

ARTICLES

THE TIGER AWAKENS: THE TUMULTUOUS TRANSFORMATION OF INDIA'S PATENT SYSTEM AND THE RISE OF INDIAN PHARMACEUTICAL INNOVATION

*Janice M. Mueller**

India developed a world-class generic drug manufacturing industry by excluding pharmaceutical products from patent protection in 1972. In 2005, India reintroduced pharmaceutical patenting in order to comply with its obligations as a WTO member. For an emerging superpower still mired in poverty and public health crises, the change did not come quickly or without controversy. This Article provides the first major comparative analysis of India's new patents regime. Based on the author's data gathering and interviews in India, the Article evaluates the regime's first eighteen months. It critiques the new law and the capacity of India's administrative and judicial infrastructure to implement it. Multiple influences shape India's "mosaic view" of patents: a huge population, widespread poverty, lack of health insurance, wariness towards foreign influences, a developed but fragmented pharmaceutical sector, a

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fledgling entrepreneurial culture of innovation among indigenous pharmaceutical and biotechnology firms, a fragile coalition government, and a vocal citizenry remarkably aware of esoteric patent law developments. Concluding that the new patents regime is neither the fully-Westernized panacea hoped for by its pro-TRIPS advocates nor the unmitigated disaster for the Indian public predicted by its fiercest critics, the Article offers recommendations for the future of India's evolving patent system.

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I. INTRODUCTION

The first day of January 2005 marked a dramatic turning point in the history of India. By deliberately excluding pharmaceutical products from patent protection for the previous 34 years, India became a world leader in high-quality generic drug manufacturing. But India's entry into the global economy at the end of the 20th century, as evidenced by membership in the World Trade Organization (WTO), compelled the nation to once again award patents on drugs. Moreover, India henceforth would have to apply internationally-accepted criteria for granting patents, and the term of its patents would have to extend twenty years beyond filing.

For an emerging superpower still mired in immense domestic poverty and public health crises, these and other fundamental changes to India's patents regime did not come quickly nor without controversy. Their implementation remains uncertain. It is far too early to empirically establish, for example, whether India's adoption of stronger patent laws will catalyze a significant shift from generic drug manufacturing to indigenous pharmaceutical innovation. What is clear, however, is that the implications of India's tumultuous patent system transformation will be felt not only within India but also around the globe.¹

From the perspective of millions suffering worldwide from life-threatening diseases, many of whom previously benefited from the low-cost products of India's thriving generic drug manufacturing sector, the introduction of a pharmaceutical product patents regime in India is viewed as an international healthcare tragedy.² That view is the extreme. The true impact of the changes will turn on implementation. Eighteen months into the new patents regime, India is actively exploiting the flexibilities inherent in the WTO's Agreement on Trade-Related Aspects of Intellectual Property (TRIPS).³ These flexibilities allow India to balance the need to protect its

1. The editorial page of the *New York Times* observed that for the world's poor, the end of India's "copycat industry for newer drugs" represents "a double hit—cutting off the supply of affordable medicines and removing the generic competition that drives down the cost of brand-name drugs." Editorial, *India's Choice*, N.Y. TIMES, Jan. 18, 2005, at A20.

2. See Yusuf K. Hamied, *Indian Pharma Industry—Decades of Struggle and Achievements* (Apr. 2, 2005) (on file with author), at 6 (characterizing enactment of India's Patents Act, 1970 (2005), as "one of the greatest predictable tragedies the world has witnessed").

3. See 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, 33 I.L.M. 1125, 1208-11 (1994) [hereinafter TRIPS].

public from the social costs of stronger patent protection while at the same time provide the necessary incentives for domestic research and development in medicines and healthcare. The transformation of the nation's patent regime is entirely consistent with a burgeoning domestic pharmaceutical and biotech industry that is beginning to invent rather than merely reverse-engineer. The traditional Indian view of patent protection as a moral wrong antithetical to public health⁴ is evolving to a more complex understanding—still in its formative implementation stages, to be sure—that a patent system can be designed and implemented to spur domestic innovation while at the same time maintaining affordable public access to life-saving patented medicines.

This article is the first major comparative analysis of India's newly strengthened patents regime, i.e., the Patents Act, 1970, as last amended in 2005 (hereinafter "India Patents Act, 1970 (2005)").⁵ The article evaluates the first eighteen months of the new regime's operation, drawing not only from published literature but also from original fact finding, data gathering, and interviews conducted in India with Indian Patent Office officials, Indian pharmaceutical industry representatives, Indian patent attorneys, and Indian patent law academics.⁶

This article places the evolution of India's patent laws in context as a reflection of the nation's political and economic journey from colonial domination to independent nation to the world's largest democracy and emerging superpower. It offers a detailed critique of India's new patents law

4. See Indira Gandhi, former Prime Minister of India, at the World Health Assembly (May 6, 1981) (stating that "[m]y idea of a better ordered world is one in which medical discoveries would be free of patents and there would be no profiteering from life or death"), in B.K. KEAYLA, CONQUEST BY PATENTS: TRIPS AGREEMENT ON PATENT LAWS: IMPACT ON PHARMACEUTICALS AND HEALTH FOR ALL 9 (Centre for Study of Global Trade System and Development 1998).

5. *Explanation of Statutory References*: Since its enactment in 1970, India's patent statute, The Patents Act, No. 34 of 1970, v.2(i)(j), officially titled "The Patents Act, 1970" has been amended three times, in 1999, 2002 and 2005. See *infra* Part II.C for further discussion of these amendments, each of which refer to the Patents Act, 1970, as the "principal Act." The most current text of the Patents Act, 1970, as amended by the 1999, 2002, and 2005 amending Acts, is reprinted in hard copy form in the booklet UNIVERSAL'S THE PATENTS ACT, 1970, AS AMENDED BY THE PATENTS (AMENDMENT) ACT ALONG WITH THE PATENTS RULES, 2003 AS AMENDED BY THE PATENTS (AMENDMENT) RULES 2005, and this consolidated version will be referred to throughout this article. Although electronic versions of each of the three amending acts are available on-line, as well as an electronic version of the principal 1970 Act (prior to any amendments), there does not exist as of August 2006 any official electronic version of the consolidated Act, i.e., a consolidated version incorporating all amendments from 1999, 2002, and 2005. See Intellectual Property India website, available at <http://patentoffice.nic.in/ipr/patent/patents.htm> (select "Patents" hyperlink) (last visited Jan. 18, 2007). The Indian Patent Office would be performing a valuable public service by posting a consolidated version of the current Patents Act in electronic form.

6. The author spent November 2005 in India conducting field research for this article.

and the capacity of India's administrative and judicial infrastructure to implement it. The potential influence of the changed law on the future of India's pharmaceutical sector is gauged as are the implications for the country's more than one billion citizens. From a vantage point beyond the extreme pro- and anti-patent views currently found in India, this article seeks to convey India's "mosaic view" of patent protection as an evolving legal and economic framework that has been shaped by a multiplicity of influences—a vast population, widespread poverty and lack of health insurance, deeply ingrained wariness towards foreign influences, a highly fragmented pharmaceutical industry, a fledgling entrepreneurial culture of innovation among indigenous pharmaceutical and biotech firms, a fragile coalition government, and a vocal citizenry remarkably aware of esoteric patent law developments.

In order to gain the economic and political benefits of participation in the WTO's trading system, India had no choice but to bring its patent laws into conformity with the WTO's intellectual property rules as set forth in TRIPS.⁷ Compliance with TRIPS was not the sole driver for the transformation of India's patents regime, however. Just as India made a deliberate choice in the 1970s to jump-start its indigenous generic drug manufacturing industry by prohibiting the grant of patents on pharmaceutical products, in 2005 it again made a deliberate choice to stimulate domestic innovation in new medicines and therapies. The pharmaceutical industry is a "sunrise sector" for India.⁸ The Indian government seeks to exploit pharmaceutical manufacturing skills well-honed in the generic drug industry to form a solid base for innovation in the development of new drugs.

With only a handful of pharmaceutical product patents having been granted in India since January 1, 2005,⁹ it is premature to draw any firm

7. See Scope of the WTO, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization Art. II(2)—Results of the Uruguay Round, 33 I.L.M. 1125 (1994) (stating that "[t]he agreements and associated legal instruments included in Annexes 1, 2 and 3 . . . are integral parts of this Agreement, binding on all Members"). The referenced "Annex 1" includes the TRIPS Agreement as Annex 1C. See TRIPS, *supra* note 3.

8. Sri Kamal Nath, Union Minister of Indus. & Commerce, *Kamal Nath's Statement on the Ordinance Relating to Patents (Third) Amendment*, at ¶ 5 (Dec. 27, 2004) [hereinafter Nath Statement], available at http://pib.nic.in/release/rel_print_page.asp?relid=6074.

9. The first pharmaceutical product patent to issue under India's new patents regime was reportedly granted on or around March 2, 2006 to Roche India Pvt. Ltd., the Indian subsidiary of Swiss pharmaceutical giant Hoffman La Roche. See P.T. Jyothi Datta, *Roche Gets Product Patent on Hepatitis C*, HINDU BUSINESS LINE, Mar. 2, 2006, available at <http://www.thehindubusinessline.com/2006/03/03/stories/2006030302040200.htm> (The patent is directed to a new-generation Hepatitis C therapy marketed by Roche under the brand name Pegasys.) [hereinafter Datta, *Roche Gets Product Patent*]. Official notice of the grant

conclusions about the impact of enhanced patent protection. Separating the influence of stronger patent laws on investment decision-making from other contributing factors such as India's highly-skilled and low-cost scientific and technical workforce is also impractical. Nevertheless, early signals indicate that India's adoption of product patent protection is positively impacting its economy. Indian pharmaceutical firms are increasing their investments in new chemical entity (NCE) research and development.¹⁰ Although the percentage of their revenues devoted to research and development is still well below that of western multinational corporations (MNCs),¹¹ investment by the indigenous firms in health care innovation is steadily increasing.¹² India is increasingly viewed as an ideal venue for clinical testing of new drugs¹³ and for contract

was not published until May 2006, however. See 2006 OFF. J. PAT. OFFICE 10000 (May 19, 2006), available at http://patentoffice.nic.in/ipr/patent/journal_archive/journal_2006/pat_arch_052006/official_journal_19052006.pdf (notice of grant of Indian Pat. No. 198,952, titled "A Physiologically Active Branched PEG-IFNa Conjugate," on Application No. 1032/MAS/1997, assigned to Hoffman-La Roche). See 2005 OFF. J. PAT. OFFICE 24056 (Oct. 28, 2005), available at http://ipindia.nic.in/ipr/patent/journal_archive/pat_arch_102005/official_journal_28102005.pdf, for a summary of Application No. 1032/MAS/1997A.

10. For example, Indian pharmaceutical major Dr. Reddy's Laboratory recently teamed with venture capital firms Citigroup Venture Capital and ICICI Venture to establish Perlecan Pharma, a new R&D venture with over \$50 million in funding for the development of NCEs. Sahad P.V. & E. Kumar Sharma, *The Long-Term Rx*, BUS. TODAY, Dec. 4, 2005, at 136, 142.

11. See Sajeev Chandran et al., *Implications of New Patent Regime on Indian Pharmaceutical Industry: Challenges and Opportunities*, 10 J. INT. PROP. RTS. 269, *passim* (2005), available at <http://www.niscair.res.in> (follow "Science Communication" hyperlink; then follow "Research Journals" hyperlink; then follow "Journal of Intellectual Property Rights" hyperlink; then follow "Full Text Search" hyperlink; then search "Implications of new patent regime on Indian pharmaceutical industry: challenges and opportunities"; then follow "Implications of New Patent Regime on Indian Pharmaceutical Industry: Challenges and Opportunities" hyperlink) (observing that "[n]ow, the specific challenge before IPI [the Indian Pharmaceutical Industry] is to start investing in basic R&D from the current abysmal level of less than 2% of total revenue to the world level of 8-10%"); David K. Tomar, Note and Comment, *A Look Into the WTO Pharmaceutical Patent Dispute Between the United States and India*, 17 WISC. INT'L L.J. 579, 583 (1999) (stating that, as of 1997, "Indian-owned companies typical[ly] spend 1% of sales on R&D, compared to an average of 15% by Western pharmaceutical companies").

12. See M. Qaiser & P. Mohan Chandran, *Patent Era Spurs Drug Discovery*, PHARMABIZ.COM (Jan. 25, 2006), at <http://www.pharmabiz.com/article/detnews.asp?articleid=31588§ionid=46&z=y>, stating that:

India has . . . realized the importance of allocating increased budgets to R&D in the wake of the product patent regime. Earlier, Indian companies invested only around 1% on R&D, but are now investing whopping amounts on R&D. In 2003-04, the top 10 Indian pharma companies spent about \$400 million on R&D. In 2004, Ranbaxy invested 7% of its \$1 billion sales on R&D, while Dr Reddy's Laboratories (DRL) spent 14% of its sales of \$446 million on R&D.

See also Nath Statement, *supra* note 8, at ¶ 5 (stating that "while Indian companies spent not even a fraction of a percent on R&D ten years ago, today the larger Indian companies are spending in the region of 6 to 8 percent of their turnover on R & D (The norm for major MNCs is 12%).").

13. See Sahad P.V. & Sharma, *supra* note 10, at 136 (stating that "[a] dozen global companies such

drug manufacturing. The Indian Patent Office is grappling with a dramatic increase in application filings by both foreign and Indian assignees; the total number of filings for fiscal year 2004-05 increased 38 percent from the previous year.¹⁴

These paradigm shifts in India's patent laws and its pharmaceutical sector more broadly reflect India's growing economic power and presence on the international stage. Once an insular society, India is today emerging as a global force to be reckoned with. "[T]he once-great nation of India is reawakening from several centuries of torpor, and . . . is poised to again be a great world power."¹⁵ India is now the world's largest democracy,¹⁶ and actively touts itself as such.¹⁷ Its population of 1.1 billion is second only to China's.¹⁸ India's economy is growing rapidly, averaging almost seven percent GDP growth in the decade since 1994;¹⁹ the average GDP growth over

as AstraZeneca, Bayer, Eli Lilly, GlaxoSmithKline, Novartis and Pfizer have chosen India as a centre for conducting clinical trials and research").

14. See INTELLECTUAL PROPERTY INDIA, OFFICE OF THE CONTROLLER GENERAL OF PATENTS, DESIGNS, TRADE MARKS AND REGISTRAR OF GEOGRAPHICAL INDICATIONS, ANNUAL REPORT 2004-05 [hereinafter ANNUAL REPORT 2004-2005] (hard copy on file with author; not available electronically as of August 2006), at 27 (Appendix C) (difference between 17,466 total filings in FY 2004-2005 and 12,613 total filings in FY 2003-2004 as a percentage of the 12,613 total filings in FY 2003-2004). The ANNUAL REPORT 2004-2005, available at http://patentoffice.nic.in/cgpdtn/annual_report_2004_2005.pdf (last visited Feb. 15, 2007). For additional data on patent application filings in India, see *infra* Part V.A.4.

15. Nicholas D. Kristof, *They're Rounding the First Turn! And the Favorite Is . . .*, N.Y. TIMES, Jan. 17, 2006, at A19.

16. See Mark Landler, "India Everywhere" *In the Alps*, N.Y. TIMES, Jan. 26, 2006, at C3 (noting India's "clamorous democracy" of "675 million eligible voters").

17. *Id.* (reporting India's elaborate public relations campaign during 2006 World Economic Forum in Davos, Switzerland, "intended to promote the country as the world's next economic superstar, and as a democratic alternative to China for the affections of foreign investors").

18. India's current population is estimated at 1.1 billion people. See Central Intelligence Agency, *India*, THE WORLD FACTBOOK (Jan. 10, 2006) (estimating India population of 1,095,351,995 as of July 2006), available at <http://www.cia.gov/cia/publications/factbook/geos/in.html> [hereinafter WORLD FACTBOOK INDIA]. China's population is estimated at 1.3 billion people. See Central Intelligence Agency, *China*, THE WORLD FACTBOOK (Jan. 10, 2006) (estimating population of 1,313,973,713 as of July 2006), available at <http://www.cia.gov/cia/publications/factbook/geos/ch.html> [hereinafter WORLD FACTBOOK CHINA].

19. WORLD FACTBOOK INDIA, *supra* note 18 (noting that India's economy "has posted an excellent average growth rate of more than 6.8% in the decade since 1994, reducing poverty by about 10 percentage points . . . [and] India probably achieved greater than 7 percent GDP growth in 2005, significantly expanding manufacturing.").

the past three years is eight percent.²⁰ “Over the past 15 years, India has been the second fastest-growing country in the world—after China”²¹

Having successfully capitalized on its large numbers of well-educated English-speaking citizens to become a major supplier of information technology services and software,²² India is now poised to become a global leader in the pharmaceutical industry. The success story of its IT sector is admittedly the clearest example of India’s growing stature in the knowledge economy,²³ but innovation in the pharmaceutical and biotechnology sectors is also on the rise. Many Indian-born scientists who have trained in the U.S. are returning to India, bringing home their experience in pharmaceutical research and development.²⁴ The country’s ever-expanding pool of scientifically-trained workers is also available to the Indian pharmaceutical industry. Almost forty percent of India’s university graduates now obtain their degrees in science and engineering, in contrast with declining enrollments in those fields in the U.S.²⁵ India’s pharmaceutical industry is fast becoming a force to

20. See Alex Perry & S. Hussain Zaidi, *Bombay’s Boom; Brash, Messy And Sexy, India’s Biggest City Embodies The Nation’s Ambition. How Bombay Is Shaping India’s Future—And Our Own*, TIME, June 26, 2006, 26, 40 (listing GDP growth as one of “10 Ways India Is Changing The World”); see also Somini Sengupta & Saritha Rai, *India Sets Goals of Rural Aid and Education*, N.Y. TIMES, Mar. 1, 2006, at A6 (reporting that India’s finance minister is predicting “8.1% economic growth for the year ending March 31, 2007”).

21. Fareed Zakaria, *India Rising; Messy, Rauous, Democratic India Is Growing Fast, And Now Many Partner Up With World’s Richest Democracy—America*, NEWSWEEK, Mar. 6, 2006, at 32.

22. WORLD FACTBOOK INDIA, *supra* note 18.

23. See Perry & Zaidi, *supra* note 20, at 41 (reporting that India’s “Internet-technology industry, which includes other outsourcing services, generated revenues of \$36 billion in 2005, up 28% from 2004.”).

24. See Interview with Dr. Swati Piramal, Nicholas Piramal India Ltd., in Mumbai, India (Nov. 24, 2005) (discussing her company’s recruitment of U.S.-trained Indian scientists) (transcript on file with author) [hereinafter Interview with Dr. Swati Piramal]; Saritha Rai, *Indians Find They Can, Indeed, Go Home Again*, N.Y. TIMES, Dec. 26, 2005, at C1 (noting “reverse brain drain” of “Indians who were educated in and worked in the United States and Europe, but who have been lured home by the surging Indian economy and its buoyant technology industry”).

25. See National Council of Applied Economic Research, *India Science Report: Science Education, Human Resources, and Public Attitude Towards Science and Technology* 7, Fig 2.2 (2005), available at <http://www.insaindia.org/India%20Science%20report-Main.pdf> (showing that 38.6% of all bachelor degrees issued in India in 2004 were awarded to science majors, which includes majors in the natural sciences, engineering, medicine, and agriculture/veterinary sciences); see also THOMAS L. FRIEDMAN, *THE WORLD IS FLAT: A BRIEF HISTORY OF THE TWENTY-FIRST CENTURY* 257 (2005) (noting that the number of Americans aged 18-24 who receive science degrees has fallen to 17th in the world, declining from third in the world thirty years ago, and that in engineering, “universities in Asian countries now produce eight times as many bachelors degrees as the United States”).

Disagreements exist as to claims that India is graduating more engineers than the U.S. See Vivek Wadhwa, *About That Engineering Gap*, BUSINESSWEEK ONLINE, Dec. 13, 2005 (disputing the “commonly cited . . . figures” that 600,000 engineers graduate annually from China’s institutions of higher education, 350,000 from India, and 70,000 from the U.S., and finding instead that the U.S. is graduating 222,335

be reckoned with in the global marketplace because of its strikingly lower costs of drug research and clinical testing.²⁶ “[F]ive qualified chemists can be hired in India for the cost of just one in America.”²⁷ Estimates are that it will cost only about \$100-200 million to develop a new drug in India, as compared to the U.S. cost of \$500-900 million.²⁸

Recent academic work on the role of intellectual property law in advanced developing economies has tended to focus more on China than India.²⁹ But India’s rapidly changing IP landscape merits just as much, if not more, attention. “The great race of the 21st century is under way between China and India to see which will be the leading power in the world in the year 2100.”³⁰ Admittedly China is far ahead of India in terms of foreign direct investment, manufacturing capability, and infrastructure.³¹ But other fundamental advantages position India as the more promising incubator for pharmaceutical innovation. Notably, India benefits from a greater degree of political and social stability. The country’s “democracy, free press and civil society . . . provide a measure of political stability . . . [thus] the risks of social and political explosions in India are declining, while in China they may be

engineers annually while India is graduating only 215,000), available at http://www.businessweek.com/smallbiz/content/dec2005/sb20051212_623922.htm.

26. For example, it has been estimated that the costs of conducting clinical trials of drugs in India is only one-seventh of that in the United States or Europe. See Sreenivasaro Vepachedu & Martha Rumore, *Patent Protection and the Pharmaceutical Industry in the Indian Union*, INTELL. PROP. TODAY, Oct. 2004, at 46.

27. Norman R. Augustine, Retired Chairman and C.E.O. Lockheed Martin Corporation, and Chair, Committee on Prospering in the Global Economy of the 21st Century, Committee on Science, Engineering, and Public Policy, Division on Policy and Global Affairs, The National Academies, Statement before the Committee on Energy and Natural Resources, U.S. Senate, (Oct. 18, 2005), in National Academy of Sciences, *RISE ABOVE THE GATHERING STORM: ENERGIZING AND EMPLOYING AMERICA FOR A BRIGHTER ECONOMIC FUTURE*, app. G at 3 (2005), available at <http://darwin.nap.edu/books/0309100399/html> [hereinafter *Gathering Storm Report*].

28. See Sahad P.V. & Sharma, *supra* note 10, at 138. See also Interview with Dr. Swati Piramal, *supra* note 24 (stating that “[i]f in the West it costs \$1B [to innovate in pharmaceuticals], we will make it at \$50 million (1/20th of the cost)”).

29. See, e.g., Robert Slate, *Judicial Copyright Enforcement in China: Shaping World Opinion on TRIPS Compliance*, 31 N.C. J. INT’L L. & COM. REG. 665 (2006); see also Jeffrey A. Andrews, *Pfizer’s Viagra Patent and the Promise of Patent Protection in China*, 28 LOY. L.A. INT’L & COMP. L. REV. 1 (2006); see also Ke Shao, *Look at My Sign!—Trademarks in China from Antiquity to the Early Modern Times*, 87 J. PAT. & TRADEMARK OFF. SOC’Y 654 (2005); see also Peter K. Yu, *From Pirates to Partners: Protecting Intellectual Property in China in the Twenty-First Century*, 50 AM. U. L. REV. 131 (2000).

30. Kristof, *supra* note 15, at A27.

31. See Perry & Zaidi, *supra* note 20, at 40 (In 2005 India’s foreign direct investment was an estimated \$8.4 billion while China’s was \$72.4 billion . . . and eighty-one percent of India’s population lives on less than \$2 per day, while in China only 47% live on that amount.).

rising.”³² “India’s democracy, for all its flaws, is real. People are free to say what they like, and they do so with relish. Governments rule by popular consent. When they lose that consent, they are replaced, and peaceably.”³³ With respect to recognition and enforcement of intellectual property rights, concerns have long existed over China’s reputation as a haven for pirating and counterfeiting,³⁴ marking that country as “the world’s Wal-mart for fake goods.”³⁵ By contrast, India benefits from a strong rule of law tradition; its court system is stable and governed by an independent, well-respected judiciary.³⁶ India’s financial structure is solid in comparison to China’s,³⁷ and India benefits from superior business management skills.³⁸ India has a “real and deep private sector (unlike China’s many state-owned and state-funded companies)”³⁹

Despite India’s recent economic growth and comparative advantages for scientific innovation, the considerable challenges it faces must not be minimized. Much of the nation remains mired in poverty, with at least 25

32. Kristof, *supra* note 15, at A27.

33. *Work in Progress*, THE ECONOMIST, Feb. 22, 1997, at S3.

34. See Todd C. Fishman, *Manufaketure*, N.Y. TIMES, Jan. 9, 2005, § 6, at 40; see also *IP Risk Tops China Factory Owners’ Concerns*, MANAGING INTELL. PROP., Aug. 1, 2006, available at <http://www.managingip.com> (reporting that among 138 respondents of “Low Cost Manufacturing in China” survey, safeguarding intellectual property was regarded as “the biggest risk area for companies with Chinese manufacturing operations in the high tech, industrial equipment and chemicals sectors.”); David L. McCombs, Haynes and Boone, LLP, Presentation to Licensing Executives Society, *Into the Mouth of the Dragon: Patent Protection and Enforcement in China* (Oct. 19-22, 2004), available at http://www.haynesboone.com/FILES/tbl_sl2PublicationsHotTopics/PublicationPDF60/1262/10_19_2004_McCombs.pdf (observing that “[t]he communist ‘collective’ mentality engrained in Chinese culture manifests itself with the belief among many that intellectual property is a commodity to be purchased and then used freely”).

35. Todd Datz, *Faked in China*, CSO ONLINE.COM (Jan. 1, 2006), available at http://www.csoonline.com/read/010106/faked_china.html.

36. In contrast, China’s legal system often fails to resolve long-standing disputes, sometimes refusing to even acknowledge that the legal complaints exist. See Joseph Kahn, *When Chinese Sue the State, Cases Are Often Smothered*, N.Y. TIMES, Dec. 28, 2005, at A1; see also McCombs, *supra* note 34 (stating that “[t]op Chinese government officials admit the judiciary system is plagued with problems such as partiality, incompetence, and corruption”).

37. Kristof, *supra* note 15, at A27 (observing that “India has a solid financial system, while China’s banking system is a catastrophe”).

38. See Rukhmini Punoose, *India’s Edge: Why The Nation’s Top Managers Fare Better Than Their Chinese Counterparts In Global Business Circles*, NEWSWEEK, Oct. 31, 2005, at E25 (explaining why India’s “top managers fare better than their Chinese counterparts in global business circles”).

39. Zakaria, *supra* note 21, at 36; see also Perry & Zaidi, *supra* note 20, at 41 (observing that the “rise of China has been the product of methodical state planning, but India’s is all about private hustle . . .”).

percent of the population still under the official poverty line.⁴⁰ More than 300 million Indians live on less than a dollar each day.⁴¹ India now has an estimated 5.7 million people living with HIV, more than any other country in the world.⁴² Although India is “world-famous for the quality of English-speaking, technically adept engineers produced by its colleges and universities,” its primary and secondary schools are in crisis.⁴³ More than half of the female population remains illiterate.⁴⁴ Caste prejudice is still deeply engrained in the culture of India,⁴⁵ “a modern state but an ancient civilization.”⁴⁶ India’s economic reforms are very recent, with the first significant moves towards a free market economy beginning only in 1991. Governmental bureaucracy continues to hamper India’s growth, which “is happening not because of the government, but largely despite it.”⁴⁷ The residue of India’s “license raj” survives, and the “inspector raj” is still very much in force.⁴⁸

Despite these formidable challenges, India is poised to foster a thriving culture of innovation in the pharmaceutical industry. The role of its new patent law framework will be pivotal. Given its burgeoning science and technology sector, skilled workforce, democratic government and stable rule of law, India presents a uniquely situated laboratory for advanced developing country⁴⁹ patent systems. The world is watching to see how India implements

40. See WORLD FACTBOOK INDIA, *supra* note 18.

41. Zakaria, *supra* note 21, at 34. But see Simon Long, *Now for the Hard Part: A Survey of Business in India*, THE ECONOMIST, June 3, 2006, at 4 (stating that 260 million live on less than \$1 a day).

42. See Perry & Zaidi, *supra* note 20, at 41 (listing the HIV crisis in India as one of “10 Ways India Is Changing The World”).

43. *Can India Work? India’s Economic Reforms*, THE ECONOMIST, June 12, 2004, Special Report section, at 2 (Although India’s college- and graduate-level educational system is a success story, its “primary and secondary schools are lamentable in many parts of the country.”) [hereinafter *Can India Work?*].

44. See WORLD FACTBOOK INDIA, *supra* note 18 (reporting a 48.3% female literacy rate for 2003).

45. See Somini Sengupta & Hari Kumar, *Quotas to Aid India’s Poor vs. Push for Meritocracy*, N.Y. TIMES, May 23, 2006 (describing problem of caste prejudice in India).

46. STEPHEN PHILIP COHEN, BROOKINGS INSTITUTE, INDIA: EMERGING POWER 20 (2001).

47. Zakaria, *supra* note 21, at 36.

48. See *Can India Work? India’s Economic Reforms*, THE ECONOMIST, June 12, 2004, Special Report (noting Indian Institute of Planning and Management study reporting that each industrial unit in India is “still visited by between 40 and 60 inspectors in the course of a month.”).

49. India is typically characterized as an “advanced developing country.” See European Commission, *Different Needs, Different Responsibilities: What is the EU Asking from Developing Countries?* (Dec. 14, 2005), available at http://ec.europa.eu/comm/trade/issues/global/development/pr141205_en.htm (stating that “advanced developing countries” include “the large emerging economies of the G20, who combine developing country status with high competitiveness in one or more export sector, such as Brazil (Agriculture), China (Manufacturing) and India (Services)”). A Rand Corporation study

its innovative patents framework. As a critical test case for the flexibilities inherent in TRIPS, the Indian experiment will determine whether and how national patent systems can truly accommodate domestic economic conditions and cultural norms while still satisfying international baseline standards.

Parts II and III of this article explore the landscape in which India's evolving patents system is positioned. Part II explains the historical evolution of India's patent laws as mirroring the country's journey from colonization to fledgling independent democracy to rising global star. Every bit of the nation's history and experience informs and shapes the patent system that India has today. Part III conveys the current complex milieu in which India's new pharmaceutical product patents regime was implemented and in which it must now function. That regime is the product of a multitude of powerful influences, including an extensive but fragmented pharmaceutical industry, a huge and vocal citizenry, and a fragile coalition government entrenched in political compromise. Parts IV and V present the substantive patent law content of the article. Part IV offers an in-depth comparative analysis and critique of the key provisions of India's new Patents Act, 1970 (2005), including a number of controversial features such as a unique anti-"evergreening" criteria for pharmaceutical patentability, pre-grant opposition, and the world's most elaborate compulsory licensing scheme. Part V assesses the capacity and capability of the Indian Patent Office and the Indian court system to implement the newly strengthened patents regime. Empirical evidence on recent patenting activity is presented, as is a comparison of Indian patent prosecution procedures with U.S. practice. A case study of recent pharmaceutical patent litigation presages conflicts between the various High Courts. Based on the preceding analysis, Part VI of the article concludes with a series of recommendations for the future of India's pharmaceutical product patents regime.

II. HISTORICAL EVOLUTION OF PATENT LAW IN INDIA

The development of India's patents regime mirrors the country's journey from colonization to independence to global citizen. Three distinct periods can be identified, each of which is detailed below. To summarize, in the first or "colonial" period the British enacted India's first patent statutes during the

published in 2006 characterizes India (along with China) as leading the group of "scientifically proficient" countries. Rand Corporation, *News Release: Rand Study Says Advanced Countries Will Benefit Most from Progress in Technology, with Lesser Benefits to Other Nations* (June 1, 2006), available at <http://www.rand.org/news/press.06/06.01.html>.

latter half of the 19th century. Although India gained its independence from the British in 1947, it was unable to enact its first independently-drafted patent laws until the 1970s due to deep political and policy divisions over the value and role of patent protection in the nation's developing economy. India's Patents Act, 1970 entered into force during the second or "post-independence" period. Although modeled on Great Britain's Patents Act, 1949, the Indian Act incorporated major departures intended to lessen the social costs imposed by largely foreign-owned patents. The Patents Act, 1970 prohibited patents on products useful as medicines and food, shortened the term of chemical process patents, and significantly expanded the availability of compulsory licensing.⁵⁰ During the third or "globalization" period from approximately 1986 to the present, India's participation in the debates over the inclusion of intellectual property within the GATT framework and its eventual entry into the World Trade Organization (WTO), along with its accession to the Paris Convention for the Protection of Industrial Property and the Patent Cooperation Treaty,⁵¹ have compelled significant strengthening of the nation's patent laws. The implementation of those changes is ongoing, and their anticipated impact remains to be fully seen. Today India stands as a rising global power with a patent system still very much in flux.

A. Colonial Period

India inherited its patent laws from the British; no earlier domestic recognition of patents has been reported.⁵² British influence in India can be

50. See P. NARAYANAN, *PATENT LAW* 7 (3d ed. 1998, Eastern Law House, 1998) [hereinafter NARAYANAN (PATENT LAW)].

51. See World Intellectual Property Organization, *Treaties Database—Contracting Parties—Paris Convention—India—Details* (noting India's accession to the 1967 Stockholm Act version of the Paris Convention on September 7, 1998, and the entry into force of that Act in India on December 7, 1998), at http://www.wipo.int/treaties/en/Remarks.jsp?cnty_id=246C; World Intellectual Property Organization, *Treaties Database—Contracting Parties—PCT—India—Details*, (noting India's accession to the Patent Cooperation Treaty (PCT) on September 7, 1998, and the entry into force of the PCT in India on December 7, 1998), at http://www.wipo.int/treaties/en/Remarks.jsp?cnty_id=500C.

52. See Amiya Kumar Bagchi, *Indian Patents Act and Its Relation to Technological Development in India: A Preliminary Investigation*, *ECON. & POL. WKLY* at 287 (Feb. 18, 1984) (contrasting patent law with most other forms of property law in India, which have domestic origins pre-dating British rule); the more likely form of pre-existing intellectual property protection in India is trade secrecy, which was more conducive to the Indian practice of managing businesses within a family or community. See TIRTHANKAR ROY, *THE ECONOMIC HISTORY OF INDIA 1857-1947* 181 (2000) (noting that "[t]he traditional Indian business firm typically functioned from within the family and community . . . [s]ometimes, belonging to a community or family helped in keeping trade secrets. In this sense the community could behave like a 'guild'").

traced back to Queen Elizabeth I's chartering of the "Governor and Company of Merchants of London trading into the East Indies" in 1600.⁵³ The English East India Company first landed on Indian soil in 1608,⁵⁴ and over the next 250 years, laid the groundwork for the British Raj.⁵⁵ The British Crown took over full control of India from the East India Company in the aftermath of the Great Indian Uprising of 1857-58,⁵⁶ and Queen Victoria was declared Empress of India in 1877⁵⁷ (despite never having set foot on Indian soil).⁵⁸ During the 1858-1905 zenith of the British Raj, almost twenty percent of Britain's exports were being shipped to India.⁵⁹ For economic reasons, as well as the perceived prestige of dominating the subcontinent, the British considered India the "jewel in the crown" of the British Empire.⁶⁰ Economic policies imposed on India were "concerned more with protecting and promoting British interests than with advancing the welfare of the Indian population."⁶¹

The British implemented the first patent statute in India in 1856, based on the British Patent Law of 1852.⁶² India's Act VI of 1856, "On Protections of Inventions," provided certain exclusive privileges to inventors of new manufactures for a 14-year term.⁶³ The 1856 Act was modified in 1859 and renamed the "Act for granting exclusive privileges to inventors."⁶⁴ According to a leading Indian treatise, the purpose of this legislation was "to enable the English Patent holders to acquire control over Indian markets."⁶⁵ The year 1872 saw enactment of the Patents and Designs Protection Act, followed by

53. DENIS JUDD, *THE LION AND THE TIGER: THE RISE AND FALL OF THE BRITISH RAJ, 1600-1947*, at 6 (2004).

54. *Id.* at 10.

55. *Id.* at 6; *see also id.* at 87 (noting that in the aftermath of the Great Indian Uprising of 1857-58, "the 1858 Government of India Act swept away the power of the [East India] Company, which was assumed by the Crown The Company continued as a trading concern, but its great days were over.").

56. *Id.* at 87 (noting that "the 1858 Government of India Act swept away the power of the Company, which was assumed by the Crown.").

57. *Id.* at 94.

58. *Id.*

59. *Id.*

60. *Id.*

61. *THE CAMBRIDGE ECONOMIC HISTORY OF INDIA, 1757-1970*, at 947 (Dharma Kumar et al. eds., 1983).

62. NARAYANAN (PATENT LAW), *supra* note 50, at 4. The statute was denominated Act VI of 1856. *Id.*

63. *See* ELIZABETH VERKEY, *LAW OF PATENTS* 15 (2005).

64. *See* NARAYANAN, *INTELLECTUAL PROPERTY LAW* 1 (Gogia Law Agency, Hyderabad, 2005) [hereinafter NARAYANAN (INTELLECTUAL PROPERTY LAW)]. The "exclusive privileges" of making, selling, and using the patented invention in India were granted for a term of 14 years from the date of filing of the patent specification. *See* NARAYANAN (PATENT LAW), *supra* note 50, at 4.

65. *See* NARAYANAN (PATENT LAW), *supra* note 50, at 4.

enactment of the Protection of Inventions Act in 1883.⁶⁶ The 1872 and 1883 acts were thereafter consolidated in the Inventions and Designs Act of 1888.⁶⁷

While the British continued to evolve the patent laws they had imposed, India's domestic technology sector grew. Although still primarily an agriculture-based economy,⁶⁸ the nation's technology industries grew significantly from the 1880s onward. Indian industrialists such as the steel baron J.N. Tata led much of this expansion.⁶⁹ By World War I, India was ranked fourteenth among industrialized nations of the world.⁷⁰ Large-scale industrialization during this period was dominated by production of textiles, food processing, and metals, however; indigenous pharmaceutical production was not part of the success story.⁷¹

Meanwhile, enactment by the British of the Indian Patents and Designs Act, 1911⁷² created for the first time a system of patent administration in India under the direction of a Controller of Patents.⁷³ The 1911 Act established a form of intra-British Empire priority system such that an applicant for an Indian patent who had within the previous twelve months filed an application for the same invention in the United Kingdom was entitled to the benefit of the earlier United Kingdom filing date;⁷⁴ publications or uses of the invention

66. *Id.*

67. VERKEY, *supra* note 63, at 16.

68. See JUDD, *supra* note 53, at 98 (noting that during British Raj, "over 70 per cent of the [Indian] population were completely dependent upon agriculture").

69. *Id.* at 100. See also ROY, *supra* note 52, at 167 (noting that "[t]he most outstanding industrial achievement of the prewar era [in India] was the Tata Iron and Steel Company. It began as a firm in 1907, and started production from 1911. Tata Steel owed its existence to its founder J.N. Tata's persistence and vision.").

70. See JUDD, *supra* note 53, at 100.

71. See ROY, *supra* note 52, at 158. Out of all Indians employed in factories in 1921, 41.62% worked in textile production, followed by 7.2 percent in food production and 4.6 percent in metals and machinery. Only 2.6% were employed in the "chemicals" industry; there are no data reported specifically for pharmaceuticals manufacturing. *Id.*; see also KUMAR ET AL., *supra* note 61, at 566 (stating that "[t]he history of large-scale private factory enterprise between 1850 and the First World War is associated almost entirely with developments in three industries—jute, cotton, and iron and steel.").

72. Indian Patents and Designs Act, 1911, No. 2 of 1911 (1911) reprinted in NARAYANAN (PATENT LAW), *supra* note 50, at 770-96 [hereinafter India Patents Act, 1911].

73. See NARAYANAN (PATENT LAW), *supra* note 50, at 4. Prior to this, the British Secretary to the Government in the Home Department had administered the patent system in India from 1857 to 1888. See Ved P. Mithal, *Patents in India*, 30 J. PAT. OFF. SOC'Y (IN) 62, 62 (1948). With the passage of the Act of 1888 responsibility for the patent system was shifted from the Home Department to the Department of Revenue and Agriculture. *Id.* In 1904, one H.C. Graves, an examiner from the British Patent Office, was appointed full-time Patent Secretary; Graves subsequently became the first Controller of Patents and Designs in 1912. *Id.* at 63-64.

74. See India Patents Act, 1911, *supra* note 72, at § 78A(1).

in India during the intervening priority period would not invalidate the Indian patent.⁷⁵ Patents granted under the 1911 Act expired sixteen years after their filing date, although extensions of up to seven additional years were available.⁷⁶ The 1911 Act remained in effect, with various amendments,⁷⁷ until an independent India enacted its first indigenous patent law more than 50 years later. Like its predecessor Acts, the 1911 permitted patenting of pharmaceutical products.

Despite industrial progress in other sectors such as steel production, the growth of India's indigenous pharmaceutical industry remained relatively stunted during British control. Multinationals reportedly used the 1911 Act to prevent Indian drug firms from manufacturing drugs invented abroad.⁷⁸ Not surprisingly, the indigenous drug makers viewed the 1911 Act as draconian.⁷⁹ Whatever the true motivations underlying the 1911 Act, it had negligible effect in terms of spurring domestic pharmaceutical (or other) innovation. For example, in 1930 a total of 1,099 patent applications were filed in India and 80 percent of these were filed by foreigners "intend[ing] mainly to establish pre-emptive claims for improvements elsewhere."⁸⁰ By the time of independence in 1947 when India's population was approximately 400 million persons, only 2,610 patent applications (on all types of inventions) were filed annually with the Indian Patent Office.⁸¹ The minuscule number of filings reflects to some degree the lack of pharmaceutical activity in India at that time. Prior to World War II, there was "virtually no basic drug manufacture in the country."⁸²

75. See *id.* § 78A(2)(a).

76. Mithal, *supra* note 73, at 69.

77. For example, in 1930 the Patents Act, 1911 was amended to provide for "patents of addition," which are patents for "improvements or modifications of inventions in respect of which protection [already] has been applied for or obtained." India Patents Act, 1911, No. 2 of 1911, (amended 1930), *reprinted in* Mithal, *supra* note 73, at 65. The patents of addition concept is retained in the current statute. See The Patents Act, No. 39 of 1970, §§ 54-56 (Universal 2005) (amended 2005).

78. See SUDIP CHAUDHURI, THE WTO AND INDIA'S PHARMACEUTICALS INDUSTRY: PATENT PROTECTION, TRIPS, AND DEVELOPING COUNTRIES 128-32 (2005).

79. See Hamied, *supra* note 2, at 3 (noting 1961 formation of Indian Drug Manufacturers Association to work for modification of then-prevailing "draconian" patent laws of India as embodied in Patents Act, 1911).

80. See KUMAR ET AL., *supra* note 61, at 639.

81. Mithal, *supra* note 73, at 64 (not specifying the numerical breakdown between Indian and foreign-owned patents); the total staff strength of the Indian Patent Office examining corps as of 1946 was "about 26" persons. *Id.*

82. Hamied, *supra* note 2, at 2.

B. Post-Independence Period

When India finally seceded from Great Britain in 1947, eighty percent of the subjects of the British Empire “gained their independence at one stroke.”⁸³ At the time of independence, India’s 400 million people represented one-fifth of the world’s population.⁸⁴ Moreover, the nation at that time was among the poorest in the world.⁸⁵ Meeting the potentially staggering demand for low-cost medicines became a paramount challenge for India’s new leaders.

After the ensuing tragedy of the Partition,⁸⁶ a fledgling independent India turned its attention to an impoverished domestic economy and eradication of the vestiges of colonization. India at this stage had little in the way of an indigenous pharmaceutical industry.⁸⁷ The unfortunate legacy of British-imposed, foreign-favoring patent laws and a largely agrarian economy⁸⁸ was a health care system in which most modern medicines were manufactured abroad, imported into India and sold there at some of the highest prices in the

83. See JUDD, *supra* note 53, at 2.

84. See LARRY COLLINS & DOMINIQUE LAPIERRE, *FREEDOM AT MIDNIGHT* xi (new ed. 2005).

85. See ROY, *supra* note 52, at 1 (stating that “[i]n 1947, India was one of the poorest countries in the world, having seen rather low rates of economic growth in the late nineteenth and the early twentieth centuries”).

86. See generally COLLINS & LAPIERRE, *supra* note 84 *passim* (detailing events leading up to India’s independence from the British Empire in 1947, the partition of the country into India, Pakistan, and East Pakistan (today Bangladesh), and the ensuing slaughter of over one million Hindus, Sikhs, and Moslems); see also JUDITH E. WALSH, *A BRIEF HISTORY OF INDIA* 205 (2006) (stating that over a million people “lost their lives in partition violence” and that more than 10 million “fled their former homes on either side of the border to become refugees within the other country”).

87. See Srividhya Ragavan, *Of the Inequals of the Uruguay Round*, 10 MARQUETTE INTELL. PROP. L. REV. 273, 301 (2006) (stating that “[w]hen India became independent, the pharmaceutical sector was dominated by multinational companies.”); see also SUNIL K. SAHU, *TECHNOLOGY TRANSFER, DEPENDENCE, AND SELF-RELIANT DEVELOPMENT IN THE THIRD WORLD: THE PHARMACEUTICAL AND MACHINE TOOL INDUSTRIES IN INDIA* 55 (Praeger 1998) (observing that

“[a]lthough the foundation of the modern pharmaceutical industry was laid in 1901 with the establishment of Bengal Chemical and Pharmaceutical Works, and the two World Wars gave a boost to the development of the industry, the progress made under British rule was insignificant and India depended largely on imports from Britain, France, and Germany for its requirements of drugs and medicines. At the time of independence, pharmaceutical operation involved merely simple packaging and bottling; it could hardly have been termed an industry.”). Cf. CHAUDHURI, *supra* note 78, at 22 (reporting that by 1939, indigenous pharmaceutical firms were supplying 13% of the medicinal requirements of India, but “still had a long way to go to attain self-sufficiency”).

