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# India's Compulsory License Model: Increased Pharmaceutical Access and Innovation Coexist

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## INDIA'S COMPULSORY LICENSE MODEL: INCREASED PHARMACEUTICAL ACCESS AND INNOVATION COEXIST

*Bela Gandhi*<sup>1</sup>

Patented medicine is a key issue for India where there is a high burden of disease, low coverage, and low per capita income.<sup>2</sup> India is known as the “pharmaceutical capital” of the world.<sup>3</sup> Generic duplicates of foreign-developed drugs permit low out-of-pocket expenses for Indian citizens.<sup>4</sup> Despite criticism of generics, it is difficult to deny that quality of life is better for India's citizens who could not afford drugs if they were patented, branded, and sold at higher prices.

Indians value affordable medicine for all. Prime Minister Indira Gandhi expresses this value in a statement: “My idea of a better ordered world is one in which medical discoveries would be free of patents and there would be no profiteering from life or death.”<sup>5</sup> This principle is important enough to create a provision in the Constitution:

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- 1 Bela Gandhi is a senior at Brigham Young University studying public relations with a minor in statistics. She will begin law school in the fall of 2020. She wishes to thank the generous effort and diligence of Kris Tina Carlston and Forrest Albinston.
  - 2 Viren Konde, *Recent Developments in Compulsory Licensing of Pharmaceutical Patents in India*, 22, *JOURNAL OF COMMERCIAL BIOTECHNOLOGY*, 64, 64-65 (2016) (discussing cases of compulsory licensing).
  - 3 *India is the pharmaceutical capital of the world today: Dr. YK Hamied*, *CMD, Cipla*, *THE ECON. TIMES* (May 11, 2011).
  - 4 Janice M. Mueller. *The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation*, 68 *U. Pitt. L. Rev.* 491, 543 (Spring 2007) (discussing India's new product and process patent model).
  - 5 *Id.* at 496.

“The State shall regard the raising of the level of nutrition and the standard of living of its people and the improvement of public health as among its primary duties.”<sup>6</sup> This reveals the public health motivations behind the Indian Patent Act of 1970. The Act took measures to protect pharmaceuticals from monopolistic practices that would make them inaccessible to many citizens. One of these measures is known as a compulsory license, “authorization permitting a third party to make, use, or sell a patented invention without the patent owner’s consent.”<sup>7</sup>

However, compulsory licensing can hurt profits which corporations have a vested interest in maintaining. A common western concern is that when patents are not protected innovation may be discouraged and alleged intellectual property rights might be denied, thus disincentivizing corporations from patenting pharmaceuticals in India. “U.S. companies [call this restriction] a patent violation while the Indian government calls it a legitimate right.”<sup>8</sup>

Despite potential profit loss, compulsory licenses improve low- and middle-income countries’ (LMI countries) access to medicine. In India, compulsory licensing has increased access to medicine while also incentivizing innovation within the country through its 2005 Patent Act. As such, India should serve as a legal model for LMI countries in protecting public health through compulsory licenses. By using compulsory licenses India has controlled multinational corporations (MNCs) and provided reliable and steady prices for populations.

This paper begins in Part I by briefly summarizing India’s role in access to medicine and how the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement provides compulsory licenses to better serve medical crises around the world. Similarly

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6 INDIA CONST. art. 47, § 4.

7 Cheri Grace, *EQUITABLE PRICING OF NEWER ESSENTIAL MEDICINES FOR DEVELOPING COUNTRIES: EVIDENCE FOR THE POTENTIAL OF DIFFERENT MECHANISMS* 47 (2003).

8 P.B. Jayakumar, *Patently Justified*, BUSINESS TODAY (Mar. 15, 2015) <https://www.businesstoday.in/magazine/features/us-mounts-pressure-on-india-on-pharma-ip-protection-impact/story/215947.html>.

situated countries are addressed in part II. Part III discusses the Nexavar case that granted a compulsory license under section 84 of India's 2005 Patent Act. This case gives insight into the government of India's views on decreased cost of medicine and the role of compulsory licenses. This section will also discuss the rejection of a separate compulsory license application and what precedents the Indian government makes by this ruling. Part IV describes a broad range of allowances to compulsory licenses under section 92 and discusses India's cleverly incorporated section 92A which allows exportation of pharmaceuticals with a compulsory license. Part V focuses on a case of preventative action by a company to avoid compulsory licensing. The consequence of this action has led to creation of biosimilars. Part VI will discuss the concerns about compulsory licenses inhibiting innovation and demonstrate why compulsory licenses can provide novel innovation within India's model. To conclude, part VII discusses India's compulsory licensing system and improvements that should be made.

