note 26, at 85 ("The defenders of [compulsory licensing] in Thailand point to the frequency of purported [compulsory licensing] now in use in the United States.").

183 *Id.*

184 *See* Ministry of Pub. Health & the Nat'l Health Sec. Off., Facts and Evidences on the 10 Burning Issues Related to the Government Use of Patents on Three Patented Essential Drugs in Thailand 62 (2007).

185 LTC HARMS, THE ENFORCEMENT OF INTELLECTUAL PROPERTY RIGHTS: A CASE BOOK 477 (3d ed. 2012), http://www.wipo.int/edocs/pubdocs/en/intproperty/791/wipo_pub_791.pdf [https://perma.cc/V47T-JVS8] (highlighting Judge Jumpol Pinyosinway of the Central Intellectual Property and International Trade Court of Thailand

FAS takes the argument one step farther by suggesting that pharmaceutical patents are damaging to innovation because the nebulous border lines for individual patents makes it difficult for other drug developers to know whether their activities constitute infringement, and that the fragmentation of property rights by large multiplicities of patents prohibits drug developers from assembling the necessary technologies for their own operations.[186] These asserted justifications for compulsory licensing of pharmaceuticals have been rejected on the following grounds.

1. Limited Statutory Exemptions for Pharmaceuticals & Medical Procedures

In relying on U.S. law as a justification for the compulsory licensing of pharmaceuticals and medical devices, the FAS overlooks the statutory conditions that go along with such a license. For example, the Hatch–Waxman Act exempts from patent-infringement liability the use of medical devices reasonably related to obtaining approval from the Food and Drug Administration (FDA).[187]

The Hatch–Waxman Act also provides a quid pro quo under which generic pharmaceutical producers receive a limited experimental-use exception to ordinary patent liability in exchange for which the patentee — typically a branded pharmaceutical manufacturer — gains an extension of up to five years in patent life to offset the time that the patented pharmaceutical is subject to regulatory review by the FDA.[188] "This tradeoff [has] ushered in huge new investments in pharmaceuticals, by both major companies and new boutique firms."[189] In contrast, the proposals advanced by the FAS provide no benefit to those who have invested in commercialization of the patented drugs.

The Medical Procedures Act of 1996 (MPA),[190] which grants limited immunity to a medical practitioner and any related health-care entity performing

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discussing that "[s]ome countries, significantly the USA, have a civil enforcement system with inbuilt penal provisions").

186 *See Global Drugmakers Complain Over Violations of Patent Rights in Russia*, THE PHARMA LETTER (Jan. 15, 2018), https://www.thepharmaletter.com/article/global-drugmakers-complain-over-violations-of-patent-rights-in-russia.

187 35 U.S.C. § 271(e)(1) (2012).

188 35 U.S.C. § 156(c), (g).

189 Epstein & Kieff, *supra* note 26, at 86.

190 Omnibus Consolidated Appropriations Act, 1997, Pub. L. No. 104-208, § 616, 110 Stat. 3009, 3067 (1996) (codified as amended at 35 U.S.C. § 287). Section

a medical or surgical procedure, is similarly distinguishable from the FAS proposals.[191] The MPA does not apply to patents "whose validity ha[s] already been judicially upheld."[192] "Nor does it bar all remedies against all possible defendants."[193] Instead, the MPA reserves ordinary damages actions against companies other than healthcare providers who, to secure substantial profits for themselves, actively promote patented remedies for use by surgeons without the consent of the patent holders.[194] Unlike the FAS's proposed legislation, application of the MPA is limited to institutional promoters who deliberately infringe patents while excluding infringement actions against physicians who may not even know that any patented procedure was involved.[195] The proposals for compulsory licensing advanced by the FAS would eliminate all remedies.

