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Indian Patent Law and TRIPS: Redrawing the Flexibility Framework in the Context of Public Policy and Health

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I. INTRODUCTION

Patent law in India had its origins in the patent system introduced by Great Britain,[1] which ruled India for almost a century.[2] It is well documented that the

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1. *See* Rajesh Sagar, *Introduction of Exclusive Privileges/Patents in Colonial India: Why and for Whose*

British influence in India had its beginning in 1600 with Queen Elizabeth I's chartering of the "Governor and Company of Merchants of London trading into the East Indies,"[3] The English East India Company ("The Company"), which first came to India in 1608 and laid the foundation for British rule over the next three decades.[4] The British Crown was eventually forced to take full control of India from the Company in 1858 as a result of a massive revolt against the Company, which is also known as India's First War of Independence.[5]

The origin of Indian patent law can be traced to 1856, when a law was enacted in India to grant certain exclusive privileges to inventors for a period of fourteen years.[6] Since the 1856 law did not have the prior sanction of the British Queen, experts opined that the Legislative Council of India did not have the authority to pass it.[7] The reason given was that since the grant of patents "in India was a prerogative of the Crown[,]" any patent law passed by the Indian legislature required the prior permission of the Crown or its representative.[8] Thus, the 1856 Act was repealed when the Indian Legislative Council passed Act IX of 1857; Act IX was followed by a new law enacted in 1859 that granted inventors the exclusive privilege to make, use, and sell their invention in India.[9] The purpose of this legislation was to help British patent holders gain control over the Indian markets, and the law contained major restrictions on the importation of technologies and inventions.[10] As a consequence, importation of technology became highly complex and prohibitively expensive.[11]

Patent law in India continued to be developed and refined over the next several decades. In 1872, the Patents and Designs Protection Act was enacted, and in 1883 the Protection of Inventions Act was enacted.[12] Finally, in 1888, both these laws were consolidated in the Inventions and Designs Act.[13] The British enactment of the Indian Patents and Designs Act, 1911, ("1911 Act") created a system of patent administration in India under the supervision of a

Benefit, 2 INTELL. PROP. Q. 164, 166 (2007).

2. DENIS JUDD, THE LION AND THE TIGER: THE RISE AND FALL OF THE BRITISH RAJ, 1600-1947, 14-27 (2004).

3. *Id.* at 6.

4. *Id.* at 10, 12-17.

5. *Id.* at 90-91.

6. Sagar, *supra* note 1, at 173.

7. *Id.* at 179.

8. *Id.*

9. Tanuja Garde, *India*, *in* INTELLECTUAL PROPERTY IN ASIA: LAW, ECONOMICS, HISTORY AND POLITICS 55, 57 (Paul Goldstein & Joseph Straus eds., 2009).

10. *See id.*

11. *See id.*

12. P. NARAYANAN, PATENT LAW 6 (3d ed. 1998).

13. *See History of Indian Patent System*, INTELL. PROP. INDIA para. 3, http://www.ipindia.nic.in/ipr/PatentHistory.htm (last visited Feb. 10, 2012).

Controller of Patents.[14] The term of patents under the 1911 Act was for sixteen years after the filing date, and in certain cases it could be extended up to seven additional years.[15] The 1911 Act remained in force—with certain amendments—and continued to govern the Indian patent system even after India got its independence from Britain in 1947.[16] It was finally repealed by the Patents Act of 1970.[17] All versions of patent law enacted by the British in India allowed for product patents in all fields of technology, including pharmaceuticals.[18]

Even during that period, courts in British India had to deal with a number of patent infringement disputes.[19] When India finally got independence from Britain in 1947, it had a huge population of 400 million people that represented one-fifth of the world's population.[20] However, the nation at that time was among the poorest in the world.[21] Slowly, Indian policy makers turned their attention to an impoverished domestic economy and eradication of the remnants of colonization.[22] While doing so, they observed that even though India had made some progress in industries like steel production,[23] India's indigenous pharmaceutical industry had been in very bad shape as a direct result of the 1911 Act.[24] The indigenous pharmaceutical industry was highly critical of this Act, as it prevented them from manufacturing reverse-engineered drugs for which foreign pharmaceuticals held a product patent in India.[25]

Even after India got its independence, its drug industry was tightly controlled by the multinational companies,[26] and most life-saving drugs like insulin, streptomycin, and penicillin were wholly imported.[27] Furthermore, a very unpopular judgment of the Bombay High Court in 1968[28] that favored a foreign patent holder over a local drug manufacturer accelerated the Indian government's

14. NARAYANAN, *supra* note 12, at 6.

15. Ved P. Mithal, *Patents in India*, 30 J. PAT. OFF. SOC'Y 62, 69 (1948).

16. *Id.* at 65-66; JUDD, *supra* note 2, at 179.

17. The Patents Act, No. 39 of 1970, INDIA CODE sec. 162(1) (1998).

18. *See* Srividhya Ragavan, *Of the Inequals of the Uruguay Round*, 10 MARQ. INTELL. PROP. L. REV. 273, 284 (2006).

19. One such infringement case was Gillette Indus. Ltd. v. Yeshwant Bros., 1937 A.I.R. 40 (Bom.) 347 (India).

20. *See* DOMINIQUE LAPIERRE & LARRY COLLINS, FREEDOM AT MIDNIGHT 27-28 (1975).

21. *See id.* at 28.

22. *See* TIRTHANKAR ROY, THE ECONOMIC HISTORY OF INDIA, 1857-1947, at 180-81 (2000).

23. INDICUS ANALYTICS, INDIAN STEEL INDUSTRY 3-4 (2009), *available at* http://www.cci.gov.in/images/media/completed/Indicussteel_20090420151842.pdf.

24. *See generally* SUDIP CHAUDHURI, THE WTO AND INDIA'S PHARMACEUTICALS INDUSTRY: PATENT PROTECTION, TRIPS, AND DEVELOPING COUNTRIES 128 (2005).

25. *Id.* at 129.

26. Ragavan, *supra* note 18, at 280.

27. *See* PLANNING COMM'N, GOV'T OF INDIA, 1ST FIVE YEAR PLAN ch. 32 paras. 94-99 (1952), *available at* http://planningcommission.nic.in/plans/planrel/fiveyr/default.html.

