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**Of the Big Daddy, the Underdog, the Mother Hen, and the Scapegoats: Balancing Pharmaceutical Innovation and Access to Healthcare in the Enforcement of Compulsory Patent Licensing in India, its Compliance with TRIPS, and *Bayer v. Natco***

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## Abstract

*Most narratives on compulsory licensing of patented drugs typically present a chasm between two competing groups of stakeholders—on one end are the generic drug manufacturers who extol compulsory patent licensing as a viable means for facilitating the production of affordably priced life-saving generic drugs, and on the other end are the patented drug manufacturers who frown upon such generic drugs as mere copycats impinging innovation and development. Set in the backdrop of a curious paradox underlined by India’s ailing healthcare sector but a thriving pharmaceutical industry, this paper chronicles the country’s past and continuing experience with compulsory licensing of patented drugs. It presents a comprehensive discussion on the existing international and domestic statutory framework for the enforcement of compulsory patent licensing in India, and also determines the extent to which the domestic law of the country is compliant with the international law with regards to the compulsory licensing of patented drugs. It analyzes the key arguments and findings in *Bayer v. Natco*, a landmark precedent involving the issuance of India’s first compulsory license for Nexavar, a patented life-enhancing drug prescribed in the treatment of certain types of advanced cancers. In light of the conflicting stakes involved, this paper finally concludes by suggesting “middle path” strategies for balancing pharmaceutical innovation and access to healthcare in the enforcement of compulsory patent licensing in India.*

## I. Introduction

India ranks second amongst the most populous countries of the world,<sup>1</sup> with a socio-economic fabric acutely fraught with unequal distribution of healthcare resources.<sup>2</sup> Amongst the various impediments stifling the growth of India’s health sector is the rise in infectious and chronic diseases such as HIV/AIDS, dengue, and tuberculosis.<sup>3</sup> This proliferation of diseases is attributable to a host of

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1. paper would not have materialized without the support and encouragement of Kanishka Bhutani. The World Factbook, as of July 2014, records India’s population as 1, 236, 344, 631, placing it second in rank to China with a population of 1,355,692,576. *The World Factbook*, CENTRAL INTELLIGENCE AGENCY, <https://www.cia.gov/library/publications/the-world-factbook/rankorder/2119rank.html> (last visited Apr. 14, 2015).
  2. Ashok Vikhe Patil et al., *Current Health Scenario in Rural India*, 10 AUST. J. RURAL HEALTH 129, 129 (2002) (“About 75% of health infrastructure, medical man power and other health resources are concentrated in urban areas where 27% of the [Indian] population live.”).
  3. PRICEWATERHOUSECOOPERS, HEALTHCARE IN INDIA: EMERGING MARKET REPORT 2007 3 (2007), available at <http://storage.globalcitizen.net/data/topic/knowledge/uploads/2009121892144290.pdf> (“[S]ome communicable diseases once thought to be under control, such as dengue fever, viral hepatitis, tuberculosis, malaria, and pneumonia, have returned in force or have developed a stubborn resistance to drugs.”).

circumstances, viz. inequitable access to affordable healthcare,<sup>4</sup> poor living and conditions and lack of hygiene,<sup>5</sup> meagre supply of adequate vaccines,<sup>6</sup> shortage of doctors and other medical professionals,<sup>7</sup> and unhealthy food and lifestyle.<sup>8</sup> Despite the implementation of various government-funded health insurance programs and schemes,<sup>9</sup> the failure of the Indian government to finance adequate healthcare facilities is laid bare by its own official data on record,<sup>10</sup> which reveals that a large number of people in India fund their health needs through out-of-pocket expenses.<sup>11</sup>

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4. ISABELLE JOUMARD & ANKIT KUMAR, ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT, IMPROVING HEALTH OUTCOMES AND HEALTH CARE IN INDIA 9 tbl.1, ECO/WKP(2015)2 (Economics Dept Working Paper No. 1184, Jan. 8, 2015), available at <http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=ECO/WKP%282015%292&docLanguage=En> (reporting the findings of a 2014 survey conducted by the Credit Suisse Research Institute, which revealed that only 16% of the households in India have access to free or partially free public health care).
  5. *Id.* at 7 (“Most [Indian] households in rural areas do not defecate in a toilet or latrine . . . which leads to infant and child diseases (such as diarrhoea) and can account for much of the variation in average child height.”).
  6. *Id.* (“Vaccination rates for diphtheria, tetanus and pertussis, for measles and for hepatitis B are all much lower [in India] than in OECD and peer countries.”).
  7. *Id.* at 9 (reporting the findings of a 2012 survey conducted by the Ministry of Health & Family Welfare, which revealed that “10% of primary health care centres are without a doctor, 37% are without a laboratory technician and 25% without a pharmacist”).
  8. Nirmalya Dutta, *What Ails India’s Healthcare System*, THE HEALTHSITE (Aug. 18, 2012, 8:50 AM), <http://www.thehealthsite.com/diseases-conditions/what-ails-indias-healthcare-system/> (“While rural India battles third world diseases like malaria and dengue, rising urbanisation has led to the middle and upper classes being afflicted with ‘developed world’ lifestyle diseases like diabetes and obesity. A fast food culture, increased smoking and alcohol consumption has led to a rise in obesity related diseases like diabetes and cardiovascular ailments.”).
  9. See generally PUBLIC HEALTH FOUNDATION OF INDIA, A CRITICAL ASSESSMENT OF THE EXISTING HEALTH INSURANCE MODELS IN INDIA 23-39 (Jan. 31, 2011), (explaining the key features of the government-funded health insurance schemes in India).
  10. NATIONAL RURAL HEALTH MISSION, MISSION DOCUMENT 3 (2005-2012) (reporting that the Union (federal) government’s budgetary allocation for public healthcare was 1.3%, while the states’ budgetary allocation was 5.5% during 2005-12) [hereinafter MISSION DOCUMENT]. See also ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT, OECD HEALTH STATISTICS 2014: HOW DOES INDIA COMPARE? 1 (2014), <http://www.oecd.org/els/health-systems/Briefing-Note-INDIA-2014.pdf> (reporting that the “[t]otal health spending accounted for only 4.0% of GDP in India in 2012, less than half the OECD average of 9.3%,” and that “India ranks well below the OECD average in terms of health expenditure per capita, with spending of only USD 157 in 2012 . . . , compared with an OECD average of USD 3484”).
  11. MONEER ALAM & R.P. TYAGI, INSTITUTE OF ECONOMIC GROWTH, POPULATION RESEARCH CENTRE, A STUDY OF OUT OF POCKET HOUSEHOLD EXPENDITURE ON DRUGS AND MEDICAL SERVICES: AN EXPLORATORY ANALYSIS OF UP, RAJASTHAN AND DELHI XIX (Oct. 2009), available at [http://www.planningcommission.nic.in/reports/sereport/ser/ser\\_drug2910.pdf](http://www.planningcommission.nic.in/reports/sereport/ser/ser_drug2910.pdf) (“[A]lmost a fifth (18.5%) of the rural households and over a tenth (11.6%) of the urban households [in India] spend more than a quarter of their total consumption budget on health care.”). See also MISSION DOCUMENT, *supra* note 10, at 3 (reporting that people hospitalized in India during 2005-2012 spent around 58% of their total annual expenditure, and that over 40% of such people borrowed heavily or sold their assets to cover their medical expenses).

A rather conspicuous paradox to India's ailing state of healthcare is the country's fast-emerging pharmaceutical sector, which appears to be broadly segregated into major groups, namely (a) multinational pharmaceutical corporations or pharmaceutical MNCs, and (b) domestic pharmaceutical corporations.<sup>12</sup> While the domestic pharmaceutical corporations are "entirely India-owned,"<sup>13</sup> the pharmaceutical MNCs operate in India through subsidiaries and "conduct varying degrees of drug manufacturing" and research within the country.<sup>14</sup> A cottage industry of studies indicates that the domestic pharmaceutical corporations in India dominate in their presence over the pharmaceutical MNCs by commanding the lion's share of the country's pharmaceutical market.<sup>15</sup> These domestic pharmaceutical corporations can be further segmented into two sub-groups—one composed of corporations that engage in original research and development (R&D) along with the manufacturing of "generic drugs,"<sup>16</sup> and another consisting of small pharmaceutical companies that only reverse-engineer patented drugs or those that have gone off-patent.<sup>17</sup> Both the R&D-engaging domestic pharmaceutical corporations as well as those that solely manufacture generic drugs rely on compulsory licensing provisions under the India's existing domestic and international patent laws to manufacture and export generic copies of patented life-saving drugs at highly subsidized rates.<sup>18</sup>

This paper is a doctrinal study focusing on the enforcement of compulsory licensing of patented drugs in India. Part II opens with a monologue chronicling the country's past and continuing experience with the compulsory licensing of patented drugs, beginning from the days when India had developed notoriety as a "pirate" nation for copying drugs patented in other countries,<sup>19</sup> until today, when it

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12. 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, 532-42 (2007), available at <http://papers.ssrn.com/sol3/papers.cfm?abstract-id=923538>.
  13. *Id.* at 532.
  14. *Id.* at 533-34.
  15. See, e.g., ERNST & YOUNG, INDIA EMERGING: PHARMA'S EVOLVING BUSINESS MODELS 24 fig.19 (2011) (indicating that MNCs operating in India hold a modicum 28% share of the country's pharmaceutical market, while the remaining 72% share is held by the country's domestic pharmaceutical corporations).
  16. *Drugs@FDA Glossary of Terms*, U.S. FOOD AND DRUG ADMINISTRATION, <http://www.fda.gov/drugs/informationondrugs/ucm079436.htm> (last visited Apr. 14, 2015) ("A generic drug is the same as a brand name drug in dosage, safety, strength, how it is taken, quality, performance, and intended use. . . . By law, a generic drug product must contain the identical amounts of the same active ingredient(s) as the brand name product. Drug products evaluated as "therapeutically equivalent" can be expected to have equal effect and no difference when substituted for the brand name product.").
  17. Mueller, *supra* note 12, at 536-37.
  18. See discussion *infra* Part III.A-B (analyzing the statutory provisions for the enforcement of compulsory patent licensing under the existing domestic and international patent laws of India)
  19. Mueller, *supra* note 12, at 514.

has earned respect from the international community for becoming the “pharmacy of the developing world.”<sup>20</sup> Part III, thereafter, presents a comprehensive discussion on the international and domestic statutory—framework for the enforcement of compulsory patent licensing in India, and also determines the extent to which the domestic law of the country is compliant with the international law with regards to the compulsory licensing of patented drugs. Part IV attempts to collate the conflicting perspectives of the various stakeholders of compulsory patent licensing in the famous *Bayer v. Natco* case involving the issuance of India’s first compulsory license for a life-enhancing patented drug. Part V concludes by suggesting plausible “middle-path” strategies for the effective enforcement of compulsory licensing of patented drugs in India.

## II. Chronicling the History of Compulsory Licensing of Patented Drugs in India

### A. *Meaning and Essentials of a Compulsory Patent License*

A compulsory license is a government-enforced contract authorizing a generic drug manufacturer to manufacture and use a patented invention for a stipulated sum of compensation to the patentee of the invention.<sup>21</sup> Such government or third-party use of a patented invention is typically non-commercial in nature,<sup>22</sup> and is needed in order to address a national need or to remedy an anti-competitive practice.<sup>23</sup> Unlike a voluntary contract where there is consensus *ad idem*,<sup>24</sup> the terms and conditions of a compulsory license are not mutually agreed upon by the

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20. Simon Reid-Henry & Hans Lofgren, *Pharmaceutical Companies Putting Health of World’s Poor at Risk*, THE GUARDIAN (July 26, 2012, 2:00 EDT), <http://www.theguardian.co.uk/global-development/poverty-matters/2012/jul/26/pharmaceutical-companies-health-worlds-poor-risk>.

21. Srividhya Ragavan, *The Jekyll and Hyde Story of International Trade: The Supreme Court in PhRMA v. Walsh and the TRIPS Agreement*, 38 U. RICH. L. REV. 777, 782 (2004), available at <https://www.law.ou.edu/faculty/facfiles/Ragavan-Final-Richmond.pdf> (“Compulsory licenses [are defined] as involuntary contract[s] between a willing buyer and an unwilling seller imposed and enforced by the state.”) (internal quotation marks omitted). See also Colleen Chien, *Cheap Drugs at What Price to Innovation: Does the Compulsory Licensing of Pharmaceuticals Hurt Innovation*, 18 BERKELEY TECH. L.J. 853, 857-58 (2003) (“Compulsory Licenses are generally defined as authorizations permitting a third party to make, use, or sell a patented invention without the patent owner’s consent.”) (internal quotation marks omitted).

22. For a discussion on the non-commercial use of patented drugs through compulsory licensing, see generally Pier DeRoo, *Public Non-Commercial Use’ Compulsory Licensing for Pharmaceutical Drugs in Government Health Care Programs*, 32 MICH. J. INT’L. L. 347 (2011), available at <http://repository.law.umich.edu/mjil/vol32/iss2/3/>.

23. Chien, *supra* note 21, at 859 (“While specific provisions vary, compulsory licenses are generally authorized in the event of undesirable behavior by the patentee, such as anti-competitive, non-working, or blocking behaviour; in the event of ‘public need,’ such as government infringement or national emergency; or in the context of food and drugs.”).

24. JAN M. SMITS, CONTRACT LAW: A COMPARATIVE INTRODUCTION 63 (2014).

licensor and the licensee, but are imposed on them by the government.<sup>25</sup> Further, the government that grants a compulsory license can also revoke or terminate it if the circumstances that led to the issuance of such a license cease to exist.<sup>26</sup>

### ***B. Historical Overview of Compulsory Patent Licensing in India***

In 1947, when India transitioned from an English colony to a sovereign democracy, the country's patent regime continued to be governed by the British-enacted Indian Patents and Designs Act of 1911,<sup>27</sup> which permitted the patenting of pharmaceutical products.<sup>28</sup> This, resultantly, barred the manufacturing of generic copies of patented drugs in India. The availability and supply of patented drugs, therefore, was largely controlled by pharmaceutical MNCs, who mostly imported them into India and sold them locally at exorbitant prices.<sup>29</sup> The unreasonably high pricing of patented drugs made them inaccessible to most in India, thus precipitating the need for providing a legitimate means for domestic pharmaceutical corporations to manufacture and sell generic copies of patented drugs at affordable prices within the country.<sup>30</sup>

The Government of India, by a resolution dated January 10, 1948, appointed Justice (Dr.) Bakshi Tek Chand, a retired judge of Lahore High Court, to chair the Patents Enquiry Committee (1948–50), whose report published in 1950 recommended provisions for enabling compulsory licensing “to counteract the misuse or abuse of patent monopolies in India.”<sup>31</sup> Based on the recommendations of this report, the Patents Act of 1911 was amended, first in 1950<sup>32</sup> and