## I. BACKGROUND

In the Patent Act of 1970, pharmaceutical product patents were prohibited, but process patents—the protection of drug manufacturing methods and equipment—were allowed. With pharmaceutical product patents out of the way, India began production of generic drugs at a fraction of the cost.<sup>9</sup>

When India joined the World Trade Organization (WTO), it was required to comply with the TRIPS agreement thus compelling India to patent pharmaceutical products. The Indian Patent Act of 1970 was amended accordingly and is known today as the Patent Act of 2005.<sup>10</sup>

Before a compulsory license can be granted a request must be rejected for a voluntary license—when a patent holder allows other companies to manufacture and distribute its patented drug. This

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9 Mueller, *supra* note 4, at 491, 576.

10 Murphy Halliburton, *INDIA AND THE PATENT WARS: PHARMACEUTICALS IN THE NEW INTELLECTUAL PROPERTY Regime* 21-37 (2017).

ensures that MNCs take seriously the requests of local companies. TRIPS specifies when a compulsory license is granted that the patent holder must be compensated. Typically, this means that the patent holder is paid 6% of total profits from the generic version. Due to the forced nature of compulsory licensing, the patent holder does not get to negotiate the royalty.<sup>11</sup> TRIPS recognizes that LMI countries are vulnerable to high prices of protected pharmaceutical patents, so the organization safeguards access to medicine using compulsory licensing.<sup>12</sup> The 2005 Patent Act is compliant with TRIPS and additionally safeguards public health with its own amendments.

Further, the Indian government stipulates its own requirements to affirm a compulsory license. The 2005 Indian Patent Act allows compulsory licensing in situations beyond a “national emergency.” This protects public health, domestic and abroad, from the potential harm of patents. In this way, India seeks to maintain balance between rewarding innovations while also providing access to medicine.<sup>13</sup>

## II. SIMILARLY SITUATED COUNTRIES

India’s model to achieve access to medicine and promote local infrastructure can be implemented by similarly situated countries. Similarly situated countries are LMI countries with a disparity in pharmaceutical access. To achieve India’s independence within the pharmaceutical industry, these countries will have pharmaceutical infrastructure to manufacture their own drugs when a compulsory license is granted. Countries like Jordan already have measures in place to protect compulsory licensing. Now, there is an opportunity to benefit from further protection while promoting innovation within its nation.

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- 11 Cynthia Ho, *ACCESS TO MEDICINE IN THE GLOBAL ECONOMY: INTERNATIONAL AGREEMENTS ON PATENTS AND RELATED RIGHTS* 137-138 (1st ed. 2011).
  - 12 WTO, *Compulsory Licensing of Pharmaceuticals and TRIPS* (2018).
  - 13 S. S. Rana & Co., *Compulsory Licensing of Patents in India*, SSRANA (2012), [https://www.ssrana.in/Intellectual%20Property/Patents/Patents\\_CompulsoryLicensing.aspx](https://www.ssrana.in/Intellectual%20Property/Patents/Patents_CompulsoryLicensing.aspx).

Jordan's patent law allows compulsory licensing but fails to elaborate or clarify "patent holder abuse" and failure of the pharmaceutical to work within Jordan.<sup>14</sup> The next section describes how India protects its citizens from these issues.

### III. SECTION 84 OF INDIA'S PATENT ACT AND THE NEXAVAR CASE

Section 84 of the Patent Act protects India from anticompetitive practices and abuses of power by MNCs.<sup>15</sup> India affirms through section 84 of the India's Patent Act local companies right to challenge the patentholder. A challenge to produce a generic pharmaceutical is based on MNC violations of the following.<sup>16</sup>

84. At any time after the expiration of three years from the date of the grant of a patent, any person interested may make an application to the Controller for grant of compulsory license on patent on any of the following grounds, namely: —  
(a) that the reasonable requirements of the public with respect to the patented invention have not been satisfied, or  
(b) that the patented invention is not available to the public at a reasonably affordable price, or  
(c) that the patented invention is not worked in the territory of India.<sup>17</sup>

A compulsory license under section 84 may be granted when the patented drug is unavailable, unaffordable, or not supplied properly to the public. This is done so patents do not impede the country's overall health. Anticompetitive behavior is addressed by Jordan in

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14 Wael Armouti. *Grounds for Compulsory License with Selected Cases Granted for Pharmaceuticals*, 26 Tul. J. Int'l & Comp. L. 381, 402 (2018).