28. *See generally* Farbwerke Hoechst & Bruning Corp. v. Unichem Lab., 1969 A.I.R. 56 (Bom.) 255 (India).

resolve to implement drastic changes in the patent law that would enable Indian companies to make drugs at much cheaper prices.[29]

The Bombay High Court judgment mentioned above dealt with a patent infringement suit filed by the owners of an Indian patent for the manufacture of new sulphonyl-urea compounds, salts of those compounds, and of anti-diabetic medications containing those compounds.[30] One of the chemical compounds covered by the patent was Tolbutamide, and "since 1957 the plaintiffs had been marketing [it] as an anti-diabetic drug in India and all over the world under the trademark 'Rastinon.'"[31]

The main argument raised by the plaintiffs was that the defendant had wrongfully infringed upon their patent by manufacturing, preparing, and selling Tolbutamide by the use of the invention disclosed in the plaintiffs' patent.[32] The first defendant admitted that it had manufactured Tolbutamide, but claimed that it "had been manufactured by the application of the processes mentioned in another patent," held by the Haffkine Institute of Bombay, the second defendant.[33] The first defendant also raised a counter-claim to revoke the patent "on the grounds of insufficiency of description, lack of novelty, want of inventive step and lack of utility."[34] The Court held the patent to be valid and restrained the first defendant from further infringement upon the plaintiffs' patent.[35]

It should be noted that the process of drafting a patent law in-tune with India's needs began immediately after independence.[36] Initially a committee under the chairmanship of Justice Tek Chand was appointed by the Indian government in 1949 to review the patent laws in India with the purpose of ensuring that the patent system was more conducive to national interests.[37] The committee submitted its interim report in 1949, providing recommendations for prevention of misuse or abuse of patent rights in India.[38] The Tek Chand Report led to an important amendment to the existing patent law in 1950 that dealt with the working of inventions and compulsory licenses/revocation.[39] The amendment also included provisions dealing with endorsement of patents "with the words 'license of right' on an application by the Government," enabling the Controller to issue such licenses.[40]

29. *See* Ragavan, *supra* note 18, at 87-88.
30. Farbwerke Hoechst & Bruning Corp., 1969 A.I.R. 56, at para. 1.
31. *Id.*
32. *Id.*
33. *Id.*
34. *Id.* at para. 2.
35. *Id.* at para. 21.
36. *See History of Indian Patent System*, *supra* note 13, at paras. 6-7.
37. *Id.* at para. 5.
38. *Id.* at para. 6.
39. *Id.* at para. 7.
40. *Id.* This included provisions dealing with compulsory license on patents dealing with food and

Though the Tek Chand Report was important, it was the second report commissioned by the Indian government, under the chairmanship of Justice N. Rajagopala Ayyangar, which set the tone and tenor of India's current patent law.[41] According to some leading scholars, the Ayyangar Report formed the backbone of the Indian patent system by recommending drastic modifications.[42] The Ayyangar Report found that multinational companies "held about 80-90% of Indian patents, but practiced less than 10% of those patents in India."[43]

The Ayyangar Report recommended revolutionary changes to India's existing patent laws to accommodate the country's inexperienced industrial sectors and to encourage and reward inventors.[44] The recommendations primarily focused on:

(i) classification of the types of inventions for which patent protection should be available;

(ii) provisions intended either to prohibit the granting of Indian patents to foreign entities or to require working of such patents in India; and

(iii) provisions intended to resist international pressures on India to join international intellectual property conventions such as the Paris Convention, which demanded national treatment.[45]

The Ayyangar Report noted that the precise provisions of any patent law should be designed with special reference to the economic conditions of the country, the level of its science and technological advances, and its future needs.[46] In spite of all the perceived shortcomings of the Indian patent system, the Ayyangar Report wanted to continue with the system, as it was one of the most desirable ways of encouraging and rewarding innovators.[47]

The Ayyangar Report led to the introduction of the Patents Bill, 1965, in the Indian parliament.[48] After deliberations including scrutiny by the Joint Parliamentary Committee, the Patents Act, 1970, was passed by the Indian

medicines, insecticide, germicide or fungicide and a process for producing substance or any invention relating to surgical or curative devices. *Id.*

41. *See generally* N. RAJAGOPALA AYYANGAR, REPORT ON THE REVISION OF THE PATENTS LAW (1959).

42. Ragavan, *supra* note 18, at 281; NARAYANAN, *supra* note 12, at 5.

43. Linda L. Lee, *Trials and TRIPS-ulations: Indian Patent Law and Novartis AG v. Union of India*, 23 BERKELEY TECH. L.J. 281, 290 (2008).

44. *See generally* AYYANGAR, *supra* note 41, at paras. 18-42.

45. *Id.*

46. *Id.* at para. 44.

47. *Id.* at para. 43.

48. *History of Indian Patent System*, *supra* note 13, at para. 8.

parliament.[49] The law contained an express prohibition dealing with patentability of pharmaceutical products;[50] however, it permitted patents on processes for making pharmaceutical compounds, even though the duration of those patents was shorter than other types of patents.[51]

The Patents Act, 1970, along with the National Drug Policy announced in 1978, acted as an incentive for public sector units like Hindustan Antibiotics Ltd. and Indian Drugs and Pharmaceuticals Ltd., along with many private sector units, to make essential drugs at affordable prices.[52] As financial resources were scarce at that time, the pharmaceutical industry emphasized generic drug production, and virtually no investment was made on original research to develop new molecules.[53]

By enacting the 1970 law, the Indian government made a conscious decision to kick-start the lagging Indian economy by supporting domestic drug manufacturing.[54] During the next three decades, India emerged as a globally recognized producer of low-price generic drugs.[55] As recently as 2005, India was ranked number one in the world with respect to generic drug production, and it is a leading exporter of medicines to developing countries, including a large percentage of medicines used combat AIDS.[56]

India's pharmaceutical patent regime began to change slowly with its accession to the World Trade Organization ("WTO") in 1995.[57] The agreements that accompany membership in the WTO cover goods, services, and intellectual property rights ("IPRs").[58] One of the most important agreements within the

49. *Id.* The 1970 law repealed and substituted the 1911 Act so far as the patents law was concerned. However, the 1911 Act continued to be applicable to designs. The provisions of the 1970 Act became effective on April 20, 1972. *Id.*

50. The Patents Act, No. 39 of 1970, INDIA CODE sec. 5(a)-(b) (1998). As per the said provisions, a patent cannot be granted for "substances intended for use, or capable of being used, as food or as medicine or drug, or . . . relating to substances prepared or produced by chemical processes (including alloys, optical glass, semi-conductors and inter-metallic compounds)." *Id.*

51. *Id.* at sec. 53 ("[I]n respect of an invention claiming the method or process of manufacture of a substance, where the substance is intended for use, or is capable of being used, as food or as a medicine or drug, be five years from the date of sealing of the patent, or seven years from the date of the patent whichever period is shorter.").