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25. Cole M. Fauver, *Compulsory Patent Licensing in the United States: An Idea Whose Time Has Come*, 8 NW. J. INT'L L. & BUS. 666, 667 (1987-1988) (“In compulsory licensing situations a court dictates the terms of the license, and the licensor’s wishes may be ignored.”).
26. Jerome H. Reichman, *Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options*, 37 J. L. MED. & ETHICS 247, 252-53 (2009).
27. The Indian Patents and Designs Act, 1911, Act No. 2 of 1911, INDIA CODE (1911) available at <http://www.theindianlawyer.in/statutesnbareacts/acts/d42.html> [hereinafter Patents Act of 1911].
28. Mueller, *supra* note 12, at 508.
29. *Id.* at 509-10. See also Srividhya Ragavan, *Of the Unequals of the Uruguay Round*, 10 MARQ. INTELL. PROP. L. REV. 273, 280 (2006) (citing the findings of a 1961 U.S. Senate Committee report to emphasize that “Indian drug prices ranked among the highest in the world”).
30. Mueller, *supra* note 12, at 510.
31. SHRI JUSTICE N. RAJAGOPALA AYYANGAR, REPORT ON THE REVISION OF THE PATENTS LAW 3 (Sept. 1959), available at <http://www.scribd.com/doc/201678355/Ayyangar-Committee-Report#scribd> [hereinafter AYYANGAR REPORT].
32. Mueller, *supra* note 12, at 511. See also THE PATENT OFFICE, INDIA, DRAFT MANUAL OF PATENT PRACTICE AND PROCEDURE 9 (3rd ed. 2008), [hereinafter DRAFT MPP]. Pursuant to the 1950 amendment to the Patents Act of 1911, an application for a compulsory patent license could be filed on the following grounds, namely: (a) that the patented invention was not being commercially worked to its fullest extent in India; (b) that the demand for the patented invention in India was not being met to an adequate extent or on reasonable terms; (c) that the importation of the patented invention was hindering its commercial working in India; (d) that the refusal of the

subsequently in 1952,<sup>33</sup> to incorporate a framework for enforcing compulsory patent licensing in India.<sup>34</sup> Despite the incorporation of compulsory patent licensing in the Patents Act of 1911, these provisions were rarely invoked due to the adversarial nature and high cost of litigation involved in deciding compulsory patent license applications.<sup>35</sup>

As the compulsory patent licensing provisions under the Patents Act of 1911 were rarely invoked, a need was felt to craft a more robust patent law system in the country. Towards this end, in 1957, the Government of India appointed Justice N. Rajagopala Ayyangar, the then sitting judge of the Madras High Court, to chair

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patentee of the patented invention to voluntarily license his invention were hindering its commercial or industrial working in India; (e) that a market for the export of the patented invention manufactured in India was not being supplied; (f) that the working of any other patented invention that substantially contributed to the establishment or development of commercial or industrial activities in India was being unfairly prejudiced; and (g) that the conditions imposed by a patentee while licensing his patented invention were unfairly prejudicing the establishment or development of commercial or industrial activities in India. *Id.*

33. Mueller, *supra* note 12, at 511. *See also* DRAFT MPP, *supra* note 32, at 9-10 (reporting that the 1952 amendment to the Patents Act of 1911 resulted in providing a mechanism for issuing compulsory patent licenses for food and medicines, insecticide, germicide or fungicide, or surgical or curative devices, and further, that such compulsory licenses could also be issued upon a notification by the Central (federal) Government in India).
34. Aside from the 1950 and 1952 amendments to the Patents Act of 1911, the recommendations of the Tek Chand Committee Report were also instrumental in the introduction of a patent reforms bill in the Parliament (India's federal legislature) in 1953. This bill, however, lapsed due the dissolution of one of the houses of the Parliament. DRAFT MPP, *supra* note 32, at 10.
35. *See* Mueller, *supra* note 12, at 511 (explaining that compulsory licenses under the Patents Act of 1911 were "rarely sought" because "patent owners retained the right to oppose the grant of such licenses and to appeal any such grants"). *See also* SUDIP CHAUDHURI, INDIAN INSTITUTE OF MANAGEMENT CALCUTTA, TRIPS AND CHANGES IN PHARMACEUTICAL PATENT REGIME IN INDIA 29 (Working Paper No. 535, Jan. 2005) (documenting the empirical findings of an earlier study conducted by the author in 1984, which revealed that due to "the hazards of obtaining a compulsory license," including "legal battles," only five compulsory license applications were submitted until 1970, of which two were allowed, one was refused, and the remaining two were withdrawn). *See also* SHAMNAD BASHEER & MRINALINI KOCHUPILLAI, THE 'COMPULSORY LICENSE' REGIME IN INDIA: PAST, PRESENT AND FUTURE: A REPORT FOR THE JPO 1 (2005) (reporting without citation to authority two cases allowing the grant of a compulsory patent license under the Patents Act of 1911). One of the cases that allowed the compulsory license application was *Raptakos, Brett & Co. (P) Ltd. v. Bengel Laboratories Ltd.*, which was decided on July 28, 1950, and ruled, *inter alia*, that the patentee's anticipated reduction in the price of its patented drug was not a valid opposition, and therefore, not a sufficient ground for refusing the grant of compulsory license to the applicant, especially when such license was being sought by the applicant for making generic copies of the patentee's therapeutic drug available to the public at a reasonably affordable price. *Id.* at 40-41. The second case that allowed a compulsory license application was *NeoPharma Industries (P) Ltd. v. Parke Davis & Co.*, which was decided on November 23, 1965, and clarified, *inter alia*, that the admissibility requirements for an application filed under the Patents Act of 1911, seeking a compulsory license for a patented drug, did not require the applicant to make initial efforts towards obtaining a voluntary license from the patentee of the drug. *Id.* at 42-43.



the Patents Revision Committee (1957–59),<sup>36</sup> whose report published in 1959 proposed “radical modifications” that went on to “form the backbone of the Indian patent system.”<sup>37</sup> Notably, the Ayyangar Report premised its “radical modifications” on the following “three-pronged strategy”: *first*, identifying the types of inventions for which patent protection should be available; *second*, determining either to prohibit the granting of Indian patents to foreign entities or to require the working of such patents in India; and *third*, determining whether or not to withstand international pressures on India to join the prevailing international intellectual property conventions.<sup>38</sup> The Ayyangar Report’s far-reaching modifications led to the enactment of the Patents Act of 1970,<sup>39</sup> which thereby repealed the Patents Act of 1911.<sup>40</sup>

The most notable features of the Patents Act of 1970 were its provisions revoking the patentability of pharmaceutical products in India.<sup>41</sup> Section 5 of the Patents Act of 1970, while prohibiting patents on “substances intended for use, or capable of being used, as food or as medicine or drug,”<sup>42</sup> permitted patents on processes for making pharmaceutical compounds.<sup>43</sup> As the Patents Act of 1970

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36. AYYANGAR REPORT, *supra* note 31, at 4. *See also* JAKKRIT KUANPOTH, PATENT RIGHTS IN PHARMACEUTICALS IN DEVELOPING COUNTRIES: MAJOR CHALLENGES FOR THE FUTURE 46 (2010).
37. Mueller, *supra* note 12, at 511-12 (explaining that the Ayyangar Report’s proposed “radical modifications” to then existing patent laws of India were aimed towards accommodating the nation’s “ fledgling technological advancement and industrialization, the need to encourage and reward inventors, and the increasing number of Indian research institutes and emphasis on technical education ”). *See also* Ragavan, *supra* note 29, at 281 n.53 (“The Ayyangar Report, as modified by the Report of the Joint Committee of Parliament in 1966, forms the backbone of the Indian patent system.”). *See generally* AYYANGAR REPORT, *supra* note 31, at 1-354.
38. Mueller, *supra* note 12, at 512.
39. The Patents Act, 1970, No. 39 of 1970, INDIA CODE (1970) [hereinafter Patents Act of 1970].
40. *Id.* § 162(1) (“The Indian Patents and Designs Act, 1911, in so far as it relates to patents, is hereby repealed . . .”).
41. Mueller, *supra* note 12, at 512. *See also* Linda L. Lee, *Trials and TRIPS-ulations: Indian Patent Law and Novartis AG v. Union of India*, 23 BERKELEY TECH. L.J. 281, 290-91 (2008). *See also* Ragavan, *supra* note 29, at 285 (explaining that the Ayyangar Committee’s proposed modification to revoke the patentability of food and pharmaceuticals, which was eventually incorporated into the Patents Act of 1970, was justified because vesting product patents in food and pharmaceuticals could deny vast sections of India’s population access to such products, thereby violating their constitutional right to life and good health).
42. Patents Act of 1970, *supra* note 39, §§ 5(a)-(b). Please note that section 5 was eventually omitted when the Patents Act of 1970 was amended in 2005 to enable the patenting of pharmaceutical products in India. *See infra* note 60 and accompanying text.
43. *See id.* § 5(b) (“[N]o patent shall be granted in respect of claims for the substances [intended for use, or capable of being used, as food or as medicine or drug] . . . , but *claims for the methods or processes of manufacture shall be patentable.*”) (emphasis added). *See also* Mueller, *supra* note 12, at 513 (“The Patents Act, 1970, also included expansive compulsory licensing provisions, such that patented processes for manufacturing substances capable of being used as medicine or food were deemed automatically endorsed with the designation licenses of right.”) (internal quotation marks omitted). *See id.* at 513 n.114 (citing examples of patented processes that were deemed to be endorsed as “licenses of right,” such as *Imperial Chem. Indus. Ltd. v. Controller Gen. of Patents*,

expressly restricted pharmaceutical products from being patented, the years that followed saw an acute proliferation of domestic pharmaceutical corporations in India,<sup>44</sup> making the country a leading producer of low-cost generic drugs in the world.<sup>45</sup>

For more than two decades after the enactment of the Patents Act of 1970, India conscientiously refrained from swearing allegiance to the then prevailing international intellectual property (IP) instruments in order to ward off potentially huge IP costs that the developed countries of the world could impose on its domestic market.<sup>46</sup> In fact, during the first three years of the Uruguay Round of the General Agreement on Tariffs and Trade,<sup>47</sup> India stoutly opposed the inclusion of IP protection within the GATT framework.<sup>48</sup> Later, however, due to an economic slowdown in the late 1980s, India reversed its anti-IP stance.<sup>49</sup> Fearing trade barriers to its exports, withdrawal of textile tariff concessions, suspension of economic aid, etc., India signed the Trade-Related Aspects of

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1987 A.I.R. 77 (Calcutta H.C.), which affirmed the Controller of Patents' order deeming the patentee-appellant's patent—a catalyst useful in hydrocarbon reforming as well as a process for making the catalyst—to be subject to licensing of right).

44. See YUSUF K. HAMEID, INDIAN PHARMA INDUSTRY: DECADES OF STRUGGLE AND ACHIEVEMENT 5 (Apr. 2005) (observing that MNCs had controlled over 70% of the pharmaceutical market in India, but following the enactment of the Patents Act of 1970, the market share of MNCs fell below 23%). Notably, the lack of patent protection to pharmaceutical products resulted in pharmaceutical MNCs restricting their business in India. See Mueller, *supra* note 12, at 513-14 (“By fiscal year (FY) 1978-79, the number of foreign-owned patent applications filed in India had decreased to 1,010, less than one quarter of the 4,248 applications filed by non-Indians ten years prior in 1968.”).
45. Drug prices in India plummeted to an all-time low following the enactment of the Patents Act of 1970. Mueller, *supra* note 12, at 514 (“The eventual economic effect of the India Patents Act, 1970, was a dramatic increase in domestic generic drug manufacturing and a sharp decline in the price of medicines sold in India. Pharmaceutical products patented outside of India could be freely copied in India under the Act, so long as the process by which they were produced did not infringe an Indian process patent . . .”). See also *id.* at 515 (“For example, the price in 1998 of the Indian equivalent of ranitidine, the active ingredient in Glaxo’s Zantac anti-ulcer medicine, was over 100 times less than the price of Zantac on the U.S. market.”).
46. Mueller, *supra* note 12, at 512 (“By holding out against membership in the prevailing international IP conventions, India hoped to develop its economy independently without arm-twisting from developed nations.”) (internal quotation marks omitted).
47. General Agreement on Tariffs and Trade, Oct. 30, 1947, 61 Stat. A3, 55 U.N.T.S. 187 [hereinafter GATT]. The GATT began in 1947 with the objective of re-structuring and streamlining multi-lateral economic relations between its member countries. The Uruguay Round, formally launched in the September of 1986 at Punta del Este, Uruguay, was the 8th round of multi-trade negotiations conducted within the framework of the GATT, with the objective to enlarge the scope of trade negotiations to include areas such as IP and trade in services, and to reform trade in agriculture and textiles. For an overview of the Uruguay Round of the GATT and its implications for developing countries, see generally WAYNE SANDIFORD, GATT AND THE URUGUAY ROUND 1-8 (Eastern Caribbean Central Bank 1994).
48. Mueller, *supra* note 12, at 517.
49. *Id.* at 517-518.

Intellectual Property Rights (TRIPS) Agreement on April 15, 1994<sup>50</sup>, and subsequently, on January 1, 1995, it became a member of the World Trade Organization (WTO).<sup>51</sup>

Since India did not have a system of affording patent protection to pharmaceutical products at the time it joined the WTO, it was granted a ten year transition period—from January 1, 1995 to January 1, 2005—to bring its domestic intellectual property law in line with the TRIPS Agreement.<sup>52</sup> Consequently, the Patents Act of 1970 was amended in three phases: *first*, in 1999, to introduce a “mailbox facility”<sup>53</sup> and to allow for “exclusive marketing rights (EMRs);”<sup>54</sup> *second*, in 2002, to modify India’s domestic provisions on the enforcement of compulsory patent licensing,<sup>55</sup> to abolish the system of “licenses of rights,”<sup>56</sup> and to

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50. Agreement on Trade Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments – Results of the Uruguay Round, 1869 U.N.T.S. 299, 33 I.L.M. 81 (1994) [hereinafter TRIPS Agreement].
51. Mueller, *supra* note 12, at 518. For a cursory understanding the WTO and how it replaced the GATT as an international organization, see generally WORLD TRADE ORGANIZATION, INFORMATION AND EXTERNAL RELATIONS DIVISION, UNDERSTANDING THE WTO 9-21 (5th ed. 2015).
52. Mueller, *supra* note 12, at 518-19. See also *id.* at 518 (“India is viewed as the nation primarily responsible for the TRIPS’ multi-year transition periods, which the multinational pharmaceutical industry had vociferously opposed.”).
53. See The Patents (Amendment) Act, No. 17 of 1999, § 2, INDIA CODE (1999), available at [http://ipindia.nic.in/ipr/patent/patact\\_99.pdf](http://ipindia.nic.in/ipr/patent/patact_99.pdf) (inserting § 5(2) into the Patents Act of 1970 for introducing provisions with respect to the “mailbox facility”) [hereinafter Patents (Amendment) Act of 1999]. The “mailbox facility” was a stop-gap arrangement wherein each pharmaceutical product patent application that was filed in India during the ten year transitional period afforded under the TRIPS Agreement—from January 1, 1995 to January 1, 2005—was put into a symbolic “black box” and assigned a filing date. See Mueller, *supra* note 12, at 519-22. Thus, as pharmaceutical product patenting was not in force during India’s transitional period between 1995 and 2005, the mailbox facility provided a “pipeline protection” of sorts to pharmaceutical product patent applications that were filed but could not be taken up for examination during this period. See *id.* at 519-20.
54. Patents (Amendment) Act of 1999, *supra* note 53, § 3 (inserting Chapter IVA into the Patents Act of 1970, containing provisions with respect to exclusive marketing rights). A select category of mailbox applicants, who met the requirements of § 24(B)(1) of the Patents (Amendment) Act of 1999, qualified for the grant of exclusive marketing rights (EMRs). See Mueller, *supra* note 12, at 525. An EMR, if conferred, afforded the mailbox applicant an exclusive right to sell or distribute his invention in India for a period of five years from the date on which such right was conferred until such time the mailbox application was allowed and the patent was granted, or until the mailbox application was finally rejected, whichever was earlier. *Id.*
55. The Patents (Amendment) Act, No. 38 of 2002, § 39, INDIA CODE (2002), available at <http://ipindia.nic.in/ipr/patent/patentg.pdf> (modifying Chapter XVI of the Patents Act of 1970 to introduce more grounds for enforcing compulsory patent licensing) [hereinafter Patents (Amendment) Act of 2002]. Pursuant to section 39 of the Patents (Amendment) Act of 2002, the following three grounds for issuing a compulsory license under the Patents Act of 1970 were introduced, namely: (a) to prevent the abuse of patent rights resulting from the non-working of a patent, (b) to address cases of national emergency or extreme urgency, or for the purposes of a public non-commercial use, and (c) to work any other related patent. *Id.* For a detailed analysis of these grounds and how they are currently enforced under the Patents Act of 1970, see discussion

formally recognize India's accession to United Nations' affiliate World Intellectual Property Organization (WIPO)<sup>57</sup> administered Paris Convention for the Protection of Industrial Property<sup>58</sup> as well as Patent Cooperation Treaty,<sup>59</sup> and *third*, in 2005, (a) to extend patent protection to products such as food, drugs, chemicals, and micro-organisms,<sup>60</sup> (b) to introduce compulsory license provisions for enabling the export of generic copies of pharmaceutical patented products to countries with no or insufficient manufacturing capacity for such products,<sup>61</sup> and (c) to introduce reforms to the "new invention," "inventive step," and "new use exclusion" criteria of patentability.<sup>62</sup> These three-phases of amendments to the Patents Act of 1970 paved the way for a piecemeal implementation of pharmaceutical product patenting in India, which consequently resulted in precluding generic drug manufacturers in the country from manufacturing generic copies of patented

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*infra* Part III.B.