15 *Id.* at 388.

16 E. J. Lane. *Indian Court Upholds BMS Sprycel Patent, but List of Challengers Grows*, FIERCEPHARMA <https://www.fiercepharma.com/regulatory/indian-court-upholds-bms-sprycel-patent-but-list-of-challengers-grows> (last visited Jul. 7, 2015).

17 The Patents Act, 1970, Subs. by Act 15 of 2005, S. 52 <http://indiacode.nic.in>.

its patent law in article 22.c “if it is decided judicially or administratively that the Patentee practices his rights in a manner that deters third parties from fair competition.”<sup>18</sup> However, deterring third parties does not stop other anticompetitive behavior such as excessive pricing or lack of availability, issues that largely affect patients rather than third parties.

India’s first granted compulsory license under section 84 was based on what India’s Patent Controller deemed an unreasonable price for patients and local manufacturers. In doing so, the Patent Controller neglected consideration for the patent holder’s R&D investment.<sup>19</sup>

The granted compulsory license was for the kidney cancer drug sold as Nexavar by the company Bayer. In 2008, Nexavar was patented in India. Four years later, an Indian company, Natco Pharma, applied for a compulsory license after Natco Pharma’s voluntary license application was quickly rejected by Bayer.<sup>20</sup> In August 2011, Natco Pharma filed a compulsory license application with the Patent Controller. In March 2012, the Controller General of Patents granted Natco Pharma the compulsory license on Nexavar.<sup>21</sup>

Natco Pharma was granted the compulsory license because Nexavar did not reach 98% of the Indian population due to a disparity in price. Bayer valued the drug at \$5,000 a month while Natco Pharma suggested the price of \$170 a month, an approximately 97% decrease in total cost.<sup>22</sup> Bayer held on to an unrealistic price for the Indian market. The compulsory license was granted because Nexavar was considered unaffordable. This violated the requirement in Section 84(b) that the drug be available to the country’s population

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18 Law No. 32 of 1999 (Jordan). *See also* Armouti, *supra* note 14, at 388.

19 Thaddeus Manu *Building National Initiatives of Compulsory Licences*, 14 J. INT’L TRADE L. & POL’Y. 23, 23-48 (2015).

20 Natasha Nayak, *Enhancing affordable pharmaceutical healthcare: Possibilities in Indian competition law regime*, 53 ECON. & POL. WKLY. 48, 51 (2018).

21 Manu, *supra* note 19, at 23-48.

22 Nayak, *supra* note 20, at 49.

at a reasonable price. This case brought forth the debate of how “reasonable affordability” should be defined.<sup>23</sup>

Bayer attempted to justify its price of Nexavar citing R&D's incurred costs during development. Bayer reasoned that generic companies incur no such R&D costs, thus allowing generics to be approximately 97% less than the branded drug. However, during the trial, Natco Pharma argued that the price of Nexavar in India should not be determined under the assumption that the entire R&D costs for a drug sold internationally be collected from the Indian market alone.<sup>24</sup> Natco Pharma reminded the court that Bayer had made an inappropriate assumption because they sell Nexavar in multiple countries, making Bayer's logic unfounded.

The justification for R&D as explained by Bayer either meant India is the only country where Bayer retrieved profits, or each country where Nexavar is sold is required to pay the same incurred costs from R&D. The cost of Nexavar must be recouped in order for Bayer to launch other pharmaceuticals, but Bayer is not entitled to profits for R&D costs multiple times over from multiple countries.

Ultimately, the Patent Controller agreed with Natco Pharma that a “reasonably affordable price” described in section 84 should be seen from the public's perspective, rather than from a company's perspective. Moving forward the Nexavar case could affect future appeals as India's judiciary appears to rule more often in favor of the patients.<sup>25</sup> After the Patent Controller granted the compulsory license, Bayer tried appealing to the Indian Patent Appellate Board (IPAB). The appeal failed, and the board upheld the decision made by the Controller. Bayer's appeal was denied because Nexavar was not available to the public at an affordable price. Reasonable affordability defined by the perspective of the public was the standard the Controller defined and the IPAB confirmed.