2. *Denial of Injunctive Relief is Not Equivalent to Compulsory License*

In support of its arguments in favor of compulsory licensing, the FAS cites the 2006 U.S. Supreme Court decision in *eBay Inc. v. MercExchange, LLC.*[196] The *eBay* case overturned the traditional rule for patent disputes under which courts would issue permanent injunctions against patent infringement "absent exceptional circumstances."[197] In *eBay,* the Supreme Court announced a more traditional four-factor test for courts to use in deciding whether to grant both damages and

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616 is entitled "Limitation on Patent Infringements Relating to A Medical Practitioner's Performance of a Medical Activity." *Id.*

191 *See* 35 U.S.C. § 287(c).

192 *See* Epstein & Kieff, *supra* note 26, at 87.

193 *Id.*

194 *Id*.

195 *See id.* ("[T]he MPA rests on efficiency justification not available to the Thai [compulsory licensing], concentrating litigation against those few institutional promoters who consciously violate the patents . . . .").

196 547 U.S. 388 (2006).

197 *See* Epstein & Kieff, *supra* note 26, at 87 (discussing *eBay Inc. v. MercExchange, LLC* and explaining "[t]his case displaced the traditional rule for patent disputes, under which 'courts will issue permanent injunctions against patent infringement absent exceptional circumstances'") (internal citation omitted).

injunctive relief in the case of patent infringement.[198] The Court held that for injunctive relief:

> A plaintiff must demonstrate: (1) that it has suffered an irreparable injury; (2) that . . . monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, [an injunction] is warranted; and (4) that the public interest would not be disserved by a permanent injunction.[199]

It is true that the *eBay* test is less protective of patents than the earlier rule, but it is not equivalent to the issuance of a compulsory license. Rather, it serves simply to eliminate one of the remedies available for a violation of patent rights, and its application has effectively been limited to patent trolls and other non-practicing entities not in competition with the alleged infringer.[200] "[B]oth before

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198 *See id*.

199 *eBay*, 547 U.S. at 391.

200 *See* Ryan T. Holte, *The Misinterpretation of* eBay v. MercExchange *and Why: An Analysis of the Case History, Precedent, and Parties*, 18 CHAP. L. REV. 677, 720 (2015). *See, e.g.*, Georgetown Rail Equip. Co. v. Holland L.P., No. 6:13-CV-366, 2016 WL 3346084, at *11 (E.D. Tex. June 16, 2016) ("Denying an injunction effectively requires Georgetown to grant a compulsory license . . . ."); Sealant Sys. Int'l v. TEK Global, S.R.L., No. 5:11-cv-00774-PSG, 2014 WL 5141819, at *5 (N.D. Cal. Oct. 13, 2014) (finding that the defendant's "proposed bargain amounts to a compulsory license"); Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc., C.A. No. 08–309–LPS, 2014 WL 2960035, at *1–2 (D. Del. June 30, 2014), *vacated on other grounds* 843 F.3d 1315 (Fed. Cir. 2016) (holding that the harm to the plaintiff "cannot be fully compensated by payment of damages"); Sanofi-Aventis Deutschland GmbH v. Glenmark Pharm. Inc., 821 F. Supp. 2d 681, 694 (D.N.J. 2011) ("Plaintiffs are essentially forced into a compulsory licensing arrangement with a direct competitor, and effectively shut out of enforcing their patent rights. Accordingly, this Court finds that remedies at law are inadequate and this factor weighs in favor of a permanent injunction."); Callaway Golf Co. v. Acushnet Co., 585 F. Supp. 2d 600, 622 (D. Del. 2008), *vacated in part on other grounds*, 576 F.3d 1331 (Fed. Cir. 2009) (granting a permanent injunction rather than a compulsory license because the patentee faced lost market share from defendant's ongoing infringement); Broadcom Corp. v. Qualcomm, Inc., No. SACV 05–467 JVS–RNBx, 2007 U.S. Dist. LEXIS 97647, at *7 (C.D. Cal. Dec. 31, 2007) (holding that while a patentee's failure to offer a replacement product for an infringing product affected the degree of

and after *eBay*, courts have routinely found monetary damages inadequate to remedy injury to the patent holder's right to exclude."[201]