56. Under section 87 of the Patents (Amendment) Act of 1999, process patents on food and medicines were automatically deemed to be endorsed as "licenses of right," thus making them available for compulsory licensing three years after the grant of the patent. However, pursuant to section 39 of the Patents (Amendment) Act of 2002, the system of "license of right" was abolished. See V.K. Unni, *Indian Patent Law and TRIPS: Redrawing the Flexibility Framework in the Context of Public Policy and Health*, 25 PAC. MCGEORGE GLOBAL BUS. & DEV. L.J. 323, 334 & n.117 (2012).
57. For an overview on the WIPO and how it operates in the international IP arena, see generally WIPO, About WIPO, <http://www.wipo.int/about-wipo/en/> (last visited June 30, 2015).
58. Paris Convention for the Protection of Industrial Property, July 14, 1967, 21 U.S.T. 1583, 828 U.N.T.S. 305, available at [http://www.wipo.int/treaties/en/ip/paris/trtdocs\\_wo020.html](http://www.wipo.int/treaties/en/ip/paris/trtdocs_wo020.html) [hereinafter Paris Convention]. The Paris Convention came into force in India on December 7, 1998, effective which date the country became obligated to comply with its principles concerning—(a) national treatment, which forbids discriminatory treatment of foreign patent applications), and (b) right of priority, which allows foreign applicants, who have previously filed patent applications in their home countries, with a twelve-month priority period to file a patent application for the same invention in India while retaining the benefit of their earlier home country filing date. See Mueller, *supra* note 12, at 527.
59. Patent Cooperation Treaty, June 19, 1970, 28 U.S.T. 7645, 1160 U.N.T.S. 231, available at <http://www.wipo.int/pct/en/texts/pdf/pct.pdf> [hereinafter PCT]. The PCT came into force in India on December 7, 1998, effective which date India began accepting national phase filings of international patent applications originally filed abroad. See Mueller, *supra* note 12, at 527.
60. The Patents (Amendment) Act, No. 15 of 2005, § 4, INDIA CODE (2005), available at [http://ipindia.nic.in/ipr/patent/patent\\_2005.pdf](http://ipindia.nic.in/ipr/patent/patent_2005.pdf) (omitting section 5 of the Patents Act of 1970, thus bringing an end to the restrictions on food and pharmaceutical product patenting in India)[hereinafter Patents (Amendment) Act of 2005].
61. *Id.* § 55 (inserting Section 92A into the Patents Act of 1970 for allowing, through compulsory patent licensing, the export of generic copies pharmaceutical patented products to countries with insufficient or no manufacturing capacity for such products). For understanding the requirements of filing a compulsory patent license application under section 92A of the Patents Act of 1970, see discussion *infra* Part III.B.1.d.
62. The Patents (Amendment) Act of 2005, *supra* note 60, §§ 2(f)-3(d) (modifying the definitions of "inventive step," "new invention," and "new use exclusion"). For a detailed analysis of the "new invention," "inventive step," and "new use exclusion" criteria of patentability under the Patents (Amendment) Act of 2005, see generally Shamnad Basheer, *India's Tryst with TRIPS: The Patents (Amendment) Act, 2005*, 1 THE INDIAN J.L. & TECH. 15, 20-25 (2005).

drugs, except by way of obtaining either a voluntary or a compulsory license in respect of such drugs.

### III. International and Domestic Statutory-Framework for the Enforcement of Compulsory Patent Licensing in India

#### A. Enforcement of Compulsory Licensing of Patented Drugs under the TRIPS Agreement

Section 5 of the TRIPS Agreement, *inter alia*, lays out a framework of substantive and procedural provisions for the enforcement of compulsory licensing.<sup>63</sup> Although the expression “compulsory license” is not used anywhere in section 5, its concept and application is implicit in the “limited exceptions” to patent protection under article 30,<sup>64</sup> and is further implicit in the caption of article 31 titled as “Other Use Without Authorization of the Right Holder.”<sup>65</sup> Article 31, at its very outset, states that a compulsory license for a patented invention may be issued to a private entity or the government, or to a third party authorized by the government.<sup>66</sup> A private entity intending to obtain a compulsory license should have “made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions,”<sup>67</sup> and such efforts should not have been successful within a reasonable period of time.<sup>68</sup> Notably, the requirement for a compulsory license applicant to make initial efforts towards obtaining a voluntary license from the patentee of an invention is dispensed with in situations of a national emergency or an extreme urgency,<sup>69</sup> or for purposes of a public non-commercial use,<sup>70</sup> or for remedying anti-competitive practices.<sup>71</sup> Moreover, a compulsory license may also be sought to work a related (second) patent, which cannot be worked without infringing an already existing (first) patent.<sup>72</sup>

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63. For a quick reference of the precise grounds on which a compulsory license may be granted under the TRIPS Agreement, see *infra* Annexure I.A.

64. Chien, *supra* note 21, at 870 (“Article 30 authorizes general exceptions to patent protection, *presumably including compulsory licensing*, but states that these exceptions must neither unreasonably conflict with a normal exploitation of the patent nor unreasonably prejudice the legitimate interests of the patent owner.”) (emphasis added) (internal quotation marks omitted).

65. *Id.* at 869-70 (stating that compulsory licensing is implicit in Article 31’s title, “Other Use Without Authorization of the Right Holder,” in that “[t]his provision permits WTO member countries to authorize compulsory licenses for use by the government or third parties subject to certain restrictions”).

66. See TRIPS Agreement, *supra* note 50, art. 31.

67. *Id.* art. 31(b).

68. *Id.*

69. *Id.*

70. *Id.*

71. *Id.* art. 31(k).

72. *Id.* art. 31(l). However, the grant of a compulsory license to work a (second) related patent is

Given that a compulsory license is contractual in nature, albeit imposed, it is enforced through a set of terms and conditions spelled out in Article 31,<sup>73</sup> which include: *first*, that the authorized use of a patented invention through compulsory licensing should be non-exclusive;<sup>74</sup> *second*, that such use should be non-assignable;<sup>75</sup> *third*, that such use should be predominantly for the supply of the licensee's domestic market,<sup>76</sup> except where such use is permitted to remedy an anti-competitive practice, in which case the licensee is permitted to manufacture and export generic copies of the patented invention to foreign markets;<sup>77</sup> *fourth*, that the patentee should be paid adequate remuneration, taking into account the economic value of the authorization;<sup>78</sup> *fifth*, that the scope and duration of the authorized use should be limited to the purpose for which it is authorized, particularly in the case of semi-conductor technology, where the licensee must work the patented invention only for a public non-commercial use or to remedy an anti-competitive practice;<sup>79</sup> and *sixth*, that such use shall be "terminated if and when the circumstances which led to it cease to exist and are unlikely to recur."<sup>80</sup> Further, article 31 directs the competent authority, deciding on the authorization of such use, to consider each request on its individual merits.<sup>81</sup> Finally, the decision of the competent authority, allowing or dismissing the authorization of such use, including its decision on the quantum of remuneration payable to the patentee, shall not be final but subject to judicial review by a higher authority.<sup>82</sup>

Notably, there are vital public health underpinnings to the enforcement of compulsory patent licensing, which come to the fore when articles 30 and 31 of the TRIPS Agreement, are read in conjunction with articles 8 and 27 therein, and are

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subject to the following three pre-conditions: *first*, that the related (second) patent shall involve an important technical advancement of considerable economic significance in relation to the already existing (first) patent; *second*, that the patentee of the already existing (first) patent shall be entitled, on reasonable terms, to a "cross-license" to use the related (second) patent; and *third*, that the compulsory license granted in respect of the already existing (first) patent shall be non-assignable except with the assignment of the related (second) patent. *Id.* art. 31(l)(i)-(iii).

73. For a quick reference of the precise terms and conditions subject to which a compulsory patent license may be granted under the TRIPS Agreement, see *infra* Annexure I.B.

74. TRIPS Agreement, *supra* note 50, art. 31(d).

75. *Id.* art. 31(e).

76. *Id.* art. 31(f).

77. *See id.* art. 31(k). Article 31(k), therefore, creates an exception to article 31(f), which otherwise limits the authorized use of a patented invention to predominantly supplying the domestic market. *See id.* art. 31(k) read with art. 31(f). *See also* Chien, *supra* note 21, at 870 ("[U]nless the patentee has engaged in anti-competitive behavior, the [authorized] use [of a patented invention through compulsory licensing] must predominantly supply the domestic market.").

78. *Id.* art. 31(h).

79. *Id.* art. 31(c).

80. *Id.* art. 31(g).

81. *Id.* art. 31(a).

82. *See id.* art. 31(i) read with art. 31(j).

further read with paragraphs 5(c) and 6 of the Doha Declaration on the TRIPS Agreement and Public Health.<sup>83</sup> While article 8 states that “[m]embers may . . . adopt measures necessary to protect public health,”<sup>84</sup> article 27 allows member countries to exclude from patentability such inventions that aid in the protection of public health.<sup>85</sup> Further, paragraph 5(c) of the Doha Declaration interprets “a national emergency or other circumstances of extreme urgency,” as stated in article 31(b) of the TRIPS Agreement, to be a public health crisis relating to “HIV/AIDS, tuberculosis, malaria and other epidemics.”<sup>86</sup> Furthermore, the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health<sup>87</sup> makes provision for allowing member countries to export a patented drug, which has been manufactured or imported under a compulsory license, to other countries with insufficient or no manufacturing capacities for such drug.<sup>88</sup> It would, therefore, not be anomalous to state that articles 30 and 31 of the

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83. World Trade Organization, Ministerial Declaration of 14 November 2001, WT/MIN(01)/DEC/2, 41 I.L.M. 746 (2002), available at [https://www.wto.org/english/thewto\\_e/minist\\_e/min01\\_e/mindecl\\_trips\\_e.pdf](https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.pdf) [hereinafter Doha Declaration].
84. TRIPS Agreement, *supra* note 50, art. 8.
85. *Id.* art. 27(2).
86. Doha Declaration, *supra* note 83, ¶ 5(c). Paragraph 5(c), by necessary implication, also states that its interpretation of what can represent “a national emergency or other circumstances of extreme urgency” is not exhaustive or restricted to situations of public health crisis alone, in that “[e]ach member [country] has the right to determine what [generally can] constitute[] a national emergency or other circumstances of extreme urgency” in situations under article 31(b) of the TRIPS Agreement that are outside the purview of public health. *See id.*
87. World Trade Organization, Decision of the General Council, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WT/L/540 (Aug. 30, 2003), available at [https://www.wto.org/english/tratop\\_e/trips\\_e/implem\\_para6\\_e.htm](https://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm) [hereinafter Implementation Decision].
88. *See id.* ¶ 6. The Implementation Decision creates an exception to article 31(f) of the TRIPS Agreement, which otherwise limits the authorized use of a patented invention to predominantly supplying the domestic market. *See id.* ¶ 6 read with ¶ 2. *See also* Bryan C. Mercurio, *TRIPS, Patents and Access to Life-Saving Drugs in the Developing World*, 8 MARQ. INTEL. PROP. L. REV. 211, 213-14 (2004), (“Paragraph 6 [of the Implementation Decision] . . . by creating an exception to [a]rticle 31(f) of the TRIPS Agreement . . . allows nations with insufficient or no manufacturing capabilities to override intellectual property protection and import generic copies of patented drugs to combat public health crisis.”). Further, the use of compulsory patent licensing in terms of the Implementation Decision is subject to certain obligations which both the importing member and the exporting member must meet. Such obligations include, among others, that the importing member must make a notification to the General Council in the following terms: (a) confirming that it has insufficient or no manufacturing capacity for the patented drug required to address its public health problem; (b) specifying the names and expected quantities of the patented drug it seeks to import in order to address its public health problem; and (c) that it has granted a compulsory license for the patented drug it seeks to import. *See* Implementation Decision, *supra* note 87, ¶ 2(a)(i)-(iii). In similar vein, the exporting member’s obligations include, among others, the following: (a) to specify the quantum of the generic copies of the patented drug that it would manufacture and export under the compulsory license; (b) to specially label or mark such copies of the drug; and (c) to notify, by way of a posting on its website or by any other means of publication, any information about the export of such copies of the patented drug. *See id.* ¶ 2(b)(i)-(iii).

TRIPS Agreement, when read with articles 8 and 27 therein, and when further read with paragraph 5(c) of the Doha Declaration and paragraph 6 of the Implementation Decision, have the effect of creating a binding bridge between the TRIPS Agreement and the concept of public health.<sup>89</sup>

## ***B. Enforcement of Compulsory Licensing of Patented Drugs under the Patents Act of 1970***

### ***1. Grounds for Issuing a Compulsory Patent License***

An application seeking a compulsory license for a patented drug must first be filed at the Office of the Controller-General of Patents, Designs and Trade Marks (hereinafter “Controller of Patents”), who is the statutory authority of first instance for the adjudication of proceedings pertaining to compulsory licensing in India.<sup>90</sup> Further, applicants seeking a compulsory patent license under the framework of the Patents Act of 1970 are typically India’s domestic pharmaceutical corporations, primarily engaged in the manufacturing of generic drugs, though an application for a compulsory patent license can also be filed by the Central (federal) Government of India.<sup>91</sup>

The various grounds on which a compulsory license for a patented drug may be granted are encapsulated in Chapter XVI, sections 82 through 94, of the Patents Act of 1970.<sup>92</sup> Broadly speaking, there are four such grounds: *first*, to prevent the abuse of patent rights;<sup>93</sup> *second*, to work a related patent;<sup>94</sup> *third*, to address cases

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89. See Chien, *supra* note 21, at 870-71 (“While [a]rticles 30 and 31 apply to patents in all fields, [a]rticles 8 and 27, as well as the Doha Declaration . . . , explicitly address the relationship between TRIPS and public health.”).

90. The Office of the Controller of Patents, a subordinate office under the Department of Industrial Policy and Promotion of the Union Ministry of Commerce and Industry, administers laws and regulations relating to intellectual property rights in India. See Shamnad Basheer, “Policy Style” Reasoning at the Indian Patent Office, 3 INTELL. PROP.Q., 309, 319 (2005). See also Mueller, *supra* note 12, at 615 (“The Controller [of Patents] has broad powers in deciding whether and on what terms to grant applications for compulsory licenses . . . . [I]n . . . [compulsory licensing] proceedings before him under the Patents Act [of 1970,] the Controller [of Patents] has certain powers of a civil court, including the power to summon and enforce the attendance of any person and to examine that person under oath, and to require the discovery and production of documents.”).