52. Santanu Mukherjee, *The Journey of Indian Patent Law Towards TRIPs Compliance*, 35 INT'L REV. INTELL. PROP. & COMPETITION L. 125, 128-29 (2004).

53. *Id.*

54. 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, 514 (2007).

55. *See id.* at 514-16.

56. *See* MEDÉCINS SANS FRONTIÈRES, UNTANGLING THE WEB OF PRICE REDUCTIONS: A PRICING GUIDE FOR THE PURCHASE OF ARVS FOR DEVELOPING COUNTRIES 3 (8th ed. 2005), *available at* http://www.doctorswithoutborders.org/publications/reports/2005/untanglingthewebv8.pdf.

57. *Member Information*: *India and the WTO*, WORLD TRADE ORG., http://www.wto.org/english/thewto_e/countries_e/india_e.htm (last visited Feb. 2, 2012).

58. Details about WTO agreements are available at *Understanding the WTO: The Agreements, Overview: A National Guide*, WORLD TRADE ORG., http://www.wto.org/english/thewto_e/whatis_e/tif_e/

WTO is the Trade-Related Aspects of Intellectual Property ("TRIPS") Agreement, which mandates that all WTO members adopt and enforce certain minimum standards of IPR protection.[59] In 1986, when the negotiations[60] for setting up the WTO began, India and other developing countries—including Brazil and Argentina—strongly opposed it on the premise that protection of IPRs fell within the mandate of the World Intellectual Property Organization ("WIPO").[61] By 1989, other developing countries changed their stance because of various coercive measures taken by the United States, and India was left alone in its opposition.[62] Thus, India—faced with the unviable alternative of remaining completely outside the WTO system—was forced to sign the TRIPS Agreement and join the WTO in 1995.[63] However, in the process, India also managed to extract crucial flexibilities with respect to patent laws that had the result of restricting the effects of the changes originally mandated by TRIPS.[64]

It is a well-accepted fact that India's objections to the TRIPS Agreement benefited many developing countries, since all of them were provided transition periods of several years by WTO to make their laws fully TRIPS compatible.[65] Even though India was not required to comply with the product patent requirements of TRIPS until 2005, it was mandated to create a mailbox for the filing of patent applications that would be examined when the 2005 changes came into effect.[66]

India's WTO entry, although a very important step, cannot be attributed as the sole reason for changing its patent/IPR laws. It also had something to do with the drastic changes in economic policy that started in the 1990's. Right from 1947, when India became independent, it adopted a closed-economy model

agrm1_e.htm (last visited Feb. 26, 2012).

59. A brief summary of the TRIPS Agreement is available at *Agreement on Trade Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods*, WORLD TRADE ORG., http://www.wto.org/english/docs_e/legal_e/ursum_e.htm#nAgreement (last visited Feb. 26, 2012).

60. The round of negotiations which led to the formation of the WTO is popularly known as The Uruguay Round. It took more than seven years to complete the process and is believed to be the largest trade negotiation in history. *The Uruguay Round*, WORLD TRADE ORG., http://www.wto.org/english/thewto_e/whatis_e/tif_e/fact5_e.htm (last visited Feb. 26, 2012).

61. *See generally* Peter Drahos, *Developing Countries and International Intellectual Property Standard-Setting* 9 (Comm'n on Intellectual Prop. Rights, Study Paper 8, 2002), *available at* http://www.iprcommission.org/papers/pdfs/study_papers/sp8_drahos_study.pdf.

62. *See* Robert C. Bird & Daniel R. Cahoy, *The Emerging BRIC Economies: Lessons from Intellectual Property Negotiation and Enforcement*, 5 NW. J. TECH. & INTELL. PROP. 400, 403-04 (2007).

63. *See* Amy Kapczynski, *Harmonization and Its Discontents: A Case Study of TRIPS Implementation in India's Pharmaceutical Sector*, 97 CAL. L. REV. 1571, 1579 (2009).

64. *Id.* at 1581.

65. George K. Foster, *Opposing Forces in a Revolution in International Patent Protection: The U.S. and India in the Uruguay Round and Its Aftermath*, 3 UCLA J. INT'L L. & FOREIGN AFF. 283, 311-12 (1998).

66. Agreement on Trade-Related Aspects of Intellectual Property Rights art. 70.8(a), Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, *available at* http://www.wto.org/english/docs_e/legal_e/27-trips.pdf.

characterized by extensive regulation and state intervention that resulted in decades of low growth rates.[67] This continued for more than four decades until 1991, when India was forced to take some concrete steps towards economic liberalization as a result of the balance of payment crisis.[68] As part of the liberalization package, India had to devalue its currency, remove various import controls, slash customs duty rates, significantly liberalize industrial licensing norms, and open up the capital markets so that foreign investment could be attracted in numerous sectors.[69]

Thus, it is possible that when India became a member of the WTO in 1995, the economic liberalization policies it implemented four years before played some role in diluting India's stiff opposition to including IPRs within the ambit of the WTO. After the economic liberalization, India was in a much better position to align its policy interests with the fundamental philosophy of the WTO. Post-1991, free trade and greater engagement with the global economy began to be accepted among its policy makers as something that was not undesirable.[70]

II. PATENT AMENDMENTS POST 1995

TRIPS accelerated the transformation of India's patent laws in a multi-phased manner that corresponded to three amendments to the Patents Act, 1970.[71] Initially a mailbox facility was established, which allowed applicants to file pharmaceutical product patent applications.[72] Applicants were to be given exclusive marketing rights ("EMRs"), subject to certain conditions, to market the product for a period up to five years from the date of grant.[73] The second amendment to the 1970 law was made in 2002.[74] This amendment brought it into conformity with TRIPS on many issues, as it provided for a twenty year patent term,[75] reversal of the burden of proof for process patent infringement,[76] and modifications to compulsory licensing requirements.[77] By virtue of the third

67. TUSHAR PODDAR & EVA YI, GOLDMAN SACHS, GLOBAL ECONOMICS PAPER NO. 152: INDIA'S RISING GROWTH POTENTIAL 4 (2007), *available at* http://www.usindiafriendship.net/viewpoints1/Indias_Rising_Growth_Potential.pdf.