> National governments have powerful alternatives if [compulsory licensing] is denied, while foreign corporations have no choice but to [acquiesce]. Even withdrawing from a country does not preclude the local use of [compulsory licensing]. And exercising that withdrawal option could require a patentee to forego lucrative sales of products not subject to [compulsory licensing].[202]

National governments are not limited in this way because "the option of state purchase at bulk discounts, followed by resale at below-market costs to citizens in need, is always available."[203]

The risk of patent trolls does not weigh in favor of compulsory licensing,[204] despite this concern being cited by the FAS in support of its proposals.[205] *Patent trolls* are "'individual inventors who do not commercialize or manufacture their inventions[,]'" which "excludes . . . any parties who are actively engaged in licensing negotiations, even if their first voluntary license has not been completed

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competition, an injunction and not merely a compulsory license was nevertheless warranted before both firms competed in the same market, which the patent holder should have the opportunity to exploit).

201 *E.g.*, Peach State Labs, Inc. v. Envtl. Mfg. Sols., LLC, No. 6:09-cv-395-Orl-28DAB, 2011 WL 13140668, at *4–5 (M.D. Fla. Aug. 12, 2011) (rejecting compulsory licensing as a remedy where it would disrupt the plaintiff's business model); FURminator, Inc. v. Kim Laube & Co., Inc., No. 4:08CV00367 ERW, 2011 WL 1226944, at *2 (E.D. Mo. Mar. 30, 2011) (rejecting a compulsory license where it would erode the price of the plaintiff's products and reduce its sales); Judkins v. HT Window Fashions Corp., 704 F. Supp. 2d 470, 476 (W.D. Pa. 2010) (holding that a compulsory license on unfavorable terms would cause irreparable harm to the plaintiff); Creative Internet Advert. Corp. v. Yahoo! Inc., 674 F. Supp. 2d 847, 852 n.6 (E.D. Tex. 2009) ("[T]he Court rejects any suggestion that it is imposing a 'compulsory license' . . . .").

202 Epstein & Kieff, *supra* note 26, at 88–89.

203 *Id.* at 89.

204 *See id*.

205 *See* Ivanov, *supra* note 166, at 80.

at the time of the defendant's patent infringement."[206] In cases of "[compulsory licensing] for pharmaceutical patents, the patentees are never . . . '*trolls*.'"[207] Instead, they are large companies manufacturing and marketing large volumes of patented drugs.[208] There are likely to be zero inadvertent infringers because new competitors in the pharmaceutical industry need to obtain state licenses to market their products.[209]

"The distinctive features of strong pharmaceutical patents" therefore eliminate the risk of *trolls*, strengthening the argument in favor of injunctive relief and against compulsory licensing.[210] Consequently, there are no known "instances in which nations have used [compulsory licensing] because foreign pharmaceutical companies refused to license . . . their products in the host country."[211] Compulsory licensing has only been used for disputing the price.[212] However, any "monopolistic buying power" of the host government contradicts any claim of hardship under the *eBay* criteria.[213]

Even in cases denying injunctive relief after *eBay*, the rationale articulated by U.S. courts does not support the FAS's reliance on these cases. For example, in *z4 Technologies, Inc. v. Microsoft Corp*, the court denied an injunction against use of the plaintiff's patented software activation technology.[214] However, the infringing technology was only a small component of the defendant's software,[215] and issuing an injunction would have inflicted irreparable harm on the defendant by requiring

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206 Epstein & Kieff, *supra* note 26, at 89 (quoting JAMES BESSEN & MICHAEL MEURER, PATENT FAILURE, HOW JUDGES, BUREAUCRATS, AND LAWYERS PUT INNOVATORS AT RISK 17 (2008)).

207 *Id.* (emphasis added).