91. See Patents Act of 1970, *supra* note 39, § 2(1)(s) (stating that a “person”, seeking a compulsory patent license under the Patents Act of 1970, “includes the Government”). See also The Patents Rules, 2003, rule 96 (updated 2015), (specifying the procedural requirements for drafting a compulsory patent license application filed by the Central Government in India) [hereinafter Patents Rules of 2003].

92. See Patents Act of 1970, *supra* note 39, §§ 82-94. For a quick reference of the precise grounds on which a compulsory license may be granted under the Patents Act of 1970, see *infra* Annexure I.A.

93. See Patents Act of 1970, *supra* note 39, § 84(1).

94. *Id.* § 91(1).



of national emergency or extreme urgency, or for purposes of a public non-commercial use;<sup>95</sup> and *fourth*, to export a pharmaceutical patent to a country with no or insufficient manufacturing capacity.<sup>96</sup> These grounds are discussed in depth in the paragraphs below.

***a. To prevent the abuse of patent rights (Section 84):***

Section 84(1) of the Patents Act of 1970 enumerates three specific instances of abuse of pharmaceutical patent rights: *first*, that the reasonable requirements of the public with respect to the patented drug have not been satisfied;<sup>97</sup> *second*, that the patented drug is not available to the public at a reasonably affordable price,<sup>98</sup> and *third*, that the patented drug is not worked in the territory of India.<sup>99</sup>

Section 84(1)(a), when read with sections 84(4) and 84(7), enumerates the various circumstances where the reasonable requirements of the public with respect to a patented drug shall be deemed not to have been satisfied.<sup>100</sup> For instance, “the reasonable requirements of the public shall be deemed not to have been satisfied” if, on account of the refusal to grant a compulsory license, “an existing trade or industry or the development thereof or the establishment of any new trade or industry in India . . . is prejudiced,”<sup>101</sup> or “the demand for the patented article has not been met to an adequate extent or on reasonable terms,”<sup>102</sup> or “a market for export of the patented article manufactured in India is not being supplied or developed,”<sup>103</sup> or “the establishment or development of commercial activities in India is prejudiced.”<sup>104</sup> The reasonable requirements of the public shall further be deemed not to have been satisfied “if, by reason of conditions imposed by the patentee upon the grant of licenses under the patent or upon the purchase, hire or use of the patented article or process, . . . the establishment or development of any trade or industry in India, is prejudiced,”<sup>105</sup> or “if the patentee imposes a condition upon the grant of licenses under the patent to provide exclusive grant back, prevention to challenges to the validity of [the] patent or coercive package licensing.”<sup>106</sup> Furthermore, the reasonable requirements of the

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95. *Id.* § 92(1).  
 96. *Id.* § 92A(1).  
 97. *See id.* § 84(1)(a).  
 98. *See id.* § 84(1)(b).  
 99. *See id.* § 84(1)(c).  
 100. *See id.* § 84(7)(a)-(e).  
 101. *Id.* § 84(7)(a)(i).  
 102. *Id.* § 84(7)(a)(ii).  
 103. *Id.* § 84 (7)(a)(iii).  
 104. *Id.* § 84 (7)(a)(iv).  
 105. *Id.* § 84 (7)(b).  
 106. *Id.* § 84 (7)(c).

public shall be deemed not to have been satisfied if a patented article is not being worked in India on a commercial scale to an adequate extent or to its fullest extent that is reasonably practicable,<sup>107</sup> or if the working of the patented drug on a commercial scale in India is being hindered by the importation of the patented article from abroad by the patentee or his agents, or by persons directly indirectly purchasing from the patentee, or by third parties against whom the patentee has not enforced the patent.<sup>108</sup>

According to section 84(1)(b), a compulsory license can also be obtained to prevent the abuse of a patented drug if such drug is not available to the public at a reasonably affordable price.<sup>109</sup> Section 84 of the Patents Act of 1970 does not make specific the possible factors that the Controller of Patents must take into consideration while determining whether or not a patented drug is reasonably priced.<sup>110</sup> Be that as it may, a generic drug manufacturer seeking a compulsory license under section 84(1)(b) of the Patents Act of 1970 has the burden to *prima facie* establish that the patented drug is not reasonably priced;<sup>111</sup> for instance, by providing evidence of the drug prices charged by the patentee in India and then comparing those prices with the prices charged by the patentee for the same drug outside of India,<sup>112</sup> or by comparing those prices with the prices of the drug's non-patented substitutes available in India.<sup>113</sup>

According to section 84(1)(c), a compulsory license can be obtained to prevent the abuse of a patented drug if such drug has not been worked in India.<sup>114</sup> Although section 84(1)(c) does not define or explain what it means to “work a patent,” courts in India have broadly interpreted the “working of a patent in India” to mean that the patented invention is locally manufactured within the territory of India.<sup>115</sup> It is noteworthy that while considering whether or not a patent has been

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107. *Id.* § 84 (7)(d). For the meaning of the expression “work a patent,” see *infra* note 115 and accompanying text.

108. *See* Patents Act of 1970, *supra* note 39, § 84(7)(e)(i)-(iii). *Contra infra* note 116 and accompanying text (highlighting the prevalent judicial trend that considers a patented article imported from abroad to have been worked in India, provided that the patentee can reasonably justify the circumstances which prevented him from manufacturing the patented article locally within India).

109. *See* Patents Act of 1970, *supra* note 39, § 84 (1)(b).

110. Mueller, *supra* note 12, at 592.

111. *See* Patents Act of 1970, *supra* note 39, § 87 (1).

112. Mueller, *supra* note 12, at 593.

113. *Id.*

114. *See* Patents Act of 1970, *supra* note 39, § 84 (1)(c).

115. Bayer Corp. v. Union of India, Writ Petition No. 1323 of 2013, July 15, 2014 (Bombay H.C.), at 48, available at <http://bombayhighcourt.nic.in/generatenewauth.php?auth=cGF0aD0uL2RhdGEvanVkZ2VtZW50cy8yMDE0LyZmbmFtZT1PU1dQMTEyODEzLnBkZiZzbWZsYWc9TG==> (“[W]hen a patent holder is faced with an application for [c]ompulsory [l]icense, it is for the patent holder to show that the patented invention / drug is worked in the territory of India by manufacture or

worked in India, the importation of such patent is also permissible, provided the patentee can reasonably explain and justify the circumstances that prevented him from manufacturing it locally within the country.<sup>116</sup>

As part of the admissibility requirements, a compulsory patent license application under section 84 can be filed at any time after the expiration of three years from the date of the grant of the patent,<sup>117</sup> and after the applicant has made efforts to obtain a license from the patentee on reasonable terms and conditions, and that such efforts have not been successful within a reasonable period, not ordinarily exceeding six months.<sup>118</sup> However, the requirement for a compulsory license applicant to make initial efforts towards obtaining a voluntary license from a patentee is dispensed with “in case of national emergency or other circumstances of extreme urgency or in case of public non-commercial use or on establishment of a ground of anticompetitive practices adopted by the patentee.”<sup>119</sup> Notably, the specific circumstances resulting in a waiver on the requirement of making initial efforts towards obtaining a voluntary license, as outlined in the proviso clause to section 84(6)(iv) of the Patents Act of 1970, are consistent with articles 31(b) and 31(k) of the TRIPS Agreement.<sup>120</sup>

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otherwise.”) (emphasis added) [hereinafter *Bayer v. Union of India* (Decision of the Bombay High Court)].

116. *Id.* at 48-49 (“Manufactur[ing of a patent] . . . may not [always] be necessary to establish [the] working [of a patent] in India . . . [W]here a patent holder satisfies the authorities, the reason why the patented invention could not be manufactured in India [sic] then the patented invention can be considered as having been worked in the territory in India even by import.”). Notably, the importation of a patent, as opposed to its local manufacturing in India, may not necessarily be a viable option for “working the patent” from both business and public health standpoint. *See* G.B. Reddy & Harunrashid A. Kadri, *Local Working of Patents: Law and Implementation in India*, 18 J. INTELL. PROP. RTS. 15, 22 (2013) (“Local production [of a patent] ensures price reduction, increases supply and competition and . . . increases domestic expertise in the production of medicines for key local diseases, increases transfer of technology and knowledge, increases employment, opens a new export market and improves foreign exchange flows.”). Nonetheless, the local manufacturing of a patent is also not always feasible, especially when its importation may be a better option towards “working the patent” in India. *See id.* at 23 (“In particular cases, [the] bulk production of patented goods from an existing plant and importing the goods to the country of patent grant may be more convenient for the patentee, rather than to establish a new industrial unit. It saves the start-up costs, manpower, maintenance cost, administrative expenses and other infrastructural expenses, including electricity, water, etc.”). Therefore, while deciding whether a patentee should be permitted to work his patent in India through its importation, a “case-to-case” basis approach is appropriate with each case being decided on its own merits. *See Bayer Corp. v. Union of India* (Decision of the Bombay High Court), *supra* note 115, at 48.
117. Patents Act of 1970, *supra* note 39, § 84(1).
118. *Id.* § 84(6)(iv) read with Explanation Clause to § 84(6)(iv) (stating that “reasonable period” in section 84(6)(iv) “shall be construed as a period not ordinarily exceeding a period of six months”).
119. *Id.* Proviso Clause to § 84(6)(iv).
120. *See* discussion *supra* Part III.A (enumerating the specific circumstances stated in articles 31(b) and 31(k) of the TRIPS Agreement, which obviate a compulsory license applicant from making initial efforts towards obtaining a voluntary license from the patentee).

Once a compulsory patent license application under section 84 is admitted and published in the official journal by the Controller of Patents, the patentee is duly notified with a copy of such application, and is provided with a reasonable opportunity to file his opposition to such application in terms of the procedure laid down in section 87 of the Patents Act of 1970.<sup>121</sup> Further, once the compulsory license applicant is notified of the patentee's opposition to his application, and only after both the applicant and the patentee have been afforded an opportunity to be heard, that the Controller of Patents decides whether the compulsory license should be denied or granted.<sup>122</sup>

***b. To work a related patent (Section 91):***

Section 91 of the Patents Act of 1970 provides that “any person who has the right to work any other patented invention either as patentee or as licensee thereof, . . . may apply . . . [for a compulsory license in respect of an already existing patent] on the ground that he is prevented or hindered without such license from working the other invention efficiently or to the best advantage possible.”<sup>123</sup> This ground for issuing a compulsory license is invoked to “alleviate the situation of blocking of patents,” wherein a related (second) patent cannot be worked without infringing another's already-existing (first) patent.<sup>124</sup>

An application filed under section 91 for a compulsory license to work a related patent must meet the following two pre-conditions: *first*, that the applicant agrees to grant to the (first) patentee a “cross-license” of the related (second) patent under reasonable terms,<sup>125</sup> and *second*, that the applicant's patented invention (second patent) has made a “substantial contribution to the establishment or development of commercial or industrial activities” in India.<sup>126</sup> Once both pre-conditions have been met, the Controller of Patents may, at his discretion, grant a compulsory license for the first patent, and also grant a cross-license for the related (second)

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121. Patents Act of 1970, *supra* note 39, §§ 87(1)-87(2). *See also* Patents Rules of 2003, *supra* note 91, rule 98(1) (providing that the patentee shall file his notice of opposition within two months from the date on which the compulsory license application filed under section 84 is published in the official journal).

122. Patents Act of 1970, *supra* note 39, § 87(4). *See also* Patents Rules of 2003, *supra* note 91, rule 98(5) (providing that the Controller of Patents shall give the licensee and the patentee no less than ten days' notice of hearing on a compulsory license application filed under section 84).

123. Patents Act of 1970, *supra* note 39, § 91(1).

124. Mueller, *supra* note 12, at 605.

125. *See* Patents Act of 1970, *supra* note 39, § 91(2)(i). *See also* Mueller, *supra* note 12, at 605 (using the term “cross-license” in relation to the license granted to the (first) patentee to use the second (related) patent owned by a compulsory license applicant under section 91 of the Patents Act of 1970).

126. Patents Act of 1970, *supra* note 39, § 91(2)(ii).

patent, if such cross-license is requested by the first patentee.<sup>127</sup> It is noteworthy that both these pre-conditions, as stipulated in section 91(2) of the Patents Act of 1970, as well as the manner in which the Controller of Patents adjudicates upon these pre-conditions under section 91(3) therein, are consistent with article 31(l)(i)-(iii) of the TRIPS Agreement.<sup>128</sup> Notably, while an application seeking a compulsory patent license under section 84(1) of the Patents Act of 1970 can be filed only after three years have expired from the date of the grant of the patent,<sup>129</sup> section 91(1) does not create any such window period as it allows a compulsory license application seeking to work a related (second) patent to be filed at any time after the grant of the (first) patent.<sup>130</sup> Further, while sections 84 and 91 may be at variance with one another insofar as the window period for filing a compulsory patent license application is concerned, both of these provisions find a common ground in section 87 of the Patents Act of 1970. That is to say, the same procedural mechanism laid down under section 87, which affords the patentee with the opportunity to oppose compulsory license applications filed under section 84,<sup>131</sup> is also followed in the case of compulsory license applications filed under section 91.<sup>132</sup>

***c. To address cases of national emergency or extreme urgency, or for purposes of a public non-commercial use (Section 92):***

Section 92 of the Patents Act of 1970 provides that at any time after the grant of a patent for a drug, if the Central (federal) Government in India officially declares by way of a gazette notification that such patented drug is necessary to address a circumstance of national emergency or an extreme urgency, or for purposes of public non-commercial use, including a public health crisis relating to HIV/AIDS, tuberculosis, malaria, or other epidemics, the Controller of Patents shall, on an

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127. *See id.* § 91(3). *See also id.* Proviso Clause to § 91(3) (“[T]he license granted by the Controller [of Patents] shall be non-assignable except with the assignment of the respective patents.”).

128. *See supra* note 72 and accompanying text. *See also* Mueller, *supra* note 12, at 606 n.653 (explaining that such consistency between section 91(2) of the Patents Act of 1970 and article 31(l) of TRIPS Agreement “enable[s] innovators to adapt foreign inventions to local needs” (quoting Jerome H. Reichman, *Compulsory Licensing of Patented Inventions: Comparing United States Law and Practice with Options under the TRIPS Agreement*, at 43, 46 (Paper presented to the AALS Mid-Year Workshop on Intellectual Property, Vancouver, British Columbia, June 14-16, 2006)).

129. *See* Patents Act of 1970, *supra* note 39, § 84(1).

130. *Id.* § 91(1).

131. *See id.* § 84 read with *id.* § 87 (1)-(4).

132. Section 91(4) of the Patents Act of 1970 allows patentees to oppose compulsory license applications filed under section 91(1) by following the procedure laid out in section 87, which is the same procedure followed by patentees while opposing compulsory license applications filed under section 84. *See id.* § 91(4) read with *id.* § 87 (1)-(4).

application made at any time after the government's official notification, grant a compulsory license for the patented drug.<sup>133</sup> Notably, the grant of a compulsory license under section 92 of the Patents Act of 1970 is consistent with article 31(b) of the TRIPS Agreement read with paragraph 5(c) of the Doha Declaration.<sup>134</sup>

It may be relevant to note that section 92 is titled as "Special Provision for compulsory licenses on notifications by Central Government."<sup>135</sup> As explicit in this title, a government notification is the immediate precursor to filing an application seeking a compulsory license under section 92. Therefore, since the admissibility of an application filed under section 92 is singularly premised on a government notification declaring the need for a compulsory patent license to address a national emergency or an extreme urgency or for purposes of a public non-commercial use, it can reasonably be inferred that the applicant filing such application is dispensed with the requirement of making initial efforts towards obtaining a voluntary license from the patentee.<sup>136</sup> Notably, the waiver on the requirement to make initial efforts towards obtaining a voluntary license, implicit in section 92(1)(i) of the Patents Act of 1970, is consistent with the proviso clause to section 84(6)(iv) therein,<sup>137</sup> and is further consistent with article 31(b) of the TRIPS Agreement.<sup>138</sup>

Although section 92 generally affords a patentee with the opportunity to oppose an application seeking a compulsory license for his patented drug,<sup>139</sup> the opportunity for such an opposition is waived if the Controller of Patents is convinced that a waiver is necessary to expedite the grant of the compulsory license for addressing a circumstance of national emergency or an extreme urgency, or a case of public non-commercial use, including a public health crisis relating to HIV/AIDS, tuberculosis, malaria, or other epidemics.<sup>140</sup> While waiving the patentee's opportunity to oppose a compulsory license application filed under

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133. *See id.* § 92(1)(i) read with § 92(3).