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23     Manu, *supra* note 19, at 23-48.

24     Nayak, *supra* note 20, at 50-52.

25     Savita Gautam & Meghna Dasgupta *Compulsory Licensing: India's Maiden Experience*, ASIA PAC. RES. & TRAINING NETWORK ON TRADE 1, 9-12 (2013), <https://www.econstor.eu/bitstream/10419/103872/1/774037490.pdf>.

The Natco-Bayer outcome should serve as a blueprint for the Indian government to increase access to medicine through decreased prices. Domestic companies and government agencies should start applying for more compulsory licenses. This will increase competition among pharmaceutical companies, thereby regulating pharmaceutical prices.<sup>26</sup>

TRIPS justified the outcome. Member states of the WTO are allowed to stipulate when compulsory licenses may be granted. India followed its laws on compulsory licensing. Section 84 allowed India to give a compulsory license and protected India from international intervention.<sup>27 28</sup>

Complying with TRIPS, Natco Pharma originally applied for a voluntary license. A short time after the voluntary license was rejected the company was granted a compulsory license by the Controller. Natco Pharma's single attempt, which the IPAB identifies more as a notice than a request, gave Natco Pharma the right to seek a compulsory license. Even though the IPAB recognized the voluntary license application as a notice, the compulsory license was still approved. Essentially Natco Pharma demanded a voluntary license from Bayer.

Although Natco Pharma did not break any of the requirements to earn a compulsory license, the way it handled its voluntary license application is cause for concern. If voluntary licensing is not taken seriously it does not give MNCs the opportunity to review local applications. A poor attempt at applying for a voluntary license weakens the TRIPS stipulation. By ignoring this issue India's government undermines voluntary licensing that is meant to protect MNCs and incentivize them to produce generic products. Moving forward India

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26 *Id.* at 9-12.

27 USTR, *2013 Special 301 Report*, OFF. U.S. TRADE REPRESENTATIVE, 1, 38 (2013). See also USTR, *2018 Special 301 Report*, OFF. U.S. TRADE REPRESENTATIVE, 1, 49 (2018).

28 USTR, *USTR releases 2018 special 301 report on intellectual property rights*, USTR (2018), <https://ustr.gov/about-us/policy-offices/press-office/press-releases/2018/april/ustr-releases-2018-special-301-report>.

should require that generic companies to go through a standardized application process to earn a voluntary license.

Though the Controller recognized Natco Pharma's weak application attempt, the compulsory license was still awarded to them. This situation makes clear that the Controller and the IPAB are extremely favorable towards the applicant and sets a precedent about how easily a company may obtain a compulsory license in the future. Without extra safeguards to protect companies from a compulsory license through a more stringent voluntary license application process, MNCs could become an easy target and be incentivized to withdraw their business from India entirely.<sup>29</sup>

Despite the court's leanings, compulsory licenses are far from normal. India's patent laws do not immediately favor generic companies over patent holders. An Indian company, BDR Pharmaceuticals, sought a compulsory license by citing a provision in India's Patent Act which tries to prevent "evergreening" as the basis for its compulsory license application. Evergreening is an attempt to approve a new patent over a seemingly new chemical compound or active ingredient thought to be "discovered" in a drug wherein reality it is only an attempt to extend the patent of the original drug.<sup>30</sup> Bristol-Myers Squibb, the patent holder, won the verdict from Delhi's High Court to uphold its patent on the leukemia drug, Sprycel (dasatinib).<sup>31</sup>

BDR violated the TRIPS requirement of first applying for a voluntary license—a requirement India knows must be upheld to ensure future compulsory licensing. After examining the case, the Delhi High Court rejected BDR's right to a compulsory license because evergreening violations are not a standard for upholding a compulsory license.

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29 Anu Singhai & Manu Singhai, *A Study of Natco v. Bayer Case: Its Effect and Current Situation*, 2 MIT INT'L J. PHARMCEUTICAL SCI. 21, 21-23 (2016) [https://www.mitpublications.org/yellow\\_images/20182-article-4.pdf](https://www.mitpublications.org/yellow_images/20182-article-4.pdf).