208 *Id.*

209 *See id.*

210 *Id.*

211 *Id.*

212 *See id.*

213 *Id.*

214 434 F. Supp. 2d 437, 444 (E.D. Tex. 2006) (holding that damages for future infringement were an adequate remedy and that the balance of hardships favored Microsoft).

215 *Id.* at 440.

a full recall of the composite product.[216] Moreover, the defendant worked to eliminate any use of the offending technology, which was tantamount to granting an injunction.[217] In addition, the defendant was required to pay $115 million in damages for its past infringement (calculated as a reasonable royalty).[218] That award far exceeds the amounts transferred under any compulsory license. "Such reasonable royalty awards are the polar opposite of [compulsory licensing], which has as its goal to set the [compulsory license] fee as close to marginal cost as possible, if not below."[219]

Other post-*eBay* cases denying injunctive relief similarly belie the FAS's reasoning. For example, in *Finisar Corp. v. DirecTV Group, Inc.*, the court refused to issue an injunction because the patentee had never taken any steps to use or license the patent.[220] However, the court also awarded $79 million in damages, far in excess of the compensation for any government-imposed compulsory license. Similarly, in *Paice LLC v. Toyota Motor Corp.*, a court refused to issue an injunction, but only on the grounds that the plaintiff had offered to license its patented products through post-trial options — which the court interpreted as an implicit acknowledgement that damages were a sufficient remedy — and because the plaintiff's business misrepresentations had driven away potential licensees.[221]

3. Government Immunity & Takings

In asserting that compulsory licensing is an accepted practice in the United States, the FAS argues that patent rights are not among the "inalienable rights of man" protected by the U.S. Constitution and that under the Takings

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216 *See id.* at 443 (finding that if it were to grant z4 a permanent injunction, Microsoft would suffer "incalculable and irreparable" injuries, but if it did not grant the injunction, z4 would face limited hardships).

217 *Id.* at 442.

218 *Id*. at 438–40, 442.

219 Epstein & Kieff, *supra* note 26, at 90.

220 2006 U.S. Dist. LEXIS 76380, at *4 (E.D. Tex. July 7, 2006); *See also* H. Tomas Gomez-Arostegui, *Prospective Compensation in Lieu of a Final Injunction in Patent and Copyright Cases*, 78 FORDHAM L. REV. 1661, 1673 (2010) (describing the court's finding that Finisar would suffer irreparable harm in the absence of an injunction).

221 No. 2:04-CV-211-DF, 2006 WL 2385139, at *5 (E.D. Tex. Aug. 16, 2006). *See also* IMX, Inc. v. LendingTree LLC, 469 F. Supp. 2d 203, 228 (D. Del. 2007) (denying an injunction but granting enhanced damages). Note that enhanced damages have never been granted in compulsory licensing cases.

Clause of the Fifth Amendment, no private patentee can resist a government demand for a compulsory license.[222]

However, the patentee whose intellectual property has been confiscated by a government taking in the United States is entitled to compensation covering both fixed and marginal costs, which the compulsory licensing system advocated by the FAS does not provide.[223]

4. Compulsory Licensing as an Antitrust Remedy

Finally, the FAS cites U.S. antitrust law as support for its argument that compulsory licensing is an accepted practice in the United States.[224] This argument is flawed because antitrust enforcement is a protracted process invoked only after a defendant has been shown to have abused its market power. Moreover, the U.S. Supreme Court has held that the possession of a patent monopoly does not in and of itself count as evidence of market power in the presence of competitive patents.[225] The approach to compulsory licensing advocated by the FAS, in

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222 *See* Richard A. Epstein, *The Constitutional Protection of Trade Secrets under the Takings Clause*, 71 U. CHI. L. REV. 57, 58 (2004).