134. *See* discussion *supra* Part III.A (noting that article 31(b) of the TRIPS Agreement, when read with paragraph 5(c) of the Doha Declaration, allows for the grant of a compulsory license to address a national emergency or circumstances of extreme urgency, including a public health crisis relating to HIV/AIDS, tuberculosis, malaria and other epidemics, or for purposes of a public non-commercial use).

135. Patents Act of 1970, *supra* note 39, § 92.

136. *See id.* § 92(1)(i).

137. *Id.* Proviso Clause to § 84(6)(iv) (stating that the requirement of a compulsory license applicant making initial efforts towards obtaining a voluntary license from the patentee "shall not be applicable in case of national emergency or other circumstances of extreme urgency or in case of public non-commercial use . . .").

138. *See* discussion *supra* Part III.A (enumerating the specific circumstances stated in article 31(b) of the TRIPS Agreement, which obviate a compulsory license applicant from making initial efforts towards obtaining a voluntary license from the patentee).

139. *See* Patents Act of 1970, *supra* note 39, § 92(2) read with §§ 87(1)-87(2).

140. *See id.* § 92(3).

section 92, the Controller of Patents should inform the patentee, “as soon as may be practicable,” of such waiver.”<sup>141</sup> Further, while fixing the terms and conditions of a compulsory license granted under section 92, the Controller of Patents shall ensure that generic copies of the patented drug are “available to the public at the lowest prices consistent with the patentees [sic] deriving a reasonable advantage from their patent rights.”<sup>142</sup>

***d. To export a pharmaceutical patent to a country with insufficient or no manufacturing capacity (Section 92A):***

Section 92A was incorporated into the Patents Act of 1970 in the year 2005<sup>143</sup> to bring it in sync with paragraph 6 of the Implementation Decision that allows countries with insufficient or no manufacturing capacities to import generic copies of patented drugs in the event of a public health crisis.<sup>144</sup> Following the text of paragraph 6 of the Implementation Decision, section 92A of the Patents Act of 1970 makes provision for the grant of a compulsory license for a patented drug, solely for manufacturing and exporting generic copies of such drug,<sup>145</sup> to address the public health problems of any country having insufficient or no manufacturing capacity for the patented drug.<sup>146</sup>

As a procedural requirement, a compulsory license application for a patented drug filed under section 92A may be allowed only if the country to which the export is being made has also granted a compulsory license for such drug, or has, by notification or otherwise, allowed the importation of such drug from India.<sup>147</sup> However, section 92A is silent on the precise quantum of the generic copies of a patented drug that a licensee is permitted to export through the means of a compulsory license granted under section 92, which thus brings it at variance with paragraph 2 of the Implementation Decision.<sup>148</sup>

It is noteworthy that section 92A is silent on whether a patentee must be afforded the opportunity to oppose a compulsory license application filed under this

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141. *Id.* Proviso Clause to § 92(3).

142. *See id.* § 92(1)(ii).

143. *See supra* note 61 and accompanying text.

144. *See* Implementation Decision, *supra* note 87, ¶ 6.

145. *See* Patents Act of 1970, *supra* note 39, § 92A(2).

146. *Id.* § 92A(1).

147. *Id.*

148. *Compare* Implementation Decision, *supra* note 87, ¶ 2, with Patents Act of 1970, *supra* note 39, § 92A. *See also supra* note 88 and accompanying text (outlining the obligations imposed on both the importing member as well as the exporting member, in terms of paragraph 2 of the Implementation Decision, which include, among others, a mutual obligation vested in both members to specify the names and expected quantities of the patented drug that the exporting member, by means of a compulsory license, needs to manufacture and export to the importing member with insufficient or no manufacturing capacity for such drug).

provision, or otherwise be heard on the matter.<sup>149</sup> The lack of such procedural mechanism, consequently, vests the Controller of Patents with a “virtually unfettered” discretion while deciding a section 92A compulsory license application,<sup>150</sup> thus bringing section 92A of the Patents Act of 1970 at variance with the other provisions therein, viz. sections 84, 91 and 92, which allow the patentee with an opportunity to oppose a compulsory license application.<sup>151</sup>

## **2. Terms and Conditions of a Compulsory Patent License**

Just like in any standard contract, the issuance of a compulsory license for a patented drug is subject to terms and conditions that are settled by the Controller of Patents at the time of granting the compulsory patent license.<sup>152</sup> These terms and conditions, as stipulated in section 90(1) of the Patents Act of 1970, include, *inter alia*, (i) that the licensee pays a reasonable sum of royalty and other remuneration to the patentee,<sup>153</sup> (ii) that the patented drug is worked to the fullest extent by the licensee and with a reasonable profit to him,<sup>154</sup> (iii) that the licensee sells the patented drug for which the license is granted at a reasonably affordable price,<sup>155</sup> (iv) that the compulsory license is non-exclusive,<sup>156</sup> (v) that the compulsory license is non-assignable,<sup>157</sup> and (vi) that the compulsory license is for the balance term of the patented drug, “unless a shorter term is consistent with

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149. Mueller, *supra* note 12, at 602.

150. *Id.* at 601.

151. *See id.* at 602.

152. *See* Patents Act of 1970, *supra* note 39, § 90 read with § 93 (“Any order for the grant of a (compulsory) license shall operate as if it were a deed granting a license executed by the patentee and all other necessary parties embodying the terms and conditions, if any, settled by the Controller.”). For a quick reference of the precise terms and conditions under which a compulsory patent license may be granted by the Controller of Patents under the Patents Act of 1970, see *infra* Annexure I.B.

153. While determining the quantum of “royalty and other remuneration” payable to the patentee, the Controller of Patents takes into consideration various relevant factors, viz. the nature of the patented drug, the expenditure incurred by the patentee in manufacturing or developing the drug, and the expenditure incurred by the patentee in obtaining a patent on the drug and for keeping such patent in force. *See* Patents Act of 1970, *supra* note 39, § 90 (1)(i).

154. *See id.* § 90 (1)(ii).

155. *See id.* § 90 (1)(iii).

156. *Id.* § 90 (1)(iv). *See also* Carlos M. Correa, *Can the TRIPS Agreement Foster Technology Transfer to Developing Countries?*, in INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME 227, 248-49 (Keith M. Maskus & Jerome H. Reichman eds., 2005) (explaining the term “non-exclusive” to mean that “the patent owner can continue to exploit . . . [his] invention and directly compete with the compulsory licensee, leveraging the advantages conferred by technical knowledge and the prestige of brand names”).

157. Patents Act of 1970, *supra* note 39, § 90 (1)(v). *See also* Correa, *supra* note 156, at 249 (explaining the term “non-assignable” to mean that “[t]he patent owner . . . retains the right to grant any voluntary licenses he wishes”).



public interest.”<sup>158</sup> Further, although a compulsory license for a patented drug is granted with the predominant purpose of supplying to the domestic market in India,<sup>159</sup> section 90(1) stipulates that generic copies of such drug may be allowed to be manufactured and exported to foreign markets under any of the following two circumstances: *first*, if the “market for export of the patented [drug] manufactured in India is not being supplied or developed;”<sup>160</sup> or *second*, if “the [compulsory] license is granted to remedy a practice determined after judicial or administrative process to be anti-competitive.”<sup>161</sup> Section 90(2) further stipulates that a compulsory license for a patented drug, upon being granted by the Controller of Patents, “shall [not] authorize the licensee to import the patented [drug] . . . or . . . [a drug] made by a patented process from abroad where such importation would, but for such authorization, constitute an infringement of the rights of the patentee.”<sup>162</sup> That is to say, the grant of a compulsory license for a patented drug shall not authorize the licensee to import generic copies of the patented drug from a country that does not have a compulsory license authorizing the export of generic copies of such drug.<sup>163</sup> However, the Central (federal) Government may, where it is of the opinion that public interest demands, direct the Controller of Patents to authorize the licensee of a compulsory license, to import generic copies of a patented drug, regardless of whether the country from which such import is being made has a compulsory license authorizing the export of generic copies of such drug.<sup>164</sup>

Notably, while section 90(1) sets out the terms and conditions that must be settled by the Controller of Patents specifically for granting a compulsory license to prevent abuse of patent rights (under section 84),<sup>165</sup> the same terms and conditions also apply when a compulsory license is granted to work a related patent (under section 91),<sup>166</sup> and when a compulsory patent license is granted to address cases of national emergency or extreme urgency, or for purposes of a public non-commercial use (under section 92).<sup>167</sup> It is, however, not clear if the terms and conditions of a

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158. See Patents Act of 1970, *supra* note 39, § 90 (1)(vi).

159. See *id.* § 90(1)(vii).

160. See *id.* § 90(1)(vii) read with § 84(7)(a)(iii). Further, unlike section 90(1)(vii) read with section 84(7)(a)(iii) of the Patents Act of 1970, there is no analogous provisions in Article 31 of the TRIPS Agreement that authorize generic drug manufacturers to export patented drugs in the event that the domestic markets for the export of such drugs is not being developed. Compare TRIPS Agreement, *supra* note 50, art. 31 (a)-(l), with Patents Act, 1970, *supra* note 39, § 90(1)(vii) read with § 84(7)(a)(iii).

161. *Id.* § 90(1)(ix).

162. See *id.* § 90(2).

163. See *id.*

164. See *id.* 90(3).

165. *Id.* § 90(1).

166. *Id.* § 91 (4).

167. *Id.* § 92 (2). Additionally, when a compulsory license is granted in circumstances of national

compulsory patent license, as set out in section 90(1), would apply when the Controller of Patents grants a compulsory license for a patented drug to enable generic copies of such drug to be manufactured and exported to countries with insufficient or no manufacturing capacity for the patented drug (under section 92A).<sup>168</sup> Be that as it may, by making provision for compulsory patent licensing to enable generic copies of a patented drug to be manufactured and exported to foreign markets outside of India, section 92A effectively creates an exception to section 90(1), which otherwise limits the use of a compulsory license for predominantly supplying to the domestic market in India.<sup>169</sup>

It may be relevant to note that the terms and conditions of a compulsory license for a patented drug, once settled by the Controller of Patents at the time of the grant of such license, are subject to a one-time revision under section 88(4) of the Patents Act of 1970.<sup>170</sup> As a procedural requirement, the licensee (holder of the compulsory license), seeking the revision of the terms and conditions of a compulsory license granted to him for a patented drug, should make an application for revision to the Controller of Patents, provided that such application is made at any time after the licensee has commercially worked the drug for at least twelve months, and on the ground that terms and conditions initially settled have proved to be so onerous that the licensee is unable to work the drug except at a loss.<sup>171</sup>

It may further be relevant to note that the Patents Act of 1970 does not explicitly provide any statutory remedies, viz. damages, specific performance, etc., that may be available if and when the terms and conditions of a compulsory patent license, as settled by the Controller of Patents at the time of its initial grant, are breached or frustrated by either contracting party (the licensee or the patentee) to such license. Notwithstanding the absence of specific provisions for remedying the breach of a compulsory patent license, the Controller of Patents may, upon an application made by a patentee or any person deriving title or interest in a patent, terminate a compulsory patent license issued for the patent, “if and when the

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emergency, extreme urgency, or for purposes of a public non-commercial use, the licensee shall make the patented drug available to the public at the lowest prices consistent with the patentee deriving a reasonable advantage from his patent rights. *Id.* § 92 (1)(ii).

168. Section 92A is silent on whether a compulsory license granted under its provisions is subject to the same terms and conditions, as set out in section 90, that apply to compulsory licenses granted under sections 84, 91 and 92, respectively, of the Patents Act of 1970. *Id.* § 92A.

169. *See id.* § 92A read with §§ 90(1)(vii),(ix).

170. *See id.* Proviso Clause to § 88(4).

171. *See id.* § 88(4). *See also* Patents Rules of 2003, *supra* note 91, rule 101(1)-(4) (providing that a licensee (holder of a compulsory license), whose application for a revision of the terms and conditions of the compulsory license has been admitted by the Controller of Patents for adjudication, shall serve a copy of such application to the patentee, who may file his notice of opposition to such application within one month from the date of such service, and also serve a copy of his notice of opposition to the licensee).

circumstances that give rise to the grant [of such license] no longer exist and such circumstances are unlikely to recur.”<sup>172</sup> While deciding an application for the termination of a compulsory patent license, the Controller of Patents shall ensure that the licensee (holder of the compulsory license) is afforded the right to object to such termination,<sup>173</sup> and shall also take into account that such licensee’s interest is not unduly prejudiced.<sup>174</sup> Notably, the circumstances under which an application seeking the termination of a compulsory patent license may be allowed, as outlined in section 94(1) the Patents Act of 1970, are consistent with the circumstances outlined in article 31(g) of the TRIPS Agreement.<sup>175</sup>

The legal validity of an order denying or granting a compulsory license for a patented drug, including the reasonableness of the terms and conditions of such license as settled by the Controller of Patents, may be challenged before the Intellectual Property Appellate Board (IPAB) by way of an appeal,<sup>176</sup> provided such appeal is made within three months from the date on which the compulsory license order is issued by the Controller of Patents, or within such further time as the IPAB, in its discretion, may allow,<sup>177</sup> subject to being “satisfied. . . that there . . .

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172. Patents Act of 1970, *supra* note 39, § 94(1).

173. *See id.* Proviso Clause to § 94(1). *See also* Patents Rules of 2003, *supra* note 91, rule 102(2)-(3) (providing that an applicant seeking the termination of a compulsory license shall serve a copy of such application to the licensee (holder of the compulsory license), who may file his objection to the application for termination within one month from the date of receipt of such application by him, and also serve a copy of his objection to the applicant).

174. Patents Act of 1970, *supra* note 39, § 94(2).

175. *See* discussion *supra* Part III.A (noting that article 31(g) of the TRIPS Agreement allows the termination of a compulsory patent “if and when the circumstances which led to . . . [the issuance of such license] cease to exist and are unlikely to recur”).

176. *See* Patents Act of 1970, *supra* note 39, § 117A(2). Section 117A(2), while categorically stating that an appeal shall lie to the IPAB against a compulsory license order issued under section 84 (to prevent the abuse of patent rights), or under section 91 (to work a related patent), or under section 92 (to address circumstances of national emergency or extreme urgency, or a case of public non-commercial use), does not mention whether an appeal shall also lie against any such order under issued section 92A (to permit the manufacturing and export of generic copies of a patented drug to countries with insufficient or no manufacturing capacity for such drug). This being the case, it can reasonably be inferred that compulsory license orders issued by the Controller of Patents under section 92A are final and non-appealable under the purview of the Patents Act of 1970. *See id.* Further, the use of the expression “any decision, order of the Controller of Patents” in section 117A(2), by necessary implication, allows an applicant, who is otherwise successful in obtaining a compulsory license, to appeal against any terms and conditions of the license, viz. a high quantum of royalty fixed by the Controller of Patents, etc., that may appear unfair or onerous to him while executing the compulsory license order at a reasonable profit. *See id.* Moreover, as an alternative to filing an appeal, such applicant who is successful in obtaining a compulsory license for a patented invention, may exercise the option of subjecting the terms and conditions of the license to a one-time revision by filing an application for revision to the Controller of Patents, provided that such application is filed at any time after the applicant has commercially worked the drug for at least twelve months, and on the ground that terms and conditions initially settled have proved to be so onerous that the he is unable to work the drug except at a loss. *Id.* § 88(4).