88. Planning Commission, Government of India, 1ST FIVE YEAR PLAN Ch. 1 ¶ 13 (Dec. 7, 1952), available at <http://planningcommission.nic.in/plans/planrel/fiveyr/default.html> (stating that “[a]griculture is still the mainstay of life for about 70 per cent of the population, and productivity in this sector is exceedingly low.”) [hereinafter FIVE YEAR PLAN].

world.⁸⁹ Multinational pharmaceutical corporations largely controlled India's drug industry.⁹⁰ Critical drugs such as insulin and penicillin were wholly imported.⁹¹ An unpopular decision of the Bombay High Court awarding the West German chemical giant Hoechst an injunction against the Indian drug maker Unichem Laboratories added fuel to the fire.⁹² India's leaders demanded major changes to the patent law in order to jump-start indigenous manufacture of medicines at affordable prices.

The Indian government wasted no time in beginning to craft an indigenous patent law. Only a few months following Independence, a

89. See CHAUDHURI, *supra* note 78, at 132 (noting the finding of an "American Senate Committee (Kefauver Committee)" that "India was among the highest priced nations in the world" with respect to drug prices); Chandran et al., *supra* note 11, at 269-80 (noting that during post-independence era and until 1970, India became "increasingly dependent on imports for bulk drugs and formulations and thus, drug prices were amongst the highest in the world."); Donald G. McNeil Jr., *Selling Cheap 'Generic' Drugs, India's Copycats Irk Industry*, N.Y. TIMES, Dec. 1, 2000, at A1.

The "Kefauver Committee" report, as referred to *supra* by CHAUDHURI, is formally known as SUBCOMMITTEE ON ANTITRUST AND MONOPOLY, U.S. SENATE JUDICIARY COMMITTEE, S. REP. NO. 448, 87TH CONG., 1ST SESS., STUDY OF ADMINISTERED PRICES IN THE DRUG INDUSTRY (June 27, 1961). The study compared prices charged for identical drugs sold in various countries. See *id.* at 32 (subcommittee "secure[d] from abroad the prices of a number of important drug products"). In several instances drug prices in India as of 1959 were higher (sometimes significantly so) than prices for identical drugs in developed countries. For example, the price in India in 1959 for the tranquilizer meprobamate was 147% of the U.S. price and higher than the price reported for any other country included in the data set except Venezuela. *Id.* at 35. The price for the tranquilizer Serpasil, although only 44% of the U.S. price, was nevertheless higher than the price charged for Serpasil in France, Austria, Germany, England, and several other developed countries. *Id.* at 36. The price in India in 1959 for the oral antidiabetic Tolbutamide was 86% of the U.S. price, but over twice the price in Austria, and higher than the price in Germany, Holland, England, France, Italy, Brazil, and Belgium. *Id.* at 37. The price in India for the broad spectrum antibiotic Chloromycetin was only 59% of the U.S. price, but nevertheless higher than the price charged in Iran, England, Mexico, and Holland. *Id.* at 40. The price charged in India for the broad spectrum antibiotic Aureomycin was 136% of the U.S. price and a higher price than that charged by any other country in the data set. *Id.* at 41. The price charged in India for the broad spectrum antibiotic Tetracycline was 128% of the U.S. price and higher than the price charged by any other country in the data set except Belgium. *Id.* at 42.

90. See Ragavan, *supra* note 87, at 280 (noting that at the time of India's 1ST FIVE YEAR PLAN, which was submitted Dec. 7, 1952, "multinationals . . . formed more than 90% of the Indian pharmaceutical industry"); Hamied, *supra* note 2, at 3 (noting that in 1971 [a year before the India Patents Act, 1970 took effect] "the MNC's controlled over 70% of the domestic pharma[ceutical] market").

91. FIVE YEAR PLAN, *supra* note 88, at Ch. 32 ¶¶ 96, 99.

92. See Bagchi, *supra* note 52, at 293 (observing that Bombay High Court's judgment in *Farbwerke Hoechst & Bruning Corp. v. Unichem Lab.*, 1969 A.I.R. 56 (Bom[bay]) 255, enjoining Unichem from further manufacture of tolbutamide, "strengthened the case for treating preparations of chemical substances including food, drugs and medicines in a special manner from a legal point of view, and this special treatment was embodied in the [Patents] Act of 1970"); see also Srividhya Ragavan, *A "Patent" Restriction on Research & Development: Infringers or Innovators?*, 2004 U. ILL. J.L. TECH. & POL'Y 73, 87-88 (2004) (discussing *Hoechst* decision).

committee was appointed by a resolution of the Indian government dated January 10, 1948 to “review the patent laws in India with a view to ensure that the patent system was more conducive to national interests.”⁹³ These efforts ultimately led to the issuance of two comprehensive reports on the patent system. The first report, authored by a committee chaired by Indian Supreme Court Justice Bakshi Tek Chand and published in 1950, explored the failure of India’s patent system to “stimulate invention and encourage exploitation of new inventions for industrial purposes.”⁹⁴ The Chand Report recommended that compulsory licenses be issued and that an “efficient machinery should be evolved to tackle the issue of abuses [of patents].”⁹⁵ Based on the Chand Report’s recommendations a patent bill was introduced in Parliament in 1953 but thereafter lapsed.⁹⁶ Although the compulsory licensing provisions of the 1911 Act were amended in 1950 and 1952 in the wake of the Chand Report, compulsory licenses were nevertheless rarely sought, at least in part because patent owners retained the right to oppose the grant of such licenses and to appeal any such grants.⁹⁷

A second government-commissioned report was likely the most important catalyst for the Patents Act, 1970. The Ayyangar Report, issued in 1959, was prepared for the Indian Ministry of Commerce and Industry and authored by a commission chaired by retired Indian Supreme Court Justice Rajagopala Ayyangar.⁹⁸ The Ayyangar Report, which has been described as “form[ing] the backbone of the Indian patent system,”⁹⁹ recommended “radical”¹⁰⁰ modifications of India’s existing patent laws to accommodate India’s fledgling technological advancement and industrialization, the need to encourage and reward inventors, and the increasing number of Indian research institutes and

93. Shri Justice N. Rajagopala Ayyangar, REPORT ON THE REVISION OF THE PATENTS LAW (September 1959), at Preface (on file at National Law School of India University, Bangalore) (reviewed by author at NLSIU Library on Nov. 18, 2005) [hereinafter Ayyangar Report].

94. NARAYANAN (INTELLECTUAL PROPERTY LAW), *supra* note 64, at 1.

95. *Id.*

96. See NARAYANAN (PATENT LAW), *supra* note 50, at 5.

97. See CHAUDHURI, *supra* note 78, at 93-94; *but see* Bagchi, *supra* note 52, at 300 (noting without citation to authority that “over the years 1971-74, under sections 22 and 23cc of the old Act (Indian Patents and Designs Act, 1911), 47 applications for compulsory licenses were made and 14 such applications were granted.”).

98. Ayyangar Report, *supra* note 93; *see also* NARAYANAN (INTELLECTUAL PROPERTY LAW), *supra* note 64, at 1.

99. Ragavan, *supra* note 87, at 281 n.53 (observing that the “Ayyangar Report, as modified by the Report of the Joint Committee of Parliament in 1966, forms the backbone of the Indian patent system”).

100. NARAYANAN (PATENT LAW), *supra* note 50, at 5.

emphasis on technical education.¹⁰¹ The report's three-pronged strategy has been summarized as:¹⁰²

- (i) identification of the types of inventions for which patent protection should be available;
- (ii) determination either to prohibit the granting of Indian patents to foreign entities or to require working of such patents in India; and
- (iii) determination to withstand international pressures on India to join international intellectual property conventions such as the Paris Convention, which required national treatment.¹⁰³

By holding out against membership in the prevailing international IP conventions, India hoped to develop its economy independently without "arm-twisting from developed nations."¹⁰⁴

As is not uncommon in Indian legislative matters, change came very slowly. Even after issuance of the Ayyangar Report, it would be more than ten years before India enacted its own patent law.¹⁰⁵ The India Patents Act, 1970¹⁰⁶ finally came into force on April 20, 1972,¹⁰⁷ "after long deliberations in Joint Select Committees and in-depth debate in both the Houses of Parliament preceded by recommendations of [the] high-powered [Tek Chand and Ayyangar] commissions . . ."¹⁰⁸ The prior Patents and Design Act, 1911, was repealed.¹⁰⁹

The most notable feature of the India Patents Act, 1970, was its repeal of patentability for pharmaceutical products. The Act specifically prohibited patents on "substances intended for use, or capable of being used, as food or

101. See NARAYANAN (INTELLECTUAL PROPERTY LAW), *supra* note 64, at 1. For example, the first of seven Indian Institutes of Technology was established in 1950. See Indian Institutes of Technology, *IIT-History*, at <http://www.iit.org/history.php> (last visited June 26, 2006) (stating the IIT system "churn[s] out and export[s] some of the most gifted engineering, computer science, and software talent on the globe."); FRIEDMAN, *supra* note 25, at 104 (2005).

102. See NARAYANAN (INTELLECTUAL PROPERTY LAW), *supra* note 64, at 2.

103. *Id.*

104. *Id.*

105. A patent bill was introduced in the Indian Lok Sabha (Lower House) in 1965 but thereafter lapsed. NARAYANAN (PATENT LAW), *supra* note 50, at 5.

106. The Patents Act, 1970 (1970), *reprinted in* NARAYANAN (PATENT LAW), *supra* note 50, at 543-97 (Appendix 1).

107. *Id.* § 1(3) n.*, *reprinted in* NARAYANAN (PATENT LAW), *supra* note 50, at 543, 543.

108. B.K. KEAYLA, *TRIPS PATENT SYSTEM: IMPLICATIONS FOR HEALTH CARE AND PHARMA INDUSTRY* 4 (2000).

109. See The Patents Act, 1970, at § 162(1) (providing that "[t]he Indian Patents and Designs Act, 1911, in so far as it relates to patents, is hereby repealed . . ."), *reprinted in* NARAYANAN (PATENT LAW), *supra* note 50, at 543, 595.

as medicine or drug, or . . . relating to substances prepared or produced by chemical processes (including alloys, optical glass, semi-conductors and inter-metallic compounds).”¹¹⁰ Processes for the making of such substances remained patentable, however,¹¹¹ but with an extremely short patent term. Process patents would only last the shorter of five (5) years from sealing or seven (7) years from the date of the patent,¹¹² while the term of all other types of patents (e.g., mechanical devices) was fourteen (14) years from the date of the patent.¹¹³ 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.”¹¹⁴ India quite bluntly set forth the justifications for its broad limitations on patent exclusivity in the 1970 Act’s statement of “general principles;” namely, “that patents are granted to encourage inventions and to secure that the inventions are worked in India on a commercial scale and . . . that they are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article”¹¹⁵

No longer able to protect their pharmaceutical product innovations in the Indian market, foreign enterprises dramatically cut back their patent filings in India. The Patents Act, 1970 went into effect on April 20, 1972.¹¹⁶ 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

110. *Id.* § 5, reprinted in NARAYANAN (PATENT LAW), *supra* note 50, at 543, 546.

111. *Id.* (stating that “no patent shall be granted in respect of claims for the substances themselves, but claims for the methods or processes of manufacture shall be patentable”).

112. *Id.* § 53(a) (providing that “in 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”), reprinted in NARAYANAN (PATENT LAW), *supra* note 50, at 543, 563. The “date of the patent” was apparently the date on which the complete specification had been filed. *See id.* at § 45(1), reprinted in NARAYANAN (PATENT LAW), *supra* note 50, at 543, 560.

113. *Id.* § 53(b), reprinted in NARAYANAN (PATENT LAW), *supra* note 50, at 543, 563.

114. *Id.* § 87 (titled “Certain patents deemed to be endorsed with the words “Licences of right”), reprinted in NARAYANAN (PATENT LAW), *supra* note 50, at 543, 574. For a reported example of a license of right, see *Imperial Chem. Indus. Ltd. v. Controller Gen. of Patents*, 1987 A.I.R. 77 (Calcutta) (decision of Calcutta High Court affirming Controller of Patents’ order deeming Imperial’s patent, claiming a catalyst useful in hydrocarbon reforming as well as a process for making the catalyst, to be subject to licensing of right).

115. The Patents Act, 1970, at § 83(a)-(b), reprinted in NARAYANAN (PATENT LAW), *supra* note 50, at 543, 573.

116. With limited exceptions, the provisions of the Patents Act, 1970 came into force on April 20, 1972. *See id.* § 1(3) and n.*, reprinted in NARAYANAN (PATENT LAW), *supra* note 50, at 543, 543.

filed by non-Indians ten years prior in 1968.¹¹⁷ Indian-owned application filing levels stayed constant, though low, during the same time period.¹¹⁸

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 (which in any event lasted only 5-7 years). India developed a reputation as a “pirate” nation adept at copying drugs invented and patented in other countries.¹¹⁹ The “pirate” label was unduly pejorative, however, and contradicted the basic principle of territoriality in patent law. No violations of any foreign patent laws occurred so long as the copied drugs were made and sold only in India (or exported only to other countries that similarly did not recognize pharmaceutical product patents).¹²⁰

In shaping its first indigenous patents regime, India made a deliberate choice to stimulate domestic drug manufacturing and reduce the price of medicines. Its Patents Act, 1970, “conceived in postcolonial days when India still suffered famines and the average Indian man could expect to live only about 40 years, was intended to encourage the founding of local industries to break the choke hold of foreign chemical companies.”¹²¹ With the possible exception of those countries that outright repealed their patent systems during the nineteenth century,¹²² no clearer example exists in modern history of a nation restructuring its patent laws “as a tool . . . to achieve its national priorities”¹²³ than India’s enactment of its Patents Act, 1970.

117. See Bagchi, *supra* note 52, at 293. In 1968, foreign entities filed 4,284 patent applications in India while Indian entities (i.e., persons or entities having resident status in India) filed 1,110 applications. In FY 1978-79, foreign entities filed 1,080 applications and Indian entities filed 1,124 applications. *Id.*

118. See *id.* (reporting that Indian entities filed 1,110 patent applications in India in 1968 and filed 1,124 applications in FY 1978-79).

119. See 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 U.C.L.A. J. INT’L L. & FOR. AFF. 283, 306-07 (1998).

120. Professor Frederick M. Scherer has observed with respect to the Indian generic firms that “[i]t’s a marvelous piece of P.R. to get these companies called pirates . . . [w]hat they’re doing is perfectly legitimate, until 2005, under the Paris convention and the Uruguay Round of trade talks.” McNeil, *supra* note 89, at A1 (quoting Scherer, an emeritus professor of public policy at Harvard University’s Kennedy School of Government).

121. *Id.*

122. Switzerland and the Netherlands did not have patent systems in the latter part of the nineteenth century. See generally ERIC SCHIFF, *INDUSTRIALIZATION WITHOUT NATIONAL PATENTS passim* (1971).

123. Ragavan, *supra* note 87, at 289.

In the wake of the new legislation, India's generic drug industry flourished as indigenous firms made huge gains in market share against the MNCs.¹²⁴ A number of MNCs left India or chose not to invest there given the lack of patent protection.¹²⁵ At the same time, scientists employed by the generic firms became skilled in process chemistry and reverse engineering.¹²⁶ Drug prices in India fell dramatically.¹²⁷ 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.¹²⁸

Despite the dramatic turnaround in domestic drug manufacturing after the Patents Act, 1970, India's generic drug industry did not become an innovator of new molecules. Virtually no research and development into new molecules was undertaken in India in the pre-TRIPS era,¹²⁹ and its indigenous pharmaceutical industry felt the effects of "brain drain" as skilled scientists left the country or remained abroad after completing their foreign training.¹³⁰

124. Hamied, *supra* note 2, at 3 (noting that in 1971 [a year before the India Patents Act, 1970 took effect] "the MNC's controlled over 70% of the domestic pharma[ceutical] market," but that by 2005, the market share of MNCs was "below 23%").

125. See Ali Imam, *How Patent Protection Helps Developing Countries*, 33 AIPLA Q.J. 377, 385 (2005) (observing that "India, one of the fastest-growing developing countries, has been unable to attract much foreign-based pharmaceutical R&D investment because of weak patent protection for pharmaceutical products."). As of 1993, "only 16 of the world's 30 largest pharmaceutical-producing countries had a direct investment position in India . . ." *Id.* at 386.

126. See Interview with Krishna Sarma, Corporate Law Group, in New Delhi, India (Nov. 14, 2005) (transcript on file with author) [hereinafter Interview with Attorney Krishna Sarma]; Interview with Dr. Swati Piramal, *supra* note 24.

127. See CHAUDHURI, *supra* note 78, at 59 (noting that under the Patents Act, 1970, the "cost-efficient processes developed by the indigenous sector could be used for manufacturing the latest drugs, introducing them at a fraction of international prices and dislodging the MNCs from the position of dominance in the domestic market.").

128. See KEAYLA, *supra* note 4, at 59 (Table 11).

129. Bagchi posits that under the Patents Act, 1970, foreign firms did not feel compelled to take out patents and abide by India's expansive compulsory licensing provisions because India never posed a "credible threat" in terms of a "high rate of innovative activity by domestic firms and research organizations." Bagchi, *supra* note 52, at 302. Domestic innovation activity was held up by a combination of factors including diversion of R&D resources to "expensive, unproductive" industry sectors such as nuclear energy and space, the failure to build stronger links between industry and research laboratories, and a "slow rate of industrial growth." *Id.*

130. See COHEN, *supra* note 46, at 117 (noting that "[a]bout half of all Indian scientists trained in the United States stay there on a semipermanent basis"); Susan Finston, *India: A Cautionary Tale on the Critical Importance of Intellectual Property Protection*, 12 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 887, 890 (2002) (observing that the then-"[l]ack of patent protection has eliminated any incentive for India's best scientific minds to develop cures for tropical diseases endemic to India, or even to remain in India to work in the domestic industry").

Even as recently as 2005, “low investments in innovative R&D and lack of resources to compete with MNCs for New Drug Discovery Research and to commercialize molecules on a worldwide basis” were still cited as weaknesses of India’s domestic pharmaceutical sector.¹³¹ Compared to Western pharmaceutical companies, the level of R&D investment of Indian firms as a percentage of total sales remains paltry.¹³² The lack of investment in new molecule R&D has disadvantaged India in a wide number of inter-connected ways:

[s]ince independence, efforts of IPI [the Indian Pharmaceutical Industry] have mostly been directed towards the development of alternative cost effective manufacturing processes for molecules already invented and patented in other countries. Very little or no effort was invested in R&D towards development of new molecules/products. Over the last few decades, this contracted patent regime in India, recognizing only process patent[s], has had a negative impact on the development of professional expertise in new chemical entity development as potential therapeutic agent[s]. This in turn also gave lesser exposure to conducting advanced clinical trials and drafting patents and patent related litigation in the areas of new chemical entities, genetic engineering, combinatorial chemistry, natural products, agro-chemicals and agricultural products.¹³³

C. Globalization Period

India’s entry onto the global stage as an emerging superpower in the waning days of the twentieth century follows a long process of domestic economic reform. Following independence from Great Britain in 1947, the government of Jawaharlal Nehru, India’s first prime minister, favored “social engineering and economic egalitarianism” which “dampened the spirit of private enterprise and profit.”¹³⁴ The British Raj was replaced with the “License Raj,” “a vast system of national and state-level licenses and quotas”

131. Federation of Indian Chambers of Commerce and Industry, FICCI REPORT FOR NATIONAL MANUFACTURING COMPETITIVENESS COUNCIL, COMPETITIVENESS OF THE INDIAN PHARMACEUTICAL INDUSTRY IN THE NEW PRODUCT PATENT REGIME 10 (Mar. 2005), available at <http://www.ficci.com/studies/pharma.pdf>.

132. See Chandran et al., *supra* note 11, at 280 (observing that “[n]ow, the specific challenge before IPI [the Indian Pharmaceutical Industry] is to start investing in basic R&D from the current abysmal level of less than 2% of total revenue to the world level of 8-10%”); Tomar, *supra* note 11, at 583 (stating that, as of 1997, “Indian-owned companies typical[ly] spend 1% of sales on R&D, compared to an average of 15% by Western pharmaceutical companies”) (citing Amy Louise Kazmin, *Now These Copycats Have to Discover New Drugs*, BUSINESS WEEK, Mar. 24, 1997, at 114).

133. Chandran et al., *supra* note 11, at 270.

134. COHEN, *supra* note 46, at 95.

which shackled Indian business.¹³⁵ Economic conditions did not improve under the subsequent tenure of Prime Minister Indira Gandhi, who nationalized industries, imposed protectionist policies and implemented stiff restrictions on foreign direct investment.¹³⁶

The first real movement to a free market for India occurred in 1991, as a result of a balance of payments crisis.¹³⁷ Led by then Finance Minister Manmohan Singh (today India's Prime Minister), the "license raj" was radically reformed. "The rupee was devalued; import controls were dismantled and customs duties slashed; industrial licensing was liberalised and the capital markets opened up."¹³⁸ These measures appear to be having the desired effect; today India's economy is growing at more than eight percent annually.¹³⁹

Despite its internal economic reforms, India led the opposition to inclusion of patent and intellectual property rights in a GATT accord for the first three years of the Uruguay Round of negotiations.¹⁴⁰ India and other developing countries viewed the GATT framework as a tool by which wealthy nations would impose strong IPRs as the cost of much-needed access for the developing world to western markets.¹⁴¹ Although initially joined in its opposition by other advanced developing countries such as Brazil, Argentina, and Mexico, when these countries changed their positions India was no longer able to "carry the day alone."¹⁴² India feared restrictions on its exports if it did not accept TRIPS.¹⁴³ In view of its declining economy in the late 1980s, India

135. *See id.*

136. *See* WALSH, *supra* note 86, at 219 (discussing Indira Gandhi's "move to the left" and nationalization of Indian private banks); *see also* GURCHARAN DAS, *INDIA UNBOUND* 157 (2002) (stating that "during the 1970s and 1980s. . . Indira Gandhi's government became even more rigid, introduced more controls, and became bureaucratic and authoritarian. It nationalized banks, discouraged foreign investment, and placed more hurdles before domestic enterprise."); *see also* STANLEY WOLPERT, *INDIA* 228 (1991) (describing Indira Gandhi's economic policies as an "Emergency Raj" designed to "distribute India's wealth more equitably and to assist the weakest, most impoverished half of society").

137. *See* COHEN, *supra* note 46, at 101.

138. *Can India Work?*, *supra* note 43.

139. *See* Sengupta & Rai, *supra* note 20 (reporting that India's finance minister is predicting an "8.1% economic growth [rate] for the year ending March 31, 2007.").

140. *See* Foster, *supra* note 119, at 311.

141. *See* Nadia Natasha Seeratan, *The Negative Impact of Intellectual Property Patent Rights on Developing Countries: An Examination of the Indian Pharmaceutical Industry*, 3 *SCHOLAR* 339, 352-53 (2001).

142. *See* Foster, *supra* note 119, at 315.

143. *See* 2 N.K. CHOWDHRY & J.C. AGGARWAL, *DUNKEL PROPOSALS: THE FINAL ACT—1994: SIGNIFICANCE FOR INDIA AND THE WORLD TRADE* 13 (1994) (quoting Indian Minister of Commerce Mr. Pranab Mukherjee as stating in Parliament on December 16, 1993 that "[w]hile India had initially not been in favour of inclusion of trade-related intellectual property rights in the scope of the Uruguay Round,

could ill afford to lose valuable textile tariff concessions and economic aid from foreign sources such as the International Monetary Fund and the U.S. government.¹⁴⁴

By 1989 India had reversed its anti-TRIPS stance and agreed to serious negotiations over patent protection, while nevertheless maintaining that the extent of patent protection required should vary with an individual country's extent of economic development.¹⁴⁵ India is viewed as the nation primarily responsible for the TRIPS' multi-year transition periods,¹⁴⁶ which the multinational pharmaceutical industry had vociferously opposed.¹⁴⁷

India signed the Uruguay Round Agreements (along with 116 other nations) on April 15, 1994,¹⁴⁸ and became a member of the WTO effective January 1, 1995.¹⁴⁹ Thus India became obligated to amend its domestic intellectual property laws in order to come into compliance with the WTO's TRIPS Agreement.¹⁵⁰ Certain implementations were required immediately while others could be postponed for the duration of the applicable transition period. Most notably, as a country that had not granted patent protection on pharmaceutical products at the time of its entry into the WTO, India was given

it had ultimately to go along with the rest of the world community. . . . If we were to opt out of the new agreement, the possibility of our major trading partners insisting upon a much earlier introduction of product patents on the threat of imposition of restriction on the export of our goods into their markets cannot be ruled out").

144. See Foster, *supra* note 119, at 315-17.

145. See *id.* at 311.

146. See *id.* at 311-12 (stating that "it is generally recognized that India was instrumental in persuading the GATT members to include the lengthy transition period for lesser-developed countries"); B.K. Zutshi, *Bringing TRIPS into the Multilateral Trading System*, in THE URUGUAY ROUND AND BEYOND: ESSAYS IN HONOR OF ARTHUR DUNKEL 35, 46 (Jagdish Bhagwati & Mathias Hirsch eds., 1999) (observing that "India had its way for a 10-year transitional period for product patents in the field of technology where product patents were not being granted at the time of entering into force of the Agreement").

147. See Robert Weissman, *A Long, Strange TRIPS: The Pharmaceutical Industry Drive to Harmonize Global Intellectual Property Rules, and the Remaining WTO Legal Alternatives Available to Third World Countries*, 17 U. PA. J. INT'L ECON. L. 1069, 1084-85 (1996).

148. See Foster, *supra* note 119, at 283.

149. See World Trade Organization, India and the WTO, at http://www.wto.org/english/thewto_e/countries_e/india_e.htm (last visited Jan. 20, 2007).

150. See World Trade Organization, Marrakesh Agreement Establishing the World Trade Organization art. II(2), available at http://www.wto.org/english/docs_e/legal_e/04-wto_e.htm (stating that "[t]he agreements and associated legal instruments included in Annexes 1, 2 and 3 . . . are integral parts of this Agreement, binding on all Members"). The referenced "Annex[] 1" includes the TRIPS Agreement as Annex 1C. See World Trade Organization, WTO Legal Texts, available at http://www.wto.org/english/docs_e/legal_e/legal_e.htm#annex1 (last visited Jan. 20, 2007).

ten years, i.e., until January 1, 2005, to fully implement that portion of TRIPS into its laws.¹⁵¹

The TRIPS-catalyzed transformation of India's patent laws has thus far involved a three-stage process¹⁵² corresponding to three acts amending the Patents Act, 1970 (referred to throughout India's patent laws as the "Principal Act"). Each stage of the process is described in further detail below, but a summary is provided here. First, a "mailbox" facility was created to establish so-called pipeline protection for pharmaceutical product patent applications filed (but not taken up by the Patent Office for examination) during India's ten-year TRIPS transition period that extended from January 1, 1995 through December 31, 2004.¹⁵³ The mailbox procedure, along with exclusive marketing rights (EMRs), was initially implemented by Presidential decree. In the aftermath of a WTO dispute proceeding brought by the U.S., India formally enacted the mailbox facility into law by Parliament's passage of the Patents (Amendment) Act, 1999.¹⁵⁴ Second, the Principal Act was amended by the Patents (Amendment) Act, 2002,¹⁵⁵ so as to provide the TRIPS-required twenty-year patent term, reversal of the burden of proof for process patent infringement, and modifications to compulsory licensing requirements.¹⁵⁶ Lastly, India put pharmaceutical product patent protection into full effect as of January 1, 2005, via the Patents (Amendment) Act, 2005.¹⁵⁷

1. The Mailbox Facility Controversy

Although the TRIPS Agreement's transitional arrangements allowed India until January 1, 2005 to begin granting patents on qualifying applications claiming pharmaceutical products,¹⁵⁸ TRIPS nonetheless required India to "provide as from the date of entry into force of the WTO Agreement [i.e., January 1, 1995] . . . a means by which applications for patents for such inventions can be filed"¹⁵⁹ In other words, India had to set up a "mailbox" facility to accept pharmaceutical product patent applications filed

151. See TRIPS, *supra* note 3, Art. 65.

152. See generally CHAUDHURI, *supra* note 78, at 65-70 (section titled "Implementation of TRIPS in India").

153. See *infra* Part II.C.1.

154. The Patents (Amendment) Act, No. 17 of 1999 (1999), available at <http://indiacode.nic.in>.

155. The Patents (Amendment) Act, No. 38 of 2002, available at <http://indiacode.nic.in>.

156. See *infra* Part II.C.3.

157. The Patents (Amendment) Act, No. 15 of 2005 (Universal 2005); see *infra* Part II.C.4.

158. See TRIPS, *supra* note 3, Art. 65.

159. *Id.* Art. 70.8(a).

during the TRIPS transition period and to assign each application a filing date. This system is also commonly referred to as “pipeline protection.”¹⁶⁰ TRIPS also required that EMRs, a short-term quasi-patent right as further detailed below, be granted during the transition period for certain mailbox applications that met additional specified criteria.¹⁶¹

Accordingly, an Ordinance (similar to an Executive Order in the U.S.) was promulgated by India’s President on December 31, 1994, while Parliament was not in session.¹⁶² Designed to implement a mailbox facility and EMRs, the Ordinance came into effect on January 1, 1995.¹⁶³ The Ordinance subsequently lapsed, however, because implementing legislation was not enacted within the requisite six-week time period following the Ordinance’s introduction.¹⁶⁴ The Indian Parliament’s Lok Sabha (Lower House) subsequently passed a bill to implement the mailbox facility but the legislation was never enacted because the Rajya Sabha (Upper House) did not pass it before Parliament was dissolved in May 1996.¹⁶⁵ The Indian legislators’ recalcitrance to amend the patent laws as required by TRIPS likely found its basis in a then-improving Indian economy and political landscape that led the lawmakers to risk U.S. ire.¹⁶⁶

The U.S. did not hesitate to employ the WTO’s dispute resolution mechanism in the face of India’s failure to formally enact the mailbox and EMR regime into law, thus triggering the “seminal TRIPS dispute before the WTO.”¹⁶⁷ In July 1996 the U.S. filed a request for consultations with India,

160. See JOHN R. THOMAS, PHARMACEUTICAL PATENT LAW 609-10 (2005).

161. See TRIPS, *supra* note 3, Art. 70.9.

162. The Patents (Amendment) Ordinance, No. 13 of 1994, *available at* http://www.wipo.int/clea/docs_new/en/in/in001en.html. The 1994 Ordinance was officially published in 81 THE GAZETTE OF INDIA (Dec. 31, 1994), *available at* <http://www.wipo.int/clea/en/fiche.jsp?uid=in001>. Presidential authority for the promulgation of ordinances is derived from the powers conferred by clause (1) of Article 123 of India’s Constitution. See Patents (Amendment) Ordinance, No. 13 of 1994, *available at* http://www.wipo.int/clea/docs_new/en/in/in001en.html (citing India Constitution and noting that “Parliament is not in session and the President is satisfied that circumstances exist which render it necessary for him to take immediate action”).

163. See The Patents (Amendment) Ordinance, No. 13 of 1994, § 1(2).

164. See CHAUDHURI, *supra* note 78, at 65-66.

165. See *id.* at 66.

166. See Foster, *supra* note 119, at 318 (stating that “India once again grew recalcitrant over patent reform in the aftermath of the Marrakech signing, when its economic position improved, and it acquired new plausible security threats”).

167. Ruth L. Okediji, *Public Welfare and the Role of the WTO: Reconsidering the TRIPS Agreement*, 17 EMORY INT’L L. REV. 819, 890 (2003). See also THOMAS, *supra* note 160, at 612 (describing the U.S.-India dispute as “a significant opinion for the newly formed WTO,” which “signaled that the WTO would take seriously the commitments of its members with respect to the TRIPS Agreement”).

the first step in the WTO dispute resolution process.¹⁶⁸ The WTO's Appellate Body held in December 1997 that by India's failure to timely amend its patent laws, India had failed to satisfy its obligation under Article 70.8(a) of the TRIPS Agreement to establish "a means" that adequately preserved novelty and priority of pharmaceutical product patent applications.¹⁶⁹ India thereafter agreed to implement the recommendations of the WTO's Dispute Settlement Body by April 1999.¹⁷⁰ An implementing bill was passed in the Rajya Sabha on December 22, 1998, but was never passed by the Lok Sabha.¹⁷¹

2. *The Patents (Amendment) Act, 1999*

Ultimately enacted in March 1999, India's Patents (Amendment) Act, 1999,¹⁷² formally implemented the mailbox procedure for patent applications claiming pharmaceutical and agro-chemical products and made it retroactive to January 1, 1995.¹⁷³ The 1999 Act also formally implemented EMRs.

Mailbox applications went into a symbolic "black box," not to be taken out for examination nor even published by the Indian Patent Office until on or after January 1, 2005.¹⁷⁴ It is now known that during India's ten-year TRIPS transition period, almost 9,000 mailbox applications were filed in the

168. See World Trade Organization, Dispute DS50, India—Patent Protection for Pharmaceutical and Agricultural Chemical Products, available at http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds50_e.htm (last visited Jan. 20, 2007).

169. See 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 (upholding the WTO panel's conclusion that "India has not complied with its obligations under Article 70.8(a) to establish 'a means' that adequately preserves novelty and priority in respect of applications for product patents in respect of pharmaceutical and agricultural chemical inventions during the transitional periods provided for in Article 65 of the TRIPS Agreement.").

170. See World Trade Organization, Dispute DS50, India—Patent Protection for Pharmaceutical and Agricultural Chemical Products, available at http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds50_e.htm (section titled "Implementation Status of Adopted Reports").

171. See CHAUDHURI, *supra* note 78, at 66.

172. The Patents (Amendment) Act, No. 17 of 1999 (1999), available at <http://indiacode.nic.in>.

173. See The Patents (Amendment) Act, No. 17 of 1999, § 1(2) (deeming Act retroactive to January 1, 1995), § 2 (inserting Section 5(2) into the Patents Act, 1970, providing that claims to substances useful as medicine or drug "may be made and shall be dealt . . . in the manner provided in Chapter IVA"), § 3 (inserting Chapter IVA into the Patents Act, 1970).

174. See The Patents (Amendment) Act, No. 17 of 1999 (providing that "[n]otwithstanding anything contained in sub-section (1) of section 12 ["Examination of application"], the Controller shall not, under that sub-section, refer an application in respect of a claim for a patent covered under sub-section (2) of section 5 to an examiner for making a report till [sic] the 31st day of December, 2004 . . ."); see also Sreenivasarao Vepachedu & Martha Rumore, *Patent Protection and the Pharmaceutical Industry in the Indian Union*, INTELL. PROP. TODAY, Oct. 2004, at 44.

four branches of the Indian Patent Office.¹⁷⁵ Although the government did not publish running totals during the transition period,¹⁷⁶ the first official “opening of the mailbox” with confirmation of the number of application filings did not occur until the latter part of March 2005.¹⁷⁷ About 84 percent of the mailbox filings were applications owned by foreign (i.e., non-Indian) entities.¹⁷⁸ These mailbox applications claimed then-unpatentable “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”¹⁷⁹ Notwithstanding their exclusion from patentability until after January 1, 2005, applications claiming such substances were permitted to be filed under what was then Section 5(2) of India’s Patents Act,¹⁸⁰ and were dealt with under special provisions set forth in the Act’s Chapter IVA (now repealed).¹⁸¹

175. A total of 8,926 mailbox applications were filed in the Indian Patent Office prior to January 1, 2005. Of these, 3,672 were filed in the Chennai branch and 1,952 were filed in the New Delhi branch. Interview with K.S. Kardam, Assistant Controller of Patents and Designs, Indian Patent Office, in New Delhi, India (Nov. 16, 2005) (notes on file with author) [hereinafter Interview with K.S. Kardam].

176. See P.T. Jyothi Datta, *Day 1 of product patent regime—Pharmaceutical industry kept guessing*, HINDU BUS. LINE, Jan. 3, 2005, available at <http://www.thehindubusinessline.com/2005/01/04/stories/2005010402840100.htm> (observing that number of mailbox applications was still not officially declared, and that “the lack of clarity on the final number of product patent applications in the box has left the domestic drug industry worried”).

177. See K.G. Narendranath, *Patent mailbox opens, Pfizer is top applicant*, FIN. EXPRESS, Mar. 21, 2005, at 1, available at http://www.financialexpress.com/fearchive_frame.php (reporting that “the Kolkata-based Patents Office [had] opened the mailbox of patent pleas for pharma and agrochem inventions for 1995-2005”).

178. *Id.* “Of a total of 8,926 patent pleas in the mailbox [1995-2004], a majority of 7,520 belong to foreign entities, while the balance 1,406 are Indian applications.” *Id.* United States-based Pfizer was the leading filer of mailbox applications, with 373 filings. *Id.* Johnson & Johnson, another U.S.-based company, was second, with 262 mailbox applications. *Id.* Among Indian companies, Dr. Reddy’s Labs filed the most mailbox applications (i.e., 205). *Id.* Ranbaxy made 38 filings. *Id.* “While US-based entities put 2,324 applications, including 2,096 pharma-related pleas, Indian submissions were 1,406 including 1,300 in pharma sector.” *Id.* “Among foreign countries, Germany made 1,238 filings including 1,134 pharma filings to occupy the third slot behind US and India, followed by UK (631/573), Switzerland (596/538), Japan (503/434), Sweden 364/351, France (322/278), Denmark (306/278) and Belgium (177/170).” *Id.*

179. The Patents Act, No. 39 of 1970, § 5(1) (Universal 2005) (amended 1999 & 2002) (“Annexe”).

180. See The Patents Act, No. 39 of 1970, § 5(2) (Universal 2005) (amended 1999 & 2002) (“Annexe”).

181. See The Patents Act, No. 39 of 1970, §§ 24A-24F (Universal 2005) (amended 1999 & 2002) (“Annexe”). Chapter IVA, titled “Exclusive Marketing Rights,” was inserted into the Patents Act, 1970, by The Patents (Amendment) Act, No. 17 of 1999, § 3 (made retroactively effective to Jan. 1, 1995), available at <http://indiacode.nic.in>, and repealed therefrom by The Patents (Amendment) Act, No. 15 of 2005, § 21 (effective Jan. 1, 2005). See The Patents Act, No. 39 of 1970 (Universal 2005) (amended 2005). Section 24A of Chapter IVA (now repealed) provided that the Controller would not refer mailbox applications to an examiner for the making of an examination report in accordance with Section 12(1) (“Examination of application”), as would normally be the case where a patent applicant has filed a request

Although the Indian Patent Office did not publish any information concerning individual mailbox applications during the ten-year TRIPS transition period, one-page summaries of filing data for each application began to be published in the on-line *Official Journal* during January 2005.¹⁸² As of June 30, 2006, after the new pharmaceutical product patents regime has been in operation for its first eighteen months, a total of approximately 6,660 mailbox application summaries have been published,¹⁸³ representing about 75

for examination (see The Patents Act, No. 39 of 1970, § 11B(1) (Universal 2005) (amended 2005) (providing that “[n]o application for a patent shall be examined unless the applicant or any other interested person makes a request in the prescribed manner for such examination within the prescribed period”), until December 31, 2004. See The Patents Act, No. 39 of 1970, § 24A(1) (Universal 2005) (amended 2002) (“Annexe”); see also The Patents Act, No. 39 of 1970, § 11B(3) (Universal 2005) (amended 2005) (providing that “[i]n case of an application in respect of a claim for a patent filed under sub-section (2) of section 5 before the 1st day of January, 2005 a request for its examination shall be made in the prescribed manner and within the prescribed period by the applicant or any other interested person”). Rather, the mailbox applications remained on hold, having been assigned a filing date, to be taken up for substantive examination on or after January 1, 2005.

182. Weekly issues of the *Official Journal of the Patent Office* published in 2005 are available at http://www.patentoffice.nic.in/ipr/patent/journal_archive/patent_journal_2005.htm.

183. A search of the *Official Journal of the Patent Office*, available at http://www.patentoffice.nic.in/ipr/patent/journal_archive/patent_journal_2005.htm (for 2005) and http://www.patentoffice.nic.in/ipr/patent/journal_archive/journal_2006/patent_journal_2006.htm (for 2006), indicates that the following numbers of mailbox application abstracts have been published in the first eighteen months of India's pharmaceutical product patents regime:

<i>Official Journal</i> <u>Publication Month</u>	<u>Number of Mailbox Applications Summaries Published</u>
Jan. 2005	40
Feb. 2005	222
Mar. 2005	4,982*
Apr. 2005	240
May 2005	8
June 2005	39
July 2005	156
Aug. 2005	56
Sept. 2005	105
Oct. 2005	83
Nov. 2005	58
Dec. 2005	92
Jan. 2006	50
Feb. 2006	45
Mar. 2006	113
Apr. 2006	112
May 2006	177
June 2006	82
Total (Jan. 2005-June 2006)	6,660

Mailbox application summaries were identified from the *Official Journal* records as those bearing the legends “Filed U/S [Under Section] 5(2) before The Patents (Amendment) Ordinance, 2004: YES” or

percent of the total of 8,926 mailbox applications filed. Currently the mailbox applications are being taken up for examination in order of the dates on which their owners (or other interested persons) previously filed requests for examination.¹⁸⁴ In November 2005, Indian Patent Office officials reported a backlog of “about four months” for examination of mailbox applications.¹⁸⁵ The framework for filing mailbox applications, as a creature of the TRIPS transition period that ended for India on December 31, 2004, is now obsolete, and those provisions have been repealed from India’s current Patents Act.¹⁸⁶

“Filed U/S 5(2) before the Patents (Amendment) Act, 2005: YES” or “Filed U/s. 5(2): YES.” All *Official Journals* published between January 21, 2005 and February 4, 2005 are composed of scanned images of publication data that required manual searching, rather than computer-searchable text fields.

* The total number of mailbox application summaries published in March 2005 is incomplete because Volume IX (out of Volumes I-X) from the Mar. 4, 2005 “Special Issue” of the *Official Journal* is missing from the Indian Patent Office’s website. See http://ipindia.nic.in/ipr/patent/journal_archive/pat_arch_040305/mumbai_wto_volume.htm (last visited Aug. 5, 2006).

184. Interview with K.S. Kardam, *supra* note 175; see also The Patents (Amendment) Rules, 2003, § 24B(2)(i) (Universal 2005) (amended 2005) (providing that “[a] request for examination of application for patent filed under sub-rule (1) shall be taken up for examination in the order in which the request is filed”). Mailbox applications for which no request for examination was filed by the end of 2005 were dropped. See Interview with K.S. Kardam, *supra* note 175; The Patents (Amendment) Rules, 2003, § 24B(1)(ii) (Universal 2005) (amended 2005) (providing that “[t]he period within which the request for examination under subsection (3) of section 11B [“Request for examination” for applications claiming subject matter under § 5(2) of the Patents Act; i.e., mailbox applications] to be made shall be thirty-six months from the date of priority or from the date of filing of the application or twelve months from the 1st day of January, 2005”). Requests for examination of mailbox applications have in most cases been filed prior to publication of the application, in contrast with the procedure for regular (i.e., non-mailbox) applications. Compare The Patents (Amendment) Rules, 2003, § 24B(1)(i) (Universal 2005) (amended 2005) (providing that “[a] request for examination under section 11B shall be made in Form 18 after the publication of the application but within thirty-six months from the date of priority of the application or from the date of filing of the application, whichever is earlier”) (emphasis added).

Explanatory Note Concerning Patents Rules: The “principal rules” for the Indian patent system are codified as India Patents Rules, 2003, available at http://www.patentoffice.nic.in/ipr/patent/patent_re_03.pdf. Since their promulgation in 2003, the principal rules have been amended in 2005 and again in 2006. The 2005 amendments are set forth as the India Patents (Amendment) Rules, 2005, available at [http://www.patentoffice.nic.in/ipr/patent/The%20Patents%20\(Amendments\)%20Rules%202005%20\(ENGLISH\).pdf](http://www.patentoffice.nic.in/ipr/patent/The%20Patents%20(Amendments)%20Rules%202005%20(ENGLISH).pdf). The 2006 amendments are set forth as the India Patents (Amendments) Rules, 2006, available at http://patentoffice.nic.in/ipr/patent/patent_rules_2006.pdf. The Indian Patent Office has not published to date an official *consolidated* version of the Patents Rules (i.e., a version showing the 2003 principal rules as modified with all subsequent amendments) [hereinafter The Patents (Amendment) Rules, 2006]. In order to determine the current language of a particular rule, one must read the 2003 principal rule and then check both the 2005 and 2006 amending acts to see if that language has been amended. A hard-copy version of The Patents Rules, as amended in 2005, is *reprinted* in UNIVERSAL’S THE PATENTS ACT, 1970, AS AMENDED BY THE PATENTS (AMENDMENT) ACT, 2005 85-157 (Universal Law Publishing Co. Pvt. Ltd. ed., 2005), and that version will be cited herein. The Indian Patents Rules will be referred to as “The Patents Rules, 2003 (Universal 2005).”

