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India's Controversial New Patent Regime: The End of Affordable Generics?

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After almost three decades of relatively little patent protection, India recently adopted a modern patent regime that finally puts India in conformity with World Trade Organization (WTO) standards.¹ These new laws signify a very dramatic shift in intellectual property policy in India and promise to impact India's pharmaceutical industry significantly.² The new patent regime has been met with intense opposition as well as support.³ Indian government officials and pharmaceutical companies assure that the patent laws will improve national research and development, increase the export of generic drugs, and finally turn Indian pharmaceutical companies into major global players.⁴ On the other hand, various public health interest groups condemn the laws as signifying "the beginning of the end of affordable generics"⁵ by cutting off the supply of affordable medicines and stifling the competition that drives down the price of brand-name drugs.⁶ An examination of the Patent Act's provisions and implications reveals that both sides of the debate have merit.

I. The Purposes of a Patent System

Patent laws recognize intellectual property rights relating to inventions.⁷ Patents allow inventors to exclusively use their inventions for a limited period of time in exchange for

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1. Press Release, Government of India, Enough Safeguards in Patents Act to Prevent Price Rise—Domestic Pharma Industry Interests Fully Protected: Kamal Nath (Apr. 4, 2005), available at <http://pib.nic.in/release/release.asp?relid=8345>.

2. Jeffrey D. Hsi, *Patent Law in India Focuses Strongly on R&D: Industry Shifts to New Paradigm*, GENETIC ENGINEERING NEWS (2005), <http://www.genengnews.com/current/article.aspx?id=663>.

3. International Centre for Trade and Sustainable Development, *Indian Parliament Approves Controversial Patent Bill*, BRIDGES WEEKLY TRADE NEWS DIGEST (Mar. 23, 2005), <http://www.ictsd.org/weekly/05-03-23/story1.htm> [hereinafter ICTSD—Patent Bill].

4. Ranjit Devraj, *Global Poor to Suffer If Denied Indian Generic Drugs—Experts*, INTER PRESS SERVICE NEWS AGENCY (Feb. 22, 2005), <http://www.ipsnews.net/africa/interna.asp?idnews=27563>.

5. ICTSD—Patent Bill, *supra* note 3.

6. Devraj, *supra* note 4.

7. Indrajit Basu, *A Brave New World Indian Drug Industry*, WASH. TIMES (Jan. 11, 2005), available at <http://www.washtimes.com/upi-breaking/20050111-114414-9131r.htm>.

their disclosure of the invention to the public.⁸ This system confers two advantages to society.⁹ First, public disclosures promote progress by ensuring that knowledge of inventions is acquired by others, who can then use this knowledge to make further improvements.¹⁰ Second, because developing new inventions requires extensive investment and risk, the promise of exclusive rights serves as an incentive to inventors to undertake their research and development efforts.¹¹ Generally, for a new drug molecule, the cost of research and development is about \$1 billion.¹² Without a guarantee of exclusivity, innovative drug companies would be unable to generate enough revenue to overcome these high costs.¹³ Overall, the loss to society from the monopoly power granted to the inventor is significantly outweighed by the potential gains society receives from the acceleration of the technological process.¹⁴

II. India's Pharmaceutical Industry

India's \$7 billion¹⁵ drug market is the fourth in the world in terms of volume and thirteenth in terms of value.¹⁶ Its drug industry consists of 24,000 drug manufacturers, roughly 500,000 chemists, and over one billion people using medicines.¹⁷ Drug exports from India reach an estimated 200 countries globally.¹⁸ India is also a major supplier of the world's generic medicines, exporting 66.7 percent of its products to developing countries.¹⁹

Between 1970 and 1994, India only allowed patents on processes, called process patents, rather than on the products of the processes themselves, called product patents.²⁰ This was seen as a compromise between India's desire to encourage innovation and its desire to allow access to foreign pharmaceuticals that might otherwise be unavailable.²¹ Under the old regime, the period of patent protection was only seven years.²² Therefore, pharmaceutical

8. Sir Purshotamdas Thakurdas, Indian Institute of Banking and Finance, Memorial Lecture in Mumbai, India: PATENTS IN GLOBAL PERSPECTIVE (Jan. 7, 2005), available at <http://www.yale.edu/opa/intl/india/levin-20050107.html>.