223 Either government in the United States (state and federal) has waived its sovereign immunity, making itself available in for payment of a reasonable royalty, or such suits are available to seek just compensation for government takings. *See* Richard A. Epstein, *The Disintegration of Intellectual Property? A Classical Liberal Response to a Premature Obituary*, 62 STAN. L. REV. 455, 514 (2010); Eugene Volokh, *Sovereign Immunity and Intellectual Property*, 73 S. CAL. L. REV. 1161, 1161 (2000). *See generally* Epstein, *supra* note 222, at 61–64 (outlining government takings in connection with intellectual property rights).

224 *See* Ivanov, *supra* note 166, at 11 ("For the American jurist it is obvious that the principles of defense of competition is the basis for the work of the institution of intellectual property rights . . . .").

225 *See* Ill. Tool Works Inc. v Indep. Ink, Inc., 547 U.S. 28, 44 (2006) (citing Int'l Salt Co. v. United States, 332 U.S. 392, 395 (1947) ("The opinion that imported the 'patent equals market power' presumption into our antitrust jurisprudence, however, provides no support for respondent's proposed alternative. In *International Salt*, it was the existence of the patent on the tying product, rather than the use of a requirements tie, that led the Court to presume market power.").

comparison, does not depend on proof of market abuse, but instead may be imposed arbitrarily by the host country.[226]

5. Policy Arguments

The FAS argues that because intellectual property rights, in contrast to real or personal property rights, "cannot be separated from one another with a high degree of objectivity," pharmaceutical patents give rise to "a multiplicity of disputes relating to their boundaries."[227] According to the FAS, this "reduces the value of intellectual property rights as a transparent system of market signals for investors."[228]

The FAS also argues that the fragmentation of patent rights impedes innovation by making it necessary for pharmaceutical companies to accrue a "large volume of objects that are unnecessary from the investment point of view."[229] These arguments, although relevant to other areas of technology, are uniquely inapplicable to pharmaceutical patents, and have been rejected on the grounds that:

> Pharmaceutical patents . . . are not subject to these twin objections, because they cover single chemical entities or groups of well-defined compounds in composition. The distinct nature of these products, and their precise chemical formulations, significantly mitigates concerns about boundary disputes. In addition, these compounds typically have direct value to end users in treating particular patients, either alone or in conjunction with one or two other compounds. That direct link between patent and consumer product significantly mitigates concerns about fragmentation.[230]

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226 *See Rossija i strany BRIKS budut sovmestno borot'sja s transnacioonal'nymi farmkompanijami* [*Russia and BRICS Countries Will Oppose the Transnational Pharmaceutical Companies*], GMP NEWS (July 16, 2017), https://gmpnews.ru/2017/07/rossiya-i-strany-briks-budut-sovmestno-borotsya-s-transnacionalnymi-farmkompaniyami [https://perma.cc/7LUY-XF5E].

227 Ivanov, *supra* note 166, at 5.

228 *Id*.

229 *Id.* at 6.

230 Epstein & Kieff, *supra* note 26, at 77.

VIII. DANGERS OF COMPULSORY LICENSING IN THE RUSSIAN PHARMACEUTICAL INDUSTRY

The FAS proposals pose a clear and present danger to the Russian pharmaceutical industry. The language of the amendments is vague and would grant sweeping discretion to the government to determine the criteria for a compulsory license based on an assertion of the "protection of life and health of people."[231] This extrajudicial compulsory-licensing procedure offers no assurance that the compulsory license will conform to the requirements of Article 30 of TRIPS and will not unjustifiably infringe the legal rights of the patent holder. Moreover, there is no requirement in the proposed legislation for an attempt at negotiations with the right holder for use of the invention on reasonable commercial terms, as required by Article 31(b) of the TRIPS Agreement.[232]

The FAS proposals to expand the availability of compulsory licensing in the Russian Federation are especially dangerous in light of reductions in government expenditures on healthcare in the past two years. In 2016 the government spent 15.7 billion rubles for the prophylaxis and treatment of HIV, hepatitis B, and hepatitis C, down from 17.5 billion rubles in 2015, even as the number of cases is rising.[233]

While the incentive to economize on government procurement of pharmaceutical products is understandable in this environment, the compulsory licensing system advocated by the FAS would not assure, or even be likely to produce, the reduced prices and increased access sought by the agency. Moreover, history reveals that in contrast to the hypothetical risk of a refusal by a foreign innovative-drug developer to supply patented pharmaceutical products in the Russian Federation, which has never occurred, the risks associated with compulsory licensing are altogether real.