185. Interview with K.S. Kardam, *supra* note 175.

186. See The Patents (Amendment) Act, No. 15 of 2005, § 21 (Universal 2005) (providing that

A handful of those who filed mailbox applications during the TRIPS transition period took the additional step of seeking EMRs for their inventions.¹⁸⁷ If granted, an EMR would convey the exclusive right to sell or distribute the invention in India for a period of five years from the grant of the EMR, until a patent was granted from the mailbox application, or until the mailbox application was finally rejected, whichever was earlier.¹⁸⁸ Thus, the eventual grant of a patent on a mailbox application also extinguished any corresponding EMR. An EMR was available only for those inventions claimed in mailbox applications that further satisfied the following elaborate set of requirements:¹⁸⁹

(1) an examination by the Indian Patent Office had concluded that the invention did not fall within any of the categories of subject matter considered to not be inventions under Section 3 of the India Patents Act (including, for example, the evergreening prohibition of Section 3(d)), nor within the scope of the Act's Section 4 prohibition on patenting inventions relating to atomic energy;¹⁹⁰

(2) 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;¹⁹¹

(3) 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;¹⁹²

(4) the convention country had granted "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;¹⁹³ and

(5) the Central Government of India had granted approval to sell or distribute the article in India.¹⁹⁴

"Chapter IVA [§§24A-24F] of the principal Act shall be omitted").

187. See CHAUDHURI, *supra* note 78, at 68 n.18 (citing information obtained from the Office of the Controller of Patents and Designs in Calcutta that as of August 2004, only 13 EMR applications had been filed).

188. See The Patents Act, No. 39 of 1970, § 24B(1) (Universal 2005) (amended 2002) ("Annexe").

189. These requirements are derived from TRIPS, *supra* note 3, Art. 70.9, which provides that "[w]here a product is the subject of a patent application in a Member in accordance with paragraph 8(a) [of Art. 70], exclusive marketing rights shall be granted, notwithstanding the provisions of Part VI, for a period of five years after obtaining marketing approval in that Member or until a product patent is granted or rejected in that Member, whichever period is shorter, provided that, subsequent to the entry into force of the WTO Agreement, a patent application has been filed and a patent granted for that product in another Member and marketing approval obtained in such other Member."

190. See The Patents Act, No. 39 of 1970, § 24A(1) (Universal 2005) (amended 2002) ("Annexe").

191. See *id.* § 24B(1)(a).

192. See *id.*

193. See *id.*

194. See *id.*

Perhaps because of the complexity of these requirements, less than twenty mailbox applicants sought EMRs,¹⁹⁵ and even fewer have successfully enforced them.¹⁹⁶

3. *The Patents (Amendment) Act, 2002*

The second of the three amending acts in the evolution of India's patent laws towards TRIPS compliance was the Patents (Amendment) Act, 2002, which took effect June 25, 2002.¹⁹⁷ The 2002 Act implemented a number of important changes, but most significant was the extension of patent term to twenty years.¹⁹⁸ The 2002 Act amended the principal Act to provide that the term of all Indian patents would henceforth expire twenty years after their application filing date.¹⁹⁹ Prior to this amendment, Indian process patents lasted only for the shorter of five (5) years from sealing or seven (7) years

195. See CHAUDHURI, *supra* note 78, at 68 n.18 (citing information obtained from the Office of the Controller of Patents and Designs in Calcutta that as of August 2004, only thirteen EMR applications had been filed); N.R. Subbaram, *Grant of Exclusive Marketing Rights (EMR) Under the Patents Act 70: Issues & Concerns*, PATENTMATICS, Oct. 2004, at <http://www.patentmatics.org/pub2004/pub10j.doc> (noting that as of October 2004, "17 [EMR] applications have been filed, out of which, 4 EMR have been granted, 4 have been rejected and the remaining 9 are pending").

196. For example, Eli Lilly's Cialis brand erectile dysfunction drug Tadalafil was the subject of a granted EMR, but enforcement of the EMR was stayed by the Indian courts. E-mail from Donald L. Corneglio, Attorney, Eli Lilly Corp., to Janice Mueller, Professor, University of Pittsburgh School of Law (Jan. 20, 2006) (on file with author) [hereinafter Email from Donald L. Corneglio to author]; see also P.T. Jyothi Datta, *Eli Lilly's Exclusive Marketing Right Under Legal Cloud*, THE HINDU BUS. LINE, Sept. 8, 2005, at <http://www.thehindubusinessline.com/2004/09/09/stories/2004090901240400.htm> (describing petition of Ajanta Pharma for stay of EMR on Cialis and Calcutta High Court order granting same in late August 2005).

The Indian courts may be inclined to treat EMRs granted to Indian companies more favorably, however. The Madras High Court in November 2005 reversed the lower court and reinstated EMR holder Wockhardt's interim injunction against Hetero, manufacturer of an infringing nadifloxacin 1% cream. See *Wockhardt Ltd. v. Hetero Drugs Ltd.*, O.S.A. Nos. 232, 233 & 234 of 2005 (Madras H.C. Nov. 25, 2005), available at <http://judis.nic.in/chennai/qrydisp.asp?tfm=5606>.

197. The Patents (Amendment) Act, No. 38 of 2002, available at <http://indiacode.nic.in> (2002), available at <http://indiacode.nic.in>.

198. As required by TRIPS, *supra* note 3, Art. 33.

199. See The Patents (Amendment) Act, No. 38 of 2002, § 27, available at <http://indiacode.nic.in>, (amending § 53(a)(1) of principal Act to provide that "the term of every patent granted, after the commencement of the Patents (Amendment) Act, 2002, and the term of every patent which has not expired and has not ceased to have effect, on the date of such commencement, under this Act, shall be twenty years from the date of filing of the application for patent"). For PCT applications designating India, the patent will expire twenty years after the PCT international filing date. See The Patents Act, No. 34 of 1970, § 53(1) (Universal 2005) (amended 2005) (*Explanation*).

from the date of the patent,²⁰⁰ while the term of all other types of patents (e.g., mechanical devices) was fourteen (14) years from the date of the patent.²⁰¹

Another notable aspect of the 2002 amendments was formal recognition in India's Patents Act of the nation's accession to two leading international intellectual property treaties, both administered by the United Nations-affiliated World Intellectual Property Organization (WIPO).²⁰² As required by TRIPS,²⁰³ India brought its laws into compliance with the provisions of the Paris Convention for the Protection of Industrial Property, which entered into force in India on December 7, 1998.²⁰⁴ India henceforth had to abide by *inter alia* the Convention's national treatment principle, which forbids discriminatory treatment of foreign applicants,²⁰⁵ as well as its right of priority, which allows foreigners who have previously filed an application for patent in their home countries a twelve-month priority period in which to file an application directed to the same invention in India while retaining the benefit of their earlier home country filing date.²⁰⁶ Also, as of December 7, 1998, India has been a party to the Patent Cooperation Treaty (PCT).²⁰⁷ As a PCT signatory, India had to begin accepting national phase filings of international applications originally filed abroad under the PCT and designating India; previously patent applications could only be filed directly with the Indian Patent Office. Accordingly, the Patents (Amendment) Act,

200. The Patents Act, No. 39 of 1970, § 53(1)(a), available at <http://indiacode.nic.in> (providing that "in 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").

The "date of the patent" was apparently the date on which the complete specification had been filed. See The Patents Act, No. 39 of 1970, § 45(1), available at <http://indiacode.nic.in>.

201. The Patents Act, No. 39 of 1970, § 53(b), available at <http://indiacode.nic.in>.

202. See WIPO, About WIPO, at <http://www.wipo.int/about-wipo/en/> (last visited Aug. 6, 2006).

203. See TRIPS, *supra* note 3, Art. 2.1 (providing that "[i]n respect of Parts II, III and IV of this Agreement, Members shall comply with Articles 1 through 12, and Article 19, of the Paris Convention (1967)").

204. See WIPO, Contracting Parties to the Paris Convention: India, at http://www.wipo.int/treaties/en/Remarks.jsp?cnty_id=246C (last visited Jan. 20, 2007) (noting India's accession to the 1967 Stockholm Act version of the Paris Convention on September 7, 1998, and the entry into force of that Act in India on December 7, 1998).

205. See Paris Convention for the Protection of Industrial Property art. 2, 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 [hereinafter Paris Convention].

206. See *id.* art. 4.

207. See WIPO, Contracting Parties to the PCT: India, at http://www.wipo.int/treaties/en/Remarks.jsp?cnty_id=500C (last visited Jan. 20, 2007) (noting India's accession to the PCT on September 7, 1998, and the entry into force of the PCT in India on December 7, 1998).

2002, included numerous provisions formally integrating Paris Convention and PCT terminology and provisions into the framework of India's principal Act.²⁰⁸

As of 2006, about sixty percent of patent applications received by the Indian Patent Office are PCT national phase filings; almost all of these are foreign-owned.²⁰⁹ However, India's membership in the PCT is not a benefit solely for foreigners—India's own citizens are filing international applications under the PCT in growing numbers. In 2005, India was ranked third highest (following the Republic of Korea and China) among the world's developing countries in the number of PCT international applications filed by its nationals.²¹⁰

The Patents (Amendment) Act, 2002, implemented a myriad of other changes intended to bring India's patents law into accord with the TRIPS Agreement, including new definitions of "invention" and "inventive step,"²¹¹ new exclusions from patentable subject matter,²¹² a new burden of proof provision for cases of process patent infringement,²¹³ and a revised compulsory licensing framework.²¹⁴ Each of these changes is discussed in further detail in Part IV, *infra*, in the context of a comprehensive analysis and critique of the most significant provisions in India's current law, The Patents Act, 1970 (2005).

208. See The Patents (Amendment) Act, No. 38 of 2002, § 3(b), available at <http://indiacode.nic.in>, (adding definition of "convention country"); *id.* § 3(e) (adding definition of "international application"); *id.* § 3(k) (adding definition of "Patent Cooperation Treaty"); §§ 6, 8(b), 58(c), available at <http://indiacode.nic.in>.

209. See *infra* Part V.A.4.

210. See Press Release, WIPO, Exceptional Growth from North East Asia in Record Year for International Patent Filings (Feb. 3, 2006), at http://wipo.int/edocs/prdocs/en/2006/wipo_pr_2006_436.html. Indian nationals filed 648 PCT international applications in 2005, as compared to 4,747 for the Republic of Korea and 2,452 for China. See *id.* India was followed by Singapore (428), South Africa (336), Brazil (283), and Mexico (136). *Id.* International applications received from developing countries accounted for 6.7% of all PCT international applications filed in 2005. See *id.*

Two Indian organizations were listed among the top 10 users of the PCT from developing countries in 2005: the Council of Scientific and Industrial Research (CSIR) and Ranbaxy Laboratories. See *id.*

PCT filings by Indian nationals have followed a generally upward trend, although with some flattening since 2003. Indian nationals have filed the following numbers of PCT international applications in the past five years: 190 in the year 2000, 295 in the year 2001, 525 in the year 2002, 764 in the year 2003, 723 in the year 2004, and 648 in the year 2005. See *id.* (table titled "PCT International Applications by Nationality of First Applicant").

211. See The Patents (Amendment) Act, No. 38 of 2002, § 3(f), available at <http://indiacode.nic.in>.

212. See *id.* § 4.

213. See *id.* § 43.

214. See *id.* § 39.

4. *The Patents (Amendment) Act, 2005*

The final step in India's implementation of the changes needed to bring its patent law into compliance with the WTO TRIPS Agreement was the most traumatic for the country. Effective January 1, 2005, India would have to provide full recognition of patent-eligibility for pharmaceutical products (i.e., substances capable of use as medicine, drug, or food).²¹⁵ In practical terms, this meant that any new patent application filed in the Indian Patent Office on or after January 1, 2005 and claiming a pharmaceutical product would need to be substantively examined for patentability, in addition to the approximately 9,000 mailbox applications filed during the 1995-2004 TRIPS transition period that already awaited examination.

In order to timely implement the necessary changes in the face of widespread political disagreement about the value of pharmaceutical product patent protection, India's President signed the Patents (Amendment) Ordinance, 2004, on December 26, 2004. Government officials described the Ordinance as "an interim measure to fulfill [India's] legal obligations within the stipulated time."²¹⁶ Commentators around the world criticized its provisions as failing to balance the public's need for access to medicines against the rights of patent owners. A *New York Times* editorial observed that "[h]eavily influenced by multinational and Indian drug makers eager to sell patented medicines to India's huge middle class, the decree is so tilted toward the pharmaceutical industry that it does not even take advantage of rights countries enjoy under the W.T.O. to protect public health."²¹⁷

Following the Ordinance's promulgation, a three-month maelstrom of intense public debate and last-minute political compromises ultimately led to significantly revised legislation,²¹⁸ which was enacted April 5, 2005, as the

215. See TRIPS, *supra* note 3, Art. 27.1 (requiring that, subject to certain permissible exclusions from patentability set forth in Articles 27.2 and 27.3, "patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application"); The Patents (Amendment) Act, No. 15 of 2005, § 4 (Universal 2005) (providing that "Section 5 of the principal Act shall be omitted."); The Patents Act, No. 39 of 1970, § 5(1)(a) (Universal 2005) (amended 2002) (providing that no patent would be granted on claims directed to "substances intended for use, or capable of being used, as food or as medicine or drug").

216. Narayan Kulkarni, Rolly Dureha & Srinivas Rao, *India Enters Product Patent Regime*, BIOSPECTRUM, Jan. 6, 2005, at <http://www.biospectrumindia.com/archive/articleDetail.asp?arid=65747&mode=disp> (quoting Commerce Minister Kamal Nath).

217. Editorial, *India's Choice*, *supra* note 1, at A20.

218. See Editorial, *Better Now, But . . .*, BUS. STANDARD, Mar. 24, 2005, at 9, available at 2005 WLNR 4569166 ("In the last few weeks, criticism of the proposed law had begun to mount, and it was clear that the critics (which included the Left parties) had a point. The main opposition, in the form of the NDA

Patents (Amendments) Act, 2005.²¹⁹ In 2005, no political party had majority power in India; the nation's several national parties were aligned in three shifting alliances: one dominated by the Congress Party (the "mainstream" party of Gandhi and Nehru, of which Prime Minister Singh is a member), another by the Bharatiya Janata Party (or "BJP," the Hindu nationalist party), and a third by the "Left" (Communist) parties.²²⁰ Shortly after the Ordinance was promulgated, the Left alliance announced that it would oppose the legislation when it came up for scheduled debate in the Indian Parliament in February 2005.²²¹ The Left viewed the legislation as harmful to India's poor.²²²

In order to appease the Left parties, the ruling Congress Party had to make last-minute amendments on ten out of twelve points "as demanded by the Left."²²³ Among other changes, these amendments "excluded embedded software from the ambit of the product patent regime and curbed the evergreening of patents by clarifying the concept of patentability in unmistakable terms."²²⁴ The amendments also encompassed pre-grant opposition, a procedure within the Patent Office allowing third party challenges to pending applications.²²⁵ The Ordinance would have narrowed the grounds on which pre-grant opposition could be based;²²⁶ a more

[National Democratic Alliance, which includes the Bharatiya Janata Party (BJP)], had also come round to the view that the Bill could not be passed in its original form, though it was the NDA government that first mooted the Bill. So the government had no choice other than to listen to the critics, since without support from the NDA or the Left, the Bill would have been defeated.") [hereinafter Editorial, *Better Now, But . . .*]; see also Interview with A.S. Krishna, Director of Corporate Affairs, Pfizer India, in New Delhi, India (Nov. 15, 2005) (transcript on file with author) (describing "[r]un-up to recognition of product patent protection" in India as "quite a turmoil") [hereinafter Interview with A.S. Krishna].

219. The Patents (Amendment) Act, No. 15 of 2005 (Universal 2005).

220. See COHEN, *supra* note 46, at 109.

221. *Patently unclear: A crucial new intellectual-property regime disappoints*, THE ECONOMIST, Jan. 22, 2005, at 63, 63 [hereinafter *Patently*].

222. See Vepachedu & Rumore, *supra* note 174, at 46 (observing that "[a]s a thriving democracy with a multiparty system, where political coalitions are the order of the day, it is a daunting task to legislate any laws that are perceived as anti-people or anti-poor").

223. *Drug patent: A Viagra for Indian pharmaceutical industry*, DECCAN HERALD, Apr. 4, 2005, at <http://www.deccanherald.com/deccanherald/apr42005/93626200543.asp>.

224. Editorial (*Better Now, But . . .*), *supra* note 218, at 9. Both of these provisions are detailed in Part IV. See *infra* Part IV.

225. See *infra* Part IV.D.1 for a complete description of India's pre-grant opposition procedure.

226. See The Patents (Amendment) Ordinance, No. 7 of 2004, § 23, available at <http://www.lawmin.nic.in/Patents%20Amendment%20Ordinance%202004.pdf> (substituting a new section 25(1) into the principal Act, which would have limited the grounds for pre-grant opposition to only "(a) patentability including novelty, inventive step and industrial applicability, or (b) non-disclosure or wrongful mentioning in complete specification, source and geographical origin of biological material used in the

expansive scope of grounds for pre-grant opposition was restored in the amended legislation.²²⁷ The Ordinance would also have denied any person who filed a pre-grant opposition under Section 25(1) of the Patents Act the right of becoming a party to any further proceedings under the Act,²²⁸ but this restriction was deleted in the Patent (Amendments) Act, 2005.²²⁹

Once the 2005 amendments were enacted in April 2005 (with retroactive effect from January 1, 2005²³⁰), India's patents law stood in its current form (referred to herein as the "Patents Act, 1970 (2005)"). No further amendments to the Act have been promulgated as of August 2006, although some of the implementing Patents Rules have changed.²³¹ Specific provisions of the Act and Rules are further examined and critiqued in Part IV *infra*.

III. CURRENT MILIEU: INDIA'S "MOsaIC VIEW" OF PATENTS

This Part conveys the socio-economic backstory in which India's new pharmaceutical product patent system was implemented and the milieu in which it now must function.²³² The ongoing debate in the United States over patent law reform, "patent trolls," the viability of business method patents, and the like,²³³ simply pales in comparison to the level of public discourse, debate and controversy in India concerning the new patents regime. Although

invention and anticipation of invention by the knowledge, oral or otherwise available within any local or indigenous community in India or elsewhere").

227. See The Patents Act, No. 39 of 1970, § 25(1) (Universal 2005) (amended 2005) (enumerating grounds (a) through (k)).

228. See The Patents (Amendment) Ordinance, No. 7 of 2004, § 23 (substituting new section 25(2) into the principal Act, which would have provided that "[n]otwithstanding anything contained in sub-section (1), the person making a representation referred to in that sub-section shall not become a party to any proceedings under this Act only for the reason that he has made such representation").

229. See The Patents Act, No. 39 of 1970, § 25(1) (Universal 2005) (amended 2005) (omitting any estoppel provision).

230. See The Patents (Amendment) Act, No. 15 of 2005, § 1(2) (Universal 2005) (providing that with minor exceptions, "the remaining provisions of this Act shall be deemed to have come into force on the 1st day of January, 2005").

231. See The Patents (Amendment) Rules, 2003, § 24B(1)(i) (amended 2006), available at http://patentoffice.nic.in/ipr/patent/patent_rules_2006.pdf (effective May 5, 2006). Applicable rule changes are further discussed *infra* Part IV.

232. See Interview with Ranjit Shahani, Managing Director, Novartis India, in Mumbai, India (Nov. 23, 2005) (transcript on file with author) ("Patent law is just one part of a bigger picture. [The] [c]anvas [is] much bigger, colorful, and more controversial than just that") [hereinafter Interview with Ranjit Shahani].

233. See generally ADAM B. JAFFE & JOSH LERNER, INNOVATION AND ITS DISCONTENTS: HOW OUR BROKEN PATENT SYSTEM IS ENDANGERING INNOVATION AND PROGRESS, AND WHAT TO DO ABOUT IT (2004).

one might distill the Indian debate over strengthened patent protection as a purely bilateral fight between research-based MNCs and Indian generic drug manufacturers, the true picture is significantly more complex and defies easy labeling. Any analysis of India's patent system must confront it through a mosaic lens as the product of a multitude of powerful influences. The political compromises required by India's complex multi-party system, as discussed above, are a key example.²³⁴ Other important influences include the unique structure of India's pharmaceutical sector, the nation's formidable demographics, the precarious nature of its health care system, and the government's imposition of price controls for essential drugs. Each factor is discussed below.

A. Fragmented Pharmaceutical Sector

India's pharmaceutical sector is highly fragmented in its structure, and that structural diversity has fundamentally contributed to a great diversity of opinion about strengthened patent protection. At the highest level of generality, the Indian pharmaceutical industry comprises two groups: the multinational corporations (MNCs) and the domestic (entirely Indian-owned) companies,²³⁵ each of which is discussed below. India's pharmaceutical market structure is very different from the U.S., where the multi-national research-based pharmaceutical manufacturers command a larger market share than generic drug manufacturers.²³⁶ In India, MNCs held only a 23% share of the Indian pharmaceutical market in 2004 as compared to the domestic

234. See *supra* Part II.C.4.

235. See Interview with A.S. Krishna, *supra* note 218.

236. See Generic Pharmaceutical Association, *Statistics: Our Industry*, at <http://www.gphaonline.org/Content/NavigationMenu/AboutGenerics/Statistics/Statistics.htm> (last visited Jan. 20, 2007) (reporting that U.S. brand pharmaceutical sales for 2005 were \$229.5 billion, compared to \$22.3 billion in U.S. generic pharmaceutical sales for 2005).

companies' 77% market share.²³⁷ "In fact, India and Japan are the only two countries where the western MNCs do not dominate."²³⁸

1. *Multinational Corporations*

Traditionally MNCs imported into India their pharmaceuticals manufactured elsewhere.²³⁹ MNCs were hesitant to manufacture in India, because they had "for many years been frustrated by low profits, caused by government-controlled prices, lack of patent protection, restrictions on foreign companies' activities and labour problems."²⁴⁰ "The weak old regime long deterred foreign firms from setting up in India to use the country's ample supply of educated workers to develop new products."²⁴¹ The Pharmaceutical Research and Manufacturers of America (PhRMA) organization took the position that India's pre-TRIPS patents law was "'designed to punish importers of patented technology into India and to coerce local production."²⁴² The group contended that the experience of most U.S. drug makers in India was "'so negative that most companies have abandoned efforts to obtain or enforce patents in India."²⁴³

Today, the strengthened patents regime in India is at least one factor (albeit among many others) spurring MNCs to reconsider past views. MNCs now see India as a "rising star,"²⁴⁴ and a good many of the leading multinational pharmaceutical firms now have subsidiaries in India.²⁴⁵ These

237. See CHAUDHURI, *supra* note 78, at 18 (Table 2.2). This is the lowest market share for MNCs during the reported time period ranging from 1952 to 2004. See *id.* The MNCs' market share was highest in 1970. *Id.* At that time, just before India enacted its Patents Act, 1970 (effective 1972), which abolished product patent protection for pharmaceuticals, the MNCs had a 68% market share and Indian domestic companies had the remaining 32%. *Id.*

MNC market share is predicted to gain slightly. See ERNST & YOUNG, UNVEILING INDIA'S PHARMACEUTICAL FUTURE 10 (2005), available at [http://www.ey.com/global/download.nsf/India/HS_INDIA/\\$file/INDIA.pdf](http://www.ey.com/global/download.nsf/India/HS_INDIA/$file/INDIA.pdf) (noting that "[t]oday, multinational pharma companies have a domestic market share of about 20 percent. . . . By 2007, they are expected to comprise about 25 percent of the market").

238. CHAUDHURI, *supra* note 78, at 17-18.

239. See, e.g., Novartis AG v. Adarsh Pharma, 29 P.T.C. [India Patent and Trade Marks Cases Reporter] 108, 126 (Madras H.C. Apr. 28, 2004) (citing affidavit revealing that "the second plaintiff [Novartis India] imports the drugs manufactured by the first plaintiff [Novartis AG of Switzerland] for distribution in India").

240. *Pharmaceuticals in India*, THE ECONOMIST, Dec. 7, 1996, at 60.

241. *Patently*, *supra* note 221, at 63.

242. McNeil, *supra* note 89, at A1 (quoting PhRMA position).

243. *Id.*

244. Saritha Rai, *Chief Sees Surge in G.E. Business in India*, N.Y. TIMES, May 28, 2005, at C13 (quoting General Electric chairman Jeffrey R. Immelt's description of India).

245. Such MNC subsidiaries can now be wholly-owned. India's Foreign Exchange Management Act

include Abbott Laboratories India Ltd., AstraZeneca Pharma India Ltd., Burroughs Wellcome India Ltd., E-Merck (India) Ltd., Glaxo India Ltd., Hoechst Marion Roussel Ltd., Novartis India Ltd., Pfizer Ltd., Sanofi Aventis, Smithkline Beecham Pharmaceuticals (India) Ltd., and Wyeth Ltd.²⁴⁶ A typical arrangement is exemplified by Novartis India, 51% of the shares of which are owned by parent company Novartis AG of Switzerland (with the remainder being owned by the Indian public).²⁴⁷ The MNCs conduct varying degrees of drug manufacturing within India. Pfizer, for example, currently maintains a single drug manufacturing facility near Mumbai, but also outsources manufacturing to about twenty Indian companies.²⁴⁸

Capitalizing on India's low labor costs and skilled workforce, several MNCs are establishing major research and development facilities in India. For example, General Electric's Jack Welch Technology Center in Bangalore is the company's largest R&D center outside the U.S.²⁴⁹ General Electric is also teaming with the Indian health care company MediCity to build a medical center outside of New Delhi, scheduled to open in 2007.²⁵⁰ The center will house "high-end medical diagnostics and clinical research" as well as a "1,800-bed multispecialty hospital incorporating alternative healing therapies."²⁵¹ Dow Chemical is finishing plans for a "large installation" to conduct research and development in India.²⁵² The facility will most likely support product development including design analysis and process engineering to support Dow's plant design.²⁵³ Although Dow views India's strengthening of its patent system as an important consideration in its decision to build in India,²⁵⁴ the primary reasons for the move include India's swift

of 2000 "allowed 100% foreign investment in a new or existing Indian company in the pharmaceutical manufacturing business." Ragavan, *supra* note 87, at 299. The lifting of FDI restrictions in the pharmaceutical industry is part of a broader withdrawal since the mid-1990s of policies put in place by India in the 1970s and 1980s to regulate MNCs. See CHAUDHURI, *supra* note 78, at 138.

246. See ERNST & YOUNG, *supra* note 237, at 9 (Exhibit 7, titled "Top Multinational Pharmas with an Active Presence in India").

247. See *Novartis AG v. Adarsh Pharma*, 29 P.T.C. 108, 126 (Madras H.C. Apr. 28, 2004) ("the first plaintiff is holding 50.93% shares in the second plaintiff company, the remaining belonging to the Indian public.").

248. See Interview with A.S. Krishna, *supra* note 218.

249. Rai, *supra* note 244.

250. *Id.*

251. *Id.*

252. Steve Lohr, *Outsourcing is Climbing Skills Ladder*, N.Y. TIMES, Feb. 16, 2006, at C1.

253. E-mail from William Banholzer, Corporate Vice President and Chief Technology Officer, Dow Chemical Company to Janice Mueller, Professor of Law, University of Pittsburgh School of Law (Feb. 23, 2006) (on file with author).

254. *Id.*

economic growth, the advantages of being in India when products need to be tailored for local conditions, and the skills of Indian scientists.²⁵⁵

The research-based MNCs led the call for stronger patent protection in India. Two leading trade groups for manufacturers of branded drugs, the Indian Pharmaceutical Association (IPA)²⁵⁶ and the Organization of Pharmaceutical Producers of India (OPPI),²⁵⁷ strongly supported the TRIPS-required reforms. OPPI took the position that “[d]ecisions on fresh investment, focus on R&D, Clinical Trials and Productive Collaboration between Indian and International companies will all take place only if there is an assured climate of world class patent protection.”²⁵⁸ The U.S.-based PhRMA declared that “[p]atent protection for pharmaceutical products will provide India’s scientists with incentives to discover and develop new life-saving drugs.”²⁵⁹

In parallel with their calls for stronger patent protection, MNCs operating in India also advocated the implementation of stronger, U.S.-style data protection laws. The MNCs interpret the TRIPS Agreement as requiring this form of data exclusivity,²⁶⁰ and the U.S. government concurs.²⁶¹ The data in question are the safety and efficacy data, derived from costly clinical trials, which MNCs must submit to government regulators when seeking approval

255. *See id.*; Lohr, *supra* note 252, at C1.

256. IPA Homepage, at <http://www.ipapharma.org> (last visited Jan. 20, 2007).

257. OPPI Homepage, at <http://www.indiaoppi.com> (last visited Jan. 20, 2007).

258. Organization of Pharmaceutical Producers of India, Pharmaceutical Industry in India, *available* at <http://www.indiaoppi.com/pharmindia.htm> (last visited Dec. 26, 2005).

259. Press Release, PhRMA, PhRMA Welcomes Passage of Patent Bill in India (Mar. 23, 2005), at http://www.phrma.org/news_room/press_releases/phrma_welcomes_passage_of_patent_bill_in_india.

260. *See* TRIPS, *supra* note 3, Art. 39.3 (“Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.”). *Contra* Carlos M. Correa, *Public Health and Patent Legislation in Developing Countries*, 3 TUL. J. TECH. & INTELL. PROP. 1, 49 (2001) (“Article 39.3 of TRIPS obliges countries to protect confidential data . . . submitted for the registration of new chemical entities, only if their generation involved a ‘considerable effort.’ Article 39.3, however, does not create exclusive rights on such data. . . . The only protection arguably conferred under TRIPS is against ‘dishonest’ commercial practices in the framework of unfair competition law.”) (internal citations omitted).

261. OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2006 SPECIAL 301 REPORT: PRIORITY WATCH LIST 13 (2006), *available* at http://www.ustr.gov/assets/Document_Library/Reports_Publications/2006/2006_Special_301_Review/asset_upload_file353_9337.pdf (stating that “[t]he United States urges India to improve its IPR regime by providing . . . protection against unfair commercial use of undisclosed test and other data submitted by pharmaceutical companies seeking marketing approval for their products”).

to market and sell new drugs.²⁶² In order to market a generic version of the same drug, a generic competitor must submit data showing bio-equivalency with the new drug. Although a generic manufacturer would not be able to legally make and sell a generic equivalent of a patented drug before the patent had expired, the generic firm with freedom to rely on the innovator's data would be in a position to seek regulatory approval early enough to facilitate market entry immediately upon the patent's expiration. Viewing this as an unfair advantage, the MNCs contend that generic manufacturers should not be allowed to copy and use their data for some period of time; for example, during the first five years after the data is published, as in the U.S.²⁶³ As of August 2006, the Indian government had not yet implemented the data exclusivity laws sought by the MNCs, although press reports suggest that such action may be imminent.²⁶⁴

2. Domestic Companies

The wholly Indian-owned domestic pharmaceutical sector is itself highly fragmented. A number of large indigenous companies engage in some original research and development along with generic drug manufacturing, while

262. See THOMAS, *supra* note 160, at 625 (stating that "national governments require sponsors of new drugs to submit preclinical, clinical, manufacturing, and other data that evidences their safety and efficacy").

263. In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984), popularly known as the Hatch-Waxman Act, currently provides five-year data exclusivity for new molecular entities (NMEs). See 21 U.S.C. § 355(c)(3)(E)(ii) (2006).

For views of Indian pharmaceutical officials advocating the need for greater data protection, see Interview with A.S. Krishna, *supra* note 218; Interview with Ranjit Shahani, *supra* note 232; Interview with Dr. Swati Piramal, *supra* note 24.

The Indian generic companies counter that stronger data protection laws could in some cases facilitate patent evergreening. See Milind Antani & Prashant Iyengar, *Towards a Law on Data Exclusivity*, PHARMABIZ.COM, Jan. 5, 2005, at <http://www.pharmabiz.com/article/detnews.asp?articleid=25566§ionid=46> (reporting concerns of Indian Pharmaceutical Alliance about patent evergreening through data protection). For example, consider a country that has adopted a five-year term of data exclusivity. If due to regulatory approval delays a patented drug did not enter the market until the 17th year of its twenty-year patent term, data exclusivity would "effectively extend the patent to 17 plus five equaling 22 years." *Id.* Government supporters also contend that even if the generic manufacturers are granted compulsory licenses to make and sell patented medicines, data exclusivity laws would prevent them from obtaining marketing approval during the time period in which data exclusivity is in operation. See Sebastian PT, *Joshi cautions govt on data exclusivity*, FIN. EXPRESS, June 17, 2006, at http://www.financialexpress.com/fe_full_story.php?content_id=130840.

264. See *id.* (citing letter of BJP leader Murli Manohar Joshi to Prime Minister Singh, asserting that certain government ministries are "on the verge of conceding to MNCs' demand of data exclusivity").

hundreds of other, smaller firms subsist exclusively on reverse-engineering drugs that are still under patent outside of India as well as those off-patent.²⁶⁵

The top three Indian pharmaceutical firms (in terms of sales reported for 2004) are Ranbaxy Laboratories Ltd., Cipla Ltd., and Dr. Reddy's Laboratories Ltd. (DRL).²⁶⁶ Although they compete against MNCs in the global generics market, Ranbaxy and DRL also engage in research partnerships and collaborations with the MNCs; Cipla thus far does not.²⁶⁷ These Indian majors are also developing significant independent R&D capabilities. Ranbaxy, which has adopted a mission statement emphasizing the company's goal of becoming a "research-based international pharmaceutical [c]ompany,"²⁶⁸ spent seven percent of its annual revenues for 2004 on research and development.²⁶⁹ For fiscal year 2005-06, DRL expended almost nine percent of its revenues on research and development.²⁷⁰

India has been a net exporter of drugs since 1988-89,²⁷¹ with the exporting done mainly by domestic companies rather than MNCs.²⁷² The U.S. is the top export target market for the Indian-owned majors.²⁷³ In 2004, for example, Ranbaxy made \$426 million in sales in the U.S. market as compared to \$217

265. See Interview with A.S. Krishna, *supra* note 218 (describing industry structure).

266. ERNST & YOUNG, *supra* note 237, at 6 (Exhibit 2). Sales figures, in U.S. \$ Millions, were:

Ranbaxy	823.93	(Dec. 2004 fiscal year end)
Cipla	484.72	(Mar. 2005 fiscal year end)
Dr. Reddy's	346.16	(Mar. 2005 fiscal year end)

Id.

267. See CHAUDHURI, *supra* note 78, at 318-19. Cipla's position may be changing, however. The company's chairman describes it as "cooperat[ing] with all companies in whatever way possible for mutual interest." E-mail from Dr. Yusuf K. Hamied, Chairman and Managing Director, Cipla Ltd., India, to Janice Mueller, Professor of Law, University of Pittsburgh School of Law (Feb. 3, 2006) (on file with author) (rejecting as inaccurate Chaudhuri's assertion that "as a matter of policy, [Cipla] does not collaborate with the MNCs at any level") [hereinafter E-mail from Dr. Yusuf K. Hamied].

268. Ranbaxy Laboratories, Ltd., Research and Development, at <http://www.ranbaxy.com/md.htm>.

269. *Building Blocks for the Future*, RANBAXY WORLD (Ranbaxy Laboratories, Ltd., Gurgaon, India), Aug. 2005, at 7, at http://www.ranbaxy.com/newsroom/rworld_aug05/rworld_2005.pdf (newsletter quoting Ranbaxy's President, Pharmaceuticals and Executive Director, Malvinder Mohan Singh, as stating that "Ranbaxy is one of the largest spender[s] on R&D (7% of sales in 2004) and has one of the largest state-of-the-art R&D infrastructure in India").

270. DR. REDDY'S LABORATORIES LTD., ANNUAL REPORT 2005-06 38 (2006), available at <http://www.drreddys.com/investors/pdf/annualreport2006.pdf> (reporting in Table 5 total revenues for FY 2005-06 of 24,267 million Rs. and R&D expenses of 2,153 million Rs.). Dr. Reddy's had seven new chemical entities in development in FY 2005-06, with "four in clinical development and three in the pre-clinical stages." *Id.* at 15.

271. CHAUDHURI, *supra* note 78, at 44.

272. *Id.* at 182-83.

273. See generally *id.* at 195-208 (describing current status of Indian exporters in the U.S. generics market and future export opportunities in the United States).

million sales in India.²⁷⁴ One way in which the Indian majors attempt to increase their share of the U.S. generics market is through aggressively challenging the validity of MNC-owned pharmaceutical patents in the U.S. courts. Ranbaxy and DRL are particularly active in attacking U.S. patents through filing Abbreviated new Drug Applications (ANDAs) with Paragraph IV certifications²⁷⁵ in the U.S. Food and Drug Administration.²⁷⁶ Because the first generic firm to successfully challenge a pharmaceutical patent gains a 180-day period of U.S. marketing exclusivity, this litigation strategy is considered high-risk/high-reward.²⁷⁷ Such risk-taking is seen as a justified counter-measure against growing competition among generic suppliers in the U.S. market. Even as more and more blockbuster drugs go off-patent, and thus may be freely copied, the number of generic manufacturers competing for the U.S. market is expanding.²⁷⁸ Indian generic drug manufacturers compete today not only against U.S. generic firms (such as Watson, Barr, and Mylan), but also generic firms based in Israel (e.g., Teva), China, Italy, and a number of other countries.²⁷⁹

In the next tier of major Indian-owned pharmaceutical companies are Wockhardt Ltd., Nicholas Piramal India Ltd., Sun Pharmaceutical Industries

274. See RANBAXY LABS. LTD., ANNUAL REPORT 2004, at 19 (2005), available at <http://www.ranbaxy.com/ar2004/ar2004.pdf>.

275. An ANDA may include a “paragraph IV certification” asserting that the pharmaceutical patent in question is invalid or will not be infringed by the ANDA applicant’s product. See 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2006).

276. The Indian generics’ strategy was quite successful initially. For example, Dr. Reddy’s introduced its generic version of Eli Lilly’s blockbuster antidepressant Prozac in the U.S. in 2001 after successfully challenging Lilly’s patent, see CHAUDHURI, *supra* note 78, at 202-03, and Ranbaxy had similar success in 2002 with a generic version of GlaxoSmithKline’s antibiotic Ceftin. See Saritha Rai, *Indian Drug Maker Says It Will Keep Attacking Patents Despite Pfizer Loss*, N.Y. TIMES, Dec. 20, 2005, at C7.

Since those early triumphs, however, no Indian company has succeeded in a Paragraph IV challenge to a U.S. pharmaceutical patent, although many have made attempts. See Ragavan, *supra* note 87, at 301 (observing that Indian companies in 2004 “filed 33% of the global filings of drug master files [DMFs] and abbreviated new drug applications [ANDAs] with the United States Food and Drug Administration [FDA].”). Filing a DMF with the U.S. FDA is required in order to obtain permission to sell bulk drugs in the U.S. See Vandana Gombar, *Indian Firms Queue Up for \$20-BN US Drug Generics*, BUSINESS STANDARD, May 8, 2006 (on file with author). In 2006, “seven of the top 10 DMF filers at the US FDA are Indian.” *Id.*

277. See CHAUDHURI, *supra* note 78, at 202-03.

278. See Rai, *supra* note 276, at C7 (“India’s leading drug companies are aggressively challenging patents because they are having trouble making much money by simply selling generic versions of drugs whose patents have already expired. The United States—their primary market—is becoming particularly price-competitive among generics.”).

279. See CHAUDHURI, *supra* note 78, at 214.

Ltd., Lupin Ltd., and Cadila Healthcare Ltd.²⁸⁰ Of this latter group, Nicholas Piramal is uniquely positioning itself as a leader in low-cost R&D and eschews any generic drug manufacturing. Nicholas Piramal touts its respect for intellectual property²⁸¹ and does not join Ranbaxy and DRL in challenging U.S. pharmaceutical patents. According to Nicholas Piramal officials, the company would prefer to partner with the U.S. firms and join with them in collaborative R&D rather than confront them in court.²⁸²

In addition to the majors, the Indian drug manufacturing sector includes a host of smaller domestic firms. Many of these firms produce primarily bulk drugs; i.e., the active ingredients present in medicines.²⁸³ A smaller number of firms produce formulations; i.e., the processing of bulk drugs into finished dosage forms such as tablets and capsules.²⁸⁴ As is the case for the majors, the export market is the mainstay of these smaller firms,²⁸⁵ but most export only to markets characterized as “unregulated.”²⁸⁶ Such markets have little or no requirements for registration and quality inspection, and include countries such as Vietnam, Syria, Jordan, Brazil, China, Korea, Taiwan, and Egypt.²⁸⁷ Of the total exports of bulk drugs and formulations from India in 2001-02, an estimated 62% were to unregulated markets.²⁸⁸ The remaining 38% of exports were to regulated markets²⁸⁹ with higher entry barriers, including the U.S. and other North American countries, Western Europe, Japan, Australia, and New Zealand.²⁹⁰

Many Indian drug manufacturing firms, large and small, vehemently opposed the recent patent law reforms. For example, Dr. Yusuf Hamied, the outspoken chairman of leading generic manufacturer Cipla, declared the enactment of the Patents Act, 1970 to be “the dawn of a Golden Age” for the Indian pharmaceutical industry,²⁹¹ while contrasting the 2005 introduction of pharmaceutical product patent protection in India as “one of the greatest

280. See ERNST & YOUNG, *supra* note 237, at 6 (Exhibit 2—based on sales reported at end of FY 2005).

281. Nicholas Piramal Ltd., About Us, at <http://www.nicholaspiramal.com/aboutus.htm> (last visited Jan. 20, 2007) (touting company’s “proven commitment to IPR”).

282. See Interview with Dr. Swati Piramal, *supra* note 24.

283. See CHAUDHURI, *supra* note 78, at 15 & 15-16 n.2.

284. See *id.*

285. For example, more than 75% of Indian bulk drug production is exported. See *id.* at 47.

286. *Id.* at 182.

287. See *id.* at 180-81.

288. See *id.* at 182 tbl. 6.1.

289. See *id.*

290. See *id.* at 180-81.

291. Hamied, *supra* note 2, at 3.

predictable tragedies the world has witnessed.”²⁹² The Indian Drug Manufacturers’ Association, a leading trade group for the nation’s generic drug manufacturing firms, warned that the strengthened patents regime would have “adverse implications for the drug industry and consumers in India. . . . As recently observed in Sub-Saharan African countries, the impact of the strong product patent protection could indeed be very grave, if the national patent law fails to provide for [an] effective and efficient compulsory license system.”²⁹³

Other Indian drug makers, primarily the major firms with significant R&D functions in addition to generic drug manufacturing, took a more favorable stance towards enhanced patent protection. For example, Ranbaxy touts India’s new patents regime as one that “provides an incentive for organizations to be innovative and promises a plethora of opportunities for forward thinking organizations that believe in research & development.”²⁹⁴ Ranbaxy seeks patents not only in India but worldwide,²⁹⁵ filing a total of 185 patent applications during 2005.²⁹⁶

As the above comparison of views about strengthened patent protection indicates, the wide disparity of opinion among Indian drug manufacturing

292. *Id.* at 6. Cipla appears to be adopting a more nuanced stance however, explaining its position as one that is not opposed to the notion of rewarding innovation but that is nevertheless strongly critical of patent-based monopolies in need-based areas such as health and food. *See id.* at 1. Doctor Hamied maintains that appropriate rewards and incentives can be given, while maintaining the public’s access to medicines, through “an automatic license of right with a suitable royalty payment on net [sic] sales to the innovator.” *Id.* at 7 (noting also that Canada, a developed country, used this framework from 1969 to 1992).

Cipla is not opposed to patents per se, and in fact the company owns a number of patents. E-mail from Dr. Yusuf K. Hamied to Professor Janice Mueller, University of Pittsburgh School of Law (Feb. 6, 2006) (on file with author). Cipla’s patents do not claim new chemical entities, however; rather, they are directed to drug delivery systems, processes, and the like. *See id.*; *see also* Preparation of Phthalanes, U.S. Patent No. 6,903,228 (issued June 7, 2005); Pharmaceutical Compositions, U.S. Patent No. 5,929,030 (issued July 27, 1999). Cipla obtains these patents for essentially defensive reasons. *See* E-mail from Dr. Yusuf K. Hamied, *supra* note 267 (explaining that “if we do not patent, we may be later stopped from marketing [the] drugs in question.”).

293. Indian Drug Manufacturers’ Association, *WTO Agreement on TRIPS*, at <http://www.idma-assn.org/Patents.html> (last visited Jan. 21, 2007).

294. *New Patent Regime: New Opportunities*, RANBAXY WORLD (Ranbaxy Labs, Ltd., Haryana, India), Aug. 2005, at 18, available at http://www.ranbaxy.com/newsroom/rworld_aug05/rworld_2005.pdf [hereinafter *New Patent Regime: New Opportunities*].

295. Ranbaxy is an active user of the PCT international patenting mechanism. In 2005, Ranbaxy was among the top ten users of the PCT from developing countries. Press Release, World Intellectual Prop. Org., Exceptional Growth from North East Asia in Record Year for International Patent Filings (Feb. 3, 2006), available at http://wipo.int/edocs/prdocs/en/2006/wipo_pr_2006_436.html.