9. *Id.*

10. *Id.*

11. *Id.*

12. Uttam Gupta, *Patent Ordinance—Innovator Still to Get Desired Comfort*, BUSINESS LINE INTERNET EDITION (Mar. 15, 2005), <http://www.blonnet.com/2005/03/15/stories/2005031501030900.htm>.

13. *Id.*

14. Thakurdas, *supra* note 8.

15. Saritha Rai, *India Adopts Patent Law Covering Pharmaceuticals*, N.Y. TIMES, Mar. 24, 2005, available at <http://www.nytimes.com/> (search "NYT Since 1981" for "India patent law pharmaceuticals"; then follow "INTERNATIONAL BUSINESS; India Adopts Patent Law Covering Pharmaceuticals" hyperlink).

16. Interview with Ranjit Shahani, President, Organization of Pharmaceutical Producers of India (Mar. 2, 2005), available at <http://www.pharmabiz.com/article/print.asp?articleid=26475>.

17. Basu, *supra* note 7.

18. Devraj, *supra* note 4.

19. Press Release, Health Gap Global Access Project, The Impact of India's Amended Patents Act on Access to Affordable HIV Treatment (Feb. 2005), available at http://www.healthgap.org/press_releases/05/020105_HGAP_FS_INDIA_IPR.pdf [hereinafter Health Gap].

20. International Centre for Trade and Sustainable Development, *Indian TRIPS-Compliance Legislation Under Fire*, BRIDGES WEEKLY TRADE NEWS DIGEST (Jan. 19, 2005), <http://www.ictsd.org/weekly/05-01-19/story2.htm> [hereinafter ICTSD—TRIPS Compliance].

21. Hsi, *supra* note 2.

22. *Id.*

companies could manufacture cheap copycat versions of patented drugs and sell the medicines at a fraction of the price, as long as a modified process was used.²³ A huge Indian generic drug industry was thus built on reverse-engineering brand-name drugs through slightly modified processes.²⁴ Every major drug in the world ended up in at least ten brands in India.²⁵

It is for this reason that Indian drugs often cost 7 to 10 percent of what they do in the United States.²⁶ Prices of AIDS anti-retroviral drugs made in India are reduced by as much as 98 percent.²⁷ For example, India recently introduced a generic version of an AIDS anti-retroviral drug at \$140 annually per person, which was significantly cheaper than the name-brand drug selling for \$12,000 annually per person.²⁸ Indian generic drug manufacturers now produce low-cost AIDS drugs for 50 percent of the 700,000 HIV patients taking antiretroviral medicines in developing countries.²⁹

III. The TRIPS Agreement of 1994

India's patent protection regime changed in 1994 when India signed the Trade Related Intellectual Property (TRIPS) agreement of the WTO.³⁰ TRIPS, which came into effect on January 1, 1995, is considered to be "the most comprehensive multilateral agreement on intellectual property" to date.³¹ TRIPS sets out minimum standards of intellectual property protection that must be met by each WTO Member country.³² In addition, TRIPS contains a differentiated timetable of compliance for three different classes of nations: developed, developing, and least developed.³³ Developed countries were required to immediately comply with the agreement.³⁴ Developing countries, such as India, were given ten years, until January 1, 2005, to comply.³⁵ The least developed countries, such as those in Africa, were given until 2016.³⁶

Generally, TRIPS requires Member countries to make patents available for any inventions, whether products or processes.³⁷ This essentially makes it illegal for domestic com-

23. Ranjit Devraj, *India: Lesser-Than-Evil Patent Law Pleases Drug Firms*, INTER PRESS SERVICE NEWS AGENCY (Mar. 24, 2005), <http://www.ipsnews.net/africa/interna.asp?idnews=28005>.