30 Ruth Pollard, *Old Becomes New in the Evergreen World of Medical Money Miracles*, SYDNEY MORNING HERALD (AUSTL.) at A4 (Aug. 13, 2004), <https://www.smh.com.au/national/old-is-new-in-evergreen-world-of-medical-money-miracles-20040813-gdjjhh.html>.

31 Lane, *supra* note 16.

Evergreening is illegal in India, but that does not mean a company has made their drug unavailable, unaffordable, or unsupplied as addressed in section 84. The basis of BDR Pharmaceuticals' claim had no foundation. While India has strict laws to protect against MNCs taking advantage of its citizens, India does not ignore the law to allow a compulsory license whenever a corporation appears to be taking advantage of the population.<sup>32</sup> India has focused the rules regarding compulsory licensing around its citizens, ensuring that the basic right to healthcare is possible.

If BDR applied for a voluntary license it may have had reasonable grounds to pursue a compulsory license under section 84. BDR had submitted its price of \$116 per month for a patient in need of Sprycel for chronic myeloid leukemia. Bristol-Myers priced the drugs at \$2,383. Perhaps if BDR followed all the stipulated requirements, its chances of a compulsory license would have increased.

The government of India does not hand out compulsory licenses every time they are requested. Both of these case outcomes are decided in a court of law and reflect India's laws and rules. India desires to protect its citizens from corporations. Access to medicine still is a rampant problem.

Yet, the BDR case is a reminder that India does not forget its laws. Instead, it works through its legal framework to achieve greater medicine access. By using specific language, India has protected itself from MNC abuse and lack of access. Jordan and other similarly situated countries can improve their access by adding precise language to prevent exploitation.

#### IV. COMPULSORY LICENSING BY THE CENTRAL GOVERNMENT AND EXPORTATION WITH SECTION 92A

Compulsory licenses are also justified through section 92 of the 2005 Patent Act which allows India's central government to grant compulsory licenses whenever it is deemed extremely necessary.

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32 Ankit Rastogi, M/s. BDR Pharmaceuticals International Pvt. Ltd. v. M/s. Bristol Myers Squibb Co. (December 2013), <https://indiancaselaws.wordpress.com/2013/12/09/ms-bdr-pharmaceuticals-international-pvt-ltd-v-ms-bristol-myers-squibb-co/>.

This differs from section 84 which only allows compulsory licenses to be granted to a company who wants to manufacture the generic. A compulsory license is deemed necessary during:

- (a) a circumstance of national emergency,
- (b) a circumstance of extreme urgency, or
- (c) a case of public non-commercial use.<sup>33</sup>

Other countries under the TRIPS agreement are able to declare a national emergency to request compulsory licenses. The 2005 Patent Act allows India-based companies to receive compulsory licenses to manufacture and export a pharmaceutical to another nation with a national pharmaceutical emergency. Section 92(A) allowed this and was incorporated in the 2005 amendment of the Patent Act for the granting of pharmaceutical product exports in certain “exceptional” circumstances. Section 92(A) focuses on India’s right to manufacture and export patented pharmaceuticals to the licensee if the country cannot manufacture the product on its own and if the licensee country is addressing a public health concern.<sup>34</sup> The licensee must notify the WTO Council of their intention to import pharmaceutical products. If the country is a member of the WTO, it must grant a compulsory license for import of drugs.<sup>35</sup>

India’s section 92(A) states that India-based companies may allow “for the manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity to address public health needs.”<sup>36</sup> Section 92(A) facilitates compulsory licenses that grant India-based companies the right to manufacture and export a patented product to the licensee. India-based companies cannot sell the drug within India itself. Thailand,

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33 The Patents Act, Sec. 92 of 2005 <http://indiacode.nic.in>.

34 Mrinalini Gupta, *India: Compulsory licensing for three more patented cancer drugs*, MONDAQ (2013), <http://www.mondaq.com/india/x/227102/Patent/Compulsory+Licensing+For+Three+More+Patented+Cancer+Drugs>.