296. RANBAXY LABS. LTD., ANNUAL REPORT 2005, at 20 (2005) (table titled “Intellectual Property Generated”), available at <http://www.ranbaxy.com/ar2005/ar2005.pdf>.

firms is completely consistent with the broad range of capabilities and expertise within the sector. As succinctly summarized by the United Kingdom's Intellectual Property Rights (IPR) Commission:

In developing countries with strong generic industries, the outlook [for stronger patent protection] is also uncertain. On the one hand, manufacturers of mainly generic drugs are likely to be adversely affected by the introduction of patent protection, and also consumers and governments who will need to pay more for drugs that receive patent protection. On the other hand, producers who are developing a research capability, or who may be able to obtain licenses from multinational companies, may perceive benefits from patent protection. These conflicting impacts explain why the introduction of patent protection in India is so controversial.²⁹⁷

The lack of hegemony within the Indian domestic drug manufacturing sector thus exerted a significant influence on the complexity of India's new patent patents regime. The sector's diversity also illustrates the fallacy of viewing the debate over patents in India as a purely two-sided argument between foreign and domestic drug companies.

Some scholars have predicted that Indian drug manufacturers will face a "push, not pull" effect of the new patent laws, such that these firms will have to increase innovative R&D activity simply to survive in a market where they will henceforth be precluded from continuing their profitable copying.²⁹⁸ Although India's enhanced patents regime will undoubtedly force some degree of change on the generic drug manufacturing firms, such predictions likely overstate the negative impact. With key patents set to expire by 2009 on molecules worth an estimated \$44 billion, the generic drug market is not likely to evaporate any time soon.²⁹⁹ Moreover, as detailed *infra*, the unique provisions of India's new patents law guarantee that generic manufacturers can continue to copy any pharmaceutical product already available on the Indian market prior to January 1, 2005.³⁰⁰ With respect to those products for which a mailbox application matures into a granted patent on or after

297. COMM'N ON INTELLECTUAL PROP. RIGHTS, INTEGRATING INTELLECTUAL PROPERTY RIGHTS AND DEVELOPMENT POLICY 37-38 (2002), available at http://www.iprcommission.org/papers/pdfs/final_report/CIPRfullfinal.pdf (PDF pages 49-50).

298. See Rishi Gupta, Note, *TRIPS Compliance: Dealing With the Consequences of Drug Patents in India*, 26 Hous. J. Int'l L. 599, 630 (2004) (citing Jean O. Lanjouw, *The Introduction of Pharmaceutical Product Patents in India: "Heartless Exploitation of the Poor and Suffering"?*, 4 NAT'L BUREAU OF ECON. RESEARCH, Working Paper No. 6366 (1998), available at <http://www.nber.org/papers/W6366>).

299. See Chandran et al., *supra* note 11, at 277.

300. See *infra* Part IV.E.

January 1, 2005, payment of a royalty to the patentee will be required but ongoing production by the generic firm cannot be restrained.³⁰¹

B. Demographics, Healthcare and Market Pricing

India's population of approximately 1.1 billion people represents one-sixth of all humanity.³⁰² The immensity of that potential consumer demand has not escaped the attention of pharmaceutical manufacturers. For example, the website of Nicholas Piramal, a leading Indian drug firm, observes that "[a]lthough buying power and pharmaceuticals penetration is currently lower [in India] than some of the more developed markets, it is expected to grow to US \$25 billion by the year 2010."³⁰³ India's current population of 1.1 billion includes a rapidly growing middle class of about 300 million.³⁰⁴ Ernst & Young reports that about one-third, or 100 million, of this group "can afford quality private health care."³⁰⁵ This wealthiest ten percent or so of the Indian population is no doubt the target market for companies such as Hoffman-La Roche, which is pricing its newly-patented Hepatitis C therapy, Pegasys, in India at about \$10,000 per patient per year.³⁰⁶

But what of the remainder of India's population, including an estimated 800 million that live on less than two dollars a day?³⁰⁷ In contrast with the U.S. and other developed countries, there is little or no social safety net for the majority of Indian citizens. They face a health care system that has been

301. *See id.*

302. As of August 2006, the world population is estimated to be approximately 6.5 billion people. *See* U.S. Census Bureau, *U.S. and World Population Clocks—POPclocks*, available at <http://www.census.gov/main/www/popclock.html> (last visited Jan. 7, 2007).

303. Nicholas Piramal India Ltd., *Corporate Strategy*, at http://www.nicholaspiramal.com/aboutus_corstrategy.htm (last visited Jan. 7, 2007).

304. Zakaria, *supra* note 21, at 39. *See also* Karina Robinson, *India Slowly Opens to the World*, INT'L HERALD TRIB. (PARIS), July 15-16, 2006, at 14 (referring to India's "expanding middle class of 250 million to 300 million people in need of financial services.").

305. ERNST & YOUNG, *supra* note 237, at 4.

306. "Pegasys was launched in India in 2003 and the cost to a patient is about Rs 2.25 lakh for six months." Datta, *Roche Gets Product Patent*, *supra* note 9. The Indian "lakh" refers to a quantity of 100,000. Thus Rs. 2.25 lakh means 225,000 rupees. At an exchange rate of about 46 rupees per U.S. dollar as of July 13, 2006, *see* Yahoo Finance Currency Converter, available at <http://finance.yahoo.com/currency>, meaning that 225,000 rupees converts to \$4,856 in U.S. currency. Thus a patient's one-year cost for Pegasys is \$9,712. This pricing of Pegasys is explained as the "total cost includ[ing] the cost of therapy, testing, monitoring and follow-up, besides the cost of the drug itself. Ribavirin, another medicine used in some cases with Pegasys, is also bundled into this package. . . ." Datta, *Roche Gets Product Patent*, *supra* note 9 (quoting Dr. G.L. Telang, Managing Director of Roche in India).

307. *See* Zakaria, *supra* note 21, at 38.

described as operating “in a state of perpetual crisis.”³⁰⁸ For example, in 2005 India’s per capita expenditure on health care was about \$28 a year, with about \$3 a year per capita spent on pharmaceuticals,³⁰⁹ as compared to per capita health care spending of \$5,635 in the U.S.³¹⁰ According to the Organisation of Pharmaceutical Producers of India, less than four percent of the Indian population carries health insurance.³¹¹ Accordingly, “in countries, such as India, where health insurance coverage is so rare, any change in the demand structure could have a significant impact on the poor.”³¹²

The lack of a well-established medical insurance industry in India may perversely benefit patients in one respect, however, which is the breadth of therapeutic alternatives available in the Indian market. The wide variety of alternatives available for many drugs operates as a lever to keep prices in check, and should continue to function even after the introduction of pharmaceutical product patent protection. According to Ranbaxy, “[d]rug pricing will continue to be market driven. In India, all major therapeutic areas have multiple drug choices and so any new drug cannot command a premium just because it has a patent.”³¹³ As a Pfizer official explained, because so few patients have private health insurance in India, most drug purchases are paid for out-of-pocket.³¹⁴ If, for example, an Indian doctor gives a patient a prescription for a branded generic drug priced above what that patient can afford, the Indian pharmacist will likely suggest an un-branded generic alternative.³¹⁵ Many more therapeutic alternatives exist in India than in the U.S., where the medical insurance system frequently imposes limits on the number of products approved for reimbursement.³¹⁶

After only eighteen months of operation of the new pharmaceutical product patents regime, it is too soon to quantitatively assess its impact on drug pricing. After all, as of March 2006 only a single pharmaceutical

308. Hamied, *supra* note 2, at 7.

309. See ERNST & YOUNG, *supra* note 237, at 4 (citing ESPICOM BUS. INTELLIGENCE, ESPICOM PHARMACEUTICALS MARKET FACT BOOK 2005 (2005)).

310. *Id.* (citing U.S. figure for 2003).

311. Organisation of Pharmaceutical Producers of India, *Pharmaceutical Industry in India*, available at <http://www.indiaoppi.com/pharminindia.htm> (last visited Jan. 7, 2007) (stating that “[h]ardly 3.5% of the population (mainly public service and industrial employees) are covered by health insurance”).

312. Ouseph Tharakan, *Access to Drugs the Key Issue*, THE FIN. EXPRESS (MUMBAI), Apr. 6, 2005, available at http://www.financialexpress.com/print.php?content_id=87106.

313. *New Patent Regime: New Opportunities*, *supra* note 294, at 18.

314. Interview with A.S. Krishna, *supra* note 218.

315. See *id.*

316. See *id.*

product patent had been issued in India.³¹⁷ The consensus view appears to be that at least in the short term, the introduction of pharmaceutical product patent protection in India will have a relatively minor overall impact on drug prices. The Indian government takes the position that “[t]he fear that prices of medicines will spiral is unfounded,” noting that “97% of all drugs manufactured in India are off-patent, and so will remain unaffected” by the new regime.³¹⁸ Another estimate is that in the short term, prices will be impacted for at most about fifteen percent of medicines sold in the Indian market.³¹⁹ Safety valves, such as compulsory licensing,³²⁰ and government-set drug price ceilings,³²¹ are also available. The scenario in which patent protection may have a more substantial and negative impact on the public is in the longer term, when a new generation of drugs will be invented and patented. At risk “are new generations of much more expensive AIDS drugs that will soon be needed worldwide as resistance builds to current medicines.”³²²

C. Cultural Norms

A number of cultural norms influence the Indian public’s traditionally negative view of patents. First, the exclusive ownership (albeit temporary) conveyed by a patent is contrary to the Indian norm of communal property ownership in villages. Despite the recent and much-publicized success of the Indian IT sector, the nation’s economy is still primarily agrarian. More than two-thirds of the Indian population still lives in villages rather than urban centers.³²³ A typical village’s economy is “functionally integrated between agriculture and handicraft industry” including “agriculturists, craftsmen, astrologers, tanners, carpenters, barbers, priests, smiths, petty retailers, musicians, record keepers, headmen, and so on.”³²⁴ Communal ownership is

317. See Datta, *Roche Gets Product Patent*, *supra* note 9.

318. Nath Statement, *supra* note 8, at ¶ 12.

319. See Chandran et al., *supra* note 11, at 269-80 (also noting that only 5 of 300 WHO Essential List drugs are in any way patent protected).

320. See discussion *infra* Part IV.

321. See discussion *infra* Part IIID.

322. Editorial, *India's Choice*, *supra* note 1, at A20.

323. See WALSH, *supra* note 86, at 287 (stating that according to the 2001 census, “72.2 percent of India’s population lives in more than 638,588 villages; 27.8 percent lives in India’s 5,161 cities and towns.”).

324. DAS, *supra* note 136, at 125.

the norm in the villages; individual creativity and ownership of the fruits of that creativity is a relatively new and foreign idea.³²⁵

India's hard-won freedom from colonial subjugation combined with the Gandhian goal of self-sufficiency³²⁶ makes its citizens understandably wary of foreign influences. A "westernized" patent system as required by the WTO TRIPS Agreement, in which over three-quarters of Indian patent applications still are foreign-owned,³²⁷ is not easily accepted by many. The words of B.K. Keayla, a leading patent system critic and convener of the National Working Group on Patent Law,³²⁸ are illustrative of this view:

If we are serious about defending the interest of our people, our objectives should be to assert our position and use every legal latitude that exists for doing so, rather than to submit ourselves obediently to certain particular interpretation of legal rectitude that we have received from the developed countries.³²⁹

India's new patents regime thus can be understood as an uneasy compromise between these opposing tensions.

Lastly, the relatively rapid pace of India's patent law transformation is also contrary to cultural norms. Although India received a ten-year transition period in which to implement pharmaceutical product protection under TRIPS, the implementation was viewed by many as far too hasty. In a nation with a "3,000-year history of growth, decay, and renewal; of invasion, absorption, and survival; of imperial conquest and imperial subordination,"³³⁰ change need not happen quickly. It is worth noting that after its independence in 1947, India did not enact its first indigenous patent law until 1970.³³¹ The current evolutionary stage of India's patents regime is for many a journey, not a destination.³³²

325. Discussion meeting with Manoj Pillai, Lex Orbis Intellectual Property Practice, New Delhi, Nov. 16, 2006.

326. See 2 THE CAMBRIDGE ECONOMIC HISTORY OF INDIA, 1757-1970, *supra* note 61, at 950 (referring to "the Gandhians who believe in a non-violent revolution, leading to decentralized, relatively self-sufficient village communities without an artificial proliferation of wants and minimal recourse to modern technology"); DAS, *supra* note 136, at 125 (discussing "Gandhi's dream of building modern India along the lines of self-governing village republics").

327. See *infra* Part V.A.4 for statistics on the composition of India's patent application filings.

328. See generally B.K. Keayla, *Amended Patents Act: A Critique*, 4 COMBAT L., June-July 2005, available at <http://www.indiatogether.org/combatalaw/vol4/issue2/>.

329. See KEAYLA, *supra* note 108.

330. COHEN, *supra* note 46, at 34.

331. The Patents Act, No. 39 of 1970 (Universal 2005).

332. See Interview with Dr. Swati Piramal, *supra* note 24. See also Frederick M. Abbott, *Beginning of a New Policy Chapter*, FIN. EXPRESS (Mumbai), Apr. 6, 2005, at <http://www.financialexpress.com/>

D. Drug Price Controls

India's new pharmaceutical product patents regime operates in the shadow of government-imposed price controls on drugs. First implemented in 1970, India's Drug Price Control Order (DPCO) set price ceilings on hundreds of essential medicines.³³³ Currently the National Pharmaceutical Pricing Authority (NPPA)³³⁴ determines which drugs will be included in the DPCO and how pricing for those drugs will be formulated.³³⁵ Although the number of included drugs has been reduced significantly over time, today the prices of 74 bulk drugs (such as penicillin, tetracycline, insulin, aspirin, ibuprofen, and ciprofloxacin)³³⁶ and the formulations containing them remain subject to strict controls.³³⁷ It is still unknown whether newly-patented pharmaceutical products will be considered for inclusion in the DPCO, but government officials have mentioned price controls as one of several tools at their disposal for protecting the Indian public from unreasonably high prices.³³⁸

IV. INDIA PATENTS ACT, 1970 (2005): ANALYSIS AND CRITIQUE

This part analyzes and critiques the significant features of India's current patent law, the India Patents Act, 1970 (2005). A number of these features are

print.php?content_id=87112 (stating that "[n]o one should mistake the new [patent] legislation as an endpoint. It is only the beginning of a new chapter in addressing public health needs in India and around the world.").

333. See CHAUDHURI, *supra* note 78, at 276; Ragavan, *supra* note 87, at 292-302 (describing historical development of DPCO from 1970 to present).

334. See generally Functions of NPPA, at <http://nppaindia.nic.in/function.html> (last visited Jan. 7, 2007).

335. See ERNST & YOUNG, *supra* note 237, at 14.

336. National Pharmaceutical Pricing Authority List of Controlled Bulk Drugs, at <http://nppaindia.nic.in/list1.html> (last visited Jan. 7, 2007).

337. See National Pharmaceutical Pricing Authority Frequently Asked Questions, at <http://nppaindia.nic.in/frequent.html#4> (last visited Jan. 7, 2007) (stating in response to Question 4 that "[o]nly 74 out of about 500 commonly used bulk drugs are kept under statutory price control. All formulations containing these bulk drugs either in a single or combination form fall under price controlled category. However, the prices of other drugs can be regulated, if warranted in public interest."). The current schedule of price-controlled bulk drugs, available at <http://nppaindia.nic.in/list1.html>, lists 75 bulk drugs.

338. Nath Statement, *supra* note 8, at ¶ 13 (observing that in addition to compulsory licensing and government acquisition of patents, "[t]here is also the Drug Price Control Order administered by the National Pharmaceuticals Price Authority. With this framework in place it is clear that the concerns and fears expressed by various sections are wholly misplaced.").

controversial and have yet to be interpreted by the Indian courts. They include detailed provisions enumerating what is and is not considered patentable subject matter, a new and ambiguous definition of the “inventive step” criterion of patentability, procedures governing both pre- and post-grant opposition, and an extensive framework for compulsory licensing.

A. Patentable Subject Matter

1. Product Patents for Pharmaceutical Substances

For the first time since 1972, India’s patents regime once again recognizes the potential patentability of pharmaceutical products. Section 4 of the Patents (Amendment) Act, 2005,³³⁹ the cornerstone provision for bringing India’s patents law into compliance with TRIPS,³⁴⁰ repealed the pre-existing statutory prohibition on the patenting of claims directed to “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).”³⁴¹

339. The Patents (Amendment) Act, No. 15 of 2005, § 4 (Universal 2005) (providing that “Section 5 of the principal Act shall be omitted”).

340. See TRIPS, *supra* note 3, Art. 27.1 (requiring that, subject to certain permissible exclusions from patentability set forth in Articles 27.2 and 27.3, “patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application”).

341. The Patents Act, No. 39 of 1970, § 5 (Universal 2005) (amended 2002). The complete text of Section 5 of The Patents Act, No. 39 of 1970 (amended 2002), as it stood prior to its amendment by The Patents (Amendment) Act, No. 15 of 2005, was as follows:

5. Inventions where only methods or processes of manufacture patentable.—(1) In the case of inventions—

(a) claiming substances intended for use, or capable of being used, as food or as medicine or drug, or

(b) relating to substances prepared or produced by chemical processes (including alloys, optical glass, semi-conductors and inter-metallic compounds),

no patent shall be granted in respect of claims for the substances themselves, but claims for the methods or processes of manufacture shall be patentable.

(2) Notwithstanding anything contained in sub-section (1), a claim for patent of an invention for a substance itself intended for use, or capable of being used, as medicine or drug, except the medicine or drug specified under sub-clause (v) of clause (1) of sub-section (1) of section 2, may be made and shall be dealt, without prejudice to the other provisions of this Act, in the manner provided in Chapter IVA.

Explanation.—For purposes of this section, “chemical process” includes biochemical, biotechnological and microbiological processes.

The immediate impact of this fundamental expansion of patentability in India is a huge influx of product patent applications awaiting examination. As discussed *supra*, approximately 9,000 mailbox applications were filed with the Indian Patent Office during the TRIPS transition period of January 1, 1995 to December 31, 2004 claiming substances capable of use as food, medicine or drug.³⁴² During the first eighteen months of the new patents regime, i.e., during January 1, 2005 to June 30, 2006, summaries of approximately 6,700 of those mailbox applications have been published.³⁴³ The Indian Patent Office began taking up the mailbox applications for examination in January 2005.³⁴⁴ In addition, regular (non-mailbox) applications claiming pharmaceutical substances began to be filed on or after January 1, 2005 and are also awaiting examination.³⁴⁵ The first pharmaceutical product patent to issue under India's new patents regime was granted in March 2006 to Hoffman-La Roche for its Hepatitis C therapy sold under the brand name Pegasys.³⁴⁶

2. *Inventions, Not Discoveries*

Section 2(1)(j) of India's patent statute now defines an "invention" as "a new product or process involving an inventive step and capable of industrial

The Patents Act, No. 39 of 1970, § 5 (Universal 2005) (amended 2002), *reprinted in* UNIVERSAL'S THE PATENTS ACT, 1970, AS AMENDED BY THE PATENTS (AMENDMENT) ACT, 2005, *supra* note 5, at 172, 173 ("Annexe") (providing provisions of Patents Act, 1970, as they stood before their omission or substitution by Patents (Amendment) Act, No. 15 of 2005).

342. *See supra* Part II.C.2.

343. *See supra* note 183.

344. *See id.*

345. For example, India Patent Application No. 00242/KOLNP/2005, titled "N-Substitute-2-Oxodihydropyridine Derivatives," was filed on January 22, 2005. The one-page summary of the application published on June 23, 2006, indicates that the claimed compound is useful "as a neuropeptide Y receptor antagonist agent and is also useful as an agent for the treatment of bulimia, obesity or diabetes." The application is assigned to Banyu Pharmaceutical Co., Ltd. of Japan. 2006 OFF. J. PAT. OFFICE 12286 (June 23, 2006), *available at* http://patentoffice.nic.in/ipr/patent/journal_archieve/journal_2006/pat_arch_062006/official_journal_23062006.pdf.

346. An Indian patent claiming a therapy for Hepatitis C, marketed under the brand name Pegasys, was reportedly granted on March 2, 2006 to Swiss pharmaceutical giant Hoffman-La Roche AG. *See* Datta, *Roche Gets Product Patent*, *supra* note 9. Official notice of the grant was not published until May 2006, however. *See* 2006 OFF. J. PAT. OFFICE 10000 (May 19, 2006), *available at* http://patentoffice.nic.in/ipr/patent/journal_archieve/journal_2006/pat_arch_052006/official_journal_19052006.pdf (notice of grant of Indian Pat. No. 198,952, titled "A Physiologically Active Branched PEG-IFNa Conjugate," on Application No. 1032/MAS/1997, assigned to Hoffman-La Roche). *See* 2005 OFF. J. PAT. OFFICE 24056 (Oct. 28, 2005), *available at* http://ipindia.nic.in/ipr/patent/journal_archieve/pat_arch_102005/official_journal_28102005.pdf, for a summary of Application No. 1032/MAS/1997A.

application.”³⁴⁷ This language was implemented via the Patents (Amendment) Act, 2002,³⁴⁸ so as to expressly incorporate the TRIPS-mandated “inventive step” criteria of patentability³⁴⁹ into the definition of an invention. The prior version of the statute omitted the inventive step criterion and defined “invention” in a more complicated (and U.S.-style³⁵⁰) manner as encompassing:

any new and useful—
 (i) art, process, method or manner of manufacture;
 (ii) machine, apparatus or other article;
 (iii) substance produced by manufacture,
 and includes any new and useful improvement of any of them, and an alleged invention.³⁵¹

India’s new definition of an invention as “a new product or process involving an inventive step and capable of industrial application” also compresses the categories of potentially patentable subject matter to simply “products and processes,” in accordance with TRIPS.³⁵²

In contrast with U.S. patent law, the new Indian definition of an invention omits “discoveries.”³⁵³ This is consistent with the European approach, which expressly excludes “discoveries” from patentability.³⁵⁴

3. *Exclusions from Patentable Subject Matter*

India’s new patent law includes an extensive list of exclusions from patentability, enumerated in Section 3 of the Patents Act, 1970 (2005). Some

347. The Patents Act, No. 39 of 1970, § 2(1)(j) (Universal 2005) (amended 2005).

348. See The Patents (Amendment) Act, No. 38 of 2002, § 3(f), available at <http://indiacode.nic.in>.

349. See TRIPS, *supra* note 3, Art. 27.1 (providing that, subject to certain exceptions, “patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, *involve an inventive step* and are capable of industrial application”) (emphasis added).

350. See 35 U.S.C. § 101 (2000) (defining potentially patentable subject matter as encompassing “any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof”).

351. The Patents Act, No. 39 of 1970, § 2(1)(j) (amended 1999).

352. See The Patents Act, No. 39 of 1970, § 2(1)(j) (Universal 2005) (amended 2005).

353. Compare 35 U.S.C. § 100(a) (2000) (providing that “[t]he term ‘invention’ means invention or discovery”). This statutory definition derives from the U.S. Constitution, which grants Congress the power to “promote the Progress of . . . useful Arts, by securing for limited Times to . . . Inventors the exclusive Right to their . . . Discoveries.” U.S. CONST. art. I, § 8, cl. 8 (emphasis added).

354. See European Patent Convention, art. 52(2)(a), Oct. 5, 1973, available at http://www.european-patent-office.org/legal/epc/pdf/epc_2006_v5_bm_en.pdf (providing that “discoveries, scientific theories and mathematical methods” shall not be regarded as inventions for which European patents are available).

of these exclusions are likely to test the limits of TRIPS-permitted exclusions. Others are unfortunately ambiguous and will require further interpretation by the Indian Patent Office and judiciary. The most significant exclusions from patentability are discussed individually below.

a. Section 3(d): Derivatives of Known Substances

In its most controversial exclusionary provision, India's new Patents Act prohibits patents on derivatives of known substances, *unless* such derivatives display significantly enhanced efficacy. Section 3(d) of the Patents Act, 1970 (2005), provides:

The following are not inventions within the meaning of this Act,—

...
(d) *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 unless such known process results in a new product or employs at least one new reactant.

Explanation.—For the purposes of this clause, 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*; . . .³⁵⁵

This express and detailed statutory presumption against patentability of derivatives, unique among the world's patent regimes, reflects a strong resentment towards ever-greening of pharmaceutical patents.³⁵⁶ “Ever-

355. The Patents Act, No. 39 of 1970, § 3(d) (Universal 2005) (amended 2005) (emphasis added except for “Explanation,” which is italicized in original). *See also* The Patents (Amendment) Act, No. 15 of 2005, § 3 (Universal 2005) (substituting the quoted language for the prior version of clause (d) of Section 3).

356. *See* Ahibhusan De and Uma Baskaran, *What the New Patent Regime Means In Practice*, MANAGING INTEL. PROP., July/Aug. 2005, at 63, 64 (commenting that the section 3(d) “amendment provides a gate for patents with improvements in efficacy for existing molecules such as polymorphic forms, at the same time restricting evergreening of patents for such forms of substances without significant efficiency in the properties.”); Manisha Singh, *India's Patent Law—Is It TRIPS Compliant?*, MANAGING INTEL. PROP., July/Aug. 2005, at 67, 69 (noting that the objective behind section 3(d)'s “elaborate explanation” is “probably to check what the Indian generic drug makers allege as evergreening”); Editorial (*Better Now, But . . .*), *supra* note 218, at 9 (stating that “the official amendments [to the Ordinance of December 2004] have . . . curbed the ever-greening of patents by clarifying the concept of patentability in unmistakable terms. Ever-greening would have allowed a patent holder, nearing the end of the 20-year life of a patent, to renew the patent for a fresh 20-year period—as many pharmaceutical companies had been preparing to do.”); Tharakan, *supra* note 312 (noting that section 3(d) “seeks to prevent the extending of

greening” in this context refers to attempts by owners of pharmaceutical product patents to effectively extend the term of those patents by obtaining related patents on modified forms of the same drug, new delivery systems for the drug, new uses of the drug, and the like.³⁵⁷ MNCs are well versed in developing new dosage forms, searching for alternative uses of established drugs, and obtaining U.S. patent protection on the results.³⁵⁸ The Indian pharmaceutical industry, including both research-based companies and major generic manufacturers, professes unity in its opposition to patent extensions through ever-greening.³⁵⁹

The patent statutes of the U.S. have no provision directly analogous to India’s Section 3(d). In some cases, U.S. courts deal with the ever-greening problem under general principles of obviousness³⁶⁰ or the doctrine of inherent

patent life by making minimal changes to the patented molecule”).

357. Robin Feldman, *Rethinking Rights in BioSpace*, 79 S. CAL. L. REV. 1, 30 (2005) (noting scholars’ concern over ever-greening, the practice of attempts by patent holders “to refresh their patents by patenting updated versions, alternative delivery methods, or other variations of the original product,” and suggesting that patenting metabolites may also be form of ever-greening). See Alfred B. Engelberg, *Special Patent Provisions for Pharmaceuticals: Have they Outlived Their Usefulness?*, 39 IDEA 389, 401 n.44 (1999) (defining ever-greening as “using a series of related patents (divisionals, continuations) covering different aspects of the same basic product invention in combination with patent term extensions to unduly prolong the exclusive market period”).

358. See Gladys Mirandah, *War on Pharmaceutical Patents Begins*, MANAGING INTELL. PROP., Feb. 2006, at 135. See also Chandran et al., *supra* note 11, at 269, 275 (observing that multinational companies adopt several “evergreening strategies” . . . “to maintain and extend the length of their patent benefits”). These strategies may include the introduction of “fixed dose combinations, as part of product life cycle management initiatives,” *id.*, the filing of “frivolous patent infringement suits . . . which result in activation of an automatic 24-30 months . . . delay in processing of generic product claim[s],” *id.*, and the acquisition of a “‘second-medical-use patent’ before expiry of [the] first patent for the molecule [of interest].” *Id.* at 276.

359. See *Pharma Sector Seeks Clear Patent Guidelines*, TIMES OF INDIA, Nov. 4, 2004, <http://timesofindia.indiatimes.com> (quoting letter from the Indian Pharmaceutical Alliance (IPA) to the Indian government’s Group of Ministers looking into amendments in patent legislation). The IPA’s letter stated that “[p]atents intended to delay the entry of generics, such as patents for polymorphs, hydrates, isomers, metabolites, substantially pure, particle size and blood levels must not be permitted.” *Id.* The IPA’s letter clarified that “there are no differences among its members, including Ranbaxy, on this issue.” *Id.*

360. See, e.g., *McNeil-PPC, Inc. v. L. Perrigo Co.*, 337 F.3d 1362, 1373 (Fed. Cir. 2003) (affirming district court’s holding that improvement patents directed to combination of anti-diarrheal drug loperamide with anti-gas drug simethicone were invalid as obvious under 35 U.S.C. § 103 in view of prior art patents held by third parties, but reversing district court’s award of attorney fees to patent challenger). The Federal Circuit noted the district court’s concern that the patentee had “set out as an objective developing products that extended the life of [its] basic patent on loperamide,” but declined to find the case exceptional under 35 U.S.C. § 285 (which would have supported an award of fees). *Id.* “While it may be considered more socially desirable for companies to seek truly novel inventions for maladies not yet treatable,” the Federal Circuit observed, “the patent laws set the standards of novelty, non-obviousness, and utility as the requirements for patentability, without making value judgments concerning the motives for making and

anticipation.³⁶¹ For example, the concept of *prima facie* obviousness as developed in U.S. patent jurisprudence operates as a presumption against the patenting of molecules that are deemed structurally similar to prior art molecules.³⁶² The presumption may be rebutted if the patent applicant or owner can demonstrate “unexpectedly” improved results stemming from the modification in question.³⁶³

In other cases, ever-greening attempts are assessed in the U.S. under the doctrine of double patenting, a rather complex amalgam of statutory and case law.³⁶⁴ At bottom, the double patenting doctrine is a prohibition on a given patent owner unfairly extending its monopoly by acquiring more than one patent on a given invention. Although there is universal agreement that a patentee cannot obtain a second patent claiming the identical invention already claimed in that patentee’s first patent,³⁶⁵ the U.S. does allow issuance of a second patent to the same patentee on a merely obvious variant of the invention claimed in that patentee’s first patent. Ideally, the second patent will be subject to terminal disclaimer, meaning that it must expire at the same time as the first patent and thereby prevent monopoly extension, as a result of the USPTO’s rejection of the second application on the ground of “obviousness-type” double patenting.³⁶⁶ Nevertheless, the issuance of a second patent to the same entity is permitted.³⁶⁷

attempting to patent new inventions of lesser medical value.” *Id.*

361. *See, e.g.*, Schering Corp. v. Geneva Pharm., Inc., 339 F.3d 1373, 1380 (Fed. Cir. 2003) (affirming district court’s judgment invalidating patent that claimed a metabolite of the antihistamine loratadine, on ground of inherent anticipation by same patentee’s earlier patent directed to loratadine (marketed as Claritin) where ingestion of loratadine inevitably formed claimed metabolite in patient’s body).

362. *See In re Dillon*, 919 F.2d 688, 692 (Fed. Cir. 1990) (*en banc*) (reaffirming that “structural similarity between claimed and prior art subject matter, proved by combining references or otherwise, where the prior art gives reason or motivation to make the claimed compositions, creates a *prima facie* case of obviousness, and that the burden (and opportunity) then falls on an applicant to rebut that *prima facie* case”).

363. *See id.* at 692-93.

364. *See generally* JANICE M. MUELLER, AN INTRODUCTION TO PATENT LAW 48-52 (2d ed. 2006).

365. In U.S. parlance, this is “same-invention type” double patenting, which is based on the language of 35 U.S.C. § 101 that “[w]hoever invents or discovers any new and useful [invention] may obtain a patent therefor.” 35 U.S.C. § 101 (2000) (emphasis added).

366. Terminal disclaimer practice in the U.S. patent system is governed by 35 U.S.C. § 253, ¶ 2 (2000) and 37 C.F.R. § 1.321 (2006).

367. Nor can obviousness-type double patenting be asserted by the USPTO when a second patent results from a restriction requirement imposed by the Office. *See* 35 U.S.C. § 121 (2000) (providing that: A patent issuing on an application with respect to which a requirement for restriction under this section has been made, or on an application filed as a result of such a requirement, shall not be used as a reference either in the Patent and Trademark Office or in the courts against a divisional

The real problem arises when the USPTO fails to reject the second application on the basis of double patenting and allows it to issue without the imposition of a terminal disclaimer. These follow-on patents can be challenged in the courts as violating the double patenting prohibition, but their invalidation is by no means automatic or rapid. Unless and until invalidated by the courts, the follow-on patent remains in force.³⁶⁸ Thus, the U.S. method of dealing with the ever-greening problem through application of double patenting doctrine is a much less straightforward approach than that taken by India.

Under India's new Patents Act, the extent of a claimed derivative's "efficacy" will be the pivotal question raised by the section 3(d) exclusion from patentability. Although the first paragraph of section 3(d) permits the patenting of a derivative that provides an "enhancement of the known efficacy" of a "known substance," the second paragraph's "Explanation" further raises the bar by requiring that the derivative and the known substance "differ *significantly* in properties with regard to efficacy."³⁶⁹ Section 3(d) thus raises both qualitative and quantitative questions—i.e., what kind of data will be required to establish "efficacy" and how great an improvement over the efficacy of the prior art invention will be required to obtain a patent.

It is likely that before these interpretive questions reach the courts, the Indian Patent Office will have to answer them.³⁷⁰ Although Patent Office officials have indicated a certain comfort level with the new efficacy criteria,³⁷¹ the ambiguity of the language³⁷² endows the Office with a great deal

application or against the original application or any patent issued on either of them, if the divisional application is filed before the issuance of the patent on the other application.).

368. The U.S. Federal Trade Commission has studied potentially anticompetitive attempts by owners of such follow on patents to obtain multiple 30-month stays before onset of generic drug competition via improperly listing the patents in the Food and Drug Administration's "Orange Book." See FEDERAL TRADE COMMISSION, *GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY* 39-57 (2002), available at <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf> (describing Commission's study of "Orange Book Patent Listing Practices and Use of Multiple 30-Month Stays").

369. The Patents Act, No. 39 of 1970, §3(d) (Universal 2005) (amended 2005) (emphasis added).

370. The first court challenge to Section 3(d) commenced in May 2006 when Swiss pharmaceutical manufacturer Novartis petitioned the Chennai (Madras) High Court to strike down Section 3(d) as non-compliant with India's obligations under the TRIPS Agreement. In a parallel proceeding Novartis also appealed the Indian Patent Office's refusal (on Section 3(d) grounds) to grant a patent on Glivec, a leukemia drug Novartis had already patented in 36 other countries. As of early February 2007 the Chennai High Court had not ruled on Novartis' petitions. For further details, see Janice Mueller, *Taking TRIPS to India—Novartis, Patent Law, and Access to Medicines*, NEW ENG. J. MED. (Feb. 8, 2007), at 541-43, available at <http://content.nejm.org/cgi/reprint/356/6/541.pdf>.

371. Interview with K.S. Kardam, *supra* note 175. In that interview K.S. Kardam (then head of the New Delhi branch of the Patent Office) stated that the Patent Office had not yet had to apply or interpret

of discretion and virtually no guidance for applying it. Nothing in India's Patents Rules³⁷³ (comparable to the United States' patent rules set forth at 37 C.F.R.) elucidates what will be required to satisfy the enhanced efficacy requirement. The latest draft Indian Manual of Patent Practice and Procedure (hereinafter "MPPP")³⁷⁴ does not provide any explicit guidance for interpreting the enhanced efficacy requirement,³⁷⁵ although an annexed set of draft guidelines for examination of pharmaceutical and biotechnological subject matter³⁷⁶ instruct that "known pharmaceutical compositions in different new dosages and different form such as capsules, tablets, syrups, suspensions, etc., are not patentable under sections 2(1)(j), 3(d) and 3(e) of the Act."³⁷⁷

The present capability of Indian Patent Office examiners to review and evaluate efficacy data submitted by pharmaceutical product patent applicants is unclear,³⁷⁸ as is the procedural mechanism for submitting such data to the examiners. This lack of transparency is not particularly surprising, however, in view of the fact that the Indian Patent Office has not granted pharmaceutical product patents for 35 years. The work-in-progress nature of the endeavor is clearly evidenced elsewhere in the MPPP, which broadly observes that "[c]riteria for granting product patents in a particular field i.e.

the new "efficacy" language. *Id.* However, in Kardam's personal view, as a chemist, the new language of section 3(d) "makes it easier to decide patentability," because "chemists know what 'efficacy' means." *Id.*

372. See Mirandah, *supra* note 358, at 135 (referring to Section 3(d) as a "nebulous provision").

373. See The Patents Rules, 2003 (Universal 2005), *supra* note 184.

374. See INDIAN PATENT OFFICE, MANUAL OF PATENT PRACTICE AND PROCEDURE (2005), available at <http://patentoffice.nic.in/ipr/patent/manual-2052005.pdf> [hereinafter MPPP]. As of August 2006, the MPPP was published on the Indian Patent Office's website but still in draft form. See *id.* at 1. Public comments on the draft MPPP were due by August 20, 2005. See Manual of Patent Practice & Procedure—Patent Office, India (2005), available at <http://patentoffice.nic.in/ipr/patent/manual.htm> (last visited Aug. 7, 2006). Patent Office officials had expected the draft MPPP to be finalized by November 30, 2005. Interview with K.S. Kardam, *supra* note 175.

Like the U.S. MANUAL OF PATENT EXAMINING PROCEDURE, the Indian MPPP does not have the force and effect of law. Rather, it is an internal document intended to provide guidance to patent examiners. See MPPP, *supra* at 4 (stating that "[t]he contents of this manual including the guidelines are merely for the purpose of illustrations and not meant for legal purposes. In case of any conflict, legal provisions of the Patents Act will prevail").

375. See MPPP, *supra* note 374, at 17-18 (discussing section 3(d) only with regard to the prohibition on new use patents and not referring to "efficacy" criterion).

376. See *id.* at 138-42 (included as "Annexure—1: Examination Guidelines for Patent Applications relating to Inventions in the field of Chemicals, Pharmaceuticals and Biotechnology").

377. *Id.* at 141 (paragraph 6.0 titled "Pharmaceutical Compositions") (emphasis added).

378. See *infra* Part V.A.2.b (discussing current staffing levels of Indian Patent Office patent examiners and the need for further recruitment, especially in the chemical arts).

chemicals, foods, pharmaceuticals or biotechnology etc. will have to be assessed carefully within the legal framework and relevant court-rulings.”³⁷⁹

Despite these uncertainties, the Indian Patent Office is the first-instance actor required to interpret and apply the new section 3(d) prohibition on pharmaceutical derivatives; the Controller of Patents reportedly has already rejected patent applications under section 3(d) in the context of deciding pre-grant oppositions.³⁸⁰ However, a different government-empowered body is soon expected to provide additional guidance on the import of Section 3(d). As part of the political compromise required to enact the India Patents Act, 1970 (2005), the Indian government charged a “Technical Expert Group” chaired by prominent scientist Dr. R.A. Mashelkar³⁸¹ with determining “whether it would be TRIPS compatible to limit the grant of patent for pharmaceutical substance to new chemical entity or to new medical entity involving one or more incentive [sic] steps.”³⁸² With its consideration of whether pharmaceutical product patents should be limited to “new chemical entit[ies],” i.e., excluding patents on mere derivatives thereof, the Mashelkar Committee’s assignment is generally understood as a referendum on section 3(d) of the India Patents Act, 1970 (2005).³⁸³ In carrying out its terms of reference, the Mashelkar Committee has taken evidence from stakeholders through presentations, interviews, and receipt of written comments.³⁸⁴ The

379. MPPP, *supra* note 374, at 138.

380. *See infra* Part IV.D.1.

381. Dr. Mashelkar is Director General of the Council of Scientific & Industrial Research (CSIR), India’s premier industrial research and development organization. *See* CSIR Leader, *available at* <http://www.csir.res.in/External/Head/aboutcsir/leader.htm> (last visited Nov. 7, 2006).

382. Government of India, Ministry of Commerce & Industry, *Order* (Apr. 5, 2005) (copy obtained from Dr. R.A. Mashelkar, Director General of the Council of Scientific & Industrial Research, on file with author). The Mashelkar committee will also examine “whether it would be TRIPS compatible to exclude micro-organisms for [sic] patenting.” *Id.* *See also Mashelkar to Head Panel on Patent Law*, *ECON. TIMES*, Apr. 6, 2005, *available at* <http://economictimes.indiatimes.com/articleshow/1070509.cms> (reporting that formation of expert committee was “a direct follow-up of the assurance given by [Minister of Commerce and Industry] Kamal Nath while moving the official amendments to the Patents (Amendment) Bill 2005 in the Lok Sabha [Lower House] on March 22 [2005]”).

383. *See* Organization of Pharmaceutical Producers of India, *supra* note 311 (stating that “[t]he patentability criteria is also narrowly defined in the new Act which is restricted only to New Chemical Entities (NCEs). Salts, esters, polymorphs, isomers, etc. are not patentable unless they ‘differ significantly in properties with regard to efficacy.’ However, this clause is being reviewed and a Committee has been formed to examine it in detail.”).

384. E-mail from Dr. R.A. Mashelkar, Director General of the Council of Scientific & Industrial Research to Professor Janice Mueller, University of Pittsburgh School of Law (Jan. 18, 2006) (on file with author).

committee's report to the Indian government was expected by the end of April 2006³⁸⁵ but has not been publicly released as of August 2006.³⁸⁶

Echoing the Indian political left and the smaller generic drug manufacturers, press coverage in India generally favors a narrow definition of patentability.³⁸⁷ But MNCs argue to the contrary that innovation is incremental, and that the new patent laws should be interpreted to allow patenting of incremental improvements such as derivatives of known substances of the type listed in section 3(d).³⁸⁸ According to the MNCs, this expansive view of patentability would directly benefit the type of innovation for which the majority of Indian drugmakers (i.e., the generic firms) are best equipped.³⁸⁹

385. See *id.* (stating that committee must complete its work "within the next three months").

386. The Mashelkar Committee's report was not published until December 2006. See R.A. Mashelkar et al., REPORT OF THE TECHNICAL EXPERT GROUP ON PATENT LAW ISSUES 1-56 (Dec. 2006) [hereinafter Mashelkar Committee Report], available at http://patentoffice.nic.in/ipr/patent/mashelkar_committee_report.doc. Although noting the existence of "a perception that even the current provisions in the Patents Act could be held to be TRIPS non-compliant," *id.* at 7, the Mashelkar Committee concluded that improper attempts to ever-green patents can be prevented "by a proper application of patentability criteria as present in the current patent regime." *Id.* Limiting the grant of pharmaceutical product patents solely to new chemical entities (NCEs) and thereby categorically excluding other forms of pharmaceutical innovation from patenting would be "likely to contravene the mandate under Article 27 [of TRIPS] to grant patents to all 'inventions.'" *Id.* at 6. The Committee did not go so far as to recommend that the controversial Section 3(d) be repealed, however. Rather, proper application of the new Patents Act must distinguish non-deserving, trivial attempts to ever-green from truly "incremental innovations," i.e., "sequential developments that build on the original patented product and [that] may be of tremendous value in a country like India." *Id.* at 7. Doctor Mashelkar and his Expert Committee colleagues concluded that "[d]etailed [g]uidelines should be formulated and rigorously used by the Indian Patent Office for examining the patent applications in the pharmaceutical sector so that the remotest possibility of granting frivolous patents is eliminated." *Id.* at 8.

387. See Editorial, *Now for a Second Dose*, ECON. TIMES, Mar. 27, 2005, at <http://economictimes.indiatimes.com/articleshow/msid-1063471,curpg-2.cms> (opining that "[i]n the case of patentability, it would be useful to accept the Mashelkar panel's recommendation on restricting patentability to new chemical entities and limiting the amplitude of novelty and utility, characteristics that make for patentability, through clear enunciation. NCEs number less than 300 since 1995.").

388. See Interview with A.S. Krishna, *supra* note 218; Interview with Ranjit Shahani, *supra* note 232 (observing that "incremental innovation happens all the time; breakthroughs are relatively rare. We should allow patents on incremental innovation. The scientists here haven't reached the breakthrough stage.").

389. See Interview with A.S. Krishna, *supra* note 218 (observing that reverse engineering and process patenting is only one step away from incremental innovations, such as new formulations and delivery systems, and that most Indian firms do not have the funds to undertake full-scale new chemical entity (NCE) drug discovery research); see also Interview with Dr. Swati Piramal, *supra* note 24 (observing that science is "not perfect," and that incremental innovation "is the norm," and asking why India's patent laws should not reflect this scientific and technical reality).

b. Section 3(d): New Uses of Known Substances

Section 3(d) of the Patents Act deals not only with chemical derivatives but also with new methods of using known pharmaceutical products, providing in pertinent part that “[merely discovering] . . . any new property or new use for a known substance” is “not [an] invention within the meaning of this Act.”³⁹⁰ For example, according to the 2005 draft MPPP, the mere discovery that a known substance such as aspirin, a known analgesic, is also useful for the treatment of cardiovascular disease, would not be considered patentable.³⁹¹ “However, a new and alternative method for preparing Aspirin is patentable.”³⁹² The latter is a *new* method of making a known substance, as opposed to a non-patentable new method of *using* a known substance.

India’s restrictive position is in sharp contrast with the U.S., which broadly permits the patenting of any new use for a known product (so long as that new use meets the requirements of novelty, nonobviousness, and utility).³⁹³ As India’s MPPP further clarifies, a “2nd or 3rd use for a known substance cannot be allowed.”³⁹⁴ This statement also contrasts India’s position with that of the European patent regimes, in which so-called “second medical use” claims are allowable.³⁹⁵ Second medical use claims, also known as “Swiss type” claims, typically recite the “use of compound X for the manufacture of a medicament for the treatment of disease Y.”