24. ICTSD—TRIPS Compliance, *supra* note 20.

25. Basu, *supra* note 7.

26. ICTSD—TRIPS Compliance, *supra* note 20.

27. Health Gap, *supra* note 19.

28. Rajindar Sachar, *Wrong Medicine: Patent Ordinance to Drive Up Drug Prices*, TIMES OF INDIA (Jan. 5, 2005), available at <http://timesofindia.indiatimes.com/articleshow/980623.cms>.

29. ICTSD—Patent Bill, *supra* note 3.

30. Basu, *supra* note 7.

31. World Trade Organization, *Overview: the TRIPS Agreement*, http://www.wto.org/english/tratop_e/trips_e/intel2_e.htm.

32. *Id.*

33. Thakurdas, *supra* note 8.

34. *Id.*

35. *Id.*

36. World Trade Organization, Ministerial Declaration on the TRIPS Agreement and Public Health of 14 November 2001, WT/MIN(01)/DEC/2, available at http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.pdf.

37. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Art. 27.1, available at http://www.wto.org/english/docs_e/legal_e/27-trips.pdf [hereinafter TRIPS].

panies to make generic copies of patented drugs.³⁸ Under TRIPS, inventions in all fields of technology may be patented as long as they meet the tests of novelty, inventiveness, and industrial applicability.³⁹ TRIPS also provides for a term of patent protection of twenty years from the filing date of the patent.⁴⁰

IV. The 2004 Ordinance

The initial product of India's efforts to comply with TRIPS was an Ordinance (the Ordinance), which is a temporary executive decree that is not debated in parliament.⁴¹ The Ordinance amended India's patent regime to include product patents and was passed on December 26, 2004, just days before the TRIPS January 1, 2005, deadline for compliance.⁴²

The Ordinance was met with heated opposition.⁴³ Various groups heavily criticized the Ordinance for failing to incorporate certain public health flexibilities allowed by TRIPS.⁴⁴ Specifically, opponents of the Ordinance believed it blatantly disregarded the 2001 Doha Declaration on public health, which states that "TRIPS should be interpreted and implemented in a manner supportive of WTO members' rights to protect health and promote access to medicine for all."⁴⁵ In addition, critics believed the Ordinance did not incorporate the August 30, 2003, decision of the TRIPS General Council, which permits the grant of compulsory licenses for export purposes to countries with little or no manufacturing capabilities.⁴⁶ Critics believed this strict regime under the Ordinance would lead to more expensive essential drugs, thereby hurting those needing access to cheap medicines while also hurting India's pharmaceutical industry, which relies heavily on generic drug production.⁴⁷

V. The 2005 Patent Amendments Act

The 2005 Patent Amendments Act (the Patent Act) was driven by requirements of TRIPS compliance as well as by India's recognition that an innovative, proprietary patent system was now necessary to becoming a global technology player.⁴⁸ The Patent Act replaced the Ordinance of 2004,⁴⁹ and several provisions of the Ordinance were amended to satisfy critics who feared increased drug prices.⁵⁰ The lower house of parliament passed the Patent Act on March 22, 2005, and the upper house made it law the following day.⁵¹ The Patent Act is effective from January 1, 2005.⁵²

38. ICTSD—Patent Bill, *supra* note 3.

39. TRIPS, *supra* note 37.

40. *Id.* at Art. 33.

41. ICTSD—Patent Bill, *supra* note 3.

42. Health Gap, *supra* note 19.

43. ICTSD—Patent Bill, *supra* note 3.

44. *Id.*

45. Sachar, *supra* note 28.

46. *Id.*

47. ICTSD—TRIPS Compliance, *supra* note 20.

48. Hsi, *supra* note 2.

49. *Id.*

50. ICTSD—Patent Bill, *supra* note 3.

51. *Id.*

52. Hsi, *supra* note 2.

A. ELEMENTS OF THE PATENT ACT

The Patent Act includes significant changes in protection of intellectual property in India.⁵³ While the Patent Act covers various aspects of intellectual property, only a few significant provisions are currently in controversy; these provisions, discussed below, relate to mailbox application procedures, compulsory licensing, pre-grant oppositions, and scope of patentability.⁵⁴