68. STEPHEN P. COHEN, INDIA: EMERGING POWER 101 (2001).

69. *Id.*; Mueller, *supra* note 54, at 517.

70. COHEN, *supra* note 68, at 101.

71. Mueller, *supra* note 54, at 519.

72. *Id.*

73. The Patents (Amendment) Act, 1999, No. 17 sec. 24(B)(1)(a)-(b), Acts of Parliament, 1999 (India), *available at* http://ipindia.nic.in/ipr/patent/patact_99.PDF.

74. The Patents (Amendment) Act, 2002, No. 38, Acts of Parliament, 2002 (India), *available at* http://www.ipindia.nic.in/ipr/patent/patentg.pdf.

75. *Id.* at sec. 27(a).

76. *Id.* at sec. 43.

77. *Id.* at sec. 39 (substituting ch. XVI, paras. 84-92).

amendment in 2005,[78] the 1970 law offered patent protection to pharmaceutical products, and in the process became substantially compliant with TRIPS.[79]

III. PATENTS AMENDMENT ACT 1999

Even though India was given exemptions from implementing pharmaceutical/agrochemical product patents until 2005, it was mandated to set up a mailbox facility for such product patent applications filed during the TRIPS transition period and to assign each application a filing date.[80] Another obligation under TRIPS was the provision dealing with the grant of EMRs for mailbox applications that met specified conditions during the transition period.[81] India initially tried to implement the mailbox facility and grant EMRs by way of a presidential order.[82] For various reasons the Indian parliament failed to pass the law dealing with mailbox facility and EMRs.[83] This prompted the United States to utilize the WTO's dispute resolution mechanism to address India's failure to enact the mailbox and EMR regime into a law.[84] The WTO's Appellate Body held in December 1997 that India's failure to make timely amendments to its patent laws had resulted in its non-fulfillment of obligations covered by Article 70.8(a) of the TRIPS Agreement, which mandated that India establish "a means" that adequately preserved novelty and priority of pharmaceutical product patent applications.[85] Finally, in March 1999, the amendment was passed by the Indian parliament; India formally implemented the mailbox procedure for pharmaceutical product patent applications and gave it retroactive application from January 1, 1995.[86]

78. *See generally* The Patents (Amendment) Act, 2005, No. 15, Acts of Parliament, 2005 (India), *available at* http://ipindia.nic.in/ipr/patent/patent_2005.pdf.

79. D.K. Nauriyal, *TRIPS-Compliant New Patents Act and Indian Pharmaceutical Sector: Directions in Strategy and R & D*, INDIAN J. ECON. & BUS. 189 (2006).

80. Mueller, *supra* note 54, at 519.

81. *Id.* at 520.

82. The Patents (Amendment) Ordinance, 1994, No. 13, Acts of Parliament, 1994 (India), *available at* http://www.wipo.int/clea/docs_new/pdf/en/in/in001en.pdf. Presidential authority for the promulgation of an ordinance is derived from Article 123(1) of the Indian Constitution. INDIA CONST. art. 123(1). Ordinances are promulgated as a stop-gap measure to deal with urgent situations when the Indian Parliament is not in session and the President of India is satisfied that circumstances exist which render it necessary for him/her to take urgent action. *Id.* Ordinances lapse six weeks after the meeting of the Parliament. *Id.* at art. 123(2)(a). The Patents (Amendment) Ordinance lapsed six weeks after the meeting of the Parliament.

83. Mueller, *supra* note 54, at 520.

84. Ruth L. Okediji, *Public Welfare and the Role of the WTO: Reconsidering the TRIPS Agreement*, 17 EMORY INT'L L. REV. 819, 890-93 (2003).

85. Appellate Body Report, *India—Patent Protection for Pharmaceutical and Agricultural Chemical Products*, WT/DS50/AB/R (Dec. 4, 1997), *available at* http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds50_e.htm.

86. Mukherjee, *supra* note 52; The Patents (Amendment) Act, 1999, No. 17 sec. 24(B)(1)(a)-(b), Acts of Parliament, 1999 (India), *available at* http://ipindia.nic.in/ipr/patent/patact_99.PDF.

Mailbox applications were deposited in a "black box," and they were not taken out for examination until March 2005.[87] During India's ten-year TRIPS transition period, 8926 mailbox applications were filed in the four branches of the Indian Patent Office.[88] The framework for filing mailbox applications, in order to comply with the TRIPS transition requirements, ended for India on December 31, 2004.[89] This means that the provisions dealing with mailbox applications/ EMRs became obsolete in 2005 and they have been repealed by way of the 2005 amendment.[90]

Few applicants who filed mailbox applications during the TRIPS transition period took the additional step of seeking EMRs for their inventions.[91] The grant of an EMR would have conferred the exclusive right to sell or distribute the invention in India for a period of five years from the date of the grant until either a patent was granted, or the application was finally rejected, whichever was earlier.[92] An EMR was granted only for those inventions claimed in mailbox applications that further satisfied the following requirements:

(a) an examination by the Indian Patent Office had established that the invention did not fall within any of the categories of subject matter considered as non-patentable inventions like business methods, frivolous inventions, mere admixture, or within the scope of the prohibition on patenting inventions relating to atomic energy;[93]

(b) the mailbox/EMR applicant had filed a patent application for the same invention, claiming the "identical article or substance" in a "convention country" on or after January 1, 1995;[94]

(c) the mailbox/EMR applicant had been granted a patent by the convention country on or after the date it filed its mailbox application in India;[95]

87. Mueller, *supra* note 54, at 521-22.

88. *Id.* at 522, n.175.

89. *Id.* at 522.

90. Mukherjee, *supra* note 52, at 7 (Patents Amendment 2005 which states that Chapter IVA of the 1970 Law shall be omitted).

91. Mueller, *supra* note 54, at 525.

92. Mukherjee, *supra* note 52; The Patents (Amendment) Act, 1999, No. 17 sec. 24(B)(1), Acts of Parliament, 1999 (India), *available at* http://ipindia.nic.in/ipr/patent/patact_99.PDF; The Patents (Amendment) Act, 2002, No. 38 sec. 4(k), Acts of Parliament, 2002 (India), *available at* http://www.ipindia.nic.in/ipr/patent/patentg.pdf.

93. The Patents (Amendment) Act, 2002, No. 38 sec. 24A(2), Acts of Parliament, 2002 (India) (non-patentable inventions are covered under Section 3 and inventions relating to atomic energy are covered in Section 4).