The question accordingly arises whether Section 3(d)’s broad exclusion of new use patents complies with TRIPS. Although Article 27.1 of TRIPS mandates that patents be available for “processes . . . in all fields of technology,” TRIPS nowhere defines “processes.” Moreover, Art. 27.3 of TRIPS explicitly permits member countries to exclude “diagnostic, therapeutic and surgical methods for the treatment of humans or animals” from patentability. India’s Patents Act already excludes such methods of treatment in Section 3(i),³⁹⁶ so one must conclude that the Section 3(d) exclusion covers

390. The Patents Act, No. 39 of 1970, § 3(d) (Universal 2005) (amended 2005).

391. See MPPP, *supra* note 374, at 17 (item I).

392. *Id.*

393. See 35 U.S.C. § 100(b) (2000) (defining the term “process” as “includ[ing] a new use of a known . . . composition of matter”).

394. MPPP, *supra* note 374, at 18 (item II).

395. See John K. McDonald, *A Patent Practitioner’s Perspective: Advising Pharmaceutical Clients*, 17 EMORY INT’L L. REV. 517, 521 (2003) (explaining that “[m]ethods of treatment are not patentable in Europe and many other jurisdictions, but you can get what’s called a second medical use claim—for example, the use of a composition in the manufacturing of a medicine useful to treat HIV/AIDS”).

396. See The Patents Act, No. 39 of 1970, § 3(i) (Universal 2005) (amended 2005) (providing that

broader ground; i.e., methods of use even beyond those contemplated within Section 3(i). If new uses of known substances as well as methods of human/animal treatment are non-patentable, the remaining patent-eligible subject matter is narrow indeed; i.e., encompassing merely new uses of new substances for purposes other than treatment of humans or animals.

Some observers contend that such broad exclusions are acceptable under TRIPS, at least in principle.³⁹⁷ Others counter that the sum total effect of Sections 3(d) and 3(i) is to effectively eliminate all method of use claims from patentability.³⁹⁸

Whether or not the broad exclusions of Section 3(d) would survive a TRIPS challenge, their potential negative impact on an important form of indigenous innovation should not be ignored.³⁹⁹ For example, ayurvedic therapies emphasizing holistic lifestyle changes and natural herb-based remedies have been practiced in India for thousands of years.⁴⁰⁰ However, innovative new ayurvedic methods of using ancient ingredients could not be protected in India under the patents statute as written, reducing incentives to develop such methods. In comparison, China's booming herbal medicine market benefits greatly from the broader availability there of patent protection.⁴⁰¹ In its zeal to prevent pharmaceutical product patent holders

"any process for the medicinal, surgical, curative, prophylactic [diagnostic, therapeutic] or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products" is "not [an] invention[] within the meaning of this Act").

397. Professor Correa has observed:

While TRIPS requires member states to protect *products* and *processes*, it does not specifically refer to the protection of new uses, thus leaving member countries free to choose whether or not to protect them. In principle, a country that broadly excludes methods of medical treatment could also broadly exclude new therapeutic uses for old products.

Correa, *supra* note 260, at 16 (footnote omitted).

398. See Manoj Pillai, *India's Patents Bill, 2005—Is It TRIPS Compliant?*, MONDAQ, Mar. 31, 2005, at <http://www.mondaq.com/article.asp?articleid=31717>.

399. See Correa, *supra* note 260, at 16 (observing that "[c]onsistency is required in defining excludable therapeutic methods. The impact of any such exclusions on local needs and industry should also be taken into account.").

400. See Amar Singh, *Role of Traditional Medicine—Ayurvedic System and a Dispensary for Every Central Village in India*, 15 GEOGRAPHIA MEDICA 216, 218 (describing ayurveda as an "ancient" system that is "well tried under Indian conditions"); Interview with Dr. Swati Piramal, *supra* note 24 (describing India's "5,000-year tradition of ayurvedic drugs"). See also WebMD Health Topics: Ayurveda Topic Overview, at http://www.webmd.com/hw/alternative_medicine/tp21271.asp (last visited Jan. 21, 2007).

401. See Interview with Dr. Swati Piramal, *supra* note 24; see also Benjamin Liu, *Past Cultural Achievement as a Future Technological Resource: Contradictions and Opportunities in the Intellectual Property Protection of Chinese Medicine in China*, 21 UCLA PAC. BASIN L.J. 75, 83-89 (2003) (section describing "Patent and CM").

from extending their monopolies through follow-on process patents, India may have suppressed an important means of stimulating indigenous innovation.

c. Section 3(j): Plants and Animals

India's new Patents Act excludes from patentability "plants and animals in whole or any part thereof other than micro-organisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals."⁴⁰² This provision was added to the Act via the 2002 amendments⁴⁰³ in order to codify domestically the TRIPS-permitted exclusion from patentability of "plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes."⁴⁰⁴ As TRIPS also contemplates, India has chosen to exclude seeds as well as varieties and species of plants and animals from patentability, but provides *sui generis* protection for this subject matter under the Protection of Plant Varieties and Farmers' Rights Act, 2001.⁴⁰⁵

The Section 3(j) treatment of "micro-organisms" as potentially patentable subject matter is important for support of India's booming indigenous biotechnology sector. Given India's cultural traditions of great respect for animals, however, the potential patentability of any life form is a difficult concept for many.⁴⁰⁶ It is not surprising, then, that the Mashelkar Committee, in addition to interpreting the scope of Section 3(d)'s exclusion of chemical derivatives,⁴⁰⁷ has also been charged with determining whether it would be

402. The Patents Act, No. 39 of 1970, § 3(j) (Universal 2005) (amended 2005).

403. See The Patents (Amendment) Act, No. 38 of 2002, § 4, available at <http://indiacode.nic.in>.

404. TRIPS, *supra* note 3, Art. 27.3(b). The provision also mandates that "Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof." *Id.*

405. The Protection of Plant Varieties and Farmers' Rights Act, 2001, No. 53, Acts of Parliament, 2001, available at <http://indiacode.nic.in/fullact1.asp?tfnm=200153>. On the topic of India's plant protection system, see generally SABINE DEMANGUE, INTELLECTUAL PROPERTY PROTECTION FOR CROP GENETIC RESOURCES: A SUITABLE SYSTEM FOR INDIA (2005).

406. See WOLPERT, *supra* note 136, at 73 (observing as part of discussion of Hinduism that:

Most Indians are gentle, nonviolent people, in part perhaps because they view all life as interrelated, and believe in the potential cosmic significance of individual deeds or actions and their implications, extending over a hundred or more lifetimes. One must be careful where one treads, for the very earthworm beneath one's foot shares cosmic connections. We never know where the ripple-current we set in motion could lead. Hindus have reported nightmares after eating beef, hearing a dead grandmother's voice crying out in agony at the pain caused by so violent a fall from vegetarian grace.).

407. See *supra* Part IV.A.3.a.

TRIPS-compliant to exclude micro-organisms from patentability.⁴⁰⁸ TRIPS explicitly requires the patentability of “micro-organisms,” but does not define the term.⁴⁰⁹ Although the Mashelkar Committee had not issued its report as of August 2006, it seems likely that the committee might propose a narrow definition of “micro-organism” so as to minimize the scope of allowable subject matter.⁴¹⁰

Absent further legislative change and/or guidance from the Mashelkar Committee on the scope of “micro-organism,” the current Patent Office position is that any “living entit[y] of natural origin” is not patentable, nor is any “living entity of artificial origin such as transgenic animals and plants [or] any part thereof.”⁴¹¹ A “living entity of artificial origin such as [a] micro-organism [or] vaccines are considered patentable,” however.⁴¹²

d. Section 3(k): Business Methods and Computer Programs Per Se

India’s new patent statute provides that “a mathematical or business method or a computer programme *per se* or algorithms” are “not inventions within the meaning of [the] Act.”⁴¹³ This prohibition was added to the Act in

408. Government of India, Ministry of Commerce & Industry, *Order* (Apr. 5, 2005) (copy obtained from Dr. R.A. Mashelkar, Director General of the Council of Scientific & Industrial Research, on file with author) (stating that Mashelkar committee will examine “whether it would be TRIPs compatible to exclude micro-organisms for [sic] patenting”).

409. See TRIPS, *supra* note 3, Art. 27.3(b).

410. Published in December 2006, the Mashelkar Committee Report, *see supra* note 386, eschewed an explicit definition of “micro-organism” but concluded that “[e]xcluding micro-organisms *per se* from patent protection would be violative of [the] TRIPS Agreement.” *Id.* at 10. The report drew a distinction between “naturally occurring micro-organisms [that] should not qualify for patenting” and “micro-organisms involving human intervention and utility [that] are patentable subject matter under the TRIPS Agreement, provided they meet the prescribed patentability criteria.” *Id.* Echoing its conclusions about the potential patentability of derivative forms of known chemical entities, the Mashelkar Committee recommended that “strict guidelines need to be formulated for examination of the patent applications involving micro-organisms from the point of view of substantial human intervention and utility.” *Id.*

411. MPPP, *supra* note 374, at 141 (¶ 7.0 in “Annexure I: Examination Guidelines for Patent Applications relating to Inventions in the field of Chemicals, Pharmaceuticals and Biotechnology”).

412. *Id.* The MPPP position that a living micro-organism or vaccine is potentially patentable subject matter is consistent with the Calcutta High Court’s landmark decision in *Dimminaco A.G. v. Controller of Patents Designs & Ors.*, IPLR 2002 July, 255, A.I.D. No. 1 of 2001 (Jan. 15, 2002) (reversing Indian Patent Office’s rejection of claim to “process for preparation of infectious bursitis vaccine,” where end product of claimed process contained a live virus). The import of the *Dimminaco* decision in India has been compared to the U.S. Supreme Court’s decision in *Diamond v. Chakrabarty*, 447 U.S. 303 (1980) (affirming patentability of living genetically-engineered bacterium). See Malathi Lakshmikumaran & Shilpi Bhattacharya, *The Dimminaco Case: A Landmark Judgment on the Patentability of Micro-Organisms*, 2003 NIPOSOUVENIR 63, available at <http://www.nipo.org.in/img2003/souvenir/TheDimminacoCase.html>.

413. The Patents Act, No. 39 of 1970, § 3(k) (amended 2005).

2002;⁴¹⁴ prior to the 2002 amendment the Act did not refer to computer programs at all.⁴¹⁵ As with the other provisions of the Patents Act, the extent to which this provision will impede patenting in the software-implemented arts depends largely on implementation. Indian Patent Office officials take the position that software embedded in hardware is potentially patentable if a technical application exists therefor,⁴¹⁶ echoing the European position.⁴¹⁷ Several recently granted Indian patents appear to be directed to software-implemented devices or systems.⁴¹⁸

414. See The Patents (Amendment) Act, No. 38 of 2002, § 4(e), available at <http://indiacode.nic.in> (inserting clauses (j) through (p) into § 3 of principal Act).

415. See The Patents Act, No. 39 of 1970, § 3(a)-(i) (amended 1999) (enumerating categories of subject matter that are not inventions within the Act).

416. See Interview with P.K. Patni, Deputy Controller of Patents and Designs, India Intellectual Property Office, New Delhi Branch, in New Delhi, India (Nov. 16, 2005) (notes on file with author).

417. The 2005 draft MPPP provides a number of examples of patentable and non-patentable subject matter under Section 3(k). Patentable subject matter would include: “[a] contents display method for displaying contents on a screen,” “[a] method for controlling an information processing apparatus, for communicating via the Internet with an external apparatus,” and “[a] method for transmitting data across an open communication channel on a wireless device that selectively opens and closes a communication channel to a wireless network, and each wireless device including a computer platform and including a plurality of device resources that selectively utilizes a communication channel to communicate with other devices across the network.” MPPP, *supra* note 374, at 22-23. Although all of these methods utilize computer programs in their operation, they are “not computer programs as such and hence [are] allowable.” *Id.* at 23.

On the other hand, the following would be considered non-patentable subject matter: “[a] method of executing a computer program, in which at least part of the copy of the program available for execution is analysed to determine whether or not any change has been made thereto, and in the event that a change is detected, a further copy of the program is retrieved and caused to be executed instead of the first copy,” and “[a] method for generating a new computer program using a software development tool.” *Id.* The latter examples are considered “programs solely intellectual in [their] context and hence not allowable.” *Id.* Also non-patentable are a “computer program product . . . claimed as ‘[a] computer program product in computer readable medium’ and ‘[a] computer-readable storage medium having a program recorded thereon.’” *Id.* at 22. These sorts of claims would be “treated as relating to software per[se], irrespective of the medium of [] storage” and therefore not patentable. *Id.*

In addition to these examples, the MPPP includes a separate set of “Examination Guidelines for Patentability of Computer-Related Inventions,” *id.* at 143-56 (“Annexure II”), which aim “to evolve uniform practice within Patent Offices and thereby eliminat[e] different interpretation[s] of the provisions of the Act.” *Id.* at 143.

418. For example, Samsung Electronics Co., Ltd. was recently granted Indian Patent No. 199,409, titled “A Data Detector and Method for Improving Performance of a Signal Processing System in Maximum Likelihood Detection.” See 2006 OFF. J. PAT. OFFICE 12304 (June 23, 2006), available at http://patentoffice.nic.in/ipr/patent/journal_archive/journal_2006/pat_arch_062006/official_journal_23062006.pdf. The Samsung patent issued from Application No. 959/CAL/1998, filed May 29, 1998. See 2005 OFF. J. PAT. OFFICE 24898 (Nov. 11, 2005), available at http://ipindia.nic.in/ipr/patent/journal_archive/pat_arch_112005/official_journal_11112005.pdf.

e. Section 3(p): Traditional Knowledge

The new Patents Act also excludes from patentability “an invention which in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components.”⁴¹⁹ This exclusion is but one of several provisions inserted into the new Act in an effort to prevent the exercise of proprietary rights in India’s genetic resources and indigenous knowledge.⁴²⁰ For example, the Act’s disclosure requirements mandate inclusion of the source and geographical origin of biological material used in the claimed invention,⁴²¹ and interested parties may oppose or petition to revoke an Indian patent on the ground that the invention claimed therein is anticipated “having regard to the knowledge, oral or otherwise, available within any local or indigenous community or elsewhere.”⁴²²

Such provisions provide India with explicit statutory bases for fending off future attempts to obtain Indian patents that exploit Indian natural resources and knowledge. The well-publicized episodes of foreign patenting of inventions derived at least to some degree from Indian natural resources such as neem tree seeds, turmeric spice, and basmati rice are considered infamous examples of biopiracy by the Indian public,⁴²³ and the government likely wants to avoid any similar embarrassments at home.

In a parallel effort, India’s National Institute of Science Communication and Information Resources is compiling a massive Traditional Knowledge Digital Library.⁴²⁴ Accessible to patent offices worldwide, the Digital Library will document India’s vast body of traditional knowledge in five languages: English, French, Japanese, Spanish, and German.⁴²⁵ The Digital Library thus creates a vast body of prior art documentation that can be relied on by patent examiners considering the patentability of claims to inventions derived from India’s indigenous resources.

419. The Patents Act, No. 39 of 1970, § 3(p) (Universal 2005) (amended 2005).

420. See N.S. Gopalakrishnan, *TRIPS and Protection of Traditional Knowledge of Genetic Resources: New Challenges to the Patents System*, 27 EUR. INTELL. PROP. REV. 11, 17 (2005).

421. See The Patents Act, No. 39 of 1970, § 10(4)(ii)(D) (Universal 2005) (amended 2005).

422. *Id.* §§ 25(2)(k), 64(1)(q) (specifying grounds for post-grant opposition and revocation, respectively).

423. See Colin Campbell, *Hands Off Their Meds*, MACLEAN’S, Mar. 27, 2006, at 40 (describing cases in which “India has had to fend off Western science’s predatory practice of filing patents on other countries’ traditional remedies”).

424. See *id.* (describing four-year effort to compile and digitize “every known piece of India’s vast body of traditional medicine, from yoga poses to simple cures for infections”).

425. See *id.*

B. Inventive Step

India now defines an “invention” as a “new product or process involving an inventive step and capable of industrial application,”⁴²⁶ thus codifying in its laws the TRIPS-required substantive minima of patentability. TRIPS does not further define the criteria of novelty, inventive step, and industrial applicability, however, leaving member countries the flexibility to fashion their own understandings thereof.⁴²⁷ Accordingly, “[l]ess technologically advanced countries may prefer to set higher standards of novelty and inventive step in order to preserve and enhance competition without violating minimum international standards.”⁴²⁸

India has exercised this flexibility by adopting a unique⁴²⁹ but rather ambiguous definition of the inventive step requirement.⁴³⁰ According to the new Patents Act, inventive step now means “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.”⁴³¹ The latest version of the Indian MPPP adds the following explanation:

Inventive step is a feature of an invention that involves technical advance as compared to existing knowledge or having economic significance or both, making the invention non obvious to a person skilled in art. Here definition of inventive step has been enlarged to include economic significance of the invention apart from already existing criteria for determining inventive [] step.⁴³²

426. The Patents Act, No. 39 of 1970, § 2(1)(j) (Universal 2005) (amended 2005).

427. The TRIPS Agreement specifies that “the term[] ‘inventive step’ . . . may be deemed by a Member to be synonymous with the term[] ‘non-obvious,’” TRIPS, *supra* note 3, Art. 27.1 n.5, but provides no definition of “non-obvious.” To the extent that “non-obvious” refers to the U.S. understanding of that term, *see* 35 U.S.C. § 103 (2000), TRIPS member countries are free to adopt that understanding or to modify it for their own purposes.

428. Correa, *supra* note 260, at 23.

429. Compare Brazil Industrial Property Law § 13, Lei No. 9,279, de 14 de maio de 1996, D.O.U. de 14.05.1996 (Brazil), available at <http://www.wipo.int/clea/en/fiche.jsp?uid=br003> (providing that “[a]n invention is endowed with inventive step provided that, to a technician versed in the subject, it is not derived in an evident or obvious way from the state of the art”).

430. The language was reportedly the result of a last-minute compromise to appease the Left parties, leaving no time for fine-tuning. *See* Interview with attorney Krishna Sarma, *supra* note 126.

431. The Patents Act, No. 39 of 1970, § 2(1)(ja) (Universal 2005) (amended 2005).

432. MPPP, *supra* note 374, at 12 (¶ 2.3).

Thus, India appears to have adopted a “nonobviousness-plus” standard. In order to be patentable, the invention must be (1) nonobvious to a person skilled in the art, but in addition, it must also (2) “involve[] technical advance as compared to the existing knowledge or hav[e] economic significance or both.”⁴³³

By engrafting new “technical advance” and “economic significance” criteria onto the standard nonobviousness requirement, India has been criticized for implementing a “vague and arbitrary” definition that fails to “reflect the distilled stock of knowledge” on what nonobviousness means.⁴³⁴ Each of the new statutory criteria certainly raises its own interpretative questions. For example, the “technical advance over existing knowledge” language invites qualitative comparisons with the prior art but is devoid of any requirement that such comparisons be made from the perspective a person of ordinary skill in the art at the time of application filing (or earlier date of invention).⁴³⁵

The “economic significance” language may be redundant with the utility/industrial applicability requirement,⁴³⁶ or it may be intended as an explicit reference to U.S.-style “commercial success” secondary considerations evidence.⁴³⁷ Because many patents are applied for well before the invention claimed therein has attained any economic significance, however, strict imposition of the new “economic significance” language is likely to prejudice independent inventors and small business entities. As is the case with method of use patenting, India’s quest to limit the patent rights of foreign pharmaceutical manufacturers may have unintended negative consequences in the form of lessened opportunities for patenting by indigenous inventors.

Although Indian legislators in the course of amending the Patents Act presumably are not bound to follow the Indian judiciary’s patent case

433. Patents Act, No. 39 of 1970, § 2(1)(ja) (Universal 2005) (amended 2005).

434. Pillai, *supra* note 398.

435. *Compare* 35 U.S.C. § 103(a) (2000) (providing that “[a] patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title [35 U.S.C.], if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.”).

436. *See* Pillai, *supra* note 398.

437. *See* Pejman F. Sharifi & Scott Blackman, *Indian Patent Law Reform and Its Impact on Pharmaceutical-Related Outsourcing*, 71 BNA PAT., TRADEMARK & COPYRIGHT J. 173, 174 (2005) (observing that “[t]he notion of economic significance in the amendment appears to be analogous to the concept of commercial success in determining non-obviousness under U.S. laws”).

precedent, it is worth noting that the statute's new definition of "inventive step" represents a departure from that precedent. In *Bishwanath Prasad v. Hindustan Metal Indus.*,⁴³⁸ the Supreme Court of India clearly equated "inventive step" with "nonobviousness" and acknowledged that the terms have "acquired special significance in the terminology of Patent Law."⁴³⁹

Whatever the established significance of "inventive step" to the judiciary (and the Patent Office), the Indian legislators discounted those understandings in favor of a broadened definition that now gives the Patent Office and courts an explicit mandate to consider a claimed invention's economic significance. Whether or not the changed definition will result in fewer new patents being granted (and more existing patents being revoked) is a subject for future empirical study. In the meantime, however, because nothing in TRIPS explicitly prevents imposition of this new definition for the inventive step criterion of patentability, it will be left to the Patent Office and the courts to interpret and apply it in individual cases.

C. Novelty

In addition to defining "invention" as discussed *supra*,⁴⁴⁰ the Patents Act, 1970 (2005) also includes a separate definition of "new invention."⁴⁴¹ First made part of the Act by the 2005 amendments,⁴⁴² a "new invention" is defined as:

[A]ny 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, i.e. the subject matter has not fallen in public domain or that it does not form part of the state of the art.⁴⁴³

438. *Bishwanath Prasad Radhey Shyam v. Hindustan Metal Indus.*, (1978) 254 S.C.R. 757, 777 (India) (upholding trial court's grant of defendant's petition for revocation under Patents Act, 1911 of patented method of making utensils on ground that invention was "neither a manner of new manufacture or novel improvement, nor did it involve any inventive step, having regard to what was publicly known or used at the date of the patent"), available at <http://www.commonlii.org/in/cases/INSC/1978/254.html>.

439. *Id.* at 765.

440. See *supra* Part IV.A.3.b.

441. The Patents Act, No. 39 of 1970, § 2(1)(l) (Universal 2005) (amended 2005).

442. See The Patents (Amendment) Act, No. 15 of 2005, § 2(1)(g).

443. The Patents Act, No. 39 of 1970, § 2(1)(l) (Universal 2005) (amended 2005). India recognizes a limited twelve-month pre-filing grace period for disclosures made with the inventor's consent in government-designated exhibitions or before learned societies. See *id.* § 31.

The intent of this definition appears to be the elimination of any geographic limitations on the source of prior art. In other words, India appears to be adopting a system in which an invention must be novel not only as compared with what was previously published or used in India, but also novel with respect to earlier publications or uses in any foreign country. This worldwide scope for prior art is entirely consistent with the standards of the European Patent Convention.⁴⁴⁴

What remains unclear, however, is whether the Indian Patent Office and/or the courts have the necessary statutory authority to apply this broadened standard for anticipation. Notably, the “new invention” definition is not incorporated into or even referred to in any other section of the new Patents Act.⁴⁴⁵ In fact, other provisions of the Act appear to affirmatively prohibit the consideration of foreign uses (as opposed to foreign publications) of inventions as prior art. For example, the extent of an Indian patent examiner’s inquiry for anticipation includes searches of documents published worldwide but makes no mention of prior use (in India or elsewhere).⁴⁴⁶ Pre-grant opposition may be based on prior public knowledge or use of an invention “in India,” but foreign uses are not mentioned.⁴⁴⁷ Post-grant oppositions operate under the same restrictions.⁴⁴⁸ In the absence of further legislative amendments to India’s patent law, clarification of this apparent discrepancy awaits decisions from the Patent Office and/or the courts.

444. See European Patent Convention, *supra* note 354, art. 54(1) (providing that “[a]n invention shall be considered to be new if it does not form part of the state of the art”); *id.* art. 54(2) (providing that “[t]he state of the art shall be held to comprise everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application”).

445. The section 2(1)(j) definition of “invention” refers to a “new product or process” but does not incorporate the phrase “new invention.” The Patents Act, No. 39 of 1970, § 2(1)(j) (Universal 2005) (amended 2005). See also E-mail from Manisha Singh, Partner, Lex Orbis Intellectual Property Practice, New Delhi, India, to Professor Janice Mueller, University of Pittsburgh School of Law (Sept. 12, 2005) (on file with author) (commenting that “the tricky part is that the new definition of ‘new invention’ remains unconnected with the definition of ‘invention’ [in section] 2(1)(j) or the grounds for opposition in Section 25(1)(d) or (e)”).

446. See The Patents Act, No. 39 of 1970, § 13 (Universal 2005) (amended 2005) (“Search for anticipation by previous publication and by prior claim.”).

447. See *id.* § 25(1)(d) (providing as ground for pre-grant opposition that “the invention . . . was publicly known or publicly used in India before the priority date . . .”); *id.* § 25(1)(e) (listing as ground for pre-grant opposition that “the invention . . . is obvious and clearly does not involve any inventive step, . . . having regard to what was used in India before the priority date”).

448. See *id.* § 25(2)(d) (limited to prior public knowledge or use “in India”); *id.* § 25(2)(e) (same).

D. Opposition System

India's new patents regime provides for both pre- and post-grant opposition. Each form of opposition is discussed below.

1. Pre-Grant Opposition

Section 25 of the India Patents Act, 1970 (2005) provides for pre-grant opposition of pending patent applications. Representation against the grant of patent by way of pre-grant opposition may be made "[w]here an application for a patent has been published but a patent has not been granted."⁴⁴⁹ "Any person" may represent against the grant of a patent by way of pre-grant opposition,⁴⁵⁰ in contrast with notices of post-grant opposition which can be filed only by "any person interested."⁴⁵¹ The grounds on which pre-grant opposition may be based include virtually all patentability criteria,⁴⁵² including anticipation, lack of inventive step, non-invention under Section 3 of the Patents Act (including the anti-evergreening provisions of Section 3(d)), insufficient or unclear description of the invention in the specification, failure to disclose the source of biological material used for the invention, and inventions which are considered traditional knowledge.⁴⁵³ In contrast with the U.S. *inter partes* reexamination system,⁴⁵⁴ the Indian Patents Act does not place any estoppel limitations on a party who previously filed a pre-grant

449. *Id.* § 25(1). The Patents Rules further specify that representation for pre-grant opposition "shall be filed at the appropriate office within a period not exceeding three months from the date of publication of the application under Section 11 A of the Act, or before the grant of patent, whichever is later." The Patents Rules, 2003 (Universal 2005), *supra* note 184, at 99-100 (§ 55(1)).

Moreover, a pre-grant opposition will not be considered by the India Patent Office until the patent applicant has filed a request for examination of its application. *See id.* at 100 (§ 55(2)) (providing that "[t]he Controller shall consider such representation only when a request for examination of the application has been filed").

450. The Patents Act, No. 39 of 1970, § 25(1) (Universal 2005) (amended 2005). In contrast, the India Patents Act, 1970, specified that "any person interested" could file a pre-grant opposition. *See* The Patents Act, No. 39 of 1970, § 25(1) (Universal 2005). It therefore appears that the current law was intended to expand opportunities for the filing of pre-grant oppositions.

451. The Patents Act, No. 39 of 1970, § 25(2) (Universal 2005) (amended 2005).

452. *See id.* § 25(1)(a)-(k).

453. *See id.*

454. *See* 35 U.S.C. § 315(c) (2000) (providing that:

A third-party requester whose request for an *inter partes* reexamination results in an order under section 313 [35 U.S.C. § 313] is estopped from asserting at a later time, in any civil action arising in whole or in part under section 1338 of title 28, . . . the invalidity of any claim finally determined to be valid and patentable on any ground which the third-party requester raised or could have raised during the *inter partes* reexamination proceedings.).

opposition and later attempts to challenge the patent's validity in a court proceeding.⁴⁵⁵

Although it is now under close scrutiny in the wake of pharmaceutical product patenting in India, pre-grant opposition is not a new feature of India's patent laws. Pre-grant opposition was first introduced in the India Patents Act, 1911,⁴⁵⁶ and carried forward in the India Patents Act, 1970.⁴⁵⁷ India's inclusion of pre-grant opposition procedures is likely modeled on the English patent laws in force at those times, which then provided for pre-grant opposition.⁴⁵⁸ Nor were the British the only patent system to have relied on pre-grant opposition; a number of other countries historically used a system of novelty-only examination but coupled it with pre-grant opposition⁴⁵⁹ as a means of supplementing the resources of the patent examiner.⁴⁶⁰

Today, however, India remains one of only a handful of countries that still permit pre-grant opposition.⁴⁶¹ Among proponents of stronger patent

455. Nothing in The Patents Act, No. 39 of 1970, § 25 (Universal 2005) (amended 2005), mentions any estoppel or preclusive effect in subsequent litigation.

456. See India Patents Act, 1911, *supra* note 72, at § 9 (titled "Opposition to grant of patent").

457. See The Patents Act, No. 39 of 1970, § 25(1) (Universal 2005) (providing that "[a]t any time within four months from the date of advertisement of the acceptance of a complete specification under this Act . . . any person interested may give notice to the Controller of opposition to the grant of the patent on any of the following grounds").

458. For example, England provided for pre-grant opposition as early as its 1852 Patent Act. See Mark D. Janis, *Patent Abolitionism*, 17 BERKELEY TECH. L.J. 899, 903 & n.16 (2002). The U.K. Patents and Designs Act, 1907, included pre-grant opposition. See Patents and Designs Act, 1907, 7 & 8 Edw. 7, § 11 (UK) (titled "Opposition to grant of patent"), reprinted in NARAYANAN (PATENT LAW), *supra* note 50, at 825, 828-29 (Appendix 16). The U.K. Patents Act, 1949, also included pre-grant opposition. See Patents Act, 1949, 12, 13 & 14 Geo. 6, c. 87, § 14 (UK), available at http://www.wipo.int/clea/docs_new/pdf/en/gb/gb003en.pdf. Pre-grant opposition in which the opposer became a formal party to the Patent Office proceedings was abolished in the U.K.'s Patents Act 1977. See NARAYANAN (PATENT LAW), *supra* note 50, at 129 n.1 (¶ 7-01 n.1).

459. See JAN VOJACEK, A SURVEY OF THE PRINCIPAL NATIONAL PATENT SYSTEMS 28 (1936) (noting that examination for novelty coupled with pre-grant opposition was first introduced by Germany and was then [in 1936] utilized in Holland, Denmark, Sweden, Norway, Finland, Austria, Czechoslovakia, Russia, Great Britain, Australia, India, and Japan).

460. See *id.* at 29 (describing pre-grant opposition as "a complement of . . . the official examination as to novelty, differing from the latter in that the public is invited to cooperate").

461. Currently, the patent laws of at least Brazil and Jordan also permit pre-grant opposition. See Jordan Patent Law for the Year 1999, Art. 14 (providing that "[a]ny person shall be entitled to object on the registration of a patent to the Registrar, within a period not exceeding three months from the date of publication in the Official Gazette of the preliminary approval of the application"), available at http://www.wipo.int/clea/docs_new/pdf/en/jo/jo011en.pdf (last visited Jan. 26, 2006); Brazil Industrial Property Law § 158, Lei No. 9,279, de 14 de maio de 1996, D.O.U. de 14.05.1996. (Brazil), available at <http://www.wipo.int/clea/en/fiche.jsp?uid=br003> (providing that after being docketed, the application shall be published so that opposition may be presented within a period of 60 (sixty) days).

Most countries that once had pre-grant opposition have abolished it in favor of post-grant opposition.

protection, pre-grant opposition is perceived as a decided weakness of India's new regime. For example, the pro-patent reform Organization of Pharmaceutical Producers of India (OPPI) advocates that India should move away from pre-grant opposition, as have "other leading countries and progressive nations."⁴⁶² The OPPI views pre-grant opposition as unduly lengthening the pendency of patent applications.⁴⁶³ The Act mandates that the party filing the pre-grant opposition receive a hearing before the Controller if requested,⁴⁶⁴ which would presumably lengthen the time to grant even if patentability was affirmed over the opposer's arguments.

The Indian Patent Office, charged with implementing the new laws, denies that pre-grant opposition will delay patent grants.⁴⁶⁵ Patent Office officials say that grant will not be postponed even in cases where an appeal is taken from the Controller's decision in the opposition.⁴⁶⁶ The government

See Nancy J. Linck et al., *A New Patent Examination System for the New Millennium*, 35 HOUS. L. REV. 305, 323 (1998) (stating that most countries "have now abandoned such [pre-grant opposition] proceedings, either because of the delay they have caused or because they wanted to harmonize their laws"). For example, Japan repealed its pre-grant opposition system effective January 1, 1996. See *id.* at 323 n.81. Germany switched from a pre-grant to post-grant opposition system in 1981. See Jay P. Kesan, *Carrots and Sticks to Create a Better Patent System*, 17 BERKELEY TECH. L.J. 763, 781 (2002) (citing correspondence with Mr. Ulrich Joos, German Patent Office (1994)). The United Kingdom abolished pre-grant opposition in its Patents Act 1977. See NARAYANAN (PATENT LAW), *supra* note 50, at 129 n.1 (¶ 7-01 n.1). A third party could nevertheless make observations concerning patentability of published patent applications under the U.K. Patents Act 1977 and have such observations considered by the Controller, but the third party did not become a party to any proceedings under the Act. See *id.*

The U.S. does not currently allow pre-grant opposition, although members of the public can submit copies of patents or publications to the USPTO which are relevant to published pending patent applications. See 37 C.F.R. § 1.99(a) (2006). Nothing in Rule 99 mandates that a USPTO examiner consider or act upon such submissions, however. See *id.* § 1.99.

462. Manojit Saha, *Drug patent: A Viagra for Indian Pharmaceutical Industry*, DECCAN HERALD (Bangalore, India), Apr. 4, 2005, available at <http://www.deccanherald.com/deccanherald/apr42005/93626200543.asp> (describing three areas where the OPPI believes that India is lagging behind in implementing "[w]orld [c]lass" intellectual property protection).

463. See *id.*

464. The Patents Act, No. 39 of 1970, § 25(1) (Universal 2005) (amended 2005) (providing that "the Controller shall, if requested by such person for being heard, hear him and dispose of such representation in such manner and within such period as may be prescribed").

Other commentators have also objected to pre-grant opposition as denying the patent applicant her due process. See Pillai, *supra* note 398 (noting that there is "no provision in the Bill enabling the Applicant to counter the pre-grant opposition," making it "a one-sided affair").

465. Interview with P.K. Patni, *supra* note 416.

466. In an interview with the author, the head of the New Delhi branch of India's Intellectual Property Office stated that an appeal from the Patent Office's decision in a pre-grant opposition to the applicable High Court would not delay the grant of a patent. Interview with K.S. Kardam, *supra* note 175. In accordance with the India Patents Rules, the Patent Office would continue with its process of granting the patent rather than putting that process "on hold" due to any pending appeal. *Id.* Mr. Kardam cited as his

views pre-grant opposition as a helpful way of getting prior art before the examiner.⁴⁶⁷ The same examiner that initially examined the application will receive and consider the pre-grant opponent's submission.⁴⁶⁸

Not surprisingly, Indian generic pharmaceutical manufacturers favored retention of pre-grant opposition in the new Patents Act.⁴⁶⁹ Early indications are that these firms will become frequent users of the procedure. For example, between January and November 2005, thirty pre-grant oppositions were filed with the Indian Patent Office's New Delhi branch alone.⁴⁷⁰ As of February 2006, "Indian drug companies including Cipla, Ranbaxy and Cadila ha[d] filed around 45 pre-grant oppositions in the form of representations with the Controller of Patents."⁴⁷¹ Many of these oppositions target recently published mailbox applications, including "Novartis' anti-asthma molecule, Pfizer's new controlled use of a known molecule and Schering's formulation for PEG Interferon Alpha conjugates."⁴⁷² Ranbaxy in September 2005 filed a pre-grant opposition against Eli Lilly's Indian patent application on the erectile dysfunction drug tadalafil (marketed as Cialis).⁴⁷³ Press reports in March

authority for this Rule 55(6), *id.*, which provides that:

After considering the representation and submission made during the hearing if so requested, the Controller shall proceed further simultaneously either rejecting the representation and granting the patent or accepting the representation and refusing the grant of patent on that application, ordinarily within one month from the completion of above proceedings.

The Patents Rules, 2003 (Universal 2005), *supra* note 184, at 100 (§ 55(6)). This language was added by the 2005 amendments to India's Patents Rules. *See* India Patents (Amendment) Rules § 23, Dec. 28, 2004, GAZETTE OF INDIA, Part II-§ 3(ii), 66 (substituting new Rules 55 to 57 for "rules 55 to 57 of the Principal [2003] Rules").

467. Interview with P.K. Patni, *supra* note 416.

468. *Id.*

469. *See Why Do We Need to Amend Patents Act?*, ECON. TIMES, Dec. 27, 2004, <http://economictimes.indiatimes.com/articleshow/971708.cms> (noting that "[t]he MNC lobby is pushing for a post-grant opposition, whereas the domestic lobby is asking for a pre-grant opposition").

470. Interview with K.S. Kardam, *supra* note 175. During the period of January through October, 2005, a total of 7,914 patent applications were filed in the New Delhi branch office (2,924 "ordinary" or directly-filed applications and 4,990 applications filed under the Patent Cooperation Treaty (PCT)). Interview with P.K. Patni, *supra* note 416. During the same January through October 2005 time period, a total of 4,106 requests for examination were filed. *Id.*

471. Mirandah, *supra* note 358, at 135.

472. *Id.*

473. E-mail from Donald L. Corneglio, *supra* note 196. Following publication of Eli Lilly's patent application summary, *see* 2005 OFF. J. PAT. OFFICE 2309 (Feb. 11, 2005), *available at* http://ipindia.nic.in/ipr/patent/journal_archieve/pat_arch_110205/official_journal_110205.pdf, Ranbaxy filed its pre-grant opposition on September 23, 2005. E-mail from Donald L. Corneglio, *supra* note 196. Lilly responded and requested a hearing. *Id.* The Indian Patent Office ordered Ranbaxy to file written arguments in December 2005. E-mail from Donald L. Corneglio, *supra* note 196. The matter was still pending as of April 2006. *Id.* *See also* P.T. Jyothi Datta, *Pharma Cos Fight Pitched Battle on Patent Turf*, HINDU BUS.

2006 estimated that over 100 pre-grant oppositions were then pending in the four Patent Office branches,⁴⁷⁴ including challenges filed by Indian generic firms against pending patent applications on Astra Zeneca's cholesterol drug Rosuvastatin, Pfizer's anti-fungal drug Voriconazole, Wockhardt's anti-bacterial drug Nadifloxacin, Gilead-Roche's bird-flu drug Oseltamivir, and Astra Aktiebolag's formulation of ulcer drug Omeprazole.⁴⁷⁵

Non-governmental organizations and healthcare advocacy groups are also using the pre-grant opposition proceeding as a new and potent weapon to challenge the grant of patents on essential medicines. On March 30, 2006, a pre-grant opposition was collectively filed by the Indian Network of People Living with HIV/AIDS, the Manipur Network of Positive People, and the Lawyers' Collective HIV/AIDS Unit in the Kolkata branch of the Indian Patent Office against the grant of a patent on Glaxo's combination therapy for HIV/AIDS.⁴⁷⁶ Sold under the brand name Combivir, the drug is a fixed-dose combination of two AIDS drugs, zidovudine and lamivudine (AZT/3TC).⁴⁷⁷ The AIDS groups' opposition is based on "technical and health grounds."⁴⁷⁸ On May 9, 2006, the Indian Patent Office heard arguments in a different pre-grant opposition filed by the Delhi Network of Positive People and the Indian Network for People Living with HIV/AIDS against the grant of a patent on Gilead Sciences' application claiming the HIV/AIDS therapy tenofovir, sold by Gilead under the brand name Viread.⁴⁷⁹

Although most of the newly-filed pre-grant oppositions are still pending, some have already succeeded in preventing the grant of Indian patents. For example, Indian cancer patients (along with generic drug manufacturers) filed a pre-grant opposition against the grant of a patent on Novartis' claimed beta-crystalline form of imatinib mesylate, the active ingredient in an anti-cancer drug sold by Swiss pharmaceutical manufacturer Novartis AG under the brand name Glivec (sometimes spelled Gleevec). According to press reports, the

LINE (Madras, India), Mar. 8, 2006, available at <http://www.blonnet.com/2006/03/08/stories/2006030801810300.htm> (reporting that Ranbaxy is opposing Eli Lilly's "erectile dysfunction drug Tadalafil").

474. See Datta, *supra* note 473 (reporting that "there are more than 40 pre-grant oppositions in Delhi, over 20 in Chennai, an excess of 15 in Mumbai, and a similar number in Kolkata").

475. See *id.*

476. Greg Aharonian, *AIDS Patent Application is Opposed in India*, INTERNET PATENT NEWS SERVICE, Mar. 30, 2006 (on file with author).

477. See *id.*

478. *Id.*

479. See Amelia Gentleman & Hari Kumar, *AIDS Groups in India Sue to Halt Patent for U.S. Drug*, N.Y. TIMES, May 12, 2006, at A4.

opposition asserted that Glivec was “a new form of an old drug,”⁴⁸⁰ presumably under Section 3(d) of the India Patents Act, 1970 (2005). The Indian Patent Office agreed, refusing on January 25, 2006 to allow the Glivec application.⁴⁸¹

Although information on pre-grant oppositions is being made public by the opposers and the press, accurate information on the volume of pre-grant opposition filings is not yet available from the Indian government. The Patent Office does not currently make public any information about the filing of pre-grant oppositions, for example, through publication of notices of such filings in the *Official Journal*.⁴⁸² The Controller’s only obligation when a party represents by way of opposition against the grant of patent, if that party has requested that it be heard, is to “hear him and dispose of such representation in such manner and within such period as may be prescribed.”⁴⁸³ The corresponding Patent Rules are silent in terms of any obligation of the Controller to give the public notice of the filing of pre-grant oppositions.⁴⁸⁴ In cases where the Controller does not deem the pre-grant opposition of sufficient merit to justify either refusal of a patent or amendment of the specification, the rules do not even require the Controller to inform the *patent applicant* of the existence of the pre-grant opposition.⁴⁸⁵

480. *See id.* The Novartis AG patent application titled “Crystal Modification of a N-Phenyl-2-Pyrimidineamine Derivative . . .,” the active ingredient in Glivec, is No. 1602/MAS/1998A, filed July 17, 1998. *See* 2005 OFF. J. PAT. OFFICE 24057 (Oct. 28, 2005), available at http://ipindia.nic.in/ipr/patent/journal_archive/pat_arch_102005/official_journal_28102005.pdf.

481. *See Notice for Termination of Exclusive Marketing Right EMR/1/2002*, 2006 OFF. J. PAT. OFFICE 9 (Feb. 17, 2006), available at http://patentoffice.nic.in/ipr/patent/journal_archive/journal_2006/pat_arch_022006/official_journal_17022006.pdf (confirming that “the Patent application 1602/Mas/98 has been refused by the Controller on 25.01.2006 as a result of pre-grant opposition”). The Controller’s refusal of Novartis’ patent application also had the effect of extinguishing its EMR, *see id.*, which had been the subject of ongoing litigation in the High Courts. *See infra* Part V.B.3.

482. *See* E-mail from Dr. Gopakumar G. Nair, Gopakumar Nair Associates, Mumbai, India, to Professor Janice Mueller, University of Pittsburgh School of Law (Feb. 10, 2006) (on file with author) (“Pre-grant oppositions form part of prosecution history. These are not published, unless a ‘spoken order’ granting or rejecting the application is made available to the opposition.”); E-mail from Manoj Pillai, Partner, Lex Orbis Intellectual Property Practice, New Delhi, India, to Professor Janice Mueller, University of Pittsburgh School of Law (Apr. 1, 2006) (on file with author) (confirming that Indian Patent Office does not publish notices of filings of pre-grant oppositions).

483. The Patents Act, No. 39 of 1970, § 25(1) (Universal 2005) (amended 2005).

484. *See* The Patents Rules, 2003 (Universal 2005), *supra* note 184, § 55 (titled “Opposition by representation against the grant of patent”).

485. *See id.* § 55(3) (providing that “[o]n consideration of the representation if the Controller is of the opinion that application for patent shall be refused or the complete specification requires amendment, he shall give a notice to the applicant to that effect”).

2. *Post-Grant Opposition*

Unlike pre-grant opposition, post-grant opposition is an entirely new feature of the India Patents Act, 1970 (2005), added by the Patents (Amendment) Act, 2005.⁴⁸⁶ Notice of post-grant opposition must be filed in the one-year window following patent grant.⁴⁸⁷ Post-grant oppositions can be filed only by “person[s] interested,”⁴⁸⁸ which the statute elsewhere defines non-exclusively as “includ[ing] a person engaged in, or in promoting, research in the same field as that to which the invention relates.”⁴⁸⁹ The grounds for post-grant opposition are essentially identical to those on which pre-grant opposition may be based, including virtually all patentability criteria.⁴⁹⁰ Post-grant oppositions will be heard by a three-person Opposition Board that does not include the original patent examiner.⁴⁹¹ After receiving the Board’s

486. See The Patents (Amendment) Act, No. 15 of 2005, § 23 (Universal 2005) (substituting into the principal Act a new § 25, titled “Opposition to the patent,” which provides for post-grant opposition in new § 25(2), for previous (2002) version of § 25, titled “Opposition to grant of patent”). Prior to the 2005 amendments, India’s patent laws provided for only pre-grant opposition. See The Patents Act, No. 39 of 1970 (as amended by The Patents (Amendment) Act, 1999 and The Patents (Amendment) Act, 2002, § 25 (Universal 2005).