1. *Mailbox Application Procedures*

While India had until January 1, 2005, to implement a new patent regime that complied with TRIPS specifications, Indian drug companies were allowed to apply for product patents as early as January 1, 1995, the effective date of the Patent Act.⁵⁵ India created a mailbox for filing product patent applications on products invented after this date.⁵⁶ The applications filed between 1995 and 2005, called mailbox applications, were held pending examination until the January 1, 2005, effective date of the Act.⁵⁷ The current number of pending mailbox applications is estimated to be from 4,700 to 12,000.⁵⁸

The Ordinance did not contain a provision allowing for continued manufacture of currently produced drugs after the grants of the mailbox patents.⁵⁹ Critics feared that this provision would cause drugs currently produced by Indian companies, for which patent applications were still pending in the mailbox, to go off the market once the patents were granted.⁶⁰ This could lead to a dramatic price increase for these drugs, as was seen in 2003 with an anti-cancer drug called Glivee, where the cost of the medication increased tenfold.⁶¹

The Patent Act remedied this provision by allowing Indian companies already producing these drugs to continue to produce them even after the drugs are patented, as long as a royalty is paid to the company owning the patent.⁶² This provides a level playing field for domestic companies who already have made substantial investments in the products.⁶³ Specifically, the provision explains that the patentee's rights begin from the date of the grant of the patent, rather than from the date of application.⁶⁴ The patentee is only entitled to receive "reasonable royalties" from those companies that have made significant investments and have been producing and marketing the drug prior to January 1, 2005, and that continue to manufacture the drug on the date of the patent grant.⁶⁵ Under this provision, no infringement suits are allowed against these companies once royalties are paid.⁶⁶

53. *Id.*

54. *Id.*

55. Basu, *supra* note 7.

56. ICTSD—TRIPS Compliance, *supra* note 20.

57. Hsi, *supra* note 2.

58. ICTSD—TRIPS Compliance, *supra* note 20.

59. Memorandum from Amit Sen Gupta, National Working Group on Patent Laws, Changes in New Patents Bill (Mar. 22, 2005), available at <http://www.cptech.org/ip/health/c/india/gupta03222005.html>.

60. *Id.*

61. *Id.*

62. *Id.*

63. Press Release, Government of India, *supra* note 1.

64. The Patents (Amendment) Act, No. 15 of 2005; India Code (2005), v. 71, at § 10(c), available at <http://indiacode.nic.in/>.

65. *Id.*

66. *Id.*

2. *Compulsory Licensing*

Compulsory licenses allow the production of patented material without authorization from the patent holder.⁶⁷ With compulsory licenses, a government may allow patents to be broken if cheaper generic drugs are required in a health emergency.⁶⁸

The Ordinance allowed for exports of patented drugs under compulsory licenses to developing countries with no manufacturing ability.⁶⁹ While this was consistent with the Doha Declaration and subsequent August 30, 2003, TRIPS General Council decision, the Ordinance added a new provision that required the importing country to first issue its own compulsory license to Indian drug makers.⁷⁰ This provision was heavily criticized because countries cannot issue compulsory licenses for products to which they do not extend patent protection.⁷¹ Since, under TRIPS, least developed countries are not required to provide patents for products until 2016, those countries in need of cheap medicine would not be able to import from India until their patent regime is finally implemented.⁷²

The Patent Act expanded the compulsory licensing provisions.⁷³ The provision was amended to provide that countries with little or no manufacturing ability can import patented drugs under compulsory licenses from India as long as they give notification of importation or otherwise authorize importation.⁷⁴ This is in addition to a country's ability to obtain compulsory licenses.⁷⁵

In addition, prior to the Patent Act, there had been widespread concern that the grant of compulsory licenses would take too long if the Patent Controller had too much time to consider issuance of compulsory licenses after the licenses were denied by patent holders.⁷⁶ The Patent Act addresses this by specifying that a reasonable time period of up to six months will be given for the Patent Controller to consider issuance of the compulsory license.⁷⁷

3. *Pre-grant Oppositions*

Pre-grant oppositions allow members of the public to challenge potentially frivolous and invalid patent applications before the patent is granted.⁷⁸ Critics believed that the Ordinance severely restricted pre-grant oppositions by reducing the number of grounds under which the patent could be opposed from nine to two and by deleting the clause which provided for hearings in person by the opposing party.⁷⁹

The Patent Act addresses these concerns by specifically providing for eleven different grounds for opposition and restoring the option of personal hearings for opponents.⁸⁰ In

67. Inside U.S. Trade, *Industry Says Indian Drug Law Violates WTO, But No WTO Case Seen*, Apr. 15, 2005, <http://www.cptech.org/ip/health/c/india/insideustrade04152005.html>.