94. *Id.* at sec. 24B(1)(a).

95. *Id.*

(d) the convention country had issued "approval to sell or distribute the article or substance" in the convention country, "on the basis of appropriate tests conducted" in the convention country on or after January 1, 1995;[96]

(e) an authority on behalf of the Indian government had given approval to sell or distribute the article in India.[97]

IV. THE PATENTS (AMENDMENT) ACT, 2002

Although the 2002 amendment brought into force numerous changes, the most significant was the extension of the patent term to twenty years.[98] The 2002 Act amended the 1970 law to ensure that the terms of all patents granted in India would expire twenty years after their application filing date.[99] Before this amendment, Indian process patents granted in the field of pharmaceuticals lasted for only five years from sealing, or seven years from the date of the patent, whichever was less, while the term of all other types of patents was fourteen years from the date of the patent.[100]

The 2002 amendment cemented India's accession to the Paris Convention[101] and Patent Co-operation Treaty.[102] The two treaties are administered by WIPO, and India signed both in 1998.[103] This meant that India had to make its laws consistent with the Paris Convention's national treatment principle—which prohibits discriminatory treatment of foreign applicants[104]—as well as its right of priority—which permits foreigners who have previously filed a patent application in their home countries a twelve-month priority period within which they can file an application for the same invention in India, while still retaining the benefit of their earlier home country filing date.[105]

96. *Id.* at sec. 24B(1)(b).

97. *See generally id.* at sec. 24B.

98. The Patents (Amendment) Act, 2002, No. 38 sec. 2, Acts of Parliament, 2002 (India), *available at* http://www.ipindia.nic.in/ipr/patent/patentg.pdf (amending section 53). This was mandated by Article 33 of the TRIPS Agreement.

99. *Id.* (amending Section 53(1)(a)).

100. *Id.*; The Patents Act, No. 39 of 1970, INDIA CODE sec. 53(1) (1998).

101. *See generally* Paris Convention for the Protection of Industrial Property, Mar. 20, 1883, 21 U.S.T. 1583, 828 U.N.T.S. 305, *available at* http://www.wipo.int/treaties/en/ip/paris/trtdocs_wo020.html.

102. Mueller, *supra* note 54, at 527; The Patent Co-operation Treaty, June 19, 1970, 28 U.S.T. 7645, 1160 U.N.T.S. 231, *available at* http://www.wipo.int/pct/en/texts/articles/atoc.htm.

103. Elijah Cocks, *India Joins the Patent Cooperation Treaty*, 1998 B.C. INTELL. PROP. & TECH. F. 111701, *available at* http://www.bc.edu/bc_org/avp/law/st_org/iptf/headlines/content/1998111701.html (last visited Feb. 23, 2012); Mueller, *supra* note 54, at 527.

104. Paris Convention for the Protection of Industrial Property, *supra* note 101, at art. 2.

105. *Id.* at art. 4(C)(1).

The 2002 amendment brought into force other changes aimed at bringing India's patents law in tune with the TRIPS Agreement, including new definitions of invention and inventive step,[106] and new exclusions from patentable subject matter like business methods,[107] algorithms,[108]and traditional knowledge.[109] The amendment also reversed the burden of proof provision involving cases of process patent infringement[110] and streamlined the compulsory licensing framework.[111] The 2002 amendment also paved the way for patentability of microorganisms.[112]

The 2002 amendment provides three grounds for seeking a compulsory patent license. First, the law provides the broadest grounds for seeking a compulsory patent license in the case of non-working of patented inventions.[113] Such a license can be sought only three years after the sealing of the concerned patent.[114] Second, there is another provision for grant of compulsory licenses on notification of the Indian government in circumstances of national emergency or extreme urgency like the breakout of epidemics.[115] Third, there is a provision for compulsory licenses in the case of certain patents that are essential to the efficient working of other patented inventions.[116] The 2002 amendment abolished the concept of Licenses of Right.[117] Under this concept, process patents pertaining to medicines and food "were automatically deemed to be endorsed with the words 'licenses of right,'" which would make them available for compulsory licensing by all applicants three years after the patent grant.[118]

106. The Patents (Amendment) Act, 2002, No. 38 sec. 3, Acts of Parliament, 2002 (India), *available at* http://www.ipindia.nic.in/ipr/patent/patentg.pdf (amending section 2(1), (j) and adding sections 2(1), (ja)).

107. *Id.* at sec. 4 (adding section 3(k)).

108. *Id.*

109. *Id.* at sec. 4 (adding section 3(p)).

110. *Id.* at sec. 43 (adding section 104A).

111. *Id.* at sec. 39 (substituting the previous provisions with a whole new chapter dealing with Compulsory Licensing, Chapter XVI).

112. *Id.* at sec. 4 (adding section 3(j) dealing with plant varieties. India drafted a new law called Protection of Plant Varieties and Farmer's Rights 2001 to give effective protection to plant varieties.).

113. *Id.* at sec. 84(1).

114. *Id.* at sec. 84.

115. *Id.* at sec. 92.

116. *Id.* at sec. 91.

117. The Patents (Amendment) Act, 1999, No. 17 sec. 87, Acts of Parliament, 1999 (India), *available at* http://ipindia.nic.in/ipr/patent/patact_99.PDF; *see* The Patents (Amendment) Act, 2002, No. 38, Acts of Parliament, 2002 (India), *available at* http://www.ipindia.nic.in/ipr/patent/patentg.pdf (abolishing section 87 of the Patents (Amendment) Act of 1999); *see also* M. B. RAO & MANJULA GURU, PATENT LAW IN INDIA 251 (2010).

118. Mueller, *supra* note 54, at 600.

V. THE PATENTS (AMENDMENT) ACT, 2005

The last step in India's implementation of the changes required to make its patent law TRIPS compliant happened by way of the 2005 amendment.[119] Through this amendment, Indian law, for the first time since 1970, allowed patent protection to substances capable of being used as pharmaceuticals, food, and agro-chemicals.[120] The 2005 amendment was preceded by a presidential ordinance in 2004.[121] After its promulgation, there were intense debates about the scope of various provisions, but the Indian Parliament enacted the 2005 amendment after making changes in the ordinance.[122]

The 2005 amendments contain many controversial features that have caused many disputes.[123] They include elaborate provisions concerning what is and is not considered patentable subject matter,[124] a new definition of the "inventive step" criterion of patentability,[125] procedures governing both pre- and post-grant opposition,[126] and a more liberal framework for compulsory licensing.[127]

VI. FLEXIBILITIES BUILT INTO THE INDIAN PATENT LAW

This section will try to cover the important features of India's current patent law, which is armed with several flexibilities that the TRIPS Agreement provides to its member states.