To begin with, pharmaceutical products produced under compulsory licenses lag behind branded products in quality and create a safety hazard for patients. In Thailand, the generic version of a medicine used to treat HIV resulted in the development of resistance to the drug in 39.6%–58% of patients taking the

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231 FED. ANTIMONOPOLY SERV., PROPOSALS TO BRING THE LEGISLATION OF THE RUSSIAN FEDERATION INTO COMPLIANCE WITH THE PROVISIONS OF THE TRIPS AGREEMENT 3 (Feb. 20, 2014).

232 *See* The Federal Law On Amending the Federal Law "On Protection of Competition" and the Federal Law "On the circulation of medicines", *supra* note 122.

233 *See* Dranishnikova, *supra* note 14.

medicine.[234] Resistance to the generic drug made it necessary for patients to go to more expensive treatment requiring hospitalization.[235] Compulsory licenses are sought mostly for recent molecules appearing in the market, which are especially susceptible to risks in terms of quality and efficacy.[236]

Experience also shows that compulsory licenses are an impediment to innovation in the pharmaceutical industry. Manufacturers of generics do not invest in the research and development of innovative medicines in the absence of adequate legal protection. In Thailand, the government agency responsible for compulsory licensing of pharmaceutical products invested in research and development less than 0.5% of the profits from pharmaceutical sales, as compared to the innovative-drug-development industry, which invests more than 17.5% of its net profits in research and development.[237]

An additional risk associated with compulsory licensing is the refusal of innovative-drug developers to register new drugs and transfer the associated technology to the domestic industry. In Thailand, one of the major pharmaceutical companies removed its products from Thailand in response to a compulsory

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234 *See* Lybecker & Fowler, *supra* note 49, at 232 (citing a 2005 Mahidol University study that found between 39.6%–58% resistance to the drug in the 300 patients investigated); Stephanie Skees, *Thai-ing up the TRIPS Agreement: Are Compulsory Licenses the Answer to Thailand's AIDS Epidemic*, 19 PACE INT'L L. REV. 233, 246–47 (2007) (explaining that the Mahidol University study found a radical increase in resistance, which was only expected to get worse).

235 *See* Lybecker & Fowler, *supra* note 49, at 232 (explaining that "second-line therapies necessitated by the drug resistance" cost patients $249 per month and also required costly hospitalization).

236 *Cf.* Shuchi Midha & Aditi Midha, *Compulsory License: Its Impact on Innovation in Pharmaceutical Sector*, 2 INT'L J. APPLICATION INNOVATION ENGINEERING & MGMT. 222, 224 (2013) (explaining that compulsory licenses are granted with the purpose of providing access to newer drugs); Lybecker & Fowler, *supra* note 49, at 224–25 (explaining the ease at which generic companies can replicate a process and commercialize a copy, and that there are risks associated with this product development and commercialization stage).

237 *See* Lybecker & Fowler, *supra* note 49, at 232 (reporting that pharmaceutical companies invest and average of 17.5% of their profits in research and development while the Thai government invest less than 0.5% of its revenue).

license, including a drug that was especially amenable to the Thai climate.[238] In addition to depriving consumers of access to life-saving medicines, compulsory licenses reduce the availability of generic and biosimilar copies.