35 S. S. Rana & Co., *supra* note 13.

36 Konde, *supra* note 2, at 66-68.

Zimbabwe,<sup>37</sup> and South Africa are a few of the countries that use compulsory licenses to import generic pharmaceuticals from India.<sup>38</sup>

This section protects countries from a medicine crisis when patents or manufacturing sites are of concern. Countries have permission to import medicine from India through the Patent Act. However, without India's Section 92(A) exportation from India would not be possible. This section safeguards India-based companies' rights to manufacture and export drugs that other countries desperately need, even if the drug has not been made as a generic in India. Jordan has followed India's example and also allows exportation of drugs when a compulsory license is granted.<sup>39</sup>

## V. THE HERCLON CASE AND THE ISSUE OF BIOSIMILARS

In 2013, India's Department of Industrial Policy and Promotion announced its exploration of a proposal from the Health Ministry to issue a compulsory license for the cancer treating drug Herclon (trastuzumab).<sup>40</sup> Under section 92, the Health Ministry advocated compulsory licensing because Herclon cost \$1,050. The government felt that this disparity between price and affordability was a case of public non-commercial use under section 92(c).<sup>41</sup>

To prevent India from granting a compulsory license Roche Holdings did not seek a patent in India for Herclon. Instead, Roche Holding gained approval in India to manufacture a generic version of Herclon. Roche Holding approved Emcure Pharmaceutical Ltd. (Emcure), an India-based company, to manufacture and sell the generic version of Herclon, known as Biceltis.<sup>42</sup> Emcure and Roche

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37 Armouti *supra* note 14, at 402.

38 CPTECH, *Examples of Health-Related Compulsory Licences*, CPTECH (2015) <http://www.cptech.org/ip/health/cl/recent-examples.html>.

39 Armouti *supra* note 14, at 394.

40 Gupta, *supra* note 34.

41 Lane, *supra* note 16.

42 THE HINDU BUS. LINE, (2012) <https://www.thehindubusinessline.com/companies/emcure-to-make-market-roche-products/article20497435.ece1>.

Holding both sold the drug in India with different versions that were marketed and sold separately. Biceltis costs approximately \$800, \$250 less than the branded original. By allowing a generic version of its drug, Roche Holdings avoided a compulsory license. This effectively prevented a case of public non-commercial use based on the new more affordable price of the generic.<sup>43</sup>

However, without a patent Roche Holdings cannot prevent other companies from developing drugs that serve similar functions as Herclon. This complicates pharmaceutical access. The companies Biocon and Mylan developed a biosimilar—a different drug that is designed to accomplish the same function—to Herclon for roughly \$650. The lower price motivates many Indian citizens to buy the cheapest option. Yet, biosimilars are typically lower quality than the branded and generic drugs. Branded drugs are required to go through trials whereas biosimilars are not. Because India does not require biosimilars to be clinically tested, the only way to ensure the safety of the drug in India is when clinical testing is required for the drug to enter another country's market.<sup>44</sup>

The side effects of biosimilars that are not globalized remain unknown in addition to the drug's effectiveness and safety for humans. Without regulation, low-cost drugs will inevitably become low-quality drugs.<sup>45</sup> The market for generics must be carefully monitored so that quality of drugs does not decrease. The quality of medicine is just as important as access.<sup>46</sup> Because of this, India should consider a testing requirement on biosimilars.

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43 Kenan Machado, *Generic Herceptin Approved in India; India's Biocon to Market Generic Version of Breast-Cancer Drug*, WALL STREET J. (2013), <https://search.proquest.com/docview/1462049894/abstract/92B769B19F244A93PQ/1?accountid=4488>.

44 Gupta, *supra* note 34.

45 G. de L. Lopes, *Cost comparison and economic implications of commonly used originator and generic chemotherapy drugs in India*, 24 ANNALS OF ONCOLOGY 13, 13-16 (2013) (discussing bio-equivalence studies).

46 Machado, *supra* note 43.

## VI. WHAT INDIA PROTECTS INNOVATION: SECTION 107A(A)

Although biosimilars are a concern to the state's welfare, they also show India's ability to innovate. India protects innovation through the combined influence of compulsory licensing and section 107A(a) of the Patent Act—an exemption of a patentee's exclusive rights.

107A. Certain acts not to be considered as infringement -For the purposes of this Act, -

(a) any act of making, constructing, using or selling a patented invention solely for uses reasonably relating to the development and submission of information required under any law for the time being in force, in India, or in a country other than India, that regulates the manufacture, construction, use or sale of any product;

(b) importation of patented products by any person from a person who is duly authorized by the patentee to sell or distribute the product, shall not be considered as an infringement of patent rights.<sup>47</sup>

Compulsory licensing has the potential to harm innovation, but Section 107A(a) endeavors to further protect pharmaceutical innovation. This exemption incentivizes innovation by allowing generic producers to experiment with patented drugs and produce them in limited quantities for research to provide generics once the patent is expired. The exemption can be used before the patent expires and is designed to promote local R&D.