A. Section 3(d) of the Patents Act

This is a newly introduced provision in the patent law, and has led to some famous patent disputes between multinational and Indian companies.[128] Section 3(d) states that

119. *Id.* at 529.

120. The Patents (Amendment) Act, 2005, No. 15 sec. 3, Acts of Parliament, 2005 (India), *available at* http://ipindia.nic.in/ipr/patent/patent_2005.pdf (deleting section 5 of the 1970 Law which prohibited product patents on the said substances).

121. The Patents (Amendment) Ordinance, 2004, No. 7, Acts of Parliament, 2004 (India), *available at* http://lawmin.nic.in/Patents%20Amendment%20Ordinance%202004.pdf.

122. Mueller, *supra* note 54, at 529-30.

123. *Id.*

124. These changes inserted by substituting Section 3(d) of the 1970 Law with a new definition. The Patents (Amendment) Act, 2005, No. 15 sec. 2, Acts of Parliament, 2005 (India), *available at* http://ipindia.nic.in/ipr/patent/patent_2005.pdf.

125. These changes inserted by substituting section 2 (ja) of the 1970 Law with a new definition. *Id.*

126. These changes inserted by substituting Sections 25 and 26 with a new definition. *Id.* at sec. 23.

127. These changes inserted by adding Section 92A to the 1970 Law. *Id.* at sec. 55.

128. Raheel Rashad Daureeawo, *The Controversy of Section 3(D) of The Indian Patent Act*, LEGAL SERVICE INDIA (Nov. 22, 2009), http://www.legalserviceindia.com/article/l400-Controversy-of-Section-3(D)-of-The-Indian-Patent-Act.html.

> the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus cannot be considered as an invention.[129]

It further clarifies that "salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy."[130]

This amendment's objective is to prevent the grant of frivolous patents on substances that are only trivial modifications of existing inventions.[131] Within the pharmaceutical industry, it is very common for companies to try to extend patent protection by obtaining separate patents on multiple attributes of a single product.[132] Even though Section 3(d) might have been the first provision targeting trivial modifications of pharmaceutical inventions to be codified anywhere in the world, many countries like the United States have devised ways to deal with such patents.[133] U.S. courts rely upon the doctrine of inherent anticipation to deal with such patents, and this was demonstrated by the U.S. Court of Appeals for the Federal Circuit ("CAFC"), which invalidated a patent on the metabolite of the antihistamine drug Loratadine because the metabolite "necessarily and inevitably" formed from ingestion of Loratadine under normal conditions.[134]

The United Kingdom also follows a similar approach while dealing with pharmaceutical patents involving trivial modifications. The England and Wales Court of Appeal, while dealing with the case of *Les Laboratoires Servier v. Apotex Inc.*, invalidated a patent on a particular crystalline form of the tert-butylamine salt of Perindopil.[135] The Court also made the following observations:

> It is the sort of patent which can give the patent system a bad name. I am not sure that much could have been done about this at the examination stage. There are other sorts of cases where the Patent Office examination is seen to be too lenient. But this is not one of them. For simply comparing the cited prior art ('341) with the patent would not reveal lack

129. The Patents (Amendment) Act, 2005, No. 15 sec. 2, Acts of Parliament, 2005 (India), *available at* http://ipindia.nic.in/ipr/patent/patent_2005.pdf.

130. *Id.*

131. *See id.* at sec. 3(d); Daureeawo, *supra* note 128.

132. Carlos M. Correa, *Public Health and Patent Legislation in Developing Countries*, 3 TUL. J. TECH. & INTELL. PROP. 1, 30 (2001).

133. Daureeawo, *supra* note 128.

134. Schering Corp. v. Geneva Pharm., Inc., 339 F.3d 1373 (Fed. Cir. 2003).

135. Full text available at Les Laboratories Servier v. Apotex, Inc., [2008] EWCA (Civ) 445, (Eng.).

> of novelty and probably not obviousness. You need the technical input of experts both in the kind of chemistry involved and in powder X-ray diffraction and some experimental evidence in order to see just how specious the application for the patent was. The only solution to this type of undesirable patent is a rapid and efficient method for obtaining its revocation. Then it can be got rid of before it does too much harm to the public interest.[136]

Scholars point out that Section 3(d) is a "bold legislative move" that has the potential to curb the illegitimate "evergreening" of patents and may compel other countries to imitate India's example in attempting to curb such practices.[137]

B. Application of Section 3(d)—Novartis Case

In May 2006, Novartis petitioned before the Madras High Court, contending that the Patent Controller erroneously rejected its patent application for the drug beta crystalline form of imantinib mesylate under Section 3(d) of the Patents Act.[138] Novartis also argued that the provision violated Article 14[139] of the Constitution of India because the wide breadth of discretion given to the patent controller could lead to discriminatory results.[140] The case was split up between the Madras High Court and the Intellectual Property Appellate Board ("IPAB").[141] The challenges on TRIPS compliance and the constitutionality of Section 3(d) were heard by the Madras High Court, which issued a judgment against Novartis.[142] The issue dealing with patentability was heard by the IPAB, which also ruled against Novartis.[143]

The High Court had to examine three issues. The first was whether Indian courts had jurisdiction to review Section 3(d)'s consistency with Article 27 of TRIPS, and to grant declaratory relief if the section was not consistent with

136. *Id.* at para. 9.

137. Rajarshi Sen & Adarsh Ramanujan, *Pruning the Evergreen Tree or Tripping up Over TRIPS?—Section 3(d) of the Indian Patents Act, 1970*, 41 INT'L REV. INTELL. PROP. & COMPETITION L. 170, 186 (2010).

138. Novartis AG v. Union of India, 2007 A.I.R. 24759 (Madras H.C.) para. 1 (2007); The Patents (Amendment) Act, 2005, No. 15 sec. 3(d), Acts of Parliament, 2005 (India), *available at* http://ipindia.nic.in/ipr/patent/patent_2005.pdf (excluding derivatives of known substances from being issued to a patent).

139. Article 14 of the Indian Constitution deals with equality before law; it states that the State shall not deny to any person equality before the law or the equal protection of the laws within the territory of India. INDIA CONST. art 14.