Many developing countries, especially those with strong markets and mid-range per capita income (Russia in particular[239]), are attractive to foreign investors in principle. However, one of the essential conditions for a profitable investment climate is the protection of intellectual property. The active use of exceptions or exclusions from patent rights sends negative signals to international pharmaceutical companies and venture capitalists who would otherwise be interested in investing in Russia. In Egypt, for example, following the issuance a compulsory license of Viagra, companies independently decided to refrain from previously planned investments worth $300 million in the pharmaceutical sector due to the weak protection of intellectual property rights.[240]

The unwillingness of innovative-drug developers to register pharmaceutical products and invest in countries where compulsory licenses are actively used is explained by the nominal compensation for the use of patents in those countries. The average royalty rate for pharmaceuticals under compulsory licenses in those countries is only 5–10% of the profits from sales of the product.[241] In Indonesia, in 2004, the royalty for the use of lamivudine and nevirapine (innovative medicines for the treatment of HIV/AIDS), was 0.5% of the sale

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238 *See generally* Cynthia M. Ho, *Unveiling Competing Patent Perspectives*, 46 HOUS. L. REV. 1047, 1063 (2009) (explaining that a heat-stable form of the drug Kaletra, which is well-suited for the Thai climate, was withdrawn).

239 According to research by Deloitte, in 2016 the Russian pharmaceutical market was number 14 in the world by volume of sales. OLEG BEREZIN ET AL., DELOITTE, REDUCING COSTS AND INTRODUCING NEW MEDICINES: TOP DEVELOPMENT TRENDS IN THE RUSSIAN PHARMACEUTICAL INDUSTRY 2016, 10 (2016).

240 *See* Sahar Aziz, *Linking Intellectual Property Rights in Developing Countries with Research and Development, Technology Transfer, and Foreign Direct Investment Policy: A Case Study of Egypt's Pharmaceutical Industry*, 10 ILSA J. INT'L & COMP. L. 1, 22 (2003) (providing an example of how the Pharmaceutical Research and Manufacturers of America (PhRMA) informed Egypt of the weak protections).

241 Satish Saroha et al., *Compulsory Licensing of Drug Products in Developing Countries*, 12 J. GENERIC MEDS. 89, 89, 91–93 (2013) (exemplifying cases where the royalty rates were 3% and 6% and reporting that pharmaceutical companies claim that royalties range from 5–10%).

price.[242] A similar result occurred Thailand.[243] Such nominal compensation does not begin to cover the investment necessary to the development of pharmaceutical products, and cannot be considered "reasonable commercial conditions" within the meaning of Article 31(b) of the TRIPS Agreement.

IX. PHARMA 2020

In the Russian Federation, 2009 marked the beginning of the "Pharma 2020" program aimed at transformation of the Russian pharmaceutical market into a source of innovative-drug development.[244] Following the announcement of Pharma 2020, international pharmaceutical companies invested significant efforts to locally manufacture patented pharmaceutical products in Russia.[245] According to Vladimir Shipkov, executive director of the Association of International Pharmaceutical Producers (an organization of 50 prominent innovative-drug manufacturers),[246] "members of the association opened more than 20 factories for

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242 James Packard Love, Research Note, *Recent Examples of the Use of Compulsory Licenses on Patents*, KNOWLEDGE ECOLOGY INT'L 12 (2007).

243 *See* Mongkol Na Songkhla, *Preface to* Ministry of Pub. Health & the Nat'l Health Sec. Off., Facts and Evidences on the 10 Burning Issues Related to the Government Use of Patents on Three Patented Essential Drugs in Thailand 62 (2007) (acknowledging concern from the pharmaceutical industry related to the Ministry of Public Health to announce the Government's use of several patented drugs).

244 *See Federal'nyi tselevoi programmy "Razvitie farmatsevticheskoi i meditsinskoi promyshlennosti Rossiiskoi Federatsii na period do 2020 goda i dal'neishuiu perspektivu"* [*Federal Target Program "Development of the Pharmaceutical and Medical Industry of the Russian Federation for the period up to 2020 and Beyond*], ROSSIISKAIA GAZETA [ROS. GAZ.] (Russian Gazette) No. 772, 1, Oct. 19, 2010 (Russ.).