177. *Id.* § 117A(4).

[was] sufficient cause for not preferring the appeal within the prescribed time.”<sup>178</sup> The decision of the IPAB, though final under the Patents Act of 1970,<sup>179</sup> is subject to judicial review under the Constitution of India.<sup>180</sup> Notably, the provisions for challenging a compulsory license order issued by the Controller of Patents—both by way of an appeal to the IPAB under section 117A(2) of the Patents Act of 1970, as well as by way of judicial review under the Constitution of India—are consistent with articles 31(i) and 31(j) of the TRIPS Agreement.<sup>181</sup>

#### **IV. *Bayer v. Natco* and its Reverberations: A Cult Classic of the Big Daddy, the Underdog, the Mother Hen, and the Scapegoats of Compulsory Patent Licensing in India**

##### ***A. The Underdog Challenges the Status Quo: Procedural History of Natco’s Compulsory License Application***

Sorafenib Tosylate, the chemical name of a drug used in the treatment of advanced hepatocellular carcinoma (HCC)<sup>182</sup>, advanced renal cell carcinoma (RCC)<sup>183</sup> and differentiated thyroid carcinoma (DTC),<sup>184</sup> was invented by Bayer HealthCare Pharmaceuticals (hereinafter “Bayer”) and Onyx Pharmaceuticals, Inc. (hereinafter “Onyx”) under mutual collaboration and co-promotion

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178. The Patents (Appeals and Applications to the Intellectual Property Appellate Board) Rules, 2011, rule 3 (2011), *notified in* THE GAZETTE OF INDIA: EXTRAORDINARY, NOTIFICATION GSR NUMBER 209(E) 8, PART II-§ 3(i) (Mar. 11, 2011).
179. There is no provision for further appeal against a decision rendered by the IPAB under the Patents Act of 1970. *See* Patents Act of 1970, *supra* note 39, § 117B.
180. The constitutional validity of a decision rendered by the IPAB under the Patents Act of 1970 can be challenged by invoking the writ jurisdiction of the state High Courts under article 226 of the Constitution of India. *See* INDIA CONST. (1950) art. 226. In similar vein, the IPAB’s decision can also be challenged before the Supreme Court of India by invoking its writ jurisdiction under article 32 of the Constitution of India. *See* INDIA CONST. (1950) art. 32. *See also* Harshad Pathak, *The Jurisdictional Dilemma Surrounding the Intellectual Property Appellate Board*, 20 J. INTELL. PROP. RTS. 51, 54 (2015) (arguing that the exercise of judicial review by the state high courts and the Supreme Court, acting under their respective writ jurisdiction, is part of the “basic structure” of Constitution of India, and therefore, a tribunal established under ordinary legislations, such as the IPAB, cannot exercise its quasi-judicial or appellate functions in a manner so as to exclude the writ jurisdiction of the state high courts and the Supreme Court of India).
181. *See* discussion *supra* Part III.A (noting that article 31(i) of the TRIPS Agreement, when read with article 31(j) therein, states that “the decision of the competent authority, allowing or dismissing the authorization of such use, including its decision on the quantum of remuneration payable to the patentee, shall not be final but subject to judicial review by a higher authority”).
182. HCC, at its advanced stages, is a type of liver cancer that cannot be treated with surgery. NEXAVAR®, <http://www.nexavar-us.com/what-is-nexavar/?p=liver/> (select “What is NEXAVAR?” hyperlink) (last visited June 30, 2015).
183. RCC, at its advanced stages, is a type of kidney cancer that cannot be treated with surgery. *Id.*
184. DTC is a type of progressing thyroid cancer that can no longer be treated with radioactive iodine. *Id.*

agreements.<sup>185</sup> Bayer obtained the patent on Sorafenib Tosylate in India in 2008, and since then has been marketing the drug within the country under its worldwide brand name “Nexavar®.”<sup>186</sup> Bayer has been selling the drug in India at US \$5,608 per month’s dose,<sup>187</sup> which must be taken by the patient on a preventive basis throughout his lifetime to increase his life expectancy.<sup>188</sup>

Finding Nexavar to be exorbitantly priced for the average Indian consumer but therapeutically indispensable as a life-extending drug, Natco Pharma Ltd. (hereinafter “Natco”), a leading Indian pharmaceutical company, approached Bayer in 2010 for a voluntary license to manufacture and sell the drug in India.<sup>189</sup> Though its negotiations with Bayer did not materialize, Natco was successful in obtaining a regulatory approval in April 2011 from the Drug Controller General of India for marketing the generic version of Nexavar in the country.<sup>190</sup>

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185. *Therapies: Nexavar (Sorafenib) Tablets*, ONYX PHARM., <http://www.onyx.com/therapies/nexavar-sorafenib-tablets> (section titled “Partner Status”) (last visited June 30, 2015) (“Onyx and Bayer each fund 50 percent of the development costs for Nexavar worldwide, excluding Japan, where Bayer funds all product development. Onyx and Bayer co-promote Nexavar in the U.S. and share equally in any profits or losses. Outside of the U.S., Bayer has exclusive marketing rights and Onyx and Bayer share profits 50/50 globally, excluding Japan, where Bayer paid Onyx a one-time payment of \$160 million in 2011, as part of its expanded collaboration agreement.”).
186. Bayer filed its patent application for Nexavar in the United States on January 13, 1999, and followed it by filing its PCT International Application, bearing PCT/US00/000648, on January 12, 2000. On July 5, 2001, Bayer’s PCT application entered the national phase of registration in India. Bayer received all requisite regulatory approvals for importing and marketing Nexavar in India by January 2008, and finally a patent no. 215758 was granted to it on March 3, 2008. For a chronological overview of when and how Bayer obtained the patent on Nexavar, first in the United States and thereafter in India, see *Natco Pharma Ltd. v. Bayer Corp.*, C.L.A. No. 1 of 2011, Mar. 9, 2012 (Controller of Patents, Mumbai), pp 4-5 available at [http://www.ipindia.nic.in/ipoNew/compulsory\\_License\\_12032012.pdf](http://www.ipindia.nic.in/ipoNew/compulsory_License_12032012.pdf) (India.) [hereinafter, *Natco v. Bayer* (Decision of the Controller of Patents)]. See also Varun Chhonkar, *Nexavar: Compulsory License Will Severely Impact Global Pharma Companies*, PATENT CIRCLE (Aug. 10, 2011, 12:23 PM), <http://patentcircle.blogspot.com/2011/08/nexavar-compulsory-license-will.html> (last visited June 30, 2015) (noting that there were no “pre-grant oppositions” filed against Bayer’s patent application for Nexavar, and grant of the patent was published on March 28, 2008, which was followed by a “one year window period for post-grant opposition” that ended on March 28, 2009).
187. SAVITA GAUTAM & MEGHNA DASGUPTA, ECONOMIC AND SOCIAL COMMISSION FOR ASIA AND THE PACIFIC, *COMPULSORY LICENSING: INDIA’S MAIDEN EXPERIENCE 8* (ARTNeT Working Paper Series, No. 137, Nov. 2013, Bangkok), available at [artnet.unescap.org/pub/wp13713.pdf](http://artnet.unescap.org/pub/wp13713.pdf).
188. See Naval Satarawala Chopra & Dinoo Muthappa, *The Curious Case of Compulsory Licensing in India*, 8 COMPETITION L. INT’L ¶ 5 (2012), available at <http://awa2013.concurrences.com/business-articles-awards/article/the-curious-case-of-compulsory> (stating that “Nexavar is a life-enhancing and not a life-saving drug . . .”). See also Josep M. Llovet et al., *Sorafenib in Advanced Hepatocellular Carcinoma*, 4 N. ENGL. J. MED. 378, 378-83 (2008), available at (documenting a study conducted on 602 people suffering from inoperable liver cancer, wherein it was found that patients who received sorafenib, also known as Nexavar, lived forty-four per cent longer than those who did not receive Nexavar).
189. See *Natco v. Bayer* (Decision of the Controller of Patents), *supra* note 186, at 6 (documenting that Natco had “proposed to sell the drug at a price of Rs. 8800/- for one month therapy” as compared to Bayer’s price of about Rs. 2,80,428/-).
190. *Id.* at 5.

In order to thwart the launching of the generic version of Nexavar in India, Bayer arraigned Natco in a suit for patent infringement, which it filed in the High Court of Delhi on June 5, 2011.<sup>191</sup> As a counter-attack, Natco not only decided to defend the patent infringement suit,<sup>192</sup> but it went a step forward and filed an application before the Controller of Patents in Bombay on July 28, 2011, seeking a compulsory license to manufacture and market the generic version of Nexavar in India under section 84(1) of the Patents Act of 1970.<sup>193</sup> Notably, notwithstanding the pendency of Bayer's patent infringement suit before the High Court of Delhi, the Controller of Patents, by his order dated August 8, 2011, admitted Natco's compulsory license application for processing.<sup>194</sup>

Aggrieved, Bayer petitioned before the High Courts of Bombay and Delhi, respectively, alleging that Natco's compulsory license application had been erroneously admitted by the Controller of Patents on a mere *prima facie* view of the matter.<sup>195</sup> This admissibility issue, however, was rejected first by the High Court of Bombay, by its order dated November 11, 2011,<sup>196</sup> and subsequently by the High Court of Delhi, by its order dated November 16, 2011,<sup>197</sup> thereby forcing Bayer to withdraw its petitions from both the courts.

Having failed to prevent the processing of Natco's compulsory license application, Bayer was left with no choice but to contest the compulsory license proceedings before the Controller of Patents. Bayer, thus, opposed Natco's application for a compulsory license on, *inter alia*, two key grounds: *first*, that Natco did not take adequate steps to obtain a voluntary license from Bayer in respect of Nexavar in terms of section 84(1) of the Patents Act of 1970,<sup>198</sup> and *second*, that although Nexavar was not being locally manufactured in India, Bayer

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191. Bayer Corp. v. Natco Pharma Ltd., C.S. (O.S.) No. 1090/2011 (Delhi H.C.), *available at* [http://www.delhihighcourt.nic.in/dhc\\_case\\_status\\_oj\\_list.asp?pno=577484](http://www.delhihighcourt.nic.in/dhc_case_status_oj_list.asp?pno=577484) [hereinafter, Bayer v. Natco (Patent Infringement Suite Before the Delhi High Court)]. As of June 30, 2015, this case continues to be pending and all interlocutory orders passed so far in this matter can be referenced via the official website of the High Court of Delhi.

192. The various interlocutory orders passed so far in Bayer Corp. v. Natco Pharma Ltd., *id.*, indicate that Natco has been defending the patent infringement suit filed by Bayer since June 2011.

193. For accessing the officially published draft of Natco's compulsory license application filed before the Controller of Patents in Mumbai, see OFFICIAL JOURNAL OF THE PATENT OFFICE at pp. 13344-63 (Publication of the Patent Office, Issue No. 32/2011, Aug. 12, 2011), *available at* <https://docs.google.com/viewer?a=v&pid=sites&srcid=ZGVmYXVsdGRvbWFpbnczcGljeWlwZmlsZXN8Z3g6NDFlNjAxZDIyOTY0MjMyMg>.

194. Natco v. Bayer (Decision of the Controller of Patents), *supra* note 186, at 6-7.

195. *Id.* at 7.

196. Bayer Corp. v. Union of India, (2011) W.P. No. 2194/2011, ¶ 4 (Bombay H.C.), *available at* <http://bombayhighcourt.nic.in/adjournlist1.php>.

197. Bayer Corp. v. Union of India, (2011) W.P.(C) No. 8062/2011, ¶ 2 (Delhi H.C.), *available at* [http://delhihighcourt.nic.in/dhc\\_case\\_status\\_oj\\_list.asp?pno=600210](http://delhihighcourt.nic.in/dhc_case_status_oj_list.asp?pno=600210).

198. Natco v. Bayer (Decision of the Controller of Patents), *supra* note 186, at 9.

had “worked” the drug on a commercial scale in the country by importing it from contract manufacturers abroad.<sup>199</sup> However, the Controller of Patents did not find merit in Bayer’s opposition, reasoning that “mere importation cannot amount to working of a patented invention.”<sup>200</sup> Interpreting the expression “worked in the territory of India,” as stated in section 84(1)(c) of the Patents Act of 1970, to mean “*manufactured to a reasonable extent in India*,”<sup>201</sup> the Controller of Patents further observed that Bayer had failed to provide a reasonable explanation as to why it had failed to set up local manufacturing facilities for developing Nexavar in India despite having held an Indian patent on the drug since 2008.<sup>202</sup>

Finally, accepting Natco’s contention that the reasonable requirements of the public in India with respect to Nexavar had not been met<sup>203</sup>, and further, that the drug had not been marketed in the country at a reasonably affordable price,<sup>204</sup> the Controller of Patents allowed the compulsory license application, thereby directing Bayer to license the manufacturing of Nexavar to Natco for a royalty of 6% of the

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199. *Id.* at pp. 38-39.

200. *Id.* at 43.

201. *Id.* at 43-44 (“[A] combined reading of Section[s] 83(c) and (f) ... [of the Patents Act, 1970] ...” makes it clear that “a patentee is obliged to contribute towards the transfer and dissemination of technology ... so as to balance the rights with the obligations. A patentee can achieve this by either manufacturing the product in India or by granting a license to any other person for manufacturing in India.”). It is further noteworthy that the Controller of Patents read articles 27(1) of the TRIPS Agreement together with articles 5(A)(1) and 5(A)(2) of the Paris Convention to rationalize the legislative intent behind having “failure to work the patent” as a ground for issuing compulsory license under section 84(1) (c) of the Patents Act of 1970. *Id.* at 41-42 (“When the Article 27(1) of TRIPS Agreement is read with .... [articles 5(A)(1) and 5(A)(2)] of the Paris Convention, it follows that importation of a patented invention shall not result in forfeiture of a patent. However, a reasonable fetter on the patent rights in the form of a compulsory license is very well within the purview of the Paris Convention and TRIPS Agreement, when there is an abuse of patent rights. It is this flexibility ... [that has resulted in] the Parliament ... incorporating a provision [section 84(1)(c) of the Patents Act, 1970] for grant of compulsory license upon [a patentee’s] failure to work the invention within the territory of India.”).

202. *See id.* at 45.

203. *Id.* at 20-24. During the course of the compulsory license proceedings, Bayer submitted before the Controller of Patents that it had sold 593 boxes of Nexavar during 2011, though there was a requirement of 2,700 boxes that year to cater to around 8,842 patients requiring the drug in India. Based on these figures, the Controller estimated that Bayer did not supply Nexavar® to more than 200 patients during 2011, which was only a little above 2% of the eligible patients, thereby concluding that the reasonable requirements of the public with respect to the drug had not been met in India in terms of §84(1)(a) of the Patents Act of 1970. *Id.* at 22.