487. See The Patents Act, No. 39 of 1970, § 25(2) (Universal 2005) (amended 2005) (“At any time after the grant of patent but before the expiry of a period of one year from the date of publication of grant of a patent, any person interested may give notice of opposition to the Controller in the prescribed manner on any of the following grounds . . .”). In contrast, an opposition against a European patent must be filed within nine months from the publication of the mention of its grant. See European Patent Convention, *supra* note 354, art. 99(1).

488. The Patents Act, No. 39 of 1970, § 25(2) (Universal 2005) (amended 2005).

489. *Id.* § 2(1)(i). This definition is “not exhaustive and would appear to be capable of a liberal interpretation.” NARAYANAN (PATENT LAW), *supra* note 50, at 181, ¶8-12. The standing requirement was first introduced in The Patents Act, 1970, mirroring the introduction of a “person interested” standing requirement for the filing of oppositions in the U.K. Patents Act of 1949. See *id.* British courts recognized that “a member of the public having no interest was not entitled to oppose the grant of a patent; as otherwise, the system might be used so as to cause a vast amount of annoyance and expense of a most objectionable character to patentees.” *Id.*

490. See The Patents Act, No. 39 of 1970, § 25(2)(a)-(k) (Universal 2005) (amended 2005) (setting forth various grounds for post-grant opposition which mirror those set forth for pre-grant opposition at § 25(1)(a)-(k)). See also *Patent Opposition Post 2005*—, LEXORBIT INTEL. PROP. PRAC. NEWSL., Fall 2005, at 3-4 (noting “negligible difference between the pre-grant and post-grant opposition”).

491. See The Patents Act, No. 39 of 1970, § 25(3)(b) (Universal 2005) (amended 2005) (providing that “[o]n receipt of such notice of opposition, the Controller shall, by order in writing, constitute a Board to be known as the Opposition Board consisting of such officers as he may determine and refer such notice of opposition along with the documents to that Board for examination and submission of its recommendations to the Controller”). See also The Patents Rules, 2003 (Universal 2005), *supra* note 184, § 56(1) (providing that on receipt of notice of opposition, the “Controller shall, by order, constitute an Opposition Board consisting of three members and nominate one of the members as the Chairman of the Board”); *id.* § 56(3) (“The examiner, who has dealt with the application for patent during the proceeding

recommendation and giving “the patentee and the opponent an opportunity of being heard,”⁴⁹² the Controller “shall order either to maintain or to amend or to revoke the patent.”⁴⁹³

Post-grant opposition is a very important aspect of European patent practice (although not yet part of U.S. patent law). Approximately six percent of patents granted under the European Patent Convention are the subject of post-grant oppositions.⁴⁹⁴ It remains to be seen whether India’s new post-grant opposition procedure will be used more or less frequently, although presumably an increasing number of oppositions will be filed as the first pharmaceutical product patents begin to issue. The number of post-grant oppositions filed against patents on any type of invention during the first eighteen months of India’s new patents regime (January 2005 through June 2006) is unknown. Nothing in the Patents Act or Rules requires the Controller to publish in the *Official Journal* the fact that a post-grant opposition has been initiated or to publish his decision and the reasons therefor; he need only share these with the parties.⁴⁹⁵

for grant of patent thereon shall not be eligible as member of [the] Opposition Board . . .”).

Exclusion of the original examiner from the post-grant Opposition Board has benefits as well as costs. See *Patent Opposition Post 2005*—, *supra* note 490, at 3-4 (stating that “[o]n one hand, this provision precludes the apprehension of bias from the mind of the opponent, on the other hand the examiner who has initially examined the application, and therefore understands the case and can provide better advice, is no more a part of the opposition proceedings”).

492. The Patents Act, No. 39 of 1970, § 25(4) (Universal 2005) (amended 2005).

493. *Id.*

494. See European Patent Office, *The EPO in Figures*, at Table 7.6, available at http://annual-report.european-patent-office.org/2004/statistics/_pdf/tab_7_6_split.pdf (reporting that during 1978 to 2004, a total of 707,456 patents were granted by the EPO and 44,885 patents were opposed, for a ratio of 6.3 %, and during 2004 alone, a total of 58,730 patents were granted by the EPO and 3,110 were opposed, for a ratio of 5.3 %). See also Gerald J. Mossinghoff & Vivian S. Kuo, *Post-Grant Review of Patents: Enhancing the Quality of the Fuel of Interest*, 43 IDEA 83, 99 (2002) (reporting 6.5 and 7.2 percent rates of opposition for European patents granted in 1999 and 2000, respectively).

495. After hearing the parties and considering the recommendation of the Opposition Board, the Controller must “notify his decision to the parties giving reasons therefore.” The Patents Rules, 2003 (Universal 2005), *supra* note 184, § 62(5).

In contrast, the complete contents of files of European patents and applications, including decisions in any opposition proceedings, are made available to the public at the EPO’s *Online Public File Inspection* facility. <http://ofi.epoline.org/view/GetDossier> (last visited July 25, 2006). “The European Patent Office’s Online Public File Inspection service implements Article 128 of the European Patent Convention, according to which the public is entitled to inspect the complete contents of the files relating to all European patent applications after they have been published.” *Id.* For example, a search of the EPO records for European Patent No. 0169672, the Harvard “oncomouse” patent, provides access to an image file of the January 16, 2003 decision of the Opposition Division maintaining the patent (titled “Interlocutory decision in opposition proceedings (Article 106(3) EPC”).

E. Prior User Rights Vis a Vis Patents from Mailbox Applications

One of the most controversial features of India's new patent law is a prohibition on lawsuits for infringement of patents that issue from the mailbox applications that were filed during the TRIPS transition period. Regardless of whether a mailbox applicant also sought and received an EMR,⁴⁹⁶ the rights conveyed by a patent issuing from a mailbox application are now subject to significant curtailment. Section 11A(7) of the Patents Act, 1970 (2005) makes the prohibition on infringement lawsuits specific to patents that issue after January 1, 2005 from mailbox applications, where a competing firm was already making and selling (presumably in India) the patented product prior to January 1, 2005.⁴⁹⁷ Owners of the effected patents will be entitled to recover only a "reasonable royalty" for ongoing infringement; injunctive relief is precluded, as is even the filing of an infringement lawsuit.⁴⁹⁸ The pertinent statutory language reads:

On and from the date of publication of the application for patent and until the date of grant of a patent in respect of such application, the applicant shall have the like privileges and rights as if a patent for the invention had been granted on the date of publication of the application:

Provided that the applicant shall not be entitled to institute any proceedings for infringement until the patent has been granted:

Provided further that the rights of a patentee in respect of [mailbox] applications made under sub-section (2) of section 5 before the 1st day of January, 2005 shall accrue from the date of grant of the patent:

*Provided also that after a patent is granted in respect of [mailbox] applications made under sub-section (2) of section 5, the patent-holder shall only be entitled to receive reasonable royalty from such enterprises which have made significant investment and were producing and marketing the concerned product prior to the 1st day of January, 2005 and which continue to manufacture the product covered by the patent on the date of grant of the patent and no infringement proceedings shall be instituted against such enterprises.*⁴⁹⁹

496. See *supra* Part II.C.2 for further discussion of exclusive marketing rights (EMRs).

497. See The Patents Act, No. 39 of 1970, § 11A(7) (Universal 2005) (amended 2005). Although the statute does not state a geographic limitation, presumably the prior user defense of § 11A(7) is limited to those enterprises who manufactured the patented drug *in India* prior to January 1, 2005 and continue to do so after January 1, 2005.

498. See *id.*

499. *Id.* (emphasis added). The quoted language was inserted into the statute by The Patents (Amendment) Act, No. 15 of 2005, § 10(c) (Universal 2005) (effective Jan. 1, 2005).

In effect, this provision combines features of both the prior user rights defense⁵⁰⁰ and compulsory licensing. The prior use of the patented invention by the competing firm is privileged and allowed to continue after the mailbox patent issues, but the patent owner will be entitled to receive a reasonable royalty for ongoing use. The distinction, however, is that a prior user right is generally implemented as a complete defense to infringement, negating the recovery of any damages by the patentee as against that prior user.

The more accurate comparison, then, is to compulsory licensing. The new remedies limitation of Section 11A(7) effectively confers on the third parties who marketed the patented drug prior to January 1, 2005 a “license of right.” Earlier versions of India’s patent laws expressly included licenses of right for patents claiming drug manufacturing processes,⁵⁰¹ but these provisions were deleted from the statute by the Patents (Amendment) Act, 2002.⁵⁰² The Section 11A(7) remedies limitation effectively returns the license of right concept to India’s patent law for mailbox patents. The distinction, however, is that it is now the patentee who appears to bear the burden of seeking its reasonable royalty recovery, while the competitor need not have obtained any governmental (or patentee) approval in advance of undertaking its manufacturing of the now-patented drug.

No other provision of India’s new patents regime more clearly displays the tensions between MNC patent holders and Indian generic pharmaceutical manufacturers. From the MNC perspective, the Section 11A(7) remedies abrogation for mailbox patents raises serious questions of TRIPS compliance and may have the potential to catalyze the filing of another dispute proceeding against India in the WTO. On the other hand, the indigenous concerns see this provision as critical to the protection of their industry and a legitimate

500. Professor Abbott has referred to the § 11A(7) remedies limitation as “a form of ‘prior user right’ adapted to India’s unique situation.” Frederick M. Abbott, *Beginning of a New Policy Chapter*, FIN. EXPRESS, Apr. 6, 2006, available at http://www.financialexpress.com/print.php?content_id=87112.

501. See The Patents Act, 1970, § 87 (titled “Certain patents deemed to be endorsed with the words ‘Licenses of right’”), reprinted in NARAYANAN (PATENT LAW), *supra* note 50, at 543, 574. For an example of a reported case on license of right, see NARAYANAN (PATENT LAW), *supra* note 50, at 27 (discussing Imperial Chem. Indus. Ltd. v. Controller General of Patents, A.I.R. 1978 (Calcutta) 77, a decision of Calcutta High Court affirming Controller of Patents’ order deeming Imperial’s patent, claiming a catalyst useful in hydrocarbon reforming as well as a process for making the catalyst, to be subject to licensing of right).

502. See The Patents (Amendment) Act, No. 38 of 2002, § 39, available at <http://indiacode.nic.in> (substituting new Chapter XVI (containing sections 82 to 94) for then-existing Chapter XVI (containing sections 82 to 98)).

interpretation and exploitation of the flexibilities provided to India by the TRIPS Agreement's transition period arrangements.⁵⁰³

Whether the Section 11A(7) remedies limitation for mailbox patents complies with TRIPS is an open question.⁵⁰⁴ The limitation on patent owner remedies has been said to "take[] away the very sanctity of Mail Box and transitional protection as envisaged in the TRIPS Agreement . . . and definitely makes the [provision] TRIPS non-compliant."⁵⁰⁵ The Organization of Pharmaceutical Producers of India (OPPI) charges that the new statutory framework "treats patent holders in respect of mail box applications on a discriminatory footing in so far as them being denied the rights and privileges from the date of publication retrospectively."⁵⁰⁶ The Office of the U.S. Trade Representative's 2005 *Special 301 Report* singled out the remedies limitation as problematic, indicated that the Office questions its TRIPS compliance, and warned that it will be closely monitoring India's implementation thereof.⁵⁰⁷

503. See CHAUDHURI, *supra* note 78, at 69 (stating that because "the Bill of 2003 [i.e., the Patents (Amendment) Bill, 2003, which was introduced into Parliament in December 2003 but later lapsed] was silent on this issue, apprehensions were expressed that if and when the MNCs get patents on these [mailbox] applications, the generic companies may not only have to suspend operations (as in the case of Gleevec [an anti-cancer drug for which Novartis obtained and successfully enforced an EMR]) but also may be hauled up for patent infringement"). Chaudhuri further explains that the new § 11A(7) of The Patents Act, 1970 (2005), means that for patents issuing from mailbox applications, "patent rights will accrue only from the date of grant of patent and [] patent infringement cases cannot be filed before the grant of [the] patent." *Id.* "Thus Indian generic companies were not required to immediately suspend production and would not face any penalty for their past manufacturing and marketing activities." *Id.* at 69-70. Under the 2005 Act, the generic firms "need not suspend production . . . [and] can continue to produce on payment of 'reasonable royalty' to patent holders . . ." *Id.* at 70.

504. Not all commentators appear to agree. See Ragavan, *supra* note 87, at 291 (stating that "[c]urrently, the Indian patent legislation is fully compliant with TRIPS").

505. See Pillai, *supra* note 398, at 3.

506. See <http://www.indiaoppi.com/pharminindia.htm> (follow "Intellectual Property Rights" hyperlink) (last visited Jan. 21, 2006).

507. The USTR's report states in pertinent part:

India took a significant positive step toward strengthening patent protection when it promulgated a temporary Patent Amendment Ordinance at the end of 2004 and then passed permanent legislation in early 2005. However, the U.S. pharmaceutical industry reports shortcomings in this patent legislation that we hope India will correct. Most notably, the new law does not permit holders of patents that will issue from "mailbox" applications to enforce their rights with respect to generic copies that continue to be marketed on the date that the patent is granted. The extent to which India's new patent legislation satisfies India's TRIPS commitments is still under review and will depend, in part, on its implementation. Thus, we will monitor closely India's implementation of the patent amendment.

United States Trade Representative, *Special Report (2005)*, available at http://www.ustr.gov/assets/Document_Library/Reports_Publications/2005/2005_Special_301/asset_upload_file195_7636.pdf.

This controversial remedies limitation had not yet been tested. As of August 2006, only a single pharmaceutical product patent had been granted in India, on a new-generation Hepatitis C treatment marketed by Hoffman-La Roche as Pegasys.⁵⁰⁸ According to Roche, no generic versions of Pegasys were being manufactured by third parties in India prior to the grant of Roche's Indian patent.⁵⁰⁹ Thus, the Section 11A(7) compulsory license/prior user right is not available to Indian generics who wish to manufacture generic versions of Pegasys, currently sold by Roche in India at a price of about \$10,000 per patient per year.⁵¹⁰

The TRIPS Agreement requires that "patent rights [shall be] enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced."⁵¹¹ India's remedies limitation for mailbox patents can be seen as discriminatory based on "the field of technology;" i.e., the field of pharmaceutical products. TRIPS also mandates that "where the subject matter of a patent is a product," the patent owner shall have the exclusive rights "to prevent third parties not having the

508. The first pharmaceutical product patent to issue under India's new patents regime was reportedly granted on March 2, 2006 to Roche India Pvt. Ltd., the Indian subsidiary of Swiss pharmaceutical giant Hoffman-La Roche. See Datta, *Roche Gets Product Patent*, *supra* note 9. Official notice of the grant was not published until May 2006, however. See 2006 OFF. J. PAT. OFFICE 10000 (May 19, 2006), available at http://patentoffice.nic.in/ipr/patent/journal_archieve/journal_2006/pat_arch_052006/official_journal_19052006.pdf (notice of grant of Indian Pat. No. 198,952, titled "A Physiologically Active Branched PEG-IFN α Conjugate," on Application No. 1032/MAS/1997, assigned to Hoffman-La Roche). See 2005 OFFICIAL J. PAT. OFFICE 24056 (Oct. 28, 2005), available at http://ipindia.nic.in/ipr/patent/journal_archieve/pat_arch_102005/official_journal_28102005.pdf, for a summary of Application No. 1032/MAS/1997A.

509. *Id.*

510. See *supra* note 306. Despite the apparent non-availability of a Section 11A(7) license, generic drug manufacturers may seek compulsory licenses to make and sell Pegasys under other provisions of India's Patents Act as discussed *infra*. For example, a compulsory license application might be filed under Section 84 of the Patents Act based on an allegation of unreasonable pricing, but such applications are not permitted until three years after patent grant. See *supra* Section IV.F.1. On the other hand, compulsory licenses would be available immediately if the Indian government declared by notification in the Patent Office's *Official Gazette* that it is necessary to make compulsory licenses available under the Roche patent in "circumstances of national emergency or . . . extreme urgency or in case of public non-commercial use." The Patents Act, No. 39 of 1970, § 92(1) (Universal 2005) (amended 2005). See also *supra* Section IV.F.2. The potential market is considerable. Approximately 11 million Indian citizens are estimated to suffer from chronic Hepatitis C. See P.T. Jyothi Datta, *Gilead Sciences-Roche Spat—Uneasy Calm Prevails Over Bird Flu Drug*, HINDU BUS. LINE, Oct. 26, 2005, available at <http://www.hinduonnet.com/thehindu/thscrip/print.pl?file=2005102702930500.htm&date=2005/10/27/&pr=bl&> [hereinafter Datta, *Gilead Science*]. This is more than twice as many as the estimated number suffering from HIV/AIDS. See Lawrence K. Altman, *New H.I.V. Cases Reported to Drop in Southern India*, N.Y. TIMES, Mar. 31, 2006, at A5 (reporting that an estimated 5.1 million Indians are now living with HIV).

511. TRIPS, *supra* note 3, Art. 27.1.

owner's consent from the acts of: making, using, offering for sale, selling, or importing[] for these purposes that product. . . ."⁵¹² India's remedies limitation for mailbox patents severely restricts these exclusive rights by limiting the patentee to reasonable royalties.

The mechanics of seeking the limited relief under the new remedies limitation on mailbox patents are also quite murky. In the absence of a patent infringement lawsuit, the statute does not specify how owners of patents issuing from mailbox applications are to establish their claim for reasonable royalties, let alone how the amount of such royalties will be determined. Presumably the determination of whether such patentees are eligible for royalties and in what amount will be made in the first instance by the Indian Patent Office in response to a claim for royalties made by the patentee. Because the Patent Office is already responsible for receiving and acting on compulsory license applications, it would not be surprising if the agency created a similar administrative procedure for mailbox patent owners seeking royalties from the generic firms that manufactured the patented invention prior to January 1, 2005. In this regard, the Patent Office may develop much-needed expertise in determining what royalty rates are "reasonable."⁵¹³

On the other hand, a patentee who questioned whether a generic firm was in fact making the patented drug in India prior to January 1, 2005, might attempt to go directly to the Indian courts by filing a lawsuit for infringement. The burden would then be placed on the generic firm to respond by showing that the remedies limitation should apply to shield it from any remedy beyond the payment of royalties. Presumably the court hearing the infringement action, if it agreed with the generic firm, would determine what royalty rate was reasonable under the circumstances of the case.

The new remedies limitation on mailbox patents raises a host of other interpretive questions that will likely await resolution by the Patent Office and/or the courts. For example, the mailbox patentee is limited to a reasonable royalty from manufacturing third parties who have made "significant investment."⁵¹⁴ One might argue that the patentee retains the right to sue and enjoin (rather than merely recover royalties from) lower-volume

512. *Id.* at Art. 28.1(a).

513. James Love, *Options to Traditional Patents*, FIN. EXPRESS, Apr. 6, 2005, available at http://www.financialexpress.com/print.php?content_id=87107 ("Soon a large number of compulsory licenses will be issued for products now manufactured in India, which are subject to the mailbox patents. This will increase the familiarity with compulsory licensing and provide needed expertise in setting reasonable remuneration to patent owners.").

514. The Patents Act, No. 39 of 1970, § 11A(7) (Universal 2005) (amended 2005).

producers, but in such cases the cost of a lawsuit may outweigh any potential recovery. The statute also speaks of royalty payments on the part of third parties that were “producing and marketing” the “concerned product” prior to January 1, 2005. Would a firm that imports the drug from abroad, rather than manufactures it in India, be subject to payment of reasonable royalties? As noted above, the statute is not even clear as to whether such “producing and marketing” must have occurred in India.⁵¹⁵ The statute also speaks of the “product covered by the patent,” which raises the question of whether the third party’s product must fall within the literal scope of the patent’s claims, or rather could be an equivalent outside the literal scope but still within the scope of the subject matter enabled by the patent’s specification.

F. Compulsory Licensing

This section describes the compulsory licensing provisions of India’s Patents Act, 1970 (2005), which are potentially applicable to all patents, not merely those issuing from mailbox applications as described in the preceding section. India’s compulsory licensing provisions are undoubtedly the broadest and most comprehensive of all the world’s patent systems,⁵¹⁶ and so they justify explanation in some detail. As codified in India’s patent law and described in further detail below, the grounds upon which compulsory licenses may be granted go “much beyond national emergency and extreme[ly] urgent situations, public health cris[is] and anti-trust situations.”⁵¹⁷ They include the failure to work the invention in India⁵¹⁸ and even the non-availability of the patented invention at a “reasonably affordable price.”⁵¹⁹ These same grounds can even form the basis for the ultimate sanction against a patent holder, in the form of government revocation of its patent.⁵²⁰

515. *See id.*

516. Interview with attorney Krishna Sarma, *supra* note 126.

517. Saha, *supra* note 462.

518. The Patents Act, No. 39 of 1970, § 84(1)(c) (Universal 2005) (amended 2005).

519. *Id.* § 84(1)(b).

520. The Patents Act, No. 39 of 1970, § 85 (Universal 2005) (amended 2005) (titled “Revocation of patents by the Controller for non-working”). Section 85 provides that, beginning two years after a compulsory license has been granted under a patent, the Central Government or any “person interested” may apply to the Controller for an order revoking the patent. The grounds on which revocation may be granted under Section 85 are the same as those on which a compulsory license under Section 84 may be granted: “the patented invention has not been worked in the territory of India or that reasonable requirements of the public with respect to the patented invention has not been satisfied or that the patented invention is not available to the public at a reasonably affordable price.” The Patents Act, No. 39 of 1970, § 85(1) (Universal 2005) (amended 2005). An application for revocation “shall ordinarily be decided within one

The expansive scope of India's compulsory licensing provisions is certainly consistent with the Patents Act's broadly stated "[g]eneral principles applicable to working of patented inventions":

- (a) that patents are granted to encourage inventions and to secure that the inventions are worked in India on a commercial scale and to the fullest extent that is reasonably practicable without undue delay;
- (b) that [patents] are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article;
- ...
- (g) that patents are granted to make the benefit of the patented invention available at reasonably affordable prices to the public.⁵²¹

Like pre-grant opposition, these guiding principles are not new ideas for India; identical provisions were included in the Patents Act, 1970⁵²² and reflect the Ayyangar Report's focus on shedding the vestiges of colonialism through encouragement of a domestic pharmaceutical manufacturing industry.

Despite what would appear to be the easy availability of compulsory licenses, India has rarely granted them. According to Indian Patent Office officials and Indian patent attorneys, fewer than half a dozen compulsory licenses have been granted in the history of India's patent system.⁵²³ Academic commentary confirms this low number, but does not indicate when the licenses were granted, under what patents, to whom, and on what grounds.⁵²⁴ Reported decisions of the Indian Patent Office or the High Courts

year of its being presented to the Controller." *Id.* § 85(4).

It is unclear whether the Indian government has granted revocation of patents under Section 85 with any frequency. For example, one article states that India's revocation provisions "have been applied ten to fifteen times in the past two decades," but cites no documentary evidence thereof. *See* Martin J. Adelman & Sonia Baldia, *Prospects and Limits of the Patent Provision in the TRIPS Agreement: The Case of India*, 29 VAND. J. TRANSNAT'L L. 507, 524 (1996).

521. The Patents Act, No. 39 of 1970, § 83 (Universal 2005) (amended 2005).

522. The Patents Act, 1970 included principles (a) and (b) verbatim. *See* The Patents Act, No. 39 of 1970, § 83(a)-(b), available at <http://indiacode.nic.in>.

523. According to one Indian Patent Office official, only three (or possibly five) compulsory licenses have been granted "in the history of the Indian Patent Office." Interview with P.K. Patni, *supra* note 416. An experienced Indian patent agent confirmed that compulsory licenses have been granted on only five occasions thus far. Interview with L. Balasubrahmanyam, Head of Intellectual Property Practice and Authorised Patent Agent, Corporate Law Group, in New Delhi, India (Nov. 14, 2005) (transcript on file with author).

524. *See* CHAUDHURI, *supra* note 78, at 93 (noting that although the Patents and Designs Act of 1911 had "elaborate" provisions for compulsory licensing, "during the British rule not a single compulsory license was granted" (citing a 1947 report of government-appointed Panel on Fine Chemicals, Drugs and Pharmaceuticals, at 15) and further noting that "till 1972, that is, when the 1970 Act came into force, only five applications were made for compulsory licences. It was granted in only two cases and refused in one

concerning compulsory licenses are scant.⁵²⁵ The low numbers of compulsory licenses granted in the past are not surprising in view of India's earlier refusal to grant patents on pharmaceutical products under the Patents Act, 1970. "[A] compulsory license was redundant in the previous [pre-2005] regime [because] [b]eing free to produce the patented drugs, the indigenous firms could develop their own processes and they [] did so. . . ."⁵²⁶ Compulsory licenses were probably not needed in the case of pharmaceutical process patents, either, because under the pre-TRIPS regime such patents lasted only five to seven years⁵²⁷ (and compulsory licenses in most cases could not even be applied for until three years after grant⁵²⁸).

Nevertheless, the fact that India has rarely granted compulsory licenses in the past does not guarantee the same infrequency in the future. Anecdotal evidence suggests that the Indian generic pharmaceutical firms will take

case. The applications were ultimately withdrawn in the remaining two cases" (citing Sudip Chaudhuri, *Indigenous Firms in Relation to the Transnational Corporations in the Drug Industry in India* (1984) (unpublished thesis, New Delhi: Jawaharlal Nehru University)); Santanu Mukherjee, *The Journey of Indian Patent Law Towards TRIPS Compliance*, 35 IIC: INT'L REV. INTELL. PROP. & COMPETITION L. 125, 146 (2004) ("It cannot be ignored that the compulsory licensing provision was hardly used earlier under the old patent law, even when there were softer provisions on compulsory licensing."); Bagchi, *supra* note 52, at 299 (compiling data in Table 5 showing that during eight-year period of fiscal years 1972-73 to 1979-80, a total of eight applications for compulsory license were filed under Section 84 of The Patents Act, 1970, and only one or two of these applications appears to have been granted).

525. Two leading treatises on Indian patent law cite virtually no Indian court cases on compulsory patent licensing. See NARAYANAN (PATENT LAW), *supra* note 50, at 259-84 (Chapter 14, titled "Compulsory Licenses, Licenses of Right and Revocation for Non-working") (citing U.K. case law entirely except for two Indian cases); VERKEY, *supra* note 63, at 319-38 (Chapter 10, titled "Compulsory Licensing") (citing no Indian cases). The only Indian cases cited by Narayanan in his chapter on compulsory licensing are *Imperial Chem. Indus. v. Controller General of Patents, Designs and Trademarks*, A.I.R. 1978 (Calcutta) 77 (High Court decision affirming Controller of Patents' order granting a "license of right" under The Patents Act, No. 39 of 1970, § 88 [now repealed]); and *Catalysts & Chems. India (West Asia) Ltd. v. Imperial Chem. Indus. Ltd.* (1976) IPLR 84 (concerning application for interim working of invention covered by patent endorsed for "licenses of right" under The Patents Act, No. 39 of 1970, § 88 [now repealed], available at <http://indiacode.nic.in>). See NARAYANAN (PATENT LAW), *supra* note 50, at 277 n.2, 282 n.1 (citing *Imperial Chem.* and *Catalysts* respectively).

526. CHAUDHURI, *supra* note 78, at 89.

527. See The Patents Act, No. 39 of 1970, § 53(a) (Universal 2005) (providing that "in 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."). The "date of sealing" in this provision was basically the date of grant, while the "date of the patent" was apparently the date on which the complete specification had been filed. See The Patents Act, No. 39 of 1970, § 45(1) (Universal 2005).

528. See The Patents Act, No. 39 of 1970, § 84(1) (Universal 2005) (providing that compulsory license applications could be filed "[a]t any time after the expiration of three years from the date of the sealing of the patent").

maximum advantage of opportunities to obtain compulsory licenses under the pharmaceutical product patents that issue from January 1, 2005 onwards. The ambiguity of the compulsory licensing provisions and the broad discretion they confer on the Controller is a source of much discomfort to MNC patent holders.⁵²⁹ The Patent Appellate Board,⁵³⁰ which will have jurisdiction to review the Patent Office's decisions on compulsory license grants and terms,⁵³¹ is likewise inexperienced in this area.⁵³²

The first test of compulsory licensing under India's new pharmaceutical product patents regime may soon arise and force the government to confront some of these uncertainties. Even before avian (bird) flu reached India in February 2006,⁵³³ the Indian government had announced plans to stockpile drugs used to treat the disease.⁵³⁴ As of November 2005, the Swiss pharmaceutical giant Hoffman-La Roche had acquired a mailbox application pending in the Indian Patent Office claiming the chemical compound

529. See Interview with A.S. Krishna, *supra* note 218.

530. See The Patents Act, No. 39 of 1970, § 116 (Universal 2005) (amended 2005) (titled "Appellate Board"). As of January 2006, the Patent Appellate Board was not yet in operation. E-mail from Manoj Pillai, Partner, Lex Orbis Intellectual Property Practice, New Delhi, India, to Professor Janice Mueller, University of Pittsburgh School of Law (Jan. 28, 2006) (on file with author) [hereinafter E-mail from Manoj Pillai (Jan. 28, 2006)]. For further discussion of the Patent Appellate Board, see *infra* Part V.A.5.

531. See The Patents Act, No. 39 of 1970, § 117A(2) (Universal 2005) (amended 2005) (providing that an "appeal shall lie to the Appellate Board from any decision, order or direction of the Controller . . . under . . . sub-sections (1) to (5) of section 84.").

532. The jurisdiction of the Patent Appellate Board to review the Controller's decisions granting compulsory licenses and setting their terms may raise a question of TRIPS compliance. The compulsory licensing provisions of TRIPS mandate that "the legal validity of any decision relating to the authorization of [a compulsory license] shall be subject to judicial review or other independent review by a distinct higher authority in that Member," TRIPS, *supra* note 3, Art. 31(i), and that "any decision relating to the remuneration provided in respect of [a compulsory license] shall be subject to judicial review or other independent review by a distinct higher authority in that Member." TRIPS, *supra* note 3, Art. 31(j). Once operational, will the Patent Appellate Board's review of the Controller's decisions on compulsory licenses constitute "independent review by a distinct higher authority" in India? As further discussed in Part V.A.5 *infra*, the Indian Central Government is responsible for appointing members to the Patent Appellate Board. See The Patents Act, No. 39 of 1970, § 117 (Universal 2005) (amended 2005). One way for a candidate to qualify as the "Technical Member" of the Patent Appellate Board is to have served as the Controller of Patents for five years. See *id.* § 116(2)(a). The issue then becomes whether a Patent Appellate Board that constitutes a former Controller of Patents would operate in a manner that is truly independent of and distinct from the Patent Office.

533. See *Farmer Dies of Bird Flu in India, Initial Tests Show*, N.Y. TIMES, Feb. 19, 2006, at A12 (reporting the announcement of India's first cases of bird flu after thousands of birds infected with the deadly A(H5N1) strain died in India's western Maharashtra state).

534. The Indian government has publicly announced plans to stockpile Tamiflu in case of a bird flu outbreak. See *India Creating Emergency Stockpile of Bird Flu Drug*, TIMES OF INDIA, Dec. 1, 2005, available at <http://timesofindia.indiatimes.com/articleshow/1313900.cms>.

oseltamivir, sold under the brand name “Tamiflu.”⁵³⁵ Roche has voluntarily licensed the Indian generic firm Hetero Drugs to make and sell Tamiflu in India,⁵³⁶ but other generics may seek a piece of the lucrative pie⁵³⁷ by applying to the Indian government for compulsory licenses when and if Roche is granted a patent on oseltamivir.⁵³⁸ Until a patent is granted,⁵³⁹ Indian generics such as Cipla and Ranbaxy remain free to copy the drug and sell it in India.⁵⁴⁰

India’s new patent law provides four avenues for seeking a compulsory patent license. Three of the four avenues are depicted in Figure 1 below (as

535. See *Tamiflu, India and the Compulsory Licensing Dilemma*—, LEXORBIT NEWSL., Nov. 7, 2005, at 2 (on file with author). Roche has sought permission from India’s Union Health Ministry to market Tamiflu in India, and its mailbox application (No. 396/DEL/96) is being processed on a fast track. *Id.* Roche acquired the ‘396 mailbox application from Gilead Sciences, Inc., the U.S. biotech firm whose scientists invented the drug. See India Patent Application No. 396/DEL/1996 A, filed Feb. 26, 1996, titled “Carbocyclic Compounds,” 2005 OFFICIAL J. PAT. OFFICE 1277 (Mar. 11, 2005), available at http://ipindia.nic.in/ipr/patent/journal_archive/pat_arch_110305/official%20journal%2011.03.2005.pdf; Datta, *Gilead Sciences*, *supra* note 510.

On November 18, 2005, the Indian Patent Office published another Roche application directed to a method of synthesizing Tamiflu. See India Patent Application No. 305/MAS/2001A, filed Sept. 4, 2001, titled “Tamiflu, Gallacarboxylic Acid Approach,” 2005 OFFICIAL J. PAT. OFFICE 25541 (Nov. 18, 2005), available at http://ipindia.nic.in/ipr/patent/journal_archive/pat_arch_112005/official_journal_18112005.pdf.

536. See *Roche Grants Tamiflu License to Hetero Drugs*, TIMES OF INDIA, Dec. 24, 2005, available at <http://timesofindia.indiatimes.com/articleshow/1344422.cms> (“Drug maker Roche Holding AG has granted a sub-licence to Hyderabad-based Hetero Drugs to produce Tamiflu for developing nations. The agreement with Hetero covers India and other developing nations and allows the company to produce a generic version of the avian flu treatment drug specifically for governments wishing to create emergency stores.”).

537. See *id.* (reporting that “[o]nce launched in the market, the drug [Tamiflu] could cost \$12 (around Rs 540) per capsule”).

538. See, e.g., Yusuf K. Hamied, Chairman and Managing Director, Cipla Ltd., *The Cipla Story on HIV and AIDS*, Address at the “Tufts in India” Seminar in Mumbai (Nov. 9, 2005), at 4 (stating that Cipla has started to produce the avian flu drug Oseltamivir and that Cipla will “provide this drug to India”) (transcript on file with author). Cipla “strongly believe[s] that when there are impending health emergencies [i]nternationally, then the patents involved should be made available to anyone on payment of a maximum 4% royalty to the inventor.” *Id.* “This would ensure that there would be no monopoly and [that the] life-saving drugs needed could be made freely available again at affordable prices.” *Id.*

539. It is by no means certain that the Indian Patent Office will grant a product patent on oseltamivir. Leading Indian generic manufacturer Cipla reportedly filed a pre-grant opposition against the Roche/Gilead patent application in April 2006. See P.T. Jyothi Datta, *Cipla Opposes Patent Application on Bird-Flu Drug*, HINDU BUS. LINE, May 1, 2006, available at <http://www.thehindubusinessline.com/2006/05/02/stories/200605022250500.htm> (reporting that “[t]he pre-grant opposition was filed at the Patent Office in New Delhi earlier this month”) [hereinafter Datta, *Cipla Opposes*]. The grounds on which Cipla challenges the oseltamivir product patent application are reported as “known prior-art, invalid claim, lack of novelty and inventive step.” *Id.*

540. See Datta, *Cipla Opposes*, *supra* note 539, at 1.

derived from India's MPPP⁵⁴¹). To summarize, the compulsory licensing avenues are:

(1) The Section 84 procedure (depicted as the middle of the three paths shown in Figure 1), which is a carryover from the Patents Act, 1970, and provides the broadest grounds for seeking a compulsory patent license (including the controversial ground of non-working). As detailed below, a compulsory license seeker under Section 84 cannot file an application until after the targeted patent has been in force for a minimum of three years, and she must make out a *prima facie* case in order to be granted the license. The patent owner can initiate an opposition proceeding against the grant of this type of compulsory license;

(2) The Section 92 procedure (depicted as the left-most of the three paths shown in Figure 1), also a carryover from the Patents Act, 1970, which is a more limited provision for the grant of compulsory licenses on notification of the Indian government in circumstances of national emergency such as public health crises;

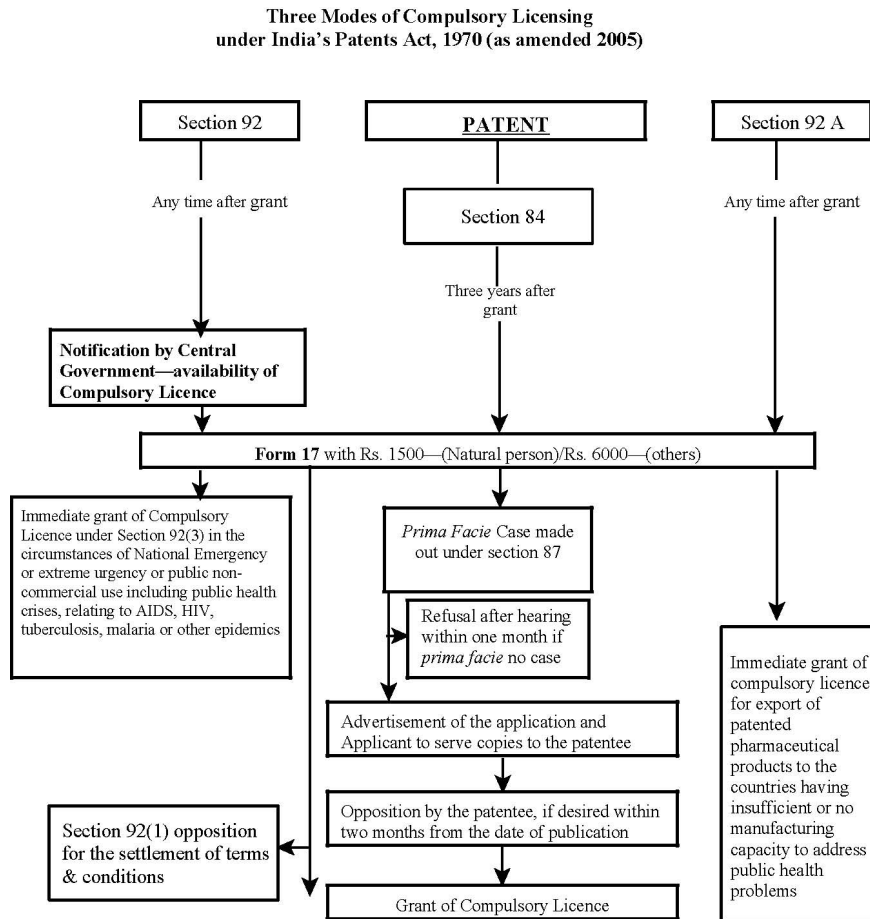
(3) The Section 92A procedure (depicted as the right-most of the three paths shown in Figure 1), newly added by the Patents (Amendment) Act, 2005. In permitting manufacture and export of patented medicines to other countries not having local manufacturing capacity, Section 92A represents India's own version of the framework set forth in the WTO's 2003 Implementation Decision of the Doha Ministerial on TRIPS and Public Health; and

(4) The Section 91 procedure (not depicted in Figure 1), which is a carryover from the Patents Act, 1970, and provides for compulsory licenses in the case of certain blocking patents.

Each of these modes of compulsory patent licensing is separately discussed following Figure 1.

541. See MPPP, *supra* note 374, at 97 (figure titled "Procedure for grant of compulsory license").

Figure 1. Three Modes of Compulsory Licensing under India's Patents Act, 1970 (2005)⁵⁴²



542. Adapted from Patent Office, India, *MANUAL OF PATENT PRACTICE AND PROCEDURE 97* (2005), available at <http://patentoffice.nic.in/ipr/patent/manual-2052005.pdf>.

1. *Compulsory Licenses under Section 84*

Applications for compulsory licenses under Section 84 of India's Patents Act, 1970 (2005) may not be filed until three years after a patent's grant.⁵⁴³ A Section 84 application may be based on any of the following three grounds:

- (a) that the reasonable requirements of the public with respect to the patented invention have not been satisfied, or
- (b) that the patented invention is not available to the public at a reasonably affordable price, or
- (c) that the patented invention is not worked in the territory of India.⁵⁴⁴

The specifics of each ground are discussed separately below, but a few general observations are in order. The stated grounds for a compulsory license under Section 84 are not new, having been carried over from the Patents Act, 1970.⁵⁴⁵ The practical difference, however, is that under India's current Act compulsory licensing is no longer a merely speculative proposition. A pharmaceutical product patents regime is now in place in India for the first time in 35 years. The history of active opposition to that regime by India's generic drug manufacturers⁵⁴⁶ significantly raises the likelihood that those firms will actively seek compulsory licenses in the future.⁵⁴⁷

There are few, if any, standing-type restraints on the identity of a Section 84 applicant for a compulsory license. Any "person interested" may apply,⁵⁴⁸ even a party to an existing consensual license previously granted by the patentee as a result of negotiation with that party.⁵⁴⁹ The existence of the pre-existing consensual license in no way estops the licensee from seeking a

543. See The Patents Act, No. 39 of 1970, § 84(1) (Universal 2005) (amended 2005).

544. *Id.*

545. Section 84(1) of The Patents Act, No. 39 of 1970, listed only ground (a) (reasonable requirements of the public not satisfied) and ground (b) (invention not available at reasonable price) as the grounds on which a compulsory license could be granted, and did not explicitly include ground (c) (non-working in India). See The Patents Act, No. 39 of 1970, § 84(1), available at <http://indiacode.nic.in>. However, the non-working ground was effectively subsumed into ground (a) via the language of Section 90, which defined "[w]hen reasonable requirement of the public [shall be] deemed not satisfied." See *id.* at § 90(a) (referring to "default of the patentee to manufacture in India to an adequate extent").

546. See *supra* Part III.A.2.b.

547. See, e.g., Love, *supra* note 513 (asserting that "[s]oon a large number of compulsory licenses will be issued for products now manufactured in India, which are subject to the mailbox patents.").

548. See The Patents Act, No. 39 of 1970, § 84(1) (Universal 2005) (amended 2005). The statute's definitional section provides (in non-exclusive fashion) that a "'person interested' includes a person engaged in, or in promoting, research in the same field as that to which the invention relates." *Id.* § 2(1)(t) (emphasis added).

549. See *id.* § 84(2).

compulsory license on the ground that the patented invention is not available to the public at a reasonable price.⁵⁵⁰

The licensee that successfully obtains a compulsory license under Section 84 is granted unusually broad rights. Not only is the compulsory licensee authorized by the government to compete with the patentee in the manufacture and sale of the patented medicine, as in any compulsory licensing situation, but also is given the right to enforce the patent against infringers if the patentee fails to do so. India's patent law provides that a Section 84 compulsory licensee may "call upon the patentee to take proceedings to prevent any infringement of the patent," and if the patentee does not do so within two months, the licensee "may institute proceedings for the infringement in his own name as though he were the patentee, making the patentee a defendant . . ."⁵⁵¹

Compulsory license applications with respect to Indian patents are filed with and granted by the Controller of Patents.⁵⁵² In considering whether to grant a compulsory license under Section 84, the Controller must take into account the following four factors:

- (i) the nature of the invention, the time which has elapsed since the sealing of the patent and the measures already taken by the patentee or any licensee to make full use of the invention;
- (ii) the ability of the applicant to work the invention to the public advantage;
- (iii) the capacity of the applicant to undertake the risk in providing capital and working the invention, if the application were granted;
- (iv) as to whether the applicant has made efforts to obtain a license from the patentee on reasonable terms and conditions and such efforts have not been successful within a reasonable period as the Controller may deem fit . . .⁵⁵³

The 2005 amendments to the principal Act added a further "Explanation" providing that the "reasonable period" of criteria (iv) "shall be construed as

550. *See id.* ("An application under this section may be made by any person notwithstanding that he is already the holder of a license under the patent and no person shall be estopped from alleging that the reasonable requirements of the public with respect to the patented invention are not satisfied or that the patented invention is not worked in the territory of India or that the patented invention is not available to the public at a reasonably affordable price by reason of any admission made by him, whether in such a license or otherwise or by reason of his having accepted such a license.").

551. *Id.* § 110. The statute further provides that "a patentee so added as defendant shall not be liable for any costs unless he enters an appearance and takes part in the proceedings." *Id.* The right of the compulsory licensee to initiate infringement proceedings is not new; identical language appeared in the 1970 Act. *See* The Patents Act, No. 39 of 1970, § 110, available at <http://indiacode.nic.in>.

552. *See infra* Part V.A.1.

553. The Patents Act, No. 39 of 1970, § 84(6) (Universal 2005) (amended 2005).

a period not ordinarily exceeding a period of six months.”⁵⁵⁴ The purpose of this amendment was presumably “to prevent patentees from dragging on voluntary negotiations to the detriment of [compulsory license] applicants.”⁵⁵⁵

a. Ground One—Section 84(1)(a)

With respect to the first ground on which a Section 84 compulsory license may be sought, i.e., whether the “reasonable requirements of the public with respect to the patented invention have not been satisfied,” the statutory scheme gives the Controller virtually unfettered discretion in determining whether this criterion has been satisfied. The statute provides that “the reasonable requirements of the public shall be deemed not to have been satisfied” if any of a host of various circumstances apply.⁵⁵⁶ For example, in

554. The Patents (Amendment) Act, No. 15 of 2005, § 52 (Universal 2005).

555. See Shamnad Basheer, *India's Tryst with TRIPS: The Patents (Amendment) Act 2005*, 1 INDIAN J.L. & TECH. (2005), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=764066 (see PDF page 8).