68. Devraj, *supra* note 23.

69. Memorandum from Amit Sen Gupta, *supra* note 59.

70. *Id.*

71. ICTSD—Patent Bill, *supra* note 3.

72. *Id.*

73. Hsi, *supra* note 2.

74. The Patents (Amendment) Act, No. 15 of 2005; India Code (2005), v. 71, at § 55(1), available at <http://indiacode.nic.in/>.

75. *Id.*

76. Memorandum from Amit Sen Gupta, *supra* note 59.

77. *Id.*

78. ICTSD—Patent Bill, *supra* note 3.

79. Memorandum from Amit Sen Gupta, *supra* note 59.

80. The Patents (Amendment) Act, No. 15 of 2005; India Code (2005), v. 71, at § 25(1), available at <http://indiacode.nic.in/>.

addition, the Patent Act extends the time for filing oppositions from three months to six months.⁸¹

4. *Scope of Patentability*

Prior to the Patent Act, there were widespread concerns that the implementation of product patents in India would result in many patents being granted on frivolous grounds.⁸² There were also concerns that this would lead to “evergreening” of patents.⁸³ Evergreening refers to renewals of expired patents by pharmaceutical companies by citing a new use for the same drug, thereby extending the patent monopoly.⁸⁴ Evergreening delays the entry of generic drugs into the market.⁸⁵

The Ordinance addressed these concerns by restricting the scope of patents granted on frivolous claims.⁸⁶ The Ordinance clarified that an inventive step must be a technical advance over previous inventions or one that has economic significance.⁸⁷ A new invention is “any invention or technology which has not been anticipated by publication in any document or used in the country or elsewhere in the world before the date of filing of patent application with complete specification.”⁸⁸ A pharmaceutical substance must be a “new entity involving one or more inventive steps.”⁸⁹ The only truly controversial provision of the Ordinance was the use of the word “mere” in explaining that a mere new use of an old molecule or any new property of a known substance was not patentable.⁹⁰ Critics objected to the use of the word “mere” because the provision was ambiguous about exactly what kind of new use is patentable.⁹¹ It could allow an applicant to claim a patent just by adding a new chemical reactant instead of developing completely new drugs.⁹² The word could also lead to endless litigation since it is susceptible to various interpretations.⁹³

The Patent Act addresses this concern by deleting the word “mere” to strengthen the provision.⁹⁴ This serves to remove any doubt of the scope of patentability by narrowing the exceptions to inventions.⁹⁵ All of the other provisions on patentability are left unchanged from the Ordinance.⁹⁶ Therefore, under the Patent Act, new uses of a known substance are not patentable, and new dosage forms are patentable only if an unexpected result is found.⁹⁷ Combinations of known substances can only be patented upon showing of enhanced ther-

81. Memorandum from Amit Sen Gupta, *supra* note 59.

82. *Id.*

83. *Id.*

84. Devraj, *supra* note 23.

85. Basu, *supra* note 7.

86. Memorandum from Amit Sen Gupta, *supra* note 59.

87. The Patents (Amendment) Act, No. 15 of 2005; India Code (2005), v. 71, at § 2(f), available at <http://indiacode.nic.in/>.

88. *Id.* at § 2(g).

89. *Id.*

90. Gupta, *supra* note 12.

91. ICTSD—TRIPS Compliance, *supra* note 20.

92. Basu, *supra* note 7.

93. Gupta, *supra* note 12.

94. Memorandum from Amit Sen Gupta, *supra* note 59.

95. Press Release, Government of India, *supra* note 1.

96. The Patents (Amendment) Act, No. 15 of 2005; India Code (2005), v. 71, at §§ 2(f)-(g), 3, available at <http://indiacode.nic.in/>.