204. *Id.* at 24-36. During the course of the compulsory license proceedings, Bayer argued that the expression “reasonably affordable price,” as stated in §84(1)(b) of the Patents Act of 1970, should be construed not just in terms of the purchasing power of the public, but primarily in terms of the cost incurred by the patentee on R&D. The Controller of Patents, however, rejected this argument, stating that the expression “reasonably affordable price” must be construed predominantly with reference to the public. Further, the fact that Bayer had not met the reasonable requirements of the Indian public with respect to Nexavar could be explained on account of the drug not being sold at a reasonably affordable price. *Id.* at 34-36.

net sales of the drug payable on a quarterly basis.<sup>205</sup>

***B. The Big Daddy Strikes Back: Bayer's Appeal before the IPAB***

Aggrieved by the decision of the Controller of Patents, Bayer appealed against the compulsory license order issued by the Controller of Patents before the IPAB. Pending the disposal of its appeal, Bayer filed an interlocutory petition for a temporary stay on the compulsory license, which was dismissed by the IPAB on September 14, 2012.<sup>206</sup> On March 4, 2013, the IPAB dismissed Bayer's appeal, thus upholding the compulsory license granted by the Controller of Patents to Natco for manufacturing and marketing the generic version of Nexavar in India.<sup>207</sup>

Bayer attacked the compulsory order of the Controller of Patents before the IPAB by fielding a two-pronged appeal. The first prong of Bayer's appeal specifically alleged three procedural irregularities pertaining to the admissibility of the compulsory license application, asserting that the Controller of Patents erred in admitting the application. First, Bayer claimed that it was not given notice and an opportunity to be heard as required by section 87(1) of the Patents Act of 1970.<sup>208</sup> Second, the Controller of Patents allegedly erred by accepting that Natco had undertaken the required reasonable steps under section 84(6)(iv) to seek a voluntary license from Bayer for manufacturing and marketing Nexavar in India.<sup>209</sup> Third, Bayer claimed that the compulsory license application should have been rejected for want of documentary evidence corroborating Natco's interest in being issued the compulsory license.<sup>210</sup>

The second prong of Bayer's appeal specifically raised five issues on the substance and merits of the impugned compulsory license order. First, in ascertaining whether the reasonable requirements of the public with respect to Nexavar had been met in India, the Controller of Patents allegedly erred by failing to consider the supply of the generic version of the drug in the Indian market by another drug manufacturer, Cipla, as well as by Bayer's self-sponsored Patient Assistance Programme (PAP).<sup>211</sup> Second, Bayer asserted that in determining whether Nexavar was reasonably affordable to the general public in India, the

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205. *Id.* at 60-61.

206. Bayer Corp. v. Union of India, M.P. Nos. 74 to 76/2012 & 108/2012, OA/35/2012/PT/MUM, Sept. 14, 2012 (IPAB, Chennai).

207. Bayer Corp. v. Union of India, No. 45 of 2013, OA/35/2012/PT/MUM, Mar. 4, 2013 (IPAB, Chennai), available at <http://www.ipabindia.in/Pdfs/Order-45-2013.pdf> [hereinafter Bayer v. Natco (Decision of the IPAB, Chennai)].

208. *Id.* at 4.

209. *Id.* at 7.

210. *See id.* 4.

211. *Id.* at 4-5.



Controller of Patents erred by failing to take into account the cost of R&D incurred by Bayer in manufacturing the drug.<sup>212</sup> Third, given that Nexavar—a palliative drug with a relatively small patient base—required a longer time to make inroads into the Indian pharmaceutical market, Bayer alleged that it was unfairly denied adjournment or extension of time by the Controller of Patents to work the drug to its fullest extent in India.<sup>213</sup> Fourth, Bayer asserted that contrary to the Controller of Patents’ holding, local manufacturing of Nexavar was not necessary for the drug to have been “worked in the territory of India” under section 84(1)(c) of the Patents Act of 1970.<sup>214</sup> And fifth, Bayer contended that the Controller of Patents arbitrarily exercised his discretionary power, vested in him under section 90 of the Patents Act of 1970, by fixing the terms and conditions of the compulsory license, particularly with respect to the sum of royalty that Natco was directed to pay to Bayer.<sup>215</sup>

### ***C. The Mother Hen Prevails: Decision of the IPAB***

The IPAB, in a well-reasoned order dated March 4, 2013, dismissed Bayer’s appeal of the compulsory license order.<sup>216</sup> In the first leg of its decision, the IPAB rejected Bayer’s challenge to the compulsory license order on procedural issues, reasoning that—*first*, as no final determination of rights could be contemplated at the initial stage of admitting Natco compulsory license application, the Controller of Patents was required to make only a *prima facie* consideration of the matter in terms of section 87(1) of the Patents Act of 1970, which further dispensed him with the obligation to provide Bayer any notice or an opportunity to be heard;<sup>217</sup> *second*, a letter from Natco to Bayer dated December 6, 2010, and Bayer’s response dated December 27, 2010, appropriately suggested that Natco had made a genuine, though failed, effort at securing a voluntary license from Bayer as required by 84(6)(iv);<sup>218</sup> and *third*, given that the Controller of Patents had all necessary evidence on record before it decided the compulsory license application on its merits and that Bayer had been duly apprised of such evidence, it could not be said that Natco had lapsed in filing documentary evidence along with its application

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212. *See id.* at 8-9.

213. *See id.* at 4.

214. *Id.*

215. *See id.* at 5.

216. *Id.*

217. *See id.* at 5-7. Moreover, given that Bayer participated in all proceedings subsequent to filing its opposition to the compulsory license application, *ipso facto*, estopped it from challenging the compulsory license order for want of notice or an opportunity to be heard. *See id.* at 5-6.

218. *Id.* at 7-10.

under section 84(3) of the Patents Act of 1970.<sup>219</sup> In the second leg of its decision, the IPAB rejected Bayer's challenge to the merits of the compulsory license order, reasoning that—*first*, as Bayer had admittedly never licensed Cipla to manufacture the generic version of Nexavar, the latter's sales of the drug on the Indian market could not be factored in to determine whether or not the reasonable requirements of the public had been met under section 84(1)(a);<sup>220</sup> *second*, Bayer's sale of the drug in India at US \$5,500 per month's dose could not be considered reasonably affordable to the public under section 84(1)(b);<sup>221</sup> *third*, despite managing to secure a patent on Nexavar four years prior to the filing of the compulsory license application, the lack of promptitude on Bayer's part in taking reasonable steps to work its patent in India provided a justified reason to the Controller of Patents to deny adjournment under section 86 of the Patents Act of 1970;<sup>222</sup> and *fourth*, though the expression “worked in the territory of India,” as stated in section 84(1)(c), could be satisfied solely by importing the patented invention, Bayer had failed to provide a reasonable explanation as to why it could not locally manufacture Nexavar in India despite having held an Indian patent on the drug since 2008.<sup>223</sup> Although Bayer lost its appeal of the compulsory license order on all counts, it managed to successfully convince the IPAB to increase the rate of royalty that had been fixed by the Controller of Patents by one per cent.<sup>224</sup>

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219. *Id.* at 11 (“[I]f there is any lapse [on Natco's part in not filing any documentary evidence], it is a procedural lapse [and] on that ground, the order cannot be set aside.”).

220. *See id.* at 17. *See also* Prashant Reddy, *Bayer Sues Cipla for Infringement of its Nexavar Patent – C.S. (O.S.) No. 523 of 2010 before the High Court of Delhi*, SPICY IP INDIA (Apr. 18, 2010, 4:24 PM), <http://spicyipindia.blogspot.com/2010/04/bayer-sues-cipla-for-infringement-of.html> (last visited May 30, 2013) (explaining that on March 23, 2010, Bayer filed a patent infringement suit against Cipla, (*Bayer Corp. v. Cipla Ltd.*, C.S. (O.S.) No. 523/2010), which as of April 12, 2013, is pending final disposal before the High Court of Delhi). It is interesting that while Bayer has been fighting tooth and nail to restrain Cipla from manufacturing the generic version of Nexavar in India, it pleaded with the IPAB to consider Cipla's sales of the drug as a relevant factor in ascertaining whether or not the reasonable requirements of public had been met in accordance with §84(1)(a) of the Patents Act of 1970. The IPAB, however, rejected this plea, reasoning that Bayer, on account of being the patentee, could not shift the burden of its patent meeting the reasonable requirements of the public to a third party. *See Bayer v. Natco* (Decision of the IPAB, Chennai), *supra* note 207, at 23 (“The law is clear that, the requirements and conditions, for grant of compulsory license must be decided with reference to the patentee alone and not a party whose presence itself is litigious. . . . Therefore, for deciding whether the conditions of section 84 are satisfied, we will not take into account the presence of Cipla.”).

221. *See id.* at 37-38.

222. *Id.* at 39-40.

223. *Id.* at 43 (“[W]ith regard to section 84(1)(c) [of the Patents Act, 1970], we find that the word ‘worked’ must be decided on a case to case basis and it may be proved in a given case, that ‘working’ can be done only by way of import, but that cannot apply to all other cases. The patentee must show why [the patent] could not be locally manufactured. A mere statement to that effect is not sufficient there must be evidence.”).

224. *Id.* at 44-45 (“[The] UNDP specifically recommends that the rate of royalty be set at 4% and

***D. The Scapegoats Rejoice: Subsequent History of the IPAB's Decision, its Aftermath in India and the International World, and Options Before Bayer***

With all its options exhausted under the purview of the Patents Act of 1970, Bayer challenged the reasonableness of the IPAB's decision by invoking the writ jurisdiction of the Bombay High Court under article 226 of the Constitution of India.<sup>225</sup> On July 15, 2014, a division bench of the Bombay High Court refused to interfere with the decision of the IPAB, thus upholding the compulsory license granted by the Controller of Patents in Mumbai to Natco for manufacturing and marketing generic copies of Nexavar.<sup>226</sup> Bayer, thereafter, filed a special leave petition before the Supreme Court of India, challenging the Bombay High Court's dismissal of its case.<sup>227</sup> On December 12, 2014, dismissed the special leave petition filed by Bayer, Stating that it was not "inclined to interfere", the Supreme Court of India dismissed the special leave petition filed by Bayer, with a caveat that all questions of law in the matter shall remain open.<sup>228</sup>

This issuance of the compulsory license to Natco for manufacturing and marketing generic copies of Bayer's Nexavar marks a new milestone in the realm of compulsory patent licensing of pharmaceutical patents in India.<sup>229</sup> While patentee drug manufacturers are decrying the decision,<sup>230</sup> generic drug manufacturers and support groups representing civil society have hailed the

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adjusted upwards as much as 2% for products of particular therapeutic value or reduced as much as 2% when the development of the product has been partly supported with public funds . . . . [Given that the manufacturing and marketing of Nexavar was wholly a privately-funded initiative, the IPAB reasoned that Bayer had] a genuine reason for revision of royalty. . . . [Accordingly, the royalty that had been fixed by the Controller of Patents at 6% of the net sales of the drug on a quarterly basis was] increase[d] [by] one percent."].

225. Bayer v. Natco (Decision of the Bombay High Court), *supra* note 115, at 2.

226. *Id.* at 52.

227. Bayer Corp. v. Union of India, Petition for Special Leave to Appeal No. 30145 / 2014, Dec. 12, 2014, 1 (Supreme Court of India).

228. *Id.*

229. See Shamnad Basheer, *Compulsory Licensing is Not a Bad Word*, SPICY IP INDIA (Mar. 5, 2013, 11:59 AM), <http://spicyipindia.blogspot.com/2013/03/compulsory-licensing-is-not-bad-word.html> (last visited June 30, 2015).

230. See, e.g., *U.S.-India Trade Relations: Hearing Before the H. Comm. on Ways & Means, Trade Subcomm.*, 2013 Leg., 113th Sess. 7 (2013) (written testimony of Roy F. Waldron, Chief IP Counsel, Pfizer, Inc.), ("Compulsory licenses are intended for use in extraordinary situations of extreme urgency or other national emergency to meet the legitimate needs of the public. Often, however, compulsory licenses may be used by competitors as a means to obtain authorization to use or transfer technology developed by others without having to pay the substantial costs associated with developing and testing the product. These copiers want to obtain a free ride or use the technology at a much-reduced cost. Also, compulsory licenses are inappropriately viewed by some governments as part of their industrial policy to establish domestic production or to reduce government expenditures for medicines.").

compulsory license decision as a breakthrough in affordable and equitable healthcare in India.<sup>231</sup>

The decision in *Bayer v. Natco* has not been well-received by the United States and the European Union, who view India's compulsory license provisions as an impediment to foreign investments and a roadblock to effective trade negotiations.<sup>232</sup> Perceiving compulsory licensing as a threat to pharmaceutical innovation, nations like the United States have the option of imposing trade sanctions in its trade agreements with India,<sup>233</sup> or challenging India's compulsory license provisions before the Dispute Settlement Body of the WTO.<sup>234</sup>

Having fought and lost its case up to the highest dispute settlement forums in India, what now are the options available to Bayer? There is a provision under the Patents Act of 1970 whereby Bayer, upon the expiration of two years from the date of the compulsory order, can apply for revocation of the order if Natco fails to work the generic version of Nexavar in India.<sup>235</sup> It may be relevant to recall here that Bayer has been fighting a patent infringement claim against Natco at the High Court of Delhi.<sup>236</sup> Ordinarily, the compulsory license issued to Natco in respect of Nexavar should, *ipso facto*, render Bayer's patent infringement suit infructuous. However, in its order dated May 31, 2013, the High Court of Delhi allowed Bayer to persist its patent infringement claim because the claim was filed before Natco

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231. See, e.g., Patralekha Chatterjee, *India's First Compulsory License Upheld, But Legal Fights Likely to Continue*, INTELL. PROP. WATCH (Mar. 4, 2013), <http://www.ip-watch.org/2013/03/04/indias-first-compulsory-licence-upheld-but-legal-fights-likely-to-continue/> (last visited Dec. 25, 2013) (“[C]ompulsory licenses will be on the rise all over the world because it is the middle path between extreme patent protectionism and patent abolitionism.”).

232. See Sukanya Narain, *The NATCO Decision: Bringing Into the Indian Patent Practice The TRIPS Flexibility of Compulsory Licensing*, 10 (Apr. 20, 2012) (unpublished manuscript, National Law University, Jodhpur), available at [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2072435](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2072435) (reporting the Special 301 comments to the US Trade Representative with regards to the compulsory licensing provisions in India's Patents Act, whereby the recommendation of eliminating price as a trigger for issuing compulsory license under Section 84(1)(b) in order to comply with TRIPS, has been proposed).

233. Reichman, *supra* note 26, at 259 (2009) (“A risk that the patentees' governments will retaliate with trade sanctions that could 'cripple the economy of the licensing nation.'”).

234. *International IP Enforcement: Protecting Patents, Trade Secrets and Market Access: Hearing Before the H. Comm. on the Judiciary, Subcomm. on Intellectual Property, Competition, and the Internet*, 2012 Leg., 112th Sess. 2 (June 27, 2012) (statement of Teresa Stanek Rea, Deputy Director, USPTO), available at <http://cdm16064.contentdm.oclc.org/cdm/ref/collection/p266901coll4/id/4117> (observing that bringing a WTO case against India's compulsory licensing provisions is one of the tools available to the USPTO that should be considered).

235. See Patents Act of 1970, *supra* note 39, § 85.

236. *Bayer v. Natco* (Patent Infringement Suite Before the Delhi High Court), *supra* note 191. As of June 30, 2015, this case continues to be pending and all interlocutory orders passed so far in this matter can be referenced via the official website of the High Court of Delhi.

filed its compulsory license application.<sup>237</sup> Therefore, if Bayer eventually wins its patent infringement claim against Natco, it may become entitled to damages to the extent of injury suffered before the compulsory license was issued.