556. See The Patents Act, No. 39 of 1970, § 84(7)(a)-(e) (Universal 2005) (amended 2005). The full text of these provisions is as follows:

84. Compulsory licenses. . . . (7) For the purposes of this Chapter, the reasonable requirements of the public shall be deemed not to have been satisfied—

- (a) if, by reason of the refusal of the patentee to grant a license or licenses on reasonable terms,—
 - (i) an existing trade or industry or the development thereof or the establishment of any new trade or industry in India or the trade or industry in India or the trade or industry of any person or class of persons trading or manufacturing in India is prejudiced; or
 - (ii) the demand for the patented article has not been met to an adequate extent or on reasonable terms; or
 - (iii) a market for export of the patented article manufactured in India is not being supplied or developed; or
 - (iv) the establishment or development of commercial activities in India is prejudiced; or
- (b) 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 manufacture, use or sale of materials not protected by the patent, or the establishment or development of any trade or industry in India, is prejudiced; or
- (c) 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 patent or coercive package licensing; or
- (d) if the patented invention is not being worked in the territory of India on a commercial scale to an adequate extent or is not being so worked to the fullest extent that is reasonably practicable; or
- (e) if the working of the patented invention in the territory of India on a commercial scale is being prevented or hindered by the importation from abroad of the patented article by—
 - (i) the patentee or persons claiming under him; or
 - (ii) persons directly or indirectly purchasing from him; or
 - (iii) other persons against whom the patentee is not taking or has not taken proceedings for infringement.

a case where the patentee has refused to voluntarily grant a license under its patent, the reasonable requirements of the public are deemed not to have been met if the Controller determines that “an existing trade or industry or the development thereof or the establishment of any new trade or industry in India or the trade or industry in India or the trade or industry of any person or class of persons trading or manufacturing in India is prejudiced.”⁵⁵⁷ Not only is this clause sloppily drafted, but more importantly given the breadth of its wording, virtually any refusal of a patentee to license could be deemed prejudicial to some form of trade in India.

Other aspects of the Section 84(1)(a) “reasonable requirements of the public with respect to the patented invention” ground give cause for concern. The ground can be deemed unsatisfied not only when a domestic industry is harmed by a patentee’s refusal to license, but also when that refusal means that “a market for *export* of the patented article manufactured in India is not being supplied or developed.”⁵⁵⁸ It is difficult to square this basis for the grant of a compulsory license with the requirement of TRIPS Article 31(f) that compulsory licenses are to be granted “predominantly for the supply of the domestic market” of the country granting the compulsory license.⁵⁵⁹ Although the WTO has recognized the need for a waiver of the Art. 31(f) requirement in certain situations of public health crises in countries having no or insufficient indigenous drug manufacturing capacity,⁵⁶⁰ India’s patent statute deals separately with that scenario in the new Section 92A avenue of compulsory licensing discussed below. The TRIPS compliance issue raised here is that the reference to supplying export markets remains in the general-purpose Section 84 avenue of compulsory licensing and is not confined to the new Section 92A procedure.

India has seemingly recognized this potential TRIPS compliance problem, however, and attempted to address it via a 2005 amendment⁵⁶¹ to counterpart Section 90 of the Patents Act, 1970 (2005), which provides a set of criteria for

Id.

557. *Id.* § 84(7)(a)(i).

558. *Id.* § 84(7)(a)(iii) (emphasis added).

559. TRIPS, *supra* note 3, Art. 31(f).

560. See WTO General Council, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WT/L/540 (Aug. 30, 2003) [hereinafter WTO Doha Implementation Decision], available at http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm.

561. See The Patents (Amendment) Act, No. 15 of 2005, § 54 (Universal 2005) (substituting new language of Section 90(1)(vii) for pre-existing text of § 90(1)(vii), which already required “that the license is granted with a predominant purpose of supplying in [*sic*] Indian market . . .,” but which did not mention Section 84(7)(a)(iii) window for exports).

determining the terms and conditions of a compulsory license granted under Section 84. The as-amended Section 90 provides that the Controller “shall endeavor to secure” that a compulsory license “is granted with a predominant purpose of supply in the Indian market and that the licensee may also export the patented product, if need be in accordance with the provisions of sub-clause (iii) of clause (a) of sub-section (7) of section 84.”⁵⁶² Although some view this language as sufficient to reconcile any conflict with TRIPS Art. 31(f),⁵⁶³ the true test will come in the provision’s implementation. There may remain sufficient ambiguity in statutory phrases such as “shall endeavor” and “if need be” to incite domestic generic firms to seek compulsory licenses under Section 84 for purposes of export from India based solely on economic grounds (apart from any public health crises that would support a § 92 or § 92A application). The Controller’s future handling of such applications is sure to be closely monitored by pharmaceutical MNCs and the U.S. Trade Representative. Of course, because a Section 84 application for compulsory license cannot be filed until three years after a patent’s grant, no such applications could be filed with respect to pharmaceutical product patents prior to 2008.⁵⁶⁴

Section 84 of India’s Patents Act also sets up compulsory licensing as a remedy for anticompetitive behavior by patentees, as contemplated by the TRIPS Agreement.⁵⁶⁵ The Section 84(1)(a) “reasonable requirements of the public with respect to the patented invention” ground may be deemed unsatisfied when a “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.”⁵⁶⁶ The explicit inclusion of anticompetitive practices as a ground for compulsory licensing under Section 84 was added to India’s patent laws for the first time by the 2002 amendments.⁵⁶⁷ The new competition law language takes advantage of

562. The Patents Act, No. 39 of 1970, § 90(1)(vii) (Universal 2005) (amended 2005) (emphasis added).

563. See Basheer, *supra* note 555, at 9.

564. Separately from the Section 84 compulsory license procedure, certain Indian product patents issuing from “mailbox” applications will be automatically subject to compulsory licenses as soon as the patents issue (some time after January 1, 2005). See *supra* Part IV.E.

565. See TRIPS, *supra* note 3, Art. 31(k) (“Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) above where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. . .”).

566. The Patents Act, No. 39 of 1970, § 84(7)(c) (Universal 2005) (amended 2005).

567. See The Patents (Amendment) Act, No. 38 of 2002, § 39, available at <http://indiacode.nic.in> (substituting new Chapter XVI comprising sections 82 to 94 for prior Chapter XVI comprising sections 82

flexibilities provided by Articles 31(k) and 40 of TRIPS. Article 40, reportedly “put forward by developing countries,”⁵⁶⁸ allows TRIPS members to adopt “appropriate measures to prevent or control [anti-competitive] practices, which may include for example exclusive grantback conditions, conditions preventing challenges to validity and coercive package licensing, in the light of the relevant laws and regulations of that Member.”⁵⁶⁹

Like TRIPS, India’s Patents Act does not further define nor elaborate on the nature of these anticompetitive practices. In ruling on compulsory license applications, the Indian Patent Office will be called upon, at least in the first instance, to determine whether a particular case of alleged anticompetitive behavior or misuse by a patentee justifies the grant of a compulsory license as a remedy. Such determinations may look to U.K. or European Union competition case law for guidance, or possibly even rely on the significant body of American patent/antitrust decisions. The direction to be taken by the Indian Patent Office and the courts presently remains difficult to predict, for modern competition law in India (and hence its application to intellectual property matters) is still very much in its infancy. A modern competition law statute was enacted in 2002 but is not yet in force; India’s Competition Commission was launched in 2003.⁵⁷⁰

b. Ground Two—Section 84(1)(b)

The second ground on which a compulsory patent license can be sought under Section 84 is “that the patented invention is not available to the public at a reasonably affordable price.”⁵⁷¹ The statute provides no guidance as to how the Controller of Patents is to determine what is a “reasonably affordable price.” A leading treatise rather unhelpfully suggests that “[w]hat is a

to 98); The Patents Act, No. 39 of 1970, § 90, available at <http://indiacode.nic.in> (titled “When reasonable requirements of the public deemed not satisfied”) (silent as to any anticompetitive behaviors such as exclusive grant backs or coercive package licensing).

568. Bruce A. Lehman, *Intellectual Property Under the Clinton Administration*, 27 GEO. WASH. J. INT’L L. & ECON. 394, 409 (1993).

569. TRIPS, *supra* note 3, Art. 40.

570. See *Brief Note on the Provisions of the Competition Act, 2002 and the Jurisdiction, Powers and Duties of the Competition Commission of India*, available at <http://www.competition-commission-india.nic.in/> (follow “About Us” hyperlink) (last visited Feb. 12, 2006). The Competition Act, 2002, is designed to replace the Monopolies & Restrictive Trade Practices Act, 1969. See *id.* The MRTP Act, which came into force during the socialist era of Indian business nationalization, is said to have “crippled private industry for a generation.” See DAS, *supra* note 136, at 168.

571. The Patents Act, No. 39 of 1970, § 84(1)(b) (Universal 2005) (amended 2005).

‘reasonable price’ for the patented article will depend upon the circumstances of each case.”⁵⁷²

As with all three grounds on which a section 84 compulsory license can be sought, the license seeker under Section 84(1)(b) must make out a *prima facie* case.⁵⁷³ Presumably a company seeking a compulsory license under an Indian pharmaceutical product patent would come forward with evidence of drug prices charged by the patentee in India and would compare those prices with the prices of non-patented substitutes available in India.⁵⁷⁴ Prices charged by the patentee for the same drug outside of India might also be relevant, particularly if lower than the prices charged in India. The patent owner would have an opportunity to counter the compulsory license applicant’s evidence with the patentee’s own evidence by initiating an opposition procedure, as described below.

c. Ground Three—Section 84(1)(c)

The third ground on which a Section 84 compulsory license may be based, i.e., “that the patented invention is not worked in the territory of India,”⁵⁷⁵ is the ground most likely to raise the ire of foreign patentees and their governments. Assuming that the word “worked” is not interpreted broadly enough to encompass imports,⁵⁷⁶ MNCs that manufacture patented pharmaceutical products outside of India but import them into India for sale there are now potentially subject to compulsory licensing of their Indian patents under Section 84(1)(c). The unresolved legal issue is whether India’s imposition of a domestic working requirement is inconsistent with TRIPS. The analysis requires a general understanding of the reasons why many countries besides India have imposed working requirements on patentees.

Domestic working requirements for patents have a long history. They were first employed by many developed countries in the 1800s as protectionist measures intended to stem the outflow of national wealth associated with the

572. NARAYANAN (PATENT LAW), *supra* note 50, at 264, ¶ 14-10.

573. The Patents Act, No. 39 of 1970, § 87(1) (Universal 2005) (amended 2005).

574. *Cf.* Novartis AG v. Adarsh Pharma, 2004 (29) P.T.C. [India Patent and Trade Marks Cases Reporter] 108, 115 (Mad[ras]) (noting in the context of an EMR dispute the defendant’s contention that patentee’s price per capsule of drug in question was Rs. 1,700 whereas defendants’ price per capsule was less than Rs. 100).

575. The Patents Act, No. 39 of 1970, § 84(1)(c) (Universal 2005) (amended 2005).

576. Such a broad interpretation would be nonsensical in light of the explicit reference in Section 84(7)(e) to “importation from abroad” of patented articles by the patentee or his purchasers.

granting of patents to foreigners.⁵⁷⁷ By stemming an otherwise entirely one-way flow of revenues from the sale of imported patented articles to the foreign patentee's home country, a working requirement forced the patentee to manufacture the invention in the patent-granting country, thereby benefiting the domestic economy through capital investment, job creation, and the like. After enactment of the Paris Convention in 1883 and its guiding principle of national treatment, which forbade signatory countries from treating foreign patent applicants or grantees any less advantageously than domestic entities,⁵⁷⁸ working requirements were nevertheless retained by many countries. Such requirements were facially neutral in that they applied to domestic and foreign patentees alike, and therefore appeared to comport with national treatment principles, but in reality represented *de facto* discrimination against foreign patentees.⁵⁷⁹

Although the original 1883 text of the Paris Convention explicitly recognized that signatory countries could provide for domestic working requirements,⁵⁸⁰ later versions of the Convention placed some restraints on the use of compulsory licensing in cases of a patentee's "failure to work."⁵⁸¹ Compulsory licenses based on the ground of failure to work or insufficient working could not be applied for before the expiration of three years from the patent's issuance,⁵⁸² and the compulsory license would be denied "if the patentee justifie[d] his inaction by legitimate reasons."⁵⁸³ Moreover, the Paris Convention provided that importation by the patentee "into the country where the patent has been granted of articles manufactured in any of the countries of the Union shall not entail *forfeiture* of the patent."⁵⁸⁴

577. See R. Carl Moy, *The History of the Patent Harmonization Treaty: Economic Self-Interest as an Influence*, 26 J. MARSHALL L. REV. 457, 475-76 (1993).

578. See Paris Convention, *supra* note 205, art. 2.

579. See Moy, *supra* note 577, at 476 n.100 (noting that "[a] domestic inventor will either already have production facilities that are located domestically or, generally speaking, be able to arrange for the construction of facilities more easily than will a foreign inventor").

580. See *id.* at 483-84 (observing that original text of Paris Convention, although silent on compulsory licensing, did provide that "[t]he patentee, however, shall be subject to the obligation of working his patent conformably to the laws of the country into which he has introduced the patented articles").

581. Paris Convention, *supra* note 205, art. 5.A.2 (providing that "[e]ach country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work").

582. *Id.* art. 5.A.4.

583. *Id.*

584. *Id.* art. 5.A.1 (emphasis added).

In light of these minor restrictions, Paris Convention signatories remained relatively unencumbered in their ability to impose domestic working requirements and compulsory licensing based on failure to domestically work.⁵⁸⁵ The 1994 adoption of the WTO TRIPS Agreement changed that calculus, however.⁵⁸⁶ Article 27.1 of TRIPS mandates that “patents shall be available and *patent rights enjoyable* without discrimination as to the place of invention, the field of technology and *whether products are imported or locally produced*.”⁵⁸⁷ Based on their interpretation of this provision, most developed countries, including the United Kingdom, have now removed domestic working requirements from their patent laws.⁵⁸⁸

Nevertheless, several advanced developing countries including India and Brazil have retained domestic working requirements to protect and create incentives for indigenous industry. Notably, Brazil’s inclusion of a failure-to-domestically-work trigger for compulsory patent licensing caused the U.S. to initiate a dispute proceeding in the WTO. On May 30, 2000 the U.S. requested consultations with Brazil concerning “those provisions of Brazil’s 1996 industrial property law (Law No. 9,279 of 14 May 1996; effective May 1997) and other related measures, which establish a ‘local working’ requirement for the enjoyability of exclusive patent rights.”⁵⁸⁹ A WTO panel never resolved the dispute, however, because the U.S. dropped its claim by July 2001,⁵⁹⁰ most likely in response to public pressure.⁵⁹¹ Thus no definitive

585. See Moy, *supra* note 577, at 488 (“[The] Paris Union has repeatedly revisited the issues of working requirements and compulsory licensing since 1883. . . . The resulting provisions place very few restrictions on national governments that wish to use these mechanisms.”) (citation omitted).

India, of course, did not accede to the Paris Convention until 1998, and hence was not subject until that time to the Convention’s relatively limited restrictions on compulsory licensing on the ground of failure to domestically work. See World Intellectual Property Organization, *Paris Convention Contracting Parties*, available at http://www.wipo.int/treaties/en/Remarks.jsp?cnty_id=246C (noting India’s accession to the 1967 Stockholm Act version of the Paris Convention on Sept. 7, 1998, and the entry into force of that Act in India on December 7, 1998).

586. See Foster, *supra* note 119, at 292 (observing that TRIPS Art. 27.1 “arguably prevents a member from imposing the local working requirements prominent under the Paris Convention”).

587. TRIPS, *supra* note 3, Art. 27.1 (emphasis added).

588. United Kingdom Commission on Intellectual Property Rights, *INTEGRATING INTELLECTUAL PROPERTY RIGHTS AND DEVELOPMENT POLICY* (2002), at 120, available at http://www.iprcommission.org/graphic/documents/final_report.htm.

589. World Trade Organization, *Dispute DS199, Brazil—Measures Affecting Patent Protection*, available at http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds199_e.htm (summarizing status of dispute as of Oct. 9, 2006).

590. See *id.*

591. See Hans Henrik Lidgard & Jeffery Atik, *Facilitating Compulsory Licensing under TRIPS in Response to the AIDS Crisis in Developing Countries*, at 9, available at <http://ssrn.com/abstract=794228>. Within two months after withdrawing its WTO complaint against Brazil, the anthrax bioterrorism scare led

WTO ruling exists on the apparent conflict between retention of local working requirements as a compulsory licensing trigger and the non-discrimination provision of TRIPS Art. 27.1.

This unresolved conflict may well be re-ignited by India's new pharmaceutical product patents regime and the susceptibility of foreign-owned product patents to compulsory licensing. The domestic working requirement is a pervasive theme of India's patent laws. India's disfavor of patented imports and its view that domestic working ought to be part of the basic *quid pro quo* for the grant of an Indian patent are further evidenced in the current Act by Section 83's statement of "general principles," which provides that Indian patents "are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article."⁵⁹² The views of India and other developing countries who retain working requirements as a tool for domestic economic enhancement will undoubtedly be challenged by MNCs that strongly prefer to consolidate production facilities in order to achieve economies of scale and related efficiencies. Foreign patentees can also be expected to cite the difficulty of navigating Indian government bureaucracy to obtain necessary permits and permission to establish domestic manufacturing facilities.⁵⁹³

The Section 84(1)(c) "not worked in the territory of India" ground for compulsory licensing also overlaps to a considerable extent with the Section 84(1)(a) ground, i.e., that "the reasonable requirements of the public with respect to the patented invention have not been satisfied."⁵⁹⁴ Criteria (d) and (e) of Section 84(7) for deeming the "reasonable requirements of the public" unsatisfied both concern non-working. Section 84(7)(d) provides that the reasonable requirements of the public are deemed unsatisfied "if the patented invention is not being worked in the territory of India on a commercial scale to an adequate extent or is not being so worked to the fullest extent that is reasonably practicable."⁵⁹⁵ Similarly, Section 84(7)(e) provides that the reasonable requirements of the public will be deemed unsatisfied "if the working of the patented invention in the territory of India on a commercial scale is being prevented or hindered by the importation from abroad of the

the U.S. government to itself threaten compulsory licensing against the German-owned patent on the antibiotic Ciprofloxacin. *Id.*

592. The Patents Act, No. 39 of 1970, § 83(b) (Universal 2005) (amended 2005).

593. However, the Patents Act provides that the Controller may postpone consideration of a compulsory license application based on non-working by up to one year where the patentee shows that it was prevented by the Indian government from practicing the invention domestically. *See id.* § 86.

594. *Id.* § 84(1)(a).

595. *Id.* § 84(7)(d).

patented article” by the patentee, his agents, or third parties against whom the patentee has not enforced the patent.⁵⁹⁶

Whether the United States ultimately challenges India’s domestic working requirement in the WTO may be tempered by the currently uncertain legislative direction of the U.S.’ own patent laws. One of the more controversial aspects of the current U.S. patent law reform movement is whether the availability of injunctive relief in cases of patent infringement should depend in some measure upon whether the patent owner itself is manufacturing the patented invention.⁵⁹⁷ Some reform proponents would prevent a non-manufacturing “patent troll” from obtaining injunctive relief against infringers. This too is a form of domestic working requirement, or at least a differential treatment of those who do not work their patents. It would be rather ironic if the U.S. were to challenge India’s domestic working requirements while at the same time contemplating a partial abrogation of remedies available to its own non-working patentees.

d. Procedure for Section 84 Compulsory License Applications

The basic procedure for seeking a compulsory license under Section 84 is depicted in the middle pathway of Figure 1 above. The compulsory license applicant initiates the process by submitting the appropriate form and fee to the Controller of Patents.⁵⁹⁸ The Controller then determines whether the application establishes a *prima facie* case.⁵⁹⁹ If it does, the Controller will publish the compulsory license application in the Patent Office’s weekly *Official Journal*⁶⁰⁰ and instruct the applicant to serve copies of the compulsory

596. *Id.* § 84(7)(e)(i)-(iii).

597. The “Patents Depend on Quality Act of 2006,” introduced in the U.S. House of Representatives on April 5, 2006 by Rep. Howard Berman, proposes adding the following language to the end of 35 U.S.C. § 283:

In determining equity, the court shall consider the fairness of the remedy in light of all the facts and the relevant interest of the parties associated with the invention. Unless an injunction is entered pursuant to a nonappealable judgment of infringement, a court shall stay the injunction pending an appeal upon an affirmative showing that the stay would not result in irreparable harm to the owner of the patent and that the balance of hardships from the stay does not favor the owner of the patent. H.R. 5096, § 8, available at <http://thomas.loc.gov/cgi-bin/query/F?c109:1:/temp/~c1094bv1yl:e27346>: (last visited Aug. 12, 2006).

598. A blank version of Form 17, titled “Application for Compulsory License,” is provided in India’s patent rules. See The Patents Rules, 2003 (Universal 2005), *supra* note 184, at Form 17, reprinted in UNIVERSAL’S THE PATENTS ACT, 1970, AS AMENDED BY THE PATENTS (AMENDMENT) ACT, 2005 (Universal Law Publishing Co. Pvt. Ltd., Delhi), at 85, 145.

599. The Patents Act, No. 39 of 1970, § 87(1) (Universal 2005) (amended 2005).

600. Issues of the *Official Journal* published during 2006 are available at <http://patentoffice.nic.in/>

license application on the patentee and any other interested parties.⁶⁰¹ The patentee has two months from the date of publication in the *Official Journal* to initiate an opposition against the grant of a compulsory license, if it desires to do so.⁶⁰² Both the compulsory license applicant and the patentee opposer will be given an “opportunity to be heard” before the Controller decides the case.⁶⁰³ In setting the terms of a Section 84 compulsory license, the Controller must endeavor to secure the patentee a royalty or other remuneration that “is reasonable, having regard to the nature of the invention [and] the expenditure incurred by the patentee in making the invention or in developing it . . . ,”⁶⁰⁴ while also providing that the compulsory licensee make a “reasonable profit”⁶⁰⁵

It remains to be seen how frequently applicants will actually seek compulsory licenses under the framework of Section 84. Some commentators have criticized the framework as unduly complicated and requiring more than TRIPS does in terms of procedural protections for patentees.⁶⁰⁶ The Indian

ipr/patent/journal_archieve/journal_2006/patent_journal_2006.htm.

601. *Id.* The 2005 amendments changed the prior statutory text, requiring that the Controller “shall advertise the application in the Official Gazette,” to “shall publish the application in the official journal.” See The Patents (Amendment) Act, No. 15 of 2005, § 53 (Universal 2005).

602. The Patents Act, No. 39 of 1970, § 87(2) (Universal 2005) (amended 2005) (providing that “[t]he patentee or any other person desiring to oppose the application may, within such time as may be prescribed or within such further time as the Controller may on application (made either before or after the expiration of the prescribed time) allow, give to the Controller notice of opposition”). The applicable Patent Office rules provide that the “prescribed time” for filing the notice of opposition is two months. See The Patents Rules, 2003 (Universal 2005), *supra* note 184, § 98(1) (providing that a “notice of opposition under sub-section (2) of section 87 shall be given in Form 14 and shall be sent to the Controller within two months from the date of the publication of the application under sub-section (1) of the said section”).

603. The Patents Act, No. 39 of 1970, § 87(4) (Universal 2005) (amended 2005). See also The Patents Rules, 2003 (Universal 2005), *supra* note 184, § 98 (titled “Notice of opposition under section 87(2)”).

604. The Patents Act, No. 39 of 1970, § 90(1)(i) (Universal 2005) (amended 2005).

605. *Id.* § 90(1)(ii).

606. See CHAUDHURI, *supra* note 78, at 91-92 (stating that the “wording of the grounds for granting compulsory licenses in Section 84 is not amenable to easy interpretation and is not operationally useful and the procedure specified is cumbersome. The procedure is open-ended without any time limit imposed for the grant of compulsory licenses. The copy of the compulsory licensing application will have to be advertised in the official gazette, though this is not required under TRIPS. . . . [I]n case of an appeal, it may be years before a compulsory license is granted, if at all. The entire process is excessively legalistic and provides the patentees the opportunity to buy time through litigation. The huge legal expenses involved in fighting the MNCs holding the patents may dissuade the generic companies from applying for licenses in the first place.”); *Public Interest Must Come First in New Patent Norms: NGOs*, *ECON. TIMES*, Dec. 1, 2004, at 2, <http://economictimes.indiatimes.com/articleshow/941721.cms> (stating that according to NGOs and the domestic industry, “the present procedure for issue of compulsory licences for commercial purpose is unduly elaborate and very time consuming and defeats the very purpose of compulsory licensing for urgently required Drugs”).

Patent Office insists, however, that the procedure for grant of a compulsory license is “not cumbersome.”⁶⁰⁷ Although the larger Indian generic firms will likely seek compulsory licenses, the possibility of having to participate in an opposition proceeding (and potential appeal therefrom⁶⁰⁸) may dissuade smaller generic firms from doing so in large numbers. As has been the case in many developed countries, India’s elaborate compulsory licensing provisions may prove to have effect primarily in background mode, providing powerful motivation for parties to negotiate consensual licenses instead of taking the risk that the government will set the license terms.

2. *Compulsory Licensing under Section 92: Notification by Government*

The second avenue for obtaining a compulsory license under an Indian patent is Section 92 of the Patents Act, which would appear to be the government’s primary vehicle under the new patents regime for ensuring that in cases of health emergencies, the Indian public has meaningful access to patented medicines. Section 92 provides for the filing of compulsory license applications at any time after the Indian Central Government has declared by notification in the Patent Office’s *Official Journal* that it is necessary to make compulsory licenses available under a particular patent (or patents) “in circumstances of national emergency or . . . extreme urgency or in case of public non-commercial use.”⁶⁰⁹ The government has not yet invoked the Section 92 procedure, but a serious outbreak of avian (bird) flu in India could serve as the necessary catalyst.⁶¹⁰

Section 92 compulsory licenses are broadly available for “all medicines, without any prior negotiation with patent owners,”⁶¹¹ in contrast with Section 84 licenses.⁶¹² When a section 92 application has been received following the

607. MPPP, *supra* note 374, at 96 (section 10.6).

608. The Controller’s decision under Section 84(4) with respect to a compulsory license application will be appealable to the Patent Appellate Board, once it is operational. *See* The Patents Act, No. 39 of 1970, § 117A(2) (Universal 2005) (amended 2005). *See also infra* Part V.A.5.

609. The Patents Act, No. 39 of 1970, § 92(1) (Universal 2005) (amended 2005).

610. *See supra* Part IV.F (discussing pending Indian patent applications directed to bird flu drug oseltamivir).

611. Love, *supra* note 513.

612. *See* The Patents Act, No. 39 of 1970, § 84(6)(iv) (Universal 2005) (amended 2005) (providing that in considering a compulsory license application filed under Section 84, the Controller shall take into account “as to whether the applicant has made efforts to obtain a license from the patentee on reasonable terms and conditions and such efforts have not been successful within a reasonable period as the Controller may deem fit”); *id.* at “Explanation” (stating that “[f]or the purposes of clause (iv), ‘reasonable period’ shall be construed as a period not ordinarily exceeding a period of six months”).

requisite government notification, the Controller “shall . . . grant the applicant a license under the patent on such terms and conditions as he thinks fit.”⁶¹³ In so setting the terms and conditions of a Section 92 license, the Controller “shall endeavour to secure that the articles manufactured under the patent shall be available to the public at the lowest prices consistent with the patentees deriving a reasonable advantage from their patent rights.”⁶¹⁴

The framework for granting compulsory licenses under Section 92 is thus reminiscent of India’s former “license of right” procedure, under which process patents pertaining to substances capable of being used as medicines or foods, as well as process patents for making chemical substances (such as alloys), were automatically deemed to be endorsed with the words “licenses of right.”⁶¹⁵ Thus designated, these patents were available for compulsory licensing by all applicants.⁶¹⁶ Some key differences between the old license of right procedure and the current Section 92 procedure are that compulsory license applications under the former could not be made until three years had passed following the patent’s issuance,⁶¹⁷ and the royalty rate for a license of right could not be greater than four percent of net sales price.⁶¹⁸ The license of right provisions of India’s patent laws were abolished in the 2002 amending Act in order to comply with TRIPS.⁶¹⁹

Procedural protections for patentees under Section 92 of the new Patents Act, 1970 (2005) are few. Although the current provision for compulsory licensing in cases of government notification of health emergencies under Section 92 has been essentially carried over from the Patents Act, 1970,⁶²⁰ the patentee’s opportunity to oppose the grant of a compulsory license has been abrogated in circumstances of health crises. The current Section 92 includes a new sub-section (3) which provides that such procedural protections (e.g., the opportunity to oppose the grant of a compulsory license and the right to be

613. *Id.* § 92(1)(i).

614. *Id.* § 92(1)(ii).

615. *See* The Patents Act, No. 39 of 1970, § 87 (titled “Certain patents deemed to be endorsed with the words ‘Licenses of right’”), *available at* <http://indiacode.nic.in>.

616. One of the few reported decisions concerning compulsory patent licensing in India is *Imperial Chem. Indus. Ltd. v. Controller General of Patents*, A.I.R. 1978 (Calcutta) 77 (affirming Controller’s order deeming Imperial’s patent to be subject to licensing of right).

617. *See* The Patents Act, No. 39 of 1970, § 87(1)(b), *available at* <http://indiacode.nic.in>.

618. *See id.* § 88(5) (providing that the royalty would “in no case exceed four per cent of the net ex-factory sale price in bulk of the patented article (exclusive of taxes levied under any law for the time being in force and any commissions payable)”).

619. *See* CHAUDHURI, *supra* note 78, at 90.

620. *See* The Patents Act, No. 39 of 1970, § 97 (titled “Special provision for compulsory licenses on notification by Central Government”), *available at* <http://indiacode.nic.in>.

heard on the matter, as would otherwise apply through Section 87) will not apply in cases of national emergency, extreme urgency, or public non-commercial use, and specifically in “public health crises, relating to Acquired Immuno Deficiency Syndrome, human immuno deficiency virus, tuberculosis, malaria or other epidemics”⁶²¹ The Controller is nevertheless required, “as soon as may be practicable,” to inform the patent holder that the Section 87 procedural protections do not apply.⁶²²

3. *Compulsory Licensing under Section 92A: Exports for Public Health*

Section 92A of India’s Patents Act, 1970 (2005) creates a new, third avenue for compulsory licensing that will permit the manufacture and export of patented pharmaceuticals from India to other countries lacking their own manufacturing capacity.⁶²³ The range of products that can be made and exported by the grantee of Section 92A compulsory license is extensive; the Act defines the relevant pharmaceutical products as “any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address public health problems and shall be inclusive of ingredients necessary for their manufacture and diagnostic kits required for their use.”⁶²⁴ Unlike a Section 84 application which cannot be filed before three years post-grant, an application for a compulsory license under Section 92A can be filed at any time after a patent has issued.⁶²⁵

The Controller’s power to grant a Section 92A compulsory license appears to be virtually unfettered. The Act provides that on receipt of a Section 92A application in the prescribed manner,⁶²⁶ the Controller “shall . . . grant a compulsory license solely for manufacture and export of the concerned pharmaceutical product to such country under such terms and conditions as

621. The Patents Act, No. 39 of 1970, § 92(3) (Universal 2005) (amended 2005).

622. *See id.*

623. *See id.* § 92A(1) (providing that a compulsory license “shall be available for manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems, provided [that a] compulsory license has been granted by such country or such country has, by notification or otherwise, allowed importation of the patented pharmaceutical products from India”).

624. *Id.* § 92A.

625. *See id.* (specifying no post-grant waiting period). *See also supra* Figure 1 (depicting “[i]mmediate grant” of a Section 92A compulsory license application).

626. As with compulsory license applications under Sections 84, 91, and 92, a Section 92A application must be filed using Form 17. *See* The Patents Rules, 2003 (Universal 2005), *supra* note 184, § 96.

may be specified and published by him.”⁶²⁷ Unlike the Section 84 compulsory license, there are (as of yet) no procedural mechanisms allowing the patent owner to oppose the grant of a Section 92A compulsory license or otherwise be heard on the matter.⁶²⁸

Section 92A implements in India’s domestic patent laws a modified version of the framework that has already been agreed to by WTO members for implementing a waiver to Article 31(f) of the TRIPS Agreement.⁶²⁹ Article 31(f) requires that non-consensual use of patented inventions to be authorized by WTO member countries in accordance with Article 31 “shall be authorized predominantly for the supply of the *domestic* market of the Member authorizing such use.”⁶³⁰ Least-developed and other countries with little or no domestic drug manufacturing capacity need to import patented drugs from other countries that do have such capacity. As written, the language of Article 31(f) precludes the grant of compulsory licenses in the manufacturing country solely for purposes of exporting the patented drugs to other countries. The need for a waiver of Article 31(f) in justified circumstances involving public health crises quickly became apparent.

In response to calls by a number of least-developed nations, WTO members in November 2001 issued a ground-breaking *Ministerial Declaration on TRIPS and Public Health* at the Fourth WTO Ministerial Conference in Doha, Qatar.⁶³¹ Paragraph six of the Declaration recognized that “WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement,” and instructed the TRIPS Council to find a solution by the end of 2002. In August 2003, the WTO’s General Council announced agreement on a scheme to solve the Paragraph six dilemma.⁶³² The Implementation Decision provided a waiver of the Article 31(f) restriction if several conditions were met. Chiefly, (1) an importing member country must notify the WTO of its lack of manufacturing capacity, and (in cases where the drug in question is patented in the importing country) that it has or will grant a compulsory license permitting the import;⁶³³ and (2)

627. The Patents Act, No. 39 of 1970, § 92A(2) (Universal 2005) (amended 2005).

628. *See id.* § 92A, *supra* Figure 1.

629. *See* WTO Doha Implementation Decision, *supra* note 560.

630. TRIPS, *supra* note 3, Art. 31(f) (emphasis added).

631. *See* World Trade Organization, *Declaration on the TRIPS Agreement and Public Health* (WT/MIN(01)/DEC/2) (Nov. 14, 2001), available at http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm [hereinafter *Declaration on the TRIPS Agreement and Public Health*].

632. WTO Doha Implementation Decision, *supra* note 560.

633. *See id.* ¶ 2(a).

an exporting member country must notify the WTO that it has granted a compulsory license for export which limits the manufacture of the patented drug product in only such amounts as are needed by the importing member country and which clearly identifies those products by specific labeling or marking.⁶³⁴ Action to prevent diversion of the products from the intended importing country to other countries is also required.⁶³⁵

Not very surprisingly, the Implementation Decision framework has been criticized as complicated and burdensome. As of August 2006, not a single WTO member country has made notification to the WTO of its intent to use the system.⁶³⁶ Despite the criticisms, WTO members reached an agreement on December 6, 2005 that will formally incorporate the framework of the August 2003 Implementation Decision into TRIPS as Article 31^{bis}.⁶³⁷ Implementation will occur after two-thirds of the WTO's 148 members have ratified the changes.⁶³⁸ Ratifications must take place by December 1, 2007; until that date, the current temporary waivers from TRIPS Art. 31(f) will remain in effect.⁶³⁹

The issue now facing India is whether the compulsory licensing framework it has implemented in its domestic law via Section 92A will be viewed by the rest of the world as compliant with the analogous TRIPS provisions. India's implementation is certainly consistent with similar activity in the European Union, China, Norway, and Canada,⁶⁴⁰ but it may be the broadest in scope. For example, India does not require as a prerequisite for issuing a Section 92A compulsory license that the importing country have already granted (or intends to grant in the future) its own compulsory license to permit the import of the patented pharmaceuticals in the importing country

634. *See id.* ¶ 2(b).

635. *See id.* ¶¶ 4 & 5.

636. As of August 2006, no importing country has yet given the WTO such a notification. *See* http://www.wto.org/english/tratop_e/trips_e/public_health_notif_import_e.htm (last visited Aug. 14, 2006). Nor has any exporting country. *See* http://www.wto.org/english/tratop_e/trips_e/public_health_notif_export_e.htm (last visited Aug. 14, 2006).

637. *See* Daniel Pruzin, *WTO Deal on TRIPS/Medicines Welcomed by Governments, Industry*, 71 BNA PAT., TRADEMARK & COPYRIGHT J. 165 (Dec. 9, 2005).

638. *Id.*

639. *Id.*

640. *See E.U. Lawmakers Pass Regulation to Allow Compulsory Licensing for Needy Nations*, 71 BNA PAT., TRADEMARK & COPYRIGHT J. 166 (Dec. 9, 2005). In addition to the European Union and India, Canada, China and Norway also have implemented similar compulsory licensing provisions in their national patent laws. *See* Emma Barraclough, *Weekly News: China to Export Drugs under Compulsory Licences*, MANAGING INTELL. PROP., Dec. 12, 2005, available at <http://www.managingip.com/default.asp?Page=9&PUBID=198&SID=603061&ISS=21054>.

(assuming that a patent covering the imported product is in force there). It is enough if the importing country “has, by notification *or otherwise*, allowed importation of the patented pharmaceutical products from India.”⁶⁴¹ Moreover, in contrast with the TRIPS framework, India’s Section 92A is completely silent on any obligation of the Indian government or the compulsory licensee to specify the amount of pharmaceutical products that will be exported, to specially label or mark those products, or to make public any information about the export by posting to a website or other means of publication.⁶⁴²

As with other open questions concerning India’s new patent laws, this TRIPS compliance issue will turn on the manner in which India actually implements its new Section 92A framework. The Controller has wide discretion to set the terms and conditions of a Section 92A compulsory license. Thus the Controller could, in each individual case, set a quantity limit on the amount of pharmaceutical product to be made and exported, require the licensee to specially package or mark its products, and so on.

Widespread use of the Section 92A avenue for compulsory licensing to export patented medicines appears likely. For example, leading Indian generic pharmaceutical manufacturer Cipla takes the position that even in situations where it will now be prevented by the new product patent regime from copying and selling patented medicines within India, the company would nevertheless be able to make those products for export to least-developed countries and to any other countries that have the legal right to import those products.⁶⁴³ There are currently fifty countries recognized by the WTO and United Nations as least-developed countries,⁶⁴⁴ so the available export market for Indian generic drug manufacturers is potentially very significant.

641. The Patents Act, No. 39 of 1970, § 92A(1) (Universal 2005) (amended 2005) (emphasis added).

642. Compare WTO Doha Implementation Decision, *supra* note 560, ¶ 2(b) with The Patents Act, No. 39 of 1970, § 92A (Universal 2005) (amended 2005).

643. E-mail from Dr. Yusuf K. Hamied (Feb. 6, 2006), *supra* note 267.

The WTO recognizes that developing and even developed Member countries may make use of the TRIPS Article 31(f) waiver framework so long as they properly notify the WTO of their intention to use the system as an importer. Least-developed countries, by contrast, are automatically deemed to be eligible importing Member countries. See WTO Doha Implementation Decision, *supra* note 560, ¶ 2(b) (defining “eligible importing Member”). A number of developed countries, including the U.S., the U.K., Germany, Japan, and Canada, have already informed the WTO that they will not be using the system as importers. See *id.* at note 3 (listing 23 countries).

644. As of August 2006, the WTO recognized 50 member countries as least developed countries in accordance with the United Nations’ designation. See World Trade Organization, *Least-Developed Countries*, available at http://www.wto.org/english/thewto_e/whatis_e/tif_e/org7_e.htm (last visited Aug. 14, 2006).

4. *Compulsory Licensing under Section 91: Blocking Patents*

The fourth mode of compulsory patent licensing recognized in India, although not depicted in Figure 1 above, is available to alleviate the situation of blocking patents; i.e., where an “improvement” or “dependent” patent cannot be practiced without infringing another’s pre-existing “basic” or “dominant” patent. Section 91 (titled “Licensing of related patents”) of India’s Patents Act provides that any person who has the right to practice a second patented invention, either as patentee or licensee thereof, may apply to the Controller for the grant of a license under a first patent on the ground that that person “is prevented or hindered without such license from working the other [second] invention efficiently or to the best advantage possible.”⁶⁴⁵ Unlike a Section 84 license, a Section 91 license may be applied for “at any time after the sealing of a patent [i.e., the first patent].”⁶⁴⁶

The Patents Act sets forth two prerequisites for the granting of a Section 91 compulsory license. First, the compulsory license applicant must show that it is in a position to grant to the first patentee a cross-license under the second patent on “reasonable terms.”⁶⁴⁷ Second, the compulsory license applicant must show that its [i.e., the second] invention “has made a substantial contribution to the establishment or development of commercial or industrial activities in the territory of India.”⁶⁴⁸ If both conditions have been met to the Controller’s satisfaction, he may “make an order on such terms as he thinks fit granting a license under the first mentioned patent and a similar order under the other [second] patent [i.e., a cross-license] if so requested by the proprietor of the first mentioned patent or his licensee. . . .”⁶⁴⁹ The procedural provisions already discussed above in relation to Article 84 compulsory licenses also

645. The Patents Act, No. 39 of 1970, § 91(1) (Universal 2005) (amended 2005).

646. *Id.*

647. *See id.* § 91(2)(i) (providing that no license shall be granted unless the Controller is satisfied “that the applicant is able and willing to grant, or procure the grant to the patentee and his licensees if they so desire, of a license in respect of the other [second] invention on reasonable terms.”).

648. *See id.* § 91(2)(ii).

649. *Id.* § 91(3) (“[T]he license granted by the Controller shall be non-assignable except with the assignment of the respective patents.”).

apply to licenses granted under Section 91;⁶⁵⁰ e.g., the patentee may oppose the grant of a compulsory license under Section 91.⁶⁵¹

The grant of a compulsory license for the purpose of alleviating a blocking patents situation is also contemplated by TRIPS, and the terms of India's Section 91 appear consistent with the requirements set forth in TRIPS Article 31(l).⁶⁵² As Professor Jerome Reichman has proposed, the implementation of this type of compulsory licensing in developing country patent regimes "enable[s] innovators to adapt foreign inventions to local needs."⁶⁵³ India's generic drug manufacturers may well engage in this type of sequential innovation, for example by developing drug delivery systems compatible with local climate conditions and distribution networks for new drugs invented abroad and patented in India by MNCs. Assuming that such a hypothetical delivery system were independently patentable despite the strictures of the anti-evergreening Section 3(d) of the Patents Act, 1970 (2005),⁶⁵⁴ the resulting delivery system patent to the generic firm might nevertheless be blocked by the MNC's drug patent. A compulsory license granted under Section 91, consistent with TRIPS Art. 31(l), would permit the generic company to exploit its own innovation while providing adequate

650. *See id.* § 91(4) (stating that "[t]he provisions of sections 87 ['Procedure for dealing with applications under sections 84 and 85'], 88 ['Powers of Controller in granting compulsory licenses'], 89 ['General purposes for granting compulsory licenses'] and 90 ['Terms and conditions of compulsory licenses'] shall apply to licenses granted under this section as they apply to licenses granted under section 84").

651. *See id.* § 87(2).

652. TRIPS, *supra* note 3, Art. 31, subpart (1) specifies that:

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

- (i) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;
- (ii) the owner of the first patent shall be entitled to a cross-licence on reasonable terms to use the invention claimed in the second patent; and
- (iii) the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.

653. Jerome H. Reichman, *Compulsory Licensing of Patented Inventions: Comparing United States Law and Practice with Options under the TRIPS Agreement*, PROCEEDINGS OF THE AALS WORKSHOP IN INTELLECTUAL PROPERTY, June 14-16, 2006, Vancouver, British Columbia, at 43, 46.

654. *See supra* Part IV.A.3, for further discussion of the Section 3(d) exclusion from patentability of certain derivative forms of known substances.

remuneration to the MNC.⁶⁵⁵ The MNC would also be entitled to a cross-license under the generic firm's patent.⁶⁵⁶

G. Other Limitations on Patentees' Exclusive Rights

1. Experimental/Research Use

India's patent statute, like those of most countries other than the U.S.,⁶⁵⁷ provides an explicit experimental use exemption from patent infringement liability. Section 47(3) of the Patents Act specifies that uses of patented inventions "for the purpose merely of experiment or research including the imparting of instructions to pupils" are not actionable as patent infringement.⁶⁵⁸

As the author has suggested elsewhere, the Section 47(3) research exemption may have special significance for software development in India.⁶⁵⁹ The outsourcing-to-India phenomenon is increasingly likely to encompass value-added work in the design and development of software.⁶⁶⁰ As protection of software innovation through patenting becomes more common, it likewise becomes increasingly likely that the R&D efforts necessary to develop new computer programs will require the use of software algorithms and programming techniques that may be proprietary. To the extent that such subject matter can be patent-protected in India,⁶⁶¹ reliance on the experimental/research use exemption from infringement liability may provide immunity from patent infringement liability for the ever-growing volume of

655. See TRIPS, *supra* note 3, Art. 31(h) (mandating that "the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization").

656. See The Patents Act, No. 39 of 1970, § 91(3) (Universal 2005) (amended 2005).

657. See generally Janice M. Mueller, *The Evanescent Experimental Use Exemption from United States Patent Infringement Liability: Implications for University/Nonprofit Research and Development*, 56 BAYLOR L. REV. 917 (2004).

658. The Patents Act, No. 39 of 1970, § 47(3) (Universal 2005) (amended 2005).

659. See Mueller, *supra* note 657, at 920 n.10.

660. See Jonathan D. Glater, *Offshore Services Grow in Lean Times*, N.Y. TIMES, Jan. 3, 2004, at C1; Steve Lohr, *Many New Causes for Old Problem of Jobs Lost Abroad*, N.Y. TIMES, Feb. 15, 2004, at 17 (citing 2002 Forrester Research study predicting that 3.3 million service jobs in the United States will move offshore by 2015, and that about 500,000 of these jobs will be in the computer software and services sector).