140. *Novartis AG*, 2007 A.I.R. at para. 6 (India).

141. *Novartis Case: Background and Update – Supreme Court of India to Recommence Hearing*, LAWYERS COLLECTIVE (Sept. 5, 2011), http://www.lawyerscollective.org/news/126-novartis-case-background-and-update-supreme-court-of-india-to-recommence-hearing.html.

142. *Novartis AG*, 2007 A.I.R. 24759 (India).

143. *Id.*; PB Jayakumar, *Novartis Loses Battle for Cancer Drug Patent*, BUS. STANDARD (July 5, 2009), http://www.business-standard.com/india/storypage.php?autono=362951.

TRIPS.[144] The second issue involved examining whether Section 3(d) was consistent with Article 27 of TRIPS.[145] The third issue was whether Section 3(d) violated Article 14 of the Constitution of India because it was vague, arbitrary, and conferred uncontrolled discretion to the Patent Controller.[146]

The Court held that it did not have jurisdiction to adjudicate a case dealing with the compliance of a domestic Indian law with an international treaty.[147] Thus, it did not grant any declaratory relief to Novartis.[148] Since the Court decided that it did not have jurisdiction to adjudicate whether a domestic law violated an international treaty, it declined to deal with the issue of whether Section 3(d) was compliant with TRIPS.[149] On the third issue, the Court held that Section 3(d) did not violate Article 14 of the Indian Constitution, was not vague or arbitrary, and did not confer uncontrolled discretion to the Patent Controller.[150] The Court concurred with the contention of the Indian Government that it had a constitutional duty to provide good health care to its citizens by giving them easy access to life-saving drugs.[151] The Court also agreed that in doing so there should be suitable legislative measures put in place to prevent evergreening of patents, which could have disastrous consequences with respect to availability of affordable medicines.[152]

C. Inventive Step

Indian patent law now defines inventive step as "a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art."[153] Thus, Indian law has tried to add new criteria like "technical advance" and "economic significance" onto the standard non-obviousness requirement. Scholars opine that the new broadened definition of

144. *Novartis AG*, 2007 A.I.R. at para. 5(a) (India).

145. *Id.* at para. 5(b).

146. *Id.* at para. 5(c).

147. *Id.* at para. 7.

148. *Id.* at para. 9. According to the Court, a declaratory relief cannot be given where it would serve no useful purpose to the petitioner. Moreover, a declaration that "the amended provision is not in discharge of India's obligation under Article 27 of 'TRIPS" would not "compel the Parliament to enact a law," thus the petitioner would not receive any relief. *Id.*

149. *Id.* at para. 8.

150. *Id.* at para. 16.

151. *Id.* at para. 19.

152. *Id.* at para. 15. Patent evergreening refers to the strategy of obtaining multiple patents that deal with different aspects of the same product, by obtaining patents on improved versions of existing products, JOHN R. THOMAS, PATENT "EVERGREENING": ISSUES IN INNOVATION AND COMPETITION (2009), *available at* http://ipmall.info/hosted_resources/crs/R40917_091113.pdf.

153. The Patents (Amendment) Act, 2005, No. 15 sec. 2, Acts of Parliament, 2005 (India), *available at* http://ipindia.nic.in/ipr/patent/patent_2005.pdf (which updates Section 2(ja)).

inventive step will give "the Patent Office and courts an explicit mandate to consider a claimed invention's economic significance."[154]

D. Pre-Grant and Post-Grant Opposition Before the Patent Controller

Indian law provides two administrative opportunities to challenge the grant of a patent before the patent offices: pre-grant and post-grant opposition.[155] India is one of the few systems to provide pre-grant as well as post-grant opposition proceedings.[156] Interestingly, most advanced countries do not follow pre-grant opposition proceedings.[157]

India's pre-grant procedure allows any person to file a pre-grant opposition with the relevant patent office.[158] "Any person" has been interpreted to cover potential generic competitors as well as social action groups representing interests of patients suffering from various diseases like cancer and AIDS.[159] The grounds upon which a pre-grant opposition can be made are also very broad.[160] The grounds for opposition mainly consist of lack of novelty, lack of inventive step, insufficiency of description, and non-patentability of the invention under the existing law.[161]

Though there is a considerable lack of information about the number of pre-grant opposition proceedings filed before the Controller, there are some studies that have put the figure at about 200 as of July 2007.[162] The Patent Controller's website during the period 2005-11 gives information about eighty cases.[163]

E. Compulsory Licensing Provisions

India's law has very expansive compulsory licensing provisions. Compulsory licensing may be invoked three years from the patent grant upon satisfying the following conditions: (1) the "reasonable requirements of the public with respect to the patented invention have not been satisfied;" (2) "the

154. Mueller, *supra* note 54, at 565.

155. The Patents (Amendment) Act, 2005, sec. 23 (which changed Section 25(1) and 25(2)).

156. Christopher Arup & Jagjit Plahe, *Pharmaceutical Patent Networks: Assessing the Influence of India's Paragraph 3(d) Internationally*, INTELL. PROP. Q. 1, 32 (2010).

157. *See* Jay P. Kesan, *Carrots and Sticks to Create a Better Patent System*, 17 BERKELEY TECH. L.J. 763, 781-82 (2002).

158. The Patents (Amendment) Act, 2005, sec. 25(1).

159. *See* Mueller, *supra* note 54, at 570-71. The Patents (Amendment) Act, 2005, Section 25(1) states that opposition shall be made by way of representation to the Controller.