245 For example, under the agreement reached between Pfizer and Russian Novamedica in July 2016, Pfizer will invest 60 to 100 million dollars in construction of a joint venture enterprise in Russia. *See* Maria Dranishnikova, *Pfizer i "Novamedika" Investirujut v Proizvodstvo Lekarstv Pod Kalugoj* [*Pfizer and Novamedica Will Invest in the Production of Drugs in Kaluga Region*], VEDOMOSTI (July 14, 2016, 12:06 AM), https://www.vedomosti.ru/business/articles/2016/07/14/649127-pfizer-novamedika-investiruyut-proizvodstvo-lekarstv-pod-kalugoi.

246 *See About AIPM*, ASS'N OF INT'L PHARMACEUTICAL MANUFACTURERS, http://www.aipm.org/en/main/about [https://perma.cc/VH4V-C5JJ] (last visited Jan. 20, 2018).

the production of [pharmaceutical products] in Russia," with an investment over the last five years of more than €2 billion.[247] In the following years, the majority of imported pharmaceutical products for which patent terms had not expired were based on investment agreements calling for localized manufacture.[248]

The advantage to localization of manufacturing in the Russian pharmaceutical market is the availability of access to innovative manufacturing technology.[249] A critical condition for the transfer of such technology by innovative-drug developers is adequate patent protection for the transferred technologies. Innovative-drug developers must have a reasonable assurance that their intellectual property rights will be protected. If there is a risk that their patented technology will be used without their consent, they will refrain from transferring technologies to Russia and efforts toward localization will be further undermined.

X. CONCLUSION

The statutory amendments proposed by the FAS are a distinctly negative signal to foreign investors. Considering the investment they have already made in the localization of production,[250] international pharmaceutical companies might remain in the Russian market in the face of such statutory amendments, but they could stop registering new drugs in Russia. The FAS legislative proposals would result in damaging interference to the functioning of the market, and raise the real

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247 *Svetlana Rayter & Anna Deryabina, Pravitel'stvo Zakrylo Rynok Dlja Deshevyh Kopij Zapatentovannyh Lekarstv* [*Government Closed the Market for Cheap Copies of Patented Medicines*], RBC NEWSPAPER (Apr. 28, 2016, 10:43 PM), https://www.rbc.ru/business/28/04/2016/572249729a79476115b525d0 [https://perma.cc/6ZEJ-QA6J].

248 *See generally* OLEG BEREZIN ET AL., *supra* note 239, at 25 (demonstrating patterns that encourage localized manufacturers of medicines subject to foreign intellectual property rights).

249 *See* Regulatory Impact Statement on the Federal Impact of Draft Federal Law on the Protection of Competition and the Circulation of Medicines, *supra* note 6 (Bruce McDonald translating) ("As pointed out by the Association "InPharma," a necessary condition to guaranteeing the access of patients to generic drugs is the readiness of manufacturing capabilities and the availability of necessary technologies among local pharmaceutical manufacturers.").

250 *Id.* (demonstrating that the Ministry includes the localization of production as one of the purposes for assessing the regulatory impact).

danger of a deficit in the development and manufacture of innovative drugs and generics alike.

Nevertheless, Russian and western drug developers are hopeful that dialog and collaboration between western companies and the Russian government will lead to an improvement in mutual understandings and cooperative relationships. International and domestic drug-developers anticipate the possibility that communications with the newly created Interdepartmental Commission will produce better results than the confiscation of patent rights proposed by the FAS.

In summary, the FAS initiatives to institutionalize the compulsory licensing of pharmaceutical patents could result in a contraction in the pharmaceutical industry and reduction of access to life-saving medicines for Russian consumers. Such dangers outweigh the short-term benefits of a temporary reduction in the price of patented medicines — which is not even guaranteed. The legislative proposals on compulsory licensing would inflict shock therapy on the industry, and should be implemented only if measures to negotiate with right holders have proved unsuccessful.