After being granted a compulsory license, Natco Pharma was barred from exporting Nexavar (sorafenat) to China's Hisun Pharmaceutical for regulatory approval by Chinese authorities. To gain approval, Hisun Pharmaceutical needed to carry out bioequivalence, a measure of how well two drugs can be used in the place of one another, and bioavailability, how effectively a dosage is dispersed to the body.

In March 2014, Bayer filed with the Delhi High Court to reject Natco Pharma's certificates for export because Bayer claimed Natco Pharma was infringing on its patent rights by exporting the drug for human clinical trials. Bayer argued the compulsory license did not permit Natco Pharma to export the drug. But the Delhi High Court allowed Natco to apply for exportation of the drug.<sup>48</sup>

The court held that exports and use of the patented product for submission was permitted by Section 107A(a) and justified by the compliance of laws outside of India. The judge expansively interpreted Section 107A(a) and held that the sale of patented products even outside India would fall within the scope of Section 107A(a), provided the sale is reasonably related to development and submission of information. The court ruled that because Natco exported the drugs for the purpose of obtaining regulatory approvals, it was permissible. The court reviewed the TRIPS agreement and Section 107A(a) with its 2005 amendment.<sup>49</sup>

Bayer appealed before the Hon'ble Division Bench and another judge interpreted Section 107A(a) even more expansively than the last holding saying the language of this provision allows patented inventions to be exported from India as long as they are for the development of innovating new pharmaceuticals required under any national laws that regulate its production.<sup>50</sup>

The judicial precedent of the case and Section 107A(a) provides a safe harbor provision to protect research and development that would otherwise be categorized as patent infringement. Researchers can now experiment with new variations on a drug to improve efficacy or attempt to create a new drug from a known active ingredient. Access to research of this type furthers novelty, innovation, and experimentation. This protection safeguards generics while also

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48 The Pharma Letter, *Bayer Cancer Drug Faces New Patent Problems In India* (Oct. 4, 2017), <https://www.thepharmaletter.com/article/bayer-cancer-drug-faces-new-nexavar-patent-problems-in-india>.

49 Anand K. Sharma & E. Robert Yoches, *U.S. Patent Litigation: A Primer For Indian Companies*, Finnegan (Apr. 2008), <https://www.finnegan.com/en/insights/u-s-patent-litigation-a-primer-forindian-companies.html>.

50 *Id.*

providing a legal platform to expand current medical knowledge. India promotes innovation through Section 107A(a). Jordan, a large drug manufacturer, can benefit from a similar clause protecting its right to innovate.

## VII. WHY INNOVATION AND COMPULSORY LICENSING MUST COEXIST

Compulsory licenses are allowed so that patent holders do not abuse their exclusive rights; thus, it protects LMI countries from companies that create monopolies on pharmaceuticals. Because the patent holder is often the only manufacturer of a drug with a very specific function other drugs cannot accomplish, pharmaceutical patent holders often find themselves with a monopoly on an irreplaceable drug. Only the corporation sells the drug and because the corporation has no competition it can price the drug however it wishes without competitors to keep price low. This is especially concerning to LMI countries where high prices can mean the difference between life and death.<sup>51</sup>

### A. *Western Concerns*

Compulsory licenses prevent exorbitantly high drug prices which helps protect poorer countries. Although now, poorer governments are concerned that granting compulsory licenses will make companies less likely to enter their markets. This concern is furthered by the U.S. Chamber of Commerce expressing its view of India's use of compulsory licenses:

An active compulsory licensing mechanism and a government bias towards its use is the most extreme option; it signals to innovative investors that patent rights are discretionary... Furthermore, pricing that does not properly value innovation has the impact of undermining and devaluing IP and access to innovation," adding that the organization would welcome an approach that is "predicated

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51 Armouti, *supra* note 14, at 396.

on consistency, transparency, predictability, and return of fair value for innovation.<sup>52</sup>

However, India's rejection of BDR Pharmaceuticals' compulsory licensing application shows that the government is consistent, transparent, and predictable in its compulsory license rulings.<sup>53</sup> India will not just give a compulsory license to any entity that applies for one. India's rulings show no bias toward compulsory licensing, but only that it will uphold its laws and protect access to medicine.