160. The Patents (Amendment) Act, 2005, sec. 25 (which updates 25(1)(a)-(k)).

161. *Id.*

162. Kapczynski, *supra* note 63, at 1599-1600.

163. *Indian Patent Office*, INTELL. PROP. INDIA (Mar. 2, 2012), http://ipindiaonline.gov.in/patentsearch1/patentsearch.aspx. Although the website lists some 120 links, only 80 currently have files attached.

patented invention is not available to the public at a reasonable price;" and (3) the patented invention is not worked in the territory of India.[164]

Additionally, the Indian government may grant a compulsory license in circumstances involving national health emergencies.[165] The law also provides mechanisms to manufacture and export patented medicines to other countries without local manufacturing capacity.[166]

F. Government Use Provision

Indian law also provides for a mechanism allowing the government to use the patented invention under certain circumstances.[167] This is more or less in sync with TRIPS requirements, and the law provides adequate remuneration to the patentee in each case—considering the economic value of the use of the patent—and stipulates that the government notify patentees of the use as soon as practicable, except in cases of emergency.[168] There is one more specific provision, dealing with medicines, that allows the government to import patented drugs or medicines "for the purpose merely of its own use or for distribution in any dispensary, hospital or other medical institution maintained by or on behalf of the Government" or designated under the Patents Act.[169]

G. Experimental Use Exemptions

According to Indian law, any person may make or use the patented invention, whether it is a product or a process—or even an article or product made by a process—for the "purpose merely of experimentation or research including the imparting of instructions to pupils."[170]

Scholars note that this provision seems more liberal than corresponding provisions in most other countries, and that it is "wide enough to even support activities such as 'inventing around' the patented invention or the making of improvements thereto."[171] Along with this general experimental use exception, Indian law also exempts experimental trials conducted on patented drugs from

164. The Patents Act, No. 39 of 1970, INDIA CODE (1995) sec. 84(1)-(6), *available at* http://indiacode.nic.in. The Patents Act also includes a list of instances where the reasonable requirements of the public shall be deemed to be unsatisfied.

165. The Patents (Amendment) Act, 2005 sec. 55 (updating § 92A).

166. *Id.*

167. The Patents Act, No. 39 of 1970, INDIA CODE sec. 100(1) (1998).

168. The Patents (Amendment) Act, 2002, No. 38, Acts of Parliament, sec. 41, 2002 (India), *available at* http://www.ipindia.nic.in/ipr/patent/patentg.pdf (updating Section 100(3)-(5)).

169. The Patents Act, No. 39 of 1970, sec. 47(4).

170. *Id.* at sec. 47(3).

171. Shamnad Basheer & Prashant Reddy, *The "Experimental Use" Exception Through a Developmental Lens*, 50 INTELL. PROP. L. REV. 831, 832 (2010).

the purview of patent infringement.[172] This provision is much wider than the corresponding U.S. law, as it allows the "making, constructing, using or selling of a 'patented invention' for the purpose of generating regulatory data to comply with both domestic (Indian) drug regulatory law, and any corresponding foreign law," while U.S. law exempts only activities connected with a regulatory submission within the United States.[173]

H. Parallel Imports

India's new Patents Act implements the principle of international "exhaustion of patent rights."[174] The expression "exhaustion of patent rights" means that right holders who sell their invention lose the right to control the resale of the invention.[175] In other words, once a patented product has been sold with the patentee's approval outside India, the subsequent importation of that same patented item into India will not amount to infringement of the Indian patent.[176] The law provides that "importation of patented products by any person from a person who is duly authorised under the law to produce and sell or distribute the product, shall not be considered as an infringement of patent rights."[177]

While most developed countries' patent regimes do not have provisions incorporating international exhaustion of patent rights, the developing and least developed countries have included them in their patent laws with the aim of ensuring their citizens' access to lower-cost medicines.[178] The TRIPS Agreement is also silent about international exhaustion, as Article 6 of the Agreement states that "nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights."[179]

172. The Patents (Amendment) Act, 2002, sec. 58 (which updates Section 107A).

173. Basheer & Reddy, *supra* note 171, at 871.

174. Enrico Bonadio, *Parallel Imports in a Global Market: Should a Generalised International Exhaustion Be the Next Step?*, 33 EUR. INTELL. PROP. REV. 153, 153 (2011).

175. *Id.*

176. *Id.*

177. The Patents (Amendment) Act, 2002, sec. 44 (which updates §107A(b)); The Patents (Amendment) Act, 2005, No. 15 sec. 58, Acts of Parliament, 2005 (India), *available at* http://ipindia.nic.in/ipr/patent/patent_2005.pdf (which updates Section 107A(b)).

178. *See* Jacqui Wise, *Access to AIDS Medicines Stumbles on Trade Rules*, 84 BULL. WORLD HEALTH ORG. 337 (2006), *available at* http://www.who.int/bulletin/volumes/84/5/news10506/en/index.html.

179. Agreement on Trade-Related Aspects of Intellectual Property Rights art. 6, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, *available at* http://www.wto.org/english/docs_e/legal_e/27-trips.pdf.

VII. CONCLUSION

More than six years have passed since India implemented its new pharmaceutical product patents regime.[180] During this period, patent application filings have increased dramatically.[181] The jury is still out on the long-term implications of patent protection on drug pricing in India. However, this article has demonstrated that the Indian government holds a number of tools to deal with that concern.

It should also be noted that India's generic drug makers, along with various social action/public interest groups, have managed to put up a strong challenge to multi-national companies holding pharmaceutical patents.[182] Instead of taking the situation lying down, they are proactively making full use of the available statutory flexibilities to challenge pharmaceutical product patents.[183]

The Indian Patent Office and courts face significant challenges in interpreting and applying the new Patent Act's provisions. While India's patent system emerges as a unique model, there will be greater demands from stake-holders to make the system more transparent. In the past two years, some significant measures have been taken to increase transparency and it is expected that more steps will follow. In the short-term, opponents of stronger patent protection may be able to take advantage of ambiguities in the interpretation of various provisions of the patent law. But this can have serious long-term consequences, as a lack of confidence in the patent system could adversely impact indigenous innovation to a large extent and foreign direct investment to a small extent. Since India's pharmaceutical industry today is completely different than what it was in 1970,[184] stronger IPRs may help them by supporting path-breaking research and development. The entire world is looking at India to see how its unique patent system is evolving, and only time will tell whether that evolution takes the form of a smooth transition or a bumpy ride.

180. *See History of Indian Patent System*, *supra* note 13.

181. *See 79,000 Patent Applications Are Pending at India Patent Office!*, INDIAN INST. PAT. & TRADEMARK ATT'Y (Aug. 6, 2010, 11:08 AM), http://www.iipta.com/ipr/79000-patent-applications-are-pending-india-patent-office.

182. SUDIP CHAUDHURI, CHAN PARK & K.M. GOPAKUMAR, FIVE YEARS INTO THE PRODUCT PATENT REGIME: INDIA'S RESPONSE 5 (2010).

183. There are numerous instances of Indian companies successfully opposing the patent applications of foreign companies; one such case is Cipla's pre-grant opposition of Novartis. *See* Novartis AG v. Union of India, 2007 A.I.R. 24759 (Madras H.C.) (2007).

184. *See History of Indian Patent System*, *supra* note 13, at para. 3.