97. Hsi, *supra* note 2.

apeutic efficacy, and pharmaceutical substances are only patentable upon showing of a synergistic effect of the components.⁹⁸

B. REACTION TO THE ACT

1. *Criticism*

Under the Patent Act, thousands of medicines that were granted patent protection in other countries between 1995 and 2005, as well as medicines that will become patent protected after January 1, 2005, will be considered for patent protection in India.⁹⁹ While the Patent Act does not cover generic drugs prior to 1995, critics of the Patent Act believe that generic production of pre-1995 versions of medicines is not enough to satisfy the treatment needs of people in developing countries.¹⁰⁰ They argue that all new drugs required to replace old, ineffective drugs will be patented and thus become unaffordable.¹⁰¹

Opponents argue that the costs to consumers as a consequence of the Patent Act will be untenable.¹⁰² They insist the new laws will stifle routine generic competition for newer, more expensive AIDS medicines and argue that twenty-year monopolies on drugs will drive up cost of treatment until the world's supply of generic HIV medicines disappears.¹⁰³ They believe that the 5.1 million Indians suffering from HIV/AIDS will be unable to afford the possible 99 percent increase in the cost of these medicines.¹⁰⁴ Similarly affected will be the majority of African nations currently importing inexpensive generic drugs from India.¹⁰⁵ Analysts predict prices on patented breakthrough drugs in India could rise to nearly U.S. levels, while prices on more common drugs should rise only moderately.¹⁰⁶ The Indian government has said it will step in if price increases are excessive, but it remains to be seen how exactly that will be implemented.¹⁰⁷ Dr. Hamied, chairman of Cipla, a company known for supplying inexpensive AIDS cocktails, is strongly opposed to the new laws. "The passage of the patent bill," he was recently quoted as saying, "for me personally and for India as a whole, is a very tragic and a very sad day. It will be the start of a predictable, long-term tragedy for the country."¹⁰⁸

Critics generally blame the compulsory licensing provisions of the Patent Act as being too complicated to provide quick relief in the case of an epidemic.¹⁰⁹ They argue that effective compulsory licensing procedures are absolutely necessary for ensuring access to affordable medicines.¹¹⁰ The Patent Act requires that, except during national emergencies, generic manufacturers must wait three years after a patent is granted before they can apply for a compulsory license to manufacture it, which critics believe is too long.¹¹¹ Other criti-

98. *Id.*

99. Health Gap, *supra* note 19.

100. *Id.*

101. Devraj, *supra* note 4.

102. Health Gap, *supra* note 19.

103. *Id.*

104. Devraj, *supra* note 4.

105. *Id.*

106. Rai, *supra* note 15.

107. *Id.*

108. *Id.*

109. Devraj, *supra* note 23.

110. ICTSD—Patent Bill, *supra* note 3.

111. *Id.*

cisms of the compulsory licensing requirements are that they fail to set a limit on royalties to be paid to patent holders, they allow drug makers to oppose the granting of a compulsory license, and they fail to establish a fixed time limit after which a compulsory license must be issued to an applicant.¹¹² Thus, critics argue, pharmaceutical companies can use these loopholes in the compulsory licensing procedures to delay the granting of compulsory licenses.¹¹³ They insist that generic manufacturers should be able to apply for compulsory licenses as soon as a patent is granted.¹¹⁴ "People in India and other developing countries have to have the right to license lifesaving drugs in a fast and easy manner, without the permission of the multinational pharmaceutical companies," said Priti Radhakrishnan, senior project officer with Lawyers Collective HIV/AIDS Unit.¹¹⁵

In addition, critics argue that product patents will be detrimental to small generic drug companies.¹¹⁶ Mergers are expected, with bigger pharmaceutical companies swallowing up smaller ones that cannot afford to undertake research and development.¹¹⁷ Opponents argue that these small companies might be priced out of the drug market and disappear.¹¹⁸ This happened in Italy following its 1984 institution of drug patents, where it went from being a major drug producer and exporter to a new importer of medicines.¹¹⁹