According to a Johns Hopkins study, potentially \$843 billion is saved each year in India by using generic substitutions. This research focuses on cost per patient, per cycle of the drug for India using generic substitutions for common cancer chemotherapy drugs. Paclitaxel (Taxol) is 23% of the original drug cost, docetaxel (Taxotere) is 24%, gemcitabine is 36%, oxaliplatin is 32%, and irinotecan is 8.9% the cost of the branded drug.<sup>54</sup> While this does not consider other countries who have benefitted from India's section 92(A), these numbers are a reminder that an increase in pharmaceutical access is a possibility for other diseases.

### *B. Indian Innovation and MNCs*

India pharmaceutical firms have been granted a large share of the Abbreviated New Drug Application (ANDA)—a request generic drugs must file to gain approvals in the U.S. before they are approved for the market. As of 2015, India's share was more than 40% of

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52 Press Trust of India, *India's Telecommunications Security Threat to WTO Compliance: US Chambers*, Business Standard (Feb. 13, 2018), [https://www.business-standard.com/article/economy-policy/india-s-telecommunications-security-threat-to-wto-compliance-us-chambers-118021300023\\_1.html](https://www.business-standard.com/article/economy-policy/india-s-telecommunications-security-threat-to-wto-compliance-us-chambers-118021300023_1.html).

53 The BDR Pharmaceutical case is discussed in part III.

54 Lopes, *supra* note 45, at 13-16.

ANDA.<sup>55</sup> India-based companies' ability to increase their market share in India shows that there has not been a decline in innovation within India. Compulsory licensing does not inhibit innovation as seen by India's market share of drugs. India's patent law focuses on the "prevention of abuse and protection of consumer interests."<sup>56</sup> The pre-TRIPS regime in India specialized in reverse engineering generic drugs. The manufacturing abilities of the old generics regime allows Indian pharmaceutical companies to increase production faster. This sturdy foundation in pharmaceuticals has increased FDA (US) approval rates of many Indian pharmaceutical companies.

Furthermore, patents provide incentives to invest in drug development. A major concern of the United States is compulsory licensing will stop corporations from recouping profits for R&D and production. India's generic regime has focused largely on a market to LMI countries where many MNCs have not bothered to tap the market. Often, this is because most people in these LMI countries cannot afford the exorbitant prices. By licensing to generic companies, a corporation can extend the reach of a drug and recoup profits from a royalty. It can negotiate its royalty rather than the typical 6% given without choice through a compulsory license. Voluntary licensing also prevents MNCs from having to build infrastructure in the area to manufacture pharmaceuticals.

Pharmaceutical prices in richer countries often tend to "subsidize" the price of drugs in LMI countries. The New York Times covered Gilead Science's application for tenofovir in India. The Times said tenofovir was sold for approximately \$5,500 in high-income countries. However, Gilead Science was selling tenofovir in LMI countries for approximately \$205. This suggests that some companies can keep prices low in LMI countries to match need and demand. It cannot be assumed that branded drugs will increase prices simply because they can. However, voluntary licensing can benefit

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55 Rakesh Basant & Shuchi Srinivasan, *Intellectual Property Protection In India And Implications For Health Innovation: Emerging Perspectives*, 3 DOVEPRESS, 57, 57-68 (2016), <https://www.dovepress.com/intellectual-property-protection-in-india-and-implications-for-health--peer-reviewed-fulltext-article-IEH>.

56 Nayak, *supra* note 20, at 53.

both companies within the nation, who earn a profit from manufacturing, and MNCs, who gain a royalty without providing for the cost of production.<sup>57</sup>

## VIII. CONCLUSION

Compulsory licensing in India increases access to medicines. Compatibility between rewarding innovation and providing much needed access is possible with compromise. If other LMI countries decide to use compulsory licenses, they should use India's Patent Act as a model to ensure protection to the patent holder while giving the country's government the ability to prove whether compulsory licenses are a valid course of action. As a model, India must work to require a stricter application process for voluntary licensing before a compulsory license may be approved by the government. It must also become strict on biosimilars and the quality of cheaper drugs by requiring clinical testing. Because of India's exportation, other countries are increasingly allowing compulsory licenses. With India as a model, countries may adopt provisions in the future to protect compulsory licenses and grant them fairly.

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57 Halliburton, *supra* note 10, at 91-99.