Albeit the decision in *Bayer v. Natco* can rightfully be characterized as one resulting in the issuance of India's first compulsory license for a patented drug, this case was not the first time that compulsory patent licensing provisions were invoked under the Patents Act of 1970.<sup>238</sup> Before Natco filed its compulsory license application in 2011, three compulsory patent license applications for pharmaceutical drugs had already been filed in India. Two of these were filed by Natco in 2007 under section 92A of the Patents Act of 1970, seeking compulsory licenses for F. Hoffman La-Roche Ltd.'s Tarceva® and Pfizer, Inc.'s SUTENT®, respectively, to manufacture and export the generic copies of these drugs to Nepal in order to address the country's health crisis.<sup>239</sup> Natco reportedly withdrew both its compulsory license applications in 2008, reasoning that the procedure under section 92A of the Patents Act of 1970 was too cumbersome.<sup>240</sup> Aside from these two applications, a third compulsory license application was filed by Cipla Ltd. in 2011 for a compulsory license for Merck Sharp and Dohme's ISENTRESS®, invoking section 84(1) of the Patents Act of 1970.<sup>241</sup> Soon thereafter, BDR Pharmaceuticals International Pvt. Ltd. (BDR) filed a compulsory license application in March 2013, under section 84(1) of the Patents Act of 1970, seeking a compulsory license for Bristol-Myers Squibb's SPRYCEL®, though this application was eventually rejected for want of procedural compliance.<sup>242</sup> On April 9, 2013, the Indian government announced its proposal to issue a compulsory license for three life-saving drugs.<sup>243</sup> More recently, on June 25, 2015, Lee Pharma

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237. *Bayer v. Natco* (Patent Infringement Suite Before the Delhi High Court), *supra* note 191, May 30, 2012, available at [http://delhihighcourt.nic.in/dhcqrydisp\\_o.asp?pn=121113&yr=2012](http://delhihighcourt.nic.in/dhcqrydisp_o.asp?pn=121113&yr=2012).

238. For a summary status report on compulsory license applications for patented drugs, which have been filed in India until June 30, 2015, see *infra* Annexure II.

239. Shamnad Basheer, *India's First "Doha" Case: Natco, Pfizer and Roche Will Be Heard Soon*, SPICY IP INDIA (Feb. 24, 2008), <http://spicyip.com/2008/02/indias-first-doha-case-natco-pfizer-and.html> (last visited June 30, 2015).

240. Shamnad Basheer, *Breaking News: Natco Withdraws "Doha" Compulsory License Application*, SPICY IP INDIA (Sept. 28, 2008), <http://spicyip.com/2008/09/breaking-news-natco-withdraws-doha.html> (last visited June 30, 2015).

241. Rajiv Kr. Choudhry, *Cipla Files for a Compulsory License Against Merck's Isentress*, SPICY IP INDIA (Apr. 5, 2011), <http://spicyip.com/2011/04/cipla-files-for-compulsory-license.html> (last visited June 30, 2015). On February 20, 2014, Mark Sharp and Dohme and Cipla announced that they had entered an "India-Specific Strategic Partnership, whereby Cipla would have a non-exclusive license to market MSD's ISENTRESS® under a different trade name in India. See Aditi Tandon, *Health Activists Concerned Over Cipla-Merck Deal for HIV Drug*, THE TRIBUNE (Feb. 21, 2014), <http://www.tribuneindia.com/2014/20140222/biz.htm#1> (last visited June 30, 2015).

242. BDR Pharma. Intl. Pvt. Ltd. v. Bristol-Myers Squibb Co., C.L.A. No. 1 of 2013, Oct. 29, 2013 (Controller of Patents, Mumbai).

243. See Thomas Bolloky, *Why Chemotherapy that Costs \$70,000 in the U.S. Costs \$2,500 in India*,

Ltd. filed an application seeking a compulsory license for AsreaZeneca's Onglyza® under section 84(1)(b) of the Patents Act of 1970, which was admitted for processing and is currently pending before the Controller of Patents in Mumbai.<sup>244</sup>

## **V. Conclusion: Carving a Middle Path for all Divergent Stakeholders of Compulsory Patent Licensing**

Given the inequitable access to healthcare in India, the government in India must strive towards the effective implementation of compulsory patent licensing of drugs throughout its territory. Towards this end, a few strategies for the enforcement of compulsory patent licensing, that would also result in facilitating public access to expensively priced branded drugs, are elucidated in the paragraphs that follow.

### ***A. Ironing Out the Ambiguities in the Compulsory Licensing Provisions under the TRIPS Agreement***

Although article 31 of the TRIPS Agreement provides a prototype framework for the enforcement of compulsory licensing provisions, it contains provisions that have not been defined, thus creating a scope for potential patent abuses resulting from the ambiguity inherent in these terms. The necessity of defining these terms further stems from the fact that a compulsory license agreement, being essentially an imposed contract, cannot be effectively enforced until its various terms and conditions are precisely defined. For instance, the expressions “public commercial non-use” has neither been defined in the TRIPS Agreement nor in the Doha Declaration.<sup>245</sup> It may be relevant to note that section 92 of the Patents Act also does not define or explain what may be construed as a “national emergency,” “extreme urgency,” or “public non-commercial use,” thus leaving the door open for a compulsory patent license potentially being granted without basis or by abusing the rights of a patentee.<sup>246</sup>

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THE ATLANTIC (Apr. 10, 2013, 2:47 PM), <http://www.theatlantic.com/archive/2013/04/Why-Chemotherapy-that-Costs-70,000-in-the-US--Costs-2,500-in-India/274847/> (last visited Dec. 25, 2013). The proposal recommends compulsory licensing of three drugs—Trastuzumab, Ixabepilone, and Dasatinib—sold by multinational pharmaceuticals in India. While Trastuzumab is a patented drug of F. Hoffman La-Roche Ltd., the patent on Ixabepilone and Dasatinib is held by Bristol-Myers Squibb. *Id.*

244. Balaji Subramanian, *Compulsory License Application Filed Over AstraZeneca's Saxagliptin*, SPICY IP INDIA (July 5, 2015), <http://spicyip.com/2015/07/compulsory-licence-application-filed-over-astrazenecas-saxagliptin.html> (last visited July 12, 2015).

245. Jamie Feldman, *Compulsory Licenses: The Dangers Behind the Current Practice*, 8 J. INT. BUS. L., 137, 164 (2009).

246. See Raadhika Gupta, *Compulsory Licensing under TRIPS: How Far it Addresses Public Health Concerns in Developing Nations*, 15 J. INTELL. PROP. RTS., 357, 360 (2010), available at

***B. Balancing the Equities Between Generic and Patented Drug Manufacturers***

The most effective way to ensure that the equities between the generic and patented drug manufacturers are balanced is by paying due allegiance to procedural propriety in the enforcement of compulsory patent licensing. The enforcement process for compulsory patent licensing must neither be overly adversarial, nor too expensive to administer.<sup>247</sup> It should be administered in a manner that ensures that the terms and conditions of the license are amicably agreed upon and effectively complied with by the parties involved in the license. The government should take steps towards setting up “a relatively predictable and easy to administer” system of compensation or royalty payable to the patentee drug manufacturer.<sup>248</sup> This can be achieved, for instance, by having in place precise guidelines or methodologies to determine the quantum or rate of royalty payable to the licensee and the manner in which it is to be paid. Moreover, the Controller of Patents should exercise his discretionary powers with reason and rationale while enforcing compulsory licensing provisions. He should ensure that the compulsory license proceeding are conducted fairly and expeditiously, and that generic drug manufacturer adheres to all procedural stipulations when filing the compulsory patent licensing application.

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<http://nopr.niscair.res.in/bitstream/123456789/10211/1/JIPR%2015%285%29%20357-363.pdf> (asserting that the absence of a precise definitions of “national emergency,” “extreme urgency,” and “public non-commercial use” in the TRIPS Agreement has resulted in national legislations (such as the Patents Act of 1970) deciding the degree of flexibility in the conditions for invoking compulsory licensing).

247. See James Love, *Compulsory Licensing: Models for State Practice in Developing Countries, Access to Medicines and Compliance with the WTO TRIPS Accord*, THIRD WORLD NETWORK 1, 29 (2004).

248. *Id.*

**ANNEXURE I**<sup>249</sup>  
**COMPARATIVE SUMMARY SHEET**  
**OF**  
**COMPULSORY PATENT LICENSING PROVISIONS**  
**UNDER**  
**THE TRIPS AGREEMENT AND THE PATENTS ACT OF 1970**

A. Grounds for Enforcement of a Compulsory Patent License:

Serial No.	Grounds	The TRIPS Agreement	The Patents Act, 1970
1.	The reasonable requirements of the public with respect to the patented invention have not been satisfied	—	§ 84(1)(a) read with § 84(4) & § 84(7)(a)-(e)
2.	The patented invention is not publicly available at a reasonably affordable price	—	§ 84(1)(b) read with § 84(4)
3.	The patented invention has been worked in the territory of India	—	§ 84(1)(c) read with § 84(4), § 84(7)(d) & § 84(7)(e)
4.	For working a related patent	Art. 31(l)(i)-(iii)	§ 91
5.	There is a national emergency	Art. 31(b) read with ¶ 5(c) of the Doha Declaration	§ 92
6.	There is an extreme urgency	Art. 31(b) read with ¶ 5(c) of the Doha Declaration	§ 92
7.	For purposes of a public non-commercial use	Art. 31(b)	§ 92
8.	For remedying an anti-competitive practice adopted by the patentee	Art. 31(k)	Proviso Clause to § 84(6)(iv) & § 90(1)(ix)
9.	For allowing generic copies of a patented drug to be exported to countries with insufficient or no manufacturing capacities during a public health crisis	¶ 6 of the Implementation Decision	§ 92A

249. Annexure I supplements Part III of this paper by providing a comparative summary sheet of the statutory provisions concerning the enforcement of compulsory patent licensing under the TRIPS Agreement and the Patents Act of 1970, respectively. See discussion *supra* Part III.A-B.



## B. Terms and Conditions of a Compulsory Patent License:

Serial No.	Terms and Conditions	The TRIPS Agreement	The Patents Act, 1970
1.	A compulsory license must be non-exclusive	Art. 31(d)	§ 90(1)(iv)
2.	A compulsory license must be non-assignable	Art. 31(e)	§ 90(1)(v)
3.	The licensee must pay royalty to the patentee as settled by the competent authority	Art. 31(h)	§ 90(1)(i)
4.	The licensee must fully work the patent at a reasonable profit	—	§ 90(1)(ii)
5.	The licensee must sell generic copies of the patented invention at affordable prices	—	§ 90(1)(iii)
6.	If a compulsory license is granted specially to address a national emergency or an extreme urgency, or for a public non-commercial use, the licensee must sell generic copies of the patented invention at the lowest prices	—	§ 92(1)(ii)
7.	The licensee must predominantly supply generic copies of the patented invention to his domestic market, with the exception to export such generic copies in three circumstances: (a) to remedy an anti-competitive practice (b) to address a public health crisis (c) if the domestic market for export is not being developed	(a) Art. 31(f) read with Art. 31(k) (b) Art. 31 (f) read with ¶ 6 of the Implementation Agreement (c) [no provision in the TRIPS Agreement]	(a) §90(1)(ix) (b) § 92A (c) § 90(1)(vii) read with §84(7)(a)(iii)
9.	The scope and duration of a compulsory license must be limited to the purpose behind its grant, especially in the case of semiconductor technology, where such license must be used only for a public non-commercial use or to remedy an anti-competitive practice	Art. 31(c)	§ 90(1)(viii)
10.	A compulsory license must be valid for the balance term of the patent, unless a shorter term is in public interest	—	§ 90(1)(vi)
11.	A compulsory license must be terminated if and when the circumstances which led to its grant cease to exist and are unlikely to recur	Art. 31(g)	—
12.	The licensee must not import the patented invention from a country that does not have a compulsory license authorizing the export of such invention	—	§ 90(2)

**ANNEXURE II<sup>250</sup>**  
**SUMMARY STATUS REPORT**  
 ON  
**COMPULSORY LICENSE APPLICATIONS FOR PATENTED DRUGS**  
**UNDER THE PATENTS ACT OF 1970**  
 (As on June 30, 2015)

Serial No.	Drug & Therapeutic Use	Parties	Ground(s)	Year of Filing & Current Status
1.	<p><b>Chemical Name:</b> Erlonitib Hydrochloride</p> <p><b>Brand Name:</b> Tarceva®</p> <p><b>Therapeutic Use:</b> Treats advanced stage non-small cell lung cancer (NSCLC)</p>	<p><b>Patentee:</b> F. Hoffmann La-Roche Ltd.</p> <p><b>Applicant:</b> Natco Pharma Ltd.</p>	For export to Nepal to address the country's health crisis [§ 92A]	<p><b>Year of Filing:</b> 2007</p> <p><b>Current Status:</b> Withdrawn in 2008, as Natco claimed the procedure under § 92A to be too cumbersome</p>
2.	<p><b>Chemical Name:</b> Sunitinib Malate</p> <p><b>Brand Name:</b> SUTENT®</p> <p><b>Therapeutic Use:</b> Treats gastrointestinal stromal tumor (GIST), advanced renal cell carcinoma (RCC), and advanced pancreatic neuroendocrine tumor (pNET)</p>	<p><b>Patentee:</b> Pfizer, Inc.</p> <p><b>Applicant:</b> Natco Pharma Ltd.</p>	For export to Nepal to address the country's health crisis [§ 92A]	<p><b>Year of Filing:</b> 2007</p> <p><b>Current Status:</b> Withdrawn in 2008, as Natco claimed the procedure under § 92A to be too cumbersome</p>

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250. Annexure II supplements Part IV.D of this paper by consolidating the information pertaining to the current status of all compulsory license applications for patented drugs filed so far under the Patents Act of 1970. See discussion *supra* Part IV.D.

Serial No.	Drug & Therapeutic Use	Parties	Ground(s)	Year of Filing & Current Status
3.	<p><b>Chemical Name:</b> Raltegravir Potassium</p> <p><b>Brand Name:</b> ISENTRESS®</p> <p><b>Therapeutic Use:</b> Treats HIV infection that causes AIDS</p>	<p><b>Patentee:</b> Merck Sharp &amp; Dohme (MSD)</p> <p><b>Applicant:</b> Cipla Ltd.</p>	The drug was not affordably priced [§ 84(1)(b)]	<p><b>Year of Filing:</b> 2011</p> <p><b>Current Status:</b> Withdrawn in 2014, as MSD and Cipla brokered a deal</p>
4.	<p><b>Chemical Name:</b> Sorafenib Tosylate</p> <p><b>Brand Name:</b> Nexavar®</p> <p><b>Therapeutic Use:</b> Treats advanced hepatocellular carcinoma (HCC), advanced renal carcinoma (RCC), and differentiated thyroid carcinoma (DTC)</p>	<p><b>Patentee:</b> Bayer Corporation</p> <p><b>Applicant:</b> Natco Pharma Ltd.</p>	Abuse of Patent Rights [§ 84(1)]	<p><b>Year of Filing:</b> 2011</p> <p><b>Current Status:</b> Granted in 2012, [Order of grant upheld by the IPAB in 2013, and subsequently by the Bombay High Court in 2014]</p>
5.	<p><b>Chemical Name:</b> Dasatinib</p> <p><b>Brand Name:</b> SPRYCEL®</p> <p><b>Therapeutic Use:</b> Treats chronic myeloid leukemia (CML)</p>	<p><b>Patentee:</b> Bristol-Myers Squibb</p> <p><b>Applicant:</b> BDR Pharmaceuticals (P) Ltd. (BDR)</p>	The drug was not affordably priced [§ 84(1)(b)]	<p><b>Year of Filing:</b> 2013</p> <p><b>Current Status:</b> Rejected in 2013, as BDR did not take steps in obtaining a voluntary license from the patentee</p>
6.	<p><b>Chemical Name:</b> Saxagliptin</p> <p><b>Brand Name:</b> Onglyza® &amp; Kombiglyze® XR (Combination of Saxagliptin &amp; Metaphormin HCL)</p> <p><b>Therapeutic Use:</b> Type II Diabetes Mellitus</p>	<p><b>Patentee:</b> Bristol-Myers Squibb (Original Patentee) AstraZeneca plc (Transferee of the Patent)</p> <p><b>Applicant:</b> Lee Pharma Ltd.</p>	The drug was not affordably priced [§ 84(1)(b)]	<p><b>Year of Filing:</b> 2015</p> <p><b>Current Status:</b> Pending</p>