Opponents of the Patent Act also downplay the effect it will have on investment and research in India.¹²⁰ They claim that profits generated by sales in India will not be substantial enough to affect the research and development agenda of multinational pharmaceutical companies.¹²¹ They also argue that foreign companies will comprise the vast majority of patent filers for India, who has not yet reached a standard of development where it will benefit from patent monopolies.¹²²

2. Praise

Big pharmaceutical companies, on the other hand, hail passage of the Patent Act.¹²³ They believe India's strong pharmaceutical and biotechnology industries have a lot to gain from strengthened patent protection.¹²⁴ They argue that India's pharmaceutical firms have the scale, trained personnel, and technical capacity to develop new drugs, and this, combined with the availability of patents and the low cost of research and development in India, could help India's pharmaceutical companies become very successful globally.¹²⁵ Many Indian drug makers are optimistic that the new patent regime will increase investment in pharmaceutical research, which will enable Indian firms to start launching global low-cost drugs in four to five years.¹²⁶ They insist that the Patent Act will lead to increased investment in

112. *Id.*

113. *Id.*

114. *Id.*

115. *Id.*

116. Basu, *supra* note 7.

117. Devraj, *supra* note 23.

118. Rai, *supra* note 15.

119. ICTSD—Patent Bill, *supra* note 3.

120. Health Gap, *supra* note 19.

121. *Id.*

122. *Id.*

123. Rai, *supra* note 15.

124. ICTSD—Patent Bill, *supra* note 3.

125. Thakurdas, *supra* note 8.

126. Rai, *supra* note 15.

the country as well as retention of Indian scientists and researchers, who might otherwise go to the United States.¹²⁷ They argue that India is likely to become a major center for outsourced clinical trials under the Patent Act.¹²⁸ Proponents of the Patent Act also argue that impact on India's large generic drug makers will not be too severe because these companies generally make off-patent medicines as well as drugs protected with patents elsewhere.¹²⁹

Proponents also deny that prices of drugs will skyrocket.¹³⁰ Shri Kamal Nath, Union Minister of Commerce and Industry, believes the Act contains enough safeguards, such as compulsory licensing provisions, to prevent price rise.¹³¹ This is because 97 percent of all drugs manufactured in India are off-patent and will thus remain unaffected.¹³² In addition, 100 percent of all essential drugs are currently not covered by patents.¹³³ Prices of drugs patented before 1995, including very important HIV treatments, will not be affected as they will be ineligible for patents, and their generic production will continue.¹³⁴

"I expect that after the first of January 2005, when the patent law comes into play in India, what we will see is maybe one or two new drugs, patented drugs, being launched in the first few years—and later one, maybe five, six, or seven. So, it is not going to be a sudden or a huge change at all," said Rajiv Gulati, general manager for Eli Lilly in New Delhi.¹³⁵

Proponents of the Patent Act also argue that the laws will not hurt the AIDS battle because compulsory licensing procedures allow India to deal with public health emergencies, where India can continue to produce significant AIDS treatments and export them to developing countries.¹³⁶ Under these provisions, developing countries can issue compulsory licenses to manufacture generic versions of Indian drugs for less cost, and least developed countries with no manufacturing ability can obtain compulsory licenses to import cheaper generic drugs from India.¹³⁷

Additionally, proponents point out that most of the large global producers of AIDS treatments have dramatically lowered the prices of their drugs in developing countries already.¹³⁸ Currently, the standard AIDS cocktail is available in Africa for just over \$1 per day, which is a price close to that offered by Indian generic producers.¹³⁹ They argue that it is not international patent laws that are preventing access to cheap drug therapies; it is the "crushing poverty of the nations most heavily affected with HIV/AIDS and the insufficiency of aid provided by developed countries."¹⁴⁰

127. ClariNet, *Pharmaceutical Industry In India Denies Patent Law Changes Will Drive Up AIDS Drug Prices And Reduce Availability*, Dec. 17, 2004, <http://quickstart.clari.net/voa/art/dn/2004-12-17-voa40.html>.

128. Thakurdas, *supra* note 8.

129. Rai, *supra* note 15.

130. Press Release, Government of India, *supra* note 1.

131. *Id.*

132. *Id.*

133. *Id.*

134. Thakurdas, *supra* note 8.

135. ClariNet, *supra* note 127.

136. Thakurdas, *supra* note 8.

137. ClariNet, *supra* note 127.

138. Thakurdas, *supra* note 8.

139. *Id.*

140. *Id.*

3. U.S. Reaction

The U.S. pharmaceutical industry believes India's Patent Act falls short of India's WTO obligations under TRIPS.¹⁴¹ First, U.S. officials believe that India's treatment of mailbox applications violates TRIPS.¹⁴² Under Article 70.8 of TRIPS, companies that filed mailbox applications prior to January 1, 2005, are required to receive patent protection as long as the applications meet the basic criteria for protection.¹⁴³ In addition, under Article 70.9 of TRIPS, products covered under the mailbox must be given five years of exclusive marketing rights in importing Member countries.¹⁴⁴ U.S. sources say that India is in clear violation of both articles 70.8 and 70.9 because the Patent Act does not provide for five years of exclusive marketing rights nor does it provide patent holders under mailbox applications with any recourse to remove products that violate their patent from the market.¹⁴⁵

Second, U.S. sources argue that India's compulsory licensing requirements fall short of WTO rules.¹⁴⁶ Aggressive compulsory licensing could destroy the very incentives that are created by a patent system and could even be illegal under TRIPS.¹⁴⁷ Article 31 of TRIPS provides that a compulsory license should only be granted after efforts have been made to obtain authorization from the patent holder within a reasonable period of time.¹⁴⁸ The Patent Act caps the reasonable period at six months.¹⁴⁹ U.S. officials believe this time period is too short since licensing negotiations can often take a couple of years.¹⁵⁰

Third, the U.S. industry's view is that the Indian treatment of "new uses" is too strict.¹⁵¹ Article 27 of TRIPS recognizes patents for any inventions as long as they meet the requirements of novelty, inventiveness, and industrial application.¹⁵² However, the Patent Act requires that drugs that are slightly altered for different uses can only be protected if the drug has undergone a "significant innovative step."¹⁵³ U.S. officials believe that this provision makes it too difficult for patent holders to obtain patent protection for drugs altered to treat different conditions.¹⁵⁴

Despite objections to certain provisions of the Patent Act, U.S. officials have not yet challenged the laws in the WTO.¹⁵⁵ Industry sources revealed that U.S. companies are still studying the Patent Act and waiting to see how the Indian government implements it before taking action.¹⁵⁶

141. Inside U.S. Trade, *supra* note 67.

142. *Id.*

143. *Id.*

144. *Id.*

145. *Id.*

146. *Id.*

147. Thakurdas, *supra* note 8.

148. Inside U.S. Trade, *supra* note 67.

149. *Id.*

150. *Id.*

151. *Id.*

152. *Id.*

153. *Id.*

154. *Id.*

155. *Id.*

156. *Id.*

VI. The Future of Indian Patent Law

India's move toward conformity with TRIPS standards appears to promise considerable national benefits.¹⁵⁷ However, while India's new Patent Act contains several features designed to reduce potential hardship to public health and prevent drastic rise of drug prices, it is uncertain at this point whether these provisions will succeed as intended.¹⁵⁸ Conversely, while these provisions are desirable and perhaps necessary to protect public health, care must also be taken to ensure that they do not ultimately undermine the intended purposes of patent protection or violate the TRIPS standards set out by the WTO.¹⁵⁹ Ultimately, implementation and enforcement of the Patent Act remain surrounded by uncertainties.¹⁶⁰ Because the Patent Act is still subject to revision, this will be an area of continuing development in the future.¹⁶¹ India's Patent Act ultimately must find a consistent balance between providing necessary benefits to innovators without compromising important national interests.¹⁶²

157. Thakurdas, *supra* note 8.

158. *Id.*

159. *Id.*

160. Hsi, *supra* note 2.

161. *Id.*

162. Gupta, *supra* note 12.