661. See The Patents Act, No. 39 of 1970, § 3(k) (Universal 2005) (amended 2005) (providing that "a mathematical or business method or a computer programme *per se* or algorithms" are not inventions within the meaning of the Act) (emphasis in original); Interview with P.K. Patni, *supra* note 416 (observing that software embedded in hardware can be claimed if a technical application exists therefor).

software development taking place in India. The existence of the experimental/research use exemption may also be a factor (albeit one of many) that will continue to motivate U.S. firms to outsource innovative software development to India, rather than to conduct such development in the U.S. without the statutory shield of an experimental/research use exemption.

2. *Data Gathering for Regulatory Approval*

India's Patents Act, 1970 (2005) includes a provision that parallels Section 271(e)(1) of the U.S. Patent Act (the "*Bolar* exemption"). The exemption was made part of U.S. patent law pursuant to the Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Act").⁶⁶² Enacted to legislatively overrule the Federal Circuit's decision in *Roche Prods., Inc. v. Bolar Pharm. Co.*,⁶⁶³ the exemption provides *inter alia* that the use of a patented invention solely for purposes reasonably related to gathering data in support of an application seeking U.S. Food and Drug Administration (FDA) approval for the manufacture and sale of a generic version of a previously FDA-approved drug (*i.e.*, an "Abbreviated New Drug Application" or ANDA) is *not* an act of U.S. patent infringement.⁶⁶⁴ Without such a provision, a generic drug manufacturer would have to wait to begin testing of an equivalent drug until after the relevant patent had expired, giving the patentee of the branded drug a *de facto* extension of the patent term.⁶⁶⁵

The parallel Indian provision is broader in scope than its U.S. counterpart. The Indian *Bolar* exemption provides:

For the purposes of this Act, . . . any act of making, constructing, using, selling or importing a patented invention solely for uses reasonably related to the development and submission of information required under any law for the time being in force, in India,

662. Pub. L. No. 98-417, 98 Stat. 1585 (1984).

663. 733 F.2d 858 (Fed. Cir. 1984).

664. See 35 U.S.C. § 271(e)(1) (2006), which provides in pertinent part:

It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs

665. The section 271(e)(1) safe harbor is not limited to testing conducted by generic drug manufacturers, however. The U.S. Supreme Court recently interpreted the scope of § 271(e)(1) in *Merck KgaA v. Integra Lifesciences I, Ltd.*, 125 S. Ct. 2372, 2380 (2005), and held it broad enough to encompass clinical (human) trials as well as pre-clinical (test tube and laboratory animal) testing activity associated with the development of new (or "pioneer") drugs.

or in a country other than India, that regulates the manufacture, construction, use, sale or import of any product . . . shall not be considered as a infringement of patent rights.⁶⁶⁶

This Indian version of the *Bolar* provision broadly exempts unlicensed data gathering uses of patented inventions for purposes of seeking regulatory approval to market *any* product (not just drugs) in *any* country. The exemption's applicability to data gathering for purposes of regulatory approval by foreign countries obviously reflects the fact that Indian companies now routinely seek approval from the U.S. FDA to sell generic drugs in the U.S. market.⁶⁶⁷ The breadth of products for which regulatory approval is sought (i.e., "any product") is also broader than the U.S.' *Bolar* exemption, which is limited to approval under U.S. federal law of "drugs" (or "veterinary biological products").⁶⁶⁸ The Indian provision's applicability to regulatory approval of "any product" likely recognizes that even in the U.S., the *Bolar* exemption's literal terms have been expanded through judicial decision; i.e., the U.S. courts have given the statutory term "drugs" some extra-literal scope by deeming it to include medical devices.⁶⁶⁹

3. *Parallel Imports*

India's new Patents Act adopts the principle of international exhaustion of patent rights; i.e., that once a patented product has been sold with the patentee's authority outside of India, the subsequent importation of that same patented item into India is not an act of infringement of the Indian patent. But the new Patents Act goes even further, by shielding importation of products acquired from sources other than the patentee in countries not yet recognizing product patent protection. Section 107A(b) of the Act 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

666. The Patents Act, No. 39 of 1970, § 107A(a) (Universal 2005) (amended 2005).

667. For example, Ranbaxy has filed more than 110 ANDAs with the U.S. Food and Drug Administration. See RANBAXY LABS. LTD., ANNUAL REPORT 2005, at 7, available at <http://www.ranbaxy.com/ar2005/ar2005.pdf>. Doctor Reddy's Laboratories Ltd. (DRL) has filed seventy ANDAs. See DR. REDDY'S LABORATORIES LTD., ANNUAL REPORT 2005-06, at 6, available at <http://www.drreddys.com/investors/pdf/annualreport2006.pdf>.

668. See 35 U.S.C. § 271(e)(1) (2006).

669. See *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 679 (1990) (affirming Federal Circuit's interpretation of 35 U.S.C. § 271(e)(1) as broad enough to encompass not only regulatory data gathering on pharmaceuticals, but also the comparable testing of medical devices).

be considered as a infringement of patent rights.”⁶⁷⁰ Two examples will illustrate the potentially very broad scope of this provision.

First, consider a hypothetical MNC that obtains a patent on a pharmaceutical product in India and also sells the same product more cheaply outside of India, for example in South Africa. A third party who purchases the product from the patentee (or its agent) in South Africa and imports it into India for re-sale there would not be liable under Section 107A(b) for infringement of the Indian patent.⁶⁷¹ This result is consistent with the traditional view of international exhaustion as one in which the patentee has obtained its “reward” by a first sale anywhere in the world.

Second, consider again the same hypothetical MNC having obtained a patent on a pharmaceutical product in India. In this variation, however, the same product is being sold by an independent source (i.e., one not connected with the patentee) in a least-developed country, for example Bangladesh, that is not yet required under TRIPS to provide pharmaceutical product patent protection.⁶⁷² In the absence of patent protection in Bangladesh, the source company is, within the language of Section 107A(b), “duly authorised under the law to produce and sell or distribute the product.”⁶⁷³ In other words, the source company can make and sell the product in Bangladesh without restriction. A third party who then purchases the product from the source in Bangladesh and imports it into India for re-sale there likewise would not be liable under Section 107A(b) for infringement of the Indian patent.

It has been suggested that Indian generic drug manufacturers could capitalize on the breadth of this provision “by shifting their manufacturing base to neighboring LDCs such as Bangladesh (which have time till 2015 to shift to a pharmaceutical product patents regime) and importing the same into India.”⁶⁷⁴ Such a strategy is not far-fetched. In fact, generic pharmaceutical production is already well established in Bangladesh. For example, Beximco,

670. The Patents Act, No. 39 of 1970, § 107A(b) (Universal 2005) (amended 2005).

671. This first hypothetical is consistent with the narrower scope of the pre-2005 version of the parallel imports provision. Prior to The Patents (Amendment) Act of 2005, the provision read as follows: “importation of patented products by any person from a person who is duly authorised *by the patentee* to sell or distribute the product, shall not be considered as a infringement of patent rights.” The Patents (Amendment) Act, No. 38 of 2002, §107A(b), *available at* <http://indiacode.nic.in> (emphasis added). The statutory language “who is duly authorised by the patentee to sell or distribute the product” was changed to “who is duly authorised under the law to produce and sell or distribute the product” by The Patents (Amendment) Act, No. 15 of 2005, § 58(b), (Universal 2005).

672. See TRIPS, *supra* note 3, Art. 66.1; *Declaration on the TRIPS Agreement and Public Health*, *supra* note 631, ¶ 7.

673. The Patents Act, No. 39 of 1970, § 107A(b) (Universal 2005) (amended 2005).

674. Basheer, *supra* note 555, at 10.

the leading generic drug manufacturer in Bangladesh, has already launched production of “Oseflu,” its version of the bird flu anti-viral Tamiflu,⁶⁷⁵ which is the subject of pending patent applications in India that are assigned to Hoffman-La Roche.⁶⁷⁶

Although most developed country patent regimes have refused to adopt the notion of international exhaustion of patent rights,⁶⁷⁷ the developing and least developed world strongly favors the concept as a means of ensuring access for its citizens to lower-cost drugs. Because the Uruguay Round debates over international exhaustion were so contentious, the TRIPS Agreement was ultimately left silent on this issue,⁶⁷⁸ providing that “[f]or the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 [national treatment] and 4 [most-favoured-nation treatment] nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.”⁶⁷⁹

If called upon to defend the legitimacy of its broad Section 107A(b) shield from infringement, India may need to rely on more than simply the silence of TRIPS. The dispute will turn on the scope and meaning of “exhaustion.” Shamnad Basheer has suggested that India’s Section 107A(b) provision violates TRIPS because by “go[ing] even beyond ‘exhaustion’ (i.e. there is no requirement that the patentee have sold the good in the country

675. See Lisa Urquhart, *Product Launches Give Beximco a Lift*, FIN. TIMES (London, England), May 3, 2006, at 22.

676. See *supra* note 535 and accompanying text.

677. For example, U.S. patent case law rejects the concept of international exhaustion of patent rights. See *Jazz Photo Corp. v. U.S. Int’l Trade Comm’n*, 264 F.3d 1094 (Fed. Cir. 2001) (confirming that “United States patent rights are not exhausted by products of foreign provenance”). Countries within the European Union are bound by decisions of the European Court of Justice (ECJ), which have thus far rejected attempts by individual member states to adopt international exhaustion in domestic intellectual property laws. See, e.g., Case C-355/96, *Silhouette International Schmied GmbH & Co. KG v. Hartlauer Handelsgesellschaft mbH*, 1998 E.C.R. I-4799. Among the leading developed country patent systems, Japan is an exception in this regard, its Supreme Court having recognized international exhaustion of patent rights in *BBS Kraftfahrzeug Technik AG v. Kabushiki Kaisha Racimex Japan and Kabushiki Kaisha JapAuto Prods.*, Case No. Heisei 7(wo)1988 (1997), available at <http://www.okuyama.com/c3v01ok.htm> (English translation).

678. See UNITED NATIONS CONFERENCE ON TRADE AND DEVELOPMENT-INTERNATIONAL CENTRE FOR TRADE AND SUSTAINABLE DEVELOPMENT, *RESOURCE BOOK ON TRIPS AND DEVELOPMENT* 97-98 (Cambridge Univ. Press 2005) (observing that during Uruguay Round negotiations in neither the WTO nor the WIPO “did governments come close to agreeing on uniform treatment of the exhaustion question”); Vincent Chiappetta, *The Desirability of Agreeing to Disagree: The WTO, TRIPS, International IPR Exhaustion and a Few Other Things*, 21 MICH. J. INT’L L. 333, 346 (2000) (explaining that issue of international exhaustion was “hotly debated” by TRIPS negotiators but “[e]ventually the exhaustion discussion exhausted the negotiators”).

679. TRIPS, *supra* note 3, Art. 6 (titled “Exhaustion”).

from where it is exported),”⁶⁸⁰ the provision “virtually extinguishes the exclusive right to import.”⁶⁸¹ India may counter that it is merely making the most of the flexibilities provided by TRIPS, particularly in view of the explicit recognition in the Doha Ministerial’s *Declaration on the TRIPS Agreement and Public Health* that “[t]he effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.”⁶⁸²

H. Process Patent Infringement

Consistent with the obligation imposed by Article 34 of the TRIPS Agreement, the 2002 amendments to India’s Patents Act implemented a provision for burden-shifting in the case of alleged infringement of a process patent. Under Section 104A of the current Patents Act, 1970 (2005),⁶⁸³ when the owner of the process patent in suit establishes that the product of the accused infringer is identical to that obtained by the patented process, the court under either of two conditions may order the burden of proof shifted to the accused infringer to disprove that its process is different from the patented process. Those conditions are that (a) the patented process is one that obtains a new product,⁶⁸⁴ or, more typically, that (b) there is a substantial likelihood

680. Basheer, *supra* note 555, at 11.

681. *Id.* at 10. See also TRIPS, *supra* note 3, Art. 28(1)(a) (including “importing” within the exclusive rights of a product patent owner).

682. *Declaration on the TRIPS Agreement and Public Health*, *supra* note 631, ¶ 5(d).

683. The text of Section 104A reads in full:

Burden of proof in case of suits concerning infringement.—(1) In any suit for infringement of a patent, where the subject matter of patent is a process for obtaining a product, the court may direct the defendant to prove that the process used by him to obtain the product, identical to the product of the patented process, is different from the patented process if,—

(a) the subject matter of the patent is a process for obtaining a new product; or
(b) there is a substantial likelihood that the identical product is made by the process, and the patentee or a person deriving title or interest in the patent from him, has been unable through reasonable efforts to determine the process actually used:

Provided that the patentee or a person deriving title or interest in the patent from him first proves that the product is identical to the product directly obtained by the patented process.

(2) In considering whether a party has discharged the burden imposed upon him by sub-section (1), the court shall not require him to disclose any manufacturing or commercial secrets, if it appears to the court that it would be unreasonable to do so.

The Patents Act, No. 39 of 1970, § 104A (Universal 2005) (amended 2005).

684. See *id.* § 104A(1)(a).

that the accused infringer is using the patented process and that the patent owner has been unable through reasonable efforts to determine the process actually used by the accused infringer.⁶⁸⁵

V. IMPLEMENTATION OF INDIA'S NEW PATENTS REGIME

A serious question exists as to whether India has the institutional capacity in place to support its newly strengthened patent system. This Part critically examines the implementation issue for each of the key actors in the new patents regime: (1) the Indian Patent Office, which examines patent applications and grants patents, adjudicates oppositions and revocation proceedings, and considers applications for compulsory licenses; and (2) the Indian court system, which tries cases alleging infringement and invalidity of issued patents.

A. *Administrative Capacity: Indian Patent Office*

This section explains the Patent Office's place in India's governmental structure and its institutional capacity in terms of physical facilities and human resources. This section also overviews the patent examination process in India, comparing it to U.S. practice; presents data on the current and anticipated levels of patenting activity and Indian Patent Office backlog; and describes the newly-created Patent Appellate Board.

1. *Political Structure*

The Indian Patent Office operates under the auspices of the Office of the Controller General of Patents, Designs and Trademarks & Registrar of Geographical Indications.⁶⁸⁶ The Office of the Controller General is part of the Indian Department of Industrial Policy & Promotion, which is in turn part of the Indian Ministry of Commerce & Industry.⁶⁸⁷ "The Controller of Patents, as well as the various examiners and other officers are appointed by the Central Government."⁶⁸⁸

685. *See id.* § 104A(1)(b).

686. *See* ANNUAL REPORT 2004-2005, *supra* note 14, at 6 (organizational chart).

687. *See id.*

688. Shammad Basheer, "Policy Style" Reasoning at the Indian Patent Office, INTELL. PROP. Q., No. 3 (2005), at 309, 319, available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=829464.

The powers given to the Controller of Patents under India's Patents Act, 1970 (2005) are remarkably broad in comparison to those of the Director of the U.S. Patent and Trademark Office.⁶⁸⁹ The following is a partial list of the enumerated powers of India's Controller:

¶¶ Upon receipt of an examiner's report that is adverse to the applicant or requires amendment of the application, the Controller "shall communicate as expeditiously as possible the gist of the objections to the applicant and shall, if so required by the applicant within the prescribed period, give him an opportunity of being heard",⁶⁹⁰

¶¶ When the Controller is satisfied that an application does not comply with the Patents Act or Patents Rules, he may refuse the application or require that it be amended to his satisfaction,⁶⁹¹

¶¶ The Controller may require an application to be divided if he concludes that its claims relate to more than one invention,⁶⁹²

¶¶ If it appears to the Controller that the practice of an invention claimed in a pending application would infringe another patent, he has the power to require that the application include a statement making reference to the potentially infringed patent, as a way of giving notice to the public.⁶⁹³ The applicant can avoid having to add this reference if it can establish to the Controller's satisfaction that reasonable grounds exist for questioning the allegedly infringed patent's validity,⁶⁹⁴ or if it otherwise amends the application to the Controller's satisfaction,⁶⁹⁵

¶¶ The Controller decides pre-grant oppositions, after a hearing if requested by the opposer;⁶⁹⁶

¶¶ Post-grant oppositions are initially heard by an Opposition Board constituted by order of the Controller;⁶⁹⁷ the Controller ultimately decides the post-grant opposition after receiving the recommendations of the Opposition Board and after affording the patentee and the opponent a hearing;⁶⁹⁸

689. *See generally* 35 U.S.C. § 2 (2006) ("Powers and Duties"); 35 U.S.C. § 3(a) (2006) ("Under Secretary and Director").

690. The Patents Act, No. 39 of 1970, § 14 (Universal 2005) (amended 2005).

691. *See id.* § 15.

692. *See id.* § 16.

693. *See id.* § 19(1).

694. *See id.* § 19(1)(a).

695. *See id.* § 19(1)(b).

696. *See id.* § 25(1).

697. *See id.* § 25(3) (b)-(c).

698. *See id.* § 25(4).

¥¥ The Controller has broad powers in deciding whether and on what terms to grant applications for compulsory licenses, as detailed *supra*;⁶⁹⁹

¥¥ When a compulsory license has been granted and in effect for more than two years, the Controller has the power to order the revocation of a patent for non-working in India;⁷⁰⁰

¥¥ The Controller also has broad evidentiary powers in carrying out his adjudicatory functions; in any proceedings before him under the Patents Act the Controller has certain powers of a civil court,⁷⁰¹ including the power to summon and enforce the attendance of any person and to examine that person under oath,⁷⁰² and to require the discovery and production of documents.⁷⁰³

Another notable feature of the Indian Patent Office is that it comprises four branch offices: Kolkata (formerly known as Calcutta), which is designated the “Head Office”; New Delhi; Chennai (formerly known as Madras); and Mumbai (formerly known as Bombay).⁷⁰⁴ The multiple-branch structure for a patent office is currently unique in the world.⁷⁰⁵ Indian residents file patent applications in the appropriate Patent Office branch for the state in which they reside or have a principal place of business.⁷⁰⁶ For a non-residents of India, the appropriate branch for filing is determined by “the address for service in India or principal place of business of his agent”⁷⁰⁷

The office of the Controller General of Patents, Designs & Trade Marks is located in Mumbai.⁷⁰⁸ Each of the four branch offices is headed by a Deputy or Assistant Controller of Patents & Designs.⁷⁰⁹

699. See *supra* Part IV.F.

700. See The Patents Act, No. 39 of 1970, § 85(3) (Universal 2005) (amended 2005).

701. See *id.* § 77(1).

702. See *id.* § 77(1)(a).

703. See *id.* § 77(1)(b).

704. See ANNUAL REPORT 2004-2005, *supra* note 14, at 6. Although all four branches accept utility patent applications, only the Kolkata branch accepts design applications. See *id.*

705. See *id.* at 3.

706. See UNIVERSAL’S THE PATENTS ACT, 1970, AS AMENDED BY THE PATENTS (AMENDMENT) ACT, 2005, at 167 (Universal Law Publishing Co. Pvt. Ltd., Delhi) (2005) (providing table titled “Territorial Jurisdiction of Appropriate Office for the Applicants”).

707. *Id.* Many foreign patent applicants reportedly select local counsel in New Delhi or Mumbai. If patent applications filed in those branches of the Patent Office are refused, appeals can be taken to the Delhi or Bombay High Courts, at least until the new Patent Appellate Board becomes operational. See *infra* Part V.A.5. The Delhi and Bombay High Courts are generally considered superior in terms of their handling of patent and business cases. See Interview with Krishna Sarma, *supra* note 126.

708. See Controller General of Patents, Designs and Trade Marks, *Addresses and Name of the Contact Persons of the Intellectual Property Offices*, available at http://patentoffice.nic.in/ipr/patent/ipo_office_add.htm (last visited June 10, 2006).

709. See *id.*

2. *Institutional Capacity*

a. *Physical Facilities*

India's physical facilities for implementation of its strengthened patents regime are quite impressive. The Government of India has funded a \$28 million modernization project⁷¹⁰ resulting in new buildings for each of the four Patent Office branches.⁷¹¹ New buildings are complete in Kolkata, Chennai, and Delhi; the Mumbai building is at an "advance[d] stage" of construction.⁷¹²

Computerization efforts are far less advanced than the brick-and-mortar improvements of the Patent Office branches. As of November 2005, Indian patent examiners had Internet access to public domain databases of prior art, but did not have the means to electronically search any proprietary databases.⁷¹³ Indian patent applications must still be filed on paper; plans for electronic filing have not yet been implemented due to contract disputes.⁷¹⁴ The Patent Office does receive some assistance of the Patent Information System (PIS), established by the government in 1980 under the auspices of the Controller General as a repository of patent information.⁷¹⁵ Located in Nagpur, India, the PIS provides full-text access to U.S., U.K., European Patent Office, PCT and Japanese patents and published applications via microfilm and CD-ROM as well as paper copies of Indian patents issued from 1912 onwards.⁷¹⁶ The PIS also provides various computerized tools such as INPADOC for searching patent bibliographic data.⁷¹⁷

710. See *India IP Office Gets Revamp*, MANAGING INTELL. PROP. (Sept. 5, 2005) available at <http://www.managingip.com> (reporting that the "Commerce and Industry Department said that the government had spend Rs1.24 billion (\$28 million) on the project to modernize India's IP offices").

711. See Indian Patent Office, *Intellectual Property: Initiatives and Status*, available at http://patentoffice.nic.in/ipr/patent/ip_ini_status.htm (last visited June 10, 2006).

712. See ANNUAL REPORT 2004-2005, *supra* note 14, at 4 (providing photographs of completed buildings at Kolkata, Chennai and Delhi).

713. See Interview with P.K. Patni, *supra* note 416.

714. See *id.*

715. See Indian Patent Office, *Office of the Patent Information System*, available at <http://patentoffice.nic.in/ipr/pis/pis.htm> (last visited June 10, 2006).

716. See *id.*

717. See *id.*

b. Human Resources

Prior to FY 2001-02 the Indian Patent Office never examined more than 5,000 patent applications in a single year.⁷¹⁸ With the new pharmaceutical product patents regime in place, patent application filings sharply on the rise, and a rapidly mounting number of pre-grant oppositions to contend with, the question of adequate levels of patent examining staff becomes much more pressing. Commentators are already questioning the Office's capacity to adequately deal with the strengthened patents regime.⁷¹⁹ India's IP system previously has been characterized as "notoriously inefficient,"⁷²⁰ and government officials seem eager to shed this negative image. Inaugurating the new Patent Office branch facility in New Delhi, Indian Commerce Minister Nath exhorted IP officials that they "must now ensure delivery of services in an equally efficient and transparent manner, befitting the working environment."⁷²¹

Current examiner staffing levels appear grossly inadequate for the onslaught of mailbox applications now awaiting examination,⁷²² a concern reportedly expressed by Indian government officials.⁷²³ According to Patent Office officials and as confirmed by the Office's ANNUAL REPORT 2004-2005, a total of 164 patent examiners were employed in the four branches of the Indian Patent Office in 2005 (not including senior staff positions such as Deputy and Assistant Controllers).⁷²⁴ It is unknown how many of these

718. See *infra* Figure 3.

719. See, e.g., Sreenivasarao Vepachedu & Martha Rumore, *Patent Protection and the Pharmaceutical Industry in the Indian Union*, INTELL. PROP. TODAY, Oct. 2004, at 46 (stating that "the inadequate patent office capacity level in India to ensure the application of patent criteria and examination of patent examinations" presents one of several challenges to implementation of the new patent laws, and noting that despite some modernization including computerization, "a backlog of patent applications still exists" in the Indian Patent Office).

720. See *India IP Office Gets Revamp*, *supra* note 710. However, the perceived inefficiency may be more an aspect of India's mishandling of trademark applications than patent applications. See *id.* (noting that India's Trade Mark Registry was ranked "worst in the world" for "two years running" in the MANAGING INTELLECTUAL PROPERTY Trade Mark Poll).

721. *Id.*

722. For data on mailbox applications, see Part II.C.2.

723. See P.T. Jyothi Datta, *First Phase Scrutiny to Cover 3,000 Drug Patent Requests*, HINDU BUS. LINE, Jan. 4, 2006, available at <http://www.blonnet.com/2006/01/05/stories/2006010503340100.htm> (citing anonymous ministry official expressing "concerns on the shortage of examiners and other technical staff" and Indian Patent Office's "problem retaining or attracting talent").

724. See Interview with K.S. Kardam, *supra* note 175 (stating that the "India IP Office now employs a total of 150-160 examiners, but 210 are budgeted, so we are recruiting"). See also ANNUAL REPORT 2004-2005, *supra* note 14, at 21 (Appendix A) ("Statement of Staff Strength As On 31st March, 2005" listing 150 examiner posts as "Working Strength" under heading "Post Under Modernization Project" and

examiners have experience or training in the chemical arts, but Patent Office officials have admitted that the Office needs more chemical examiners.⁷²⁵

Recruiting efforts appear to be underway, or at least contemplated. The total “sanctioned strength” for Indian patent examiner positions as of March 31, 2005 was 212 positions,⁷²⁶ so it appears that the Office has authorization to hire at least about fifty new examiners. The numbers may be higher; the Indian press has reported that “[t]he government is in the process of recruiting nearly 300 patent examiners.”⁷²⁷

Training for Indian patent examiners is provided to some degree through the Intellectual Property Training Institute (IPTI) in Nagpur, which provides courses that “aim to improve the legal and technical ability of examiners and to enhance the qualitative level of the examination.”⁷²⁸ The degree of formal training available beyond the IPTI courses is unknown.

3. *Patent Examination Procedure*

Figure 2 below provides a flow-chart of prosecution procedures in the Indian Patent Office. Key features are highlighted below and compared to U.S. practice; additional details are provided in the India Patents Rules, 2003 (2006)⁷²⁹ and the Indian MANUAL OF PATENT PRACTICE AND PROCEDURE.⁷³⁰

fourteen examiner posts as “Working Strength” under heading “Regular”).

725. See Interview with K.S. Kardam, *supra* note 175.

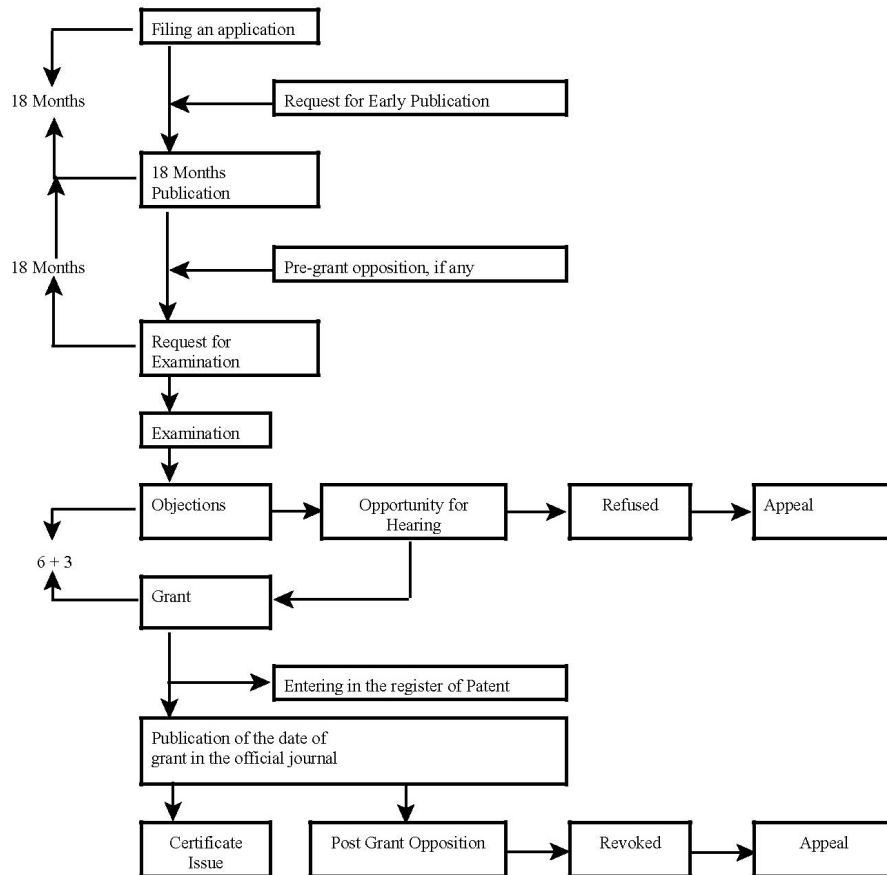
726. See ANNUAL REPORT 2004-2005, *supra* note 14, at 21 (Appendix A) (“Statement of Staff Strength As On 31st March, 2005” listing 190 examiner posts as “Sanctioned Strength” under heading “Post Under Modernization Project” and 22 examiner posts as “Sanctioned Strength” under heading “Regular”).

727. Adarsh SV, *Harmonised Global Patent Search May Become a Reality*, FIN. EXPRESS, Aug. 20, 2005, available at http://www.financialexpress.com/fe_full_story.php?content_id=99772#.

728. See ANNUAL REPORT 2004-2005, *supra* note 14, at 71 (describing “Training Programme for Examiners of Patents and Designs”).

729. See *supra* note 184.

730. MPPP, *supra* note 374.

Figure 2. Indian Patent Office Examination Procedure⁷³¹

Patent applications are typically filed with the Indian Patent Office in the English language. Although Hindi and English are both official languages of the Office,⁷³² translation of applications or patents from English to Hindi is not required.⁷³³ International applications filed under the PCT in other languages

731. Adapted from *Intellectual Prop. India, Dep't of Indus. Policy and Promotion, Gov't of India, PATENT OFFICE* (Nov. 2005) (brochure on file with author).

732. See MPPP, *supra* note 374, § 5.13(iii).

733. See Patrick Mirandah, *Enforcement of Patent Rights in India and South East Asia: A Comparative Analysis*, BNA WORLD INTELL. PROP. REP. (June 2006) (noting that India, along with Malaysia, Singapore, and the Philippines, “do[es] not require the translation of the patent specifications if they are in English”).

must be accompanied by an English language translation in order to enter national phase examination in India.⁷³⁴

Consistent with current U.S. practice,⁷³⁵ India facilitates claims of domestic priority via the filing of provisional applications (for “ordinary” applications, not those filed as PCT national phase applications or as “convention” applications claiming the benefit of an earlier foreign priority date under the Paris Convention).⁷³⁶ The provisional application need not include any claims; it must merely provide a description of the invention and a title.⁷³⁷ Provided that a complete [i.e., non-provisional] specification is filed within the subsequent twelve months, each claim thereof that is “fairly based on the matter disclosed in the [provisional] specification” will be assigned the priority date on which the provisional specification was filed.⁷³⁸ The complete specification must conclude with one or more claims⁷³⁹ and notably, in addition to a full and particular description of the invention and its use,⁷⁴⁰ must disclose “the best method of performing the invention which is known to the applicant and for which he is entitled to claim protection.”⁷⁴¹

Several important differences exist between Indian and U.S. patent filing and examination procedures. As depicted in Figure 2 above, substantive examination will not begin in the Indian Patent Office until the applicant (or other interested person) files a request for examination subsequent to publication (at 18 months or earlier) of the application in question.⁷⁴² A separate filing fee is due in connection with the request for examination.⁷⁴³ Under the most recent amendments to India’s Patents Rules, an applicant now has up to 48 months after the application’s filing or priority date in which to make the request.⁷⁴⁴ Applications for which a request for examination is not

734. See MPPP, *supra* note 374, § 5.13(iii).

735. The filing of a provisional application in the USPTO is governed by 35 U.S.C. § 111(b) (2000).

736. See The Patents Act, No. 39 of 1970, § 9(1) (Universal 2005) (amended 2005).

737. See *id.* § 10(1).

738. See *id.* § 11(2).

739. See *id.* § 10(4)(c).

740. See *id.* § 10(4)(a).

741. *Id.* § 10(4)(b). In contrast with India’s retention of a best mode requirement, recent U.S. patent law reform efforts contemplate elimination of the requirement. If enacted into law, the U.S. Patent Reform Act of 2005 would repeal the best mode requirement currently set forth in 35 U.S.C. § 112, ¶ 1. See H.R. 2795, 109th Congress, § 4(d)(1)(B) (2005).

742. See The Patents Act, No. 39 of 1970, § 11B(1) (Universal 2005) (amended 2005) (providing that “[n]o application for a patent shall be examined unless the applicant or any other interested person makes a request in the prescribed manner for such examination within the prescribed period”).

743. See ANNUAL REPORT 2004-05, *supra* note 14, at 30 (Appendix G, item 5).

744. See The Patents (Amendments) Rules, 2006, *supra* note 184, § 8(a)(i) (amending time limit from previous thirty-six months to new forty-eight months).

made within that period are considered withdrawn.⁷⁴⁵ When the request for examination has been timely filed, the Controller refers the application to an examiner who will make an examination report to the Controller.⁷⁴⁶ The Patents Rules now specify that a first examination report must ordinarily be issued to the applicant within six months of her request for examination.⁷⁴⁷

Figure 2 above includes the notation “6 + 3” between the arrows connecting “Objections” to “Grant,” which notation referred to the time periods provided under the 2005 version of India’s Patents Rules for responding to the examiner’s report. The “6 + 3” notation indicated that the applicant had six months after receiving the examiner’s first statement of objection in which to put the application in order for grant,⁷⁴⁸ with an additional three-month extension of time available upon request “in circumstances beyond the control of the applicant.”⁷⁴⁹ The “6 + 3” notation is no longer correct. The 2006 amendments to the Patents Rules, which took effect May 5, 2006, mandate that “the time for putting an application in order for grant under section 21 [of the Patents Act] shall be twelve months from the date on which the first statement of objection is issued to the applicant to comply with the requirements.”⁷⁵⁰ No extension of time beyond the twelve months is available under the current Patent Rules.

Figure 2 above also depicts “18 Months Publication,” but the Indian notion of “publication” in this context is far less transparent than that of U.S. and European patent practice. At eighteen months after an application’s filing or priority date,⁷⁵¹ or earlier if the applicant so requests,⁷⁵² the Indian Patent Office posts a one-page summary of data concerning the application on the

745. See The Patents Act, No. 39 of 1970, § 11B(4) (Universal 2005) (amended 2005).

746. See *id.* § 12(1).

747. See The Patents (Amendments) Rules, 2006, *supra* note 184, § 8(c) (amending Rule 24B(3)).

748. See The Patents Rules, 2003 (Universal 2005), *supra* note 184, § 24B(4)(i).

749. See *id.* § 24B(4)(ii).

750. The Patents (Amendments) Rules, 2006, *supra* note 184, § 8(d) (substituting new language for prior Rule 24B(4)(i)-(ii)).

751. See The Patents Act, No. 39 of 1970, § 11A(3) (Universal 2005) (amended 2005); The Patents Rules, 2003 (Universal 2005), *supra* note 184, § 24 (providing that “[t]he period for which an application for patent shall not ordinarily be open to public under sub-section (1) of section 11A shall be eighteen months from the date of filing of application or the date of priority of the application, whichever is earlier”). The 2006 amendments to the Patents Rules extended the Controller’s window for publication. See The Patents (Amendment) Rules, 2006, *supra* note 184, § 7 (adding the following proviso in rule 24 of the principal rules: “Provided that the period within which the Controller shall publish the application in the Journal shall ordinarily be one month from the date of expiry of said period, or one month from the date of request for publication under rule 24A.”).

752. See The Patents Act, No. 39 of 1970, § 11A(2) (Universal 2005) (amended 2005).

Internet via its weekly on-line *Official Journal*.⁷⁵³ The application summary “shall include the particulars of the date of application, number of application, name and address of the applicant identifying the application and an abstract,”⁷⁵⁴ but does not include any claims. After the application summary has been published, “the patent office may, on payment of such fee as may be prescribed, make the specification and drawings, if any, of such application available to the public.”⁷⁵⁵ The Patent Office’s website confirms that copies of “accepted Indian patent specification[s] (in paper form)” are available for 30 rupees “per specification (Printed)” at any of the Office’s four branches.⁷⁵⁶ Thus, it is currently impossible to access in electronic form the full text of a patent application filed in the Indian Patent Office.⁷⁵⁷

Another major difference between Indian Patent Office practice and that of the U.S. (and other developed countries) is the availability of pre-grant opposition, as depicted in Figure 2 above. Part IV.D.1 of this article discussed pre-grant opposition in greater detail and the specifics will not be repeated here. The potential for pre-grant opposition to significantly extend patent application pendency is self-evident.

Also in contrast with U.S. practice, maintenance fees (termed “renewal fees”) for Indian patents are due every year beginning in the second year after grant.⁷⁵⁸ Like the U.S. system, however, India’s renewal fees are progressively higher in the later years of a patent’s life.⁷⁵⁹

753. Weekly issues of the *Official Journal* are available at [HTTP://patentoffice.nic.in/ipr/patent/journal_archive/journal_2006/patent_journal_2006.htm](http://patentoffice.nic.in/ipr/patent/journal_archive/journal_2006/patent_journal_2006.htm) (last visited June 21, 2006).

754. The Patents Act, No. 39 of 1970, § 5 (Universal 2005) (amended 2005). Unfortunately the four branch offices of the Indian Patent Office have not adopted a uniform format for supplying even this limited information. For example, application summaries from the Kolkata and Mumbai branch clearly indicate whether the application in question was a mailbox application filed during the TRIPS transition period under then-Section 5(2) of the Patents Act; application summaries from the New Delhi and Chennai branches do not. See, e.g., The Indian Patent Office, *Official Journal*, May 23, 2006, available at http://patentoffice.nic.in/ipr/patent/journal_archive/journal_2006/pat_arch_062006/official_journal_23062006.pdf (contrasting summaries of Application No. 00081/KOL/2004 [PDF page 315] and Application No. 74/MUM/2004 [PDF page 109] with summaries of Application No. 686/CHE/2004A [PDF page 97] and Application No. 1038/DEL/2004 [PDF page 121]).

755. The Patents Act, No. 39 of 1970, § 6(b) (Universal 2005) (amended 2005).

756. See Intellectual Property India, *Publications of Patent Office* (item 2), available at <http://patentoffice.nic.in/ipr/patent/publications.htm> (last visited June 21, 2006).

757. Of course, the full text of international applications filed and published in accordance with the PCT and designating India can be viewed at the WIPO’s electronic search facility, available at <http://www.wipo.int/pctdb/en/> (last visited Aug. 14, 2006).

758. See The Patents Act, No. 39 of 1970, § 53(2) (Universal 2005) (amended 2005); The Patents Rules, 2003 (Universal 2005), *supra* note 184, sched. 1, at entry 17(i)-(xvii) (listing annual renewal fees).

759. See The Patents Rules, 2003 (Universal 2005), *supra* note 184, sched. 1, at entry 17(i)-(xvii).

Lastly, like the rest of the world other than the U.S., India operates on a first-to-file system for determining time-wise priority between rival inventors. In other words, if two applicants independently filed Indian patent applications directed to the same invention, the application with the earlier filing date will be granted (all other patentability criteria being satisfied) because it would anticipate the claims of the application with the later filing date. This is most clearly illustrated by Section 13 of India's Patents Act, which provides that an invention claimed in a complete specification is considered anticipated if it was disclosed "before the date of filing of the applicant's complete specification in any specification filed in pursuance of an application for a patent made in India"⁷⁶⁰ or if it was "claimed in any claim of any other complete specification published on or after the date of filing of the applicant's complete specification," where the other specification was filed "in pursuance of an application for patent made in India" and entitled to the benefit of a filing date earlier than the applicant's filing date.⁷⁶¹

4. Increasing Number of Filings and Application Pendency

The volume of patent applications filed in India has increased dramatically since the nation joined the WTO. Figure 3 below sets forth the number of patent applications filed, examined, and granted by the Indian Patent Office for a ten-year period spanning April 1, 1995 to March 31, 2005. Although the approximately 17,500 patent applications filed in India in FY 2004-05 is still a minuscule number by U.S. standards,⁷⁶² it represents a 148% increase over the ten-year period depicted in Figure 3.⁷⁶³

760. The Patents Act, No. 39 of 1970, § 13(1)(a) (Universal 2005) (amended 2005).

761. *Id.* § 13(1)(b).

762. By comparison, over 400,000 patent applications were filed in the U.S. Patent and Trademark Office during FY 2005. See 2005 USPTO, Performance & Accountability Rep., tbl. 2, available at http://www.uspto.gov/web/offices/com/annual/2005/060402_table2.html (reporting for FY 2005 that a total of 409,532 patent applications were filed, comprising 381,797 utility patent applications, 25,304 design patent applications, 1,288 plant patent applications, and 1,143 reissue applications).

763. See ANNUAL REPORT 2004-2005, *supra* note 14, Appendix C, at 27 (showing a 148% increase in 2004-05 filings of 17,466 over 1995-96 filings of 7,036).

Figure 3. Patenting Activity in India, 1995-2005⁷⁶⁴

	1995- 1996	1996- 1997	1997- 1998	1998- 1999	1999- 2000	2000- 2001	2001- 2002	2002- 2003	2003- 2004	2004- 2005
Filed	7036	8562	10155	8954	4824	8503	10592	11466	12613	17466
Examined	2862	3042	2688	2931	2824	4264	5104	9538	10709	14813
Granted	1533	907	1844	1800	1881	1318	1591	1379	2469	1911

Figure 3 illustrates a relatively steady increase in the number of applications filed each year since FY 1995-96, with the exception of 1999-2000 (a transition year for PCT implementation in India⁷⁶⁵). Notably, the “Filed” data in Figure 3 include almost all of the approximately 9,000 mailbox applications claiming substances capable of use as food, medicine or drug that were filed during the TRIPS transition period of 1995-2004.⁷⁶⁶ As explained herein,⁷⁶⁷ none of these mailbox applications were taken up for examination (nor a summary even published) prior to January 1, 2005, so the “Examined” data in Figure 3 for 1995-2004 do not reflect them.

The full implementation of India’s new pharmaceutical product patents regime effective January 1, 2005 appears to have catalyzed patent application filings to an even greater degree than did India’s joining the WTO. The number of patent applications filed in India during FY 2004-05 notably increased by approximately 38 percent over the previous year.⁷⁶⁸

764. *Id.* app. D at 28. The above figures exclude design applications, which are the subject of a separate statute, the Designs Act, 2000. *See id.* at 39-46 (reporting on administration of the Design Act, 2000 for the year 2004-05). The reporting year for Figure 3 data runs from April 1 to March 31 for each year reported. *See id.* app. A at 21 (referring to data “as on 31st March, 2005”).

765. The dramatic drop in application filings in FY 1999-2000 is likely explained by India’s entry into the Patent Cooperation Treaty (PCT) effective December 7, 1998. Between the 1998-99 fiscal year and the 1999-2000 fiscal year, directly-filed applications owned by foreigners dropped from 6,707 to 2,349. *See* ANNUAL REPORT 2004-2005, *supra* note 14, Appendix C at 27. In the 1999-2000 fiscal year, the first in which PCT filings were received by the Indian Patent Office, only 269 PCT national phase applications were filed. *See id.* In the following year (FY 2000-2001), 4,164 PCT national phase applications were filed. *See id.* These numbers indicate that about two-thirds of foreign filers stopped filing directly in India and switched to PCT filing when this option became available. *See id.*

766. The 1995-96 application filing data in Figure 3 begin on April 1, 1995. Applicants were first able to file mailbox applications on January 1, 1995, the first day of the TRIPS transition period. Therefore, those mailbox applications filed between January 1 and March 31, 1995, are not reflected in Figure 3.

767. *See supra* Part II.C.2.

768. *See* ANNUAL REPORT 2004-2005, *supra* note 14, App. C at 27 (difference between 17,466 total filings in FY 2004-2005 and 12,613 total filings in FY 2003-2004 as a percentage of the 12,613 total filings

Approximately 37 percent of these FY 2004-05 filings claimed chemical-, drug-, or food-related inventions.⁷⁶⁹ The 2004-05 fiscal reporting year includes the first three months (January through March, 2005) during which regular (i.e., non-mailbox) applications claiming pharmaceutical substances could be filed.

As in other developing countries, the majority of applicants for Indian patents are foreigners. For the last four years, the majority (about 60 percent) of patent applications filed in India have been foreign-owned⁷⁷⁰ “PCT national phase” applications filed in accordance with the provisions of the WIPO-administered Patent Cooperation Treaty (PCT); i.e., applications originating as PCT international applications filed abroad and designating India,⁷⁷¹ rather than as applications filed directly with the Indian Patent Office.⁷⁷² India became a member of the PCT effective December 7, 1998.⁷⁷³ By the 2000-01

in FY 2003-2004).

769. *See id.* app. E at 29. This 37 percent does not include biotechnology-related filings, of which there were 1,214 in FY 2004-05, or about ten percent of the total of 17,466 filings. The remaining breakdown of application filings for FY 2004-05 is 1,079 in electrical; 3,304 in mechanical; 2,787 in computer/electronics, and 2,659 classified as “general.” *See id.*

770. The PCT national phase filings received by the Indian Patent Office are primarily applications assigned to foreigners (i.e., non-Indians), but in FY 2004-05 a small number of Indian entities also began to file via the PCT rather than originally filing applications in the Indian Patent Office. *See* ANNUAL REPORT 2004-2005, *supra* note 14, App. C at 27 (indicating that in 2004-05, Indian entities filed 345 PCT national phase applications and 26 convention applications, as compared to 3,630 ordinary applications).

771. A PCT applicant files a single “international application” with the patent office of her home country (acting as a PCT “receiving office”), or with the International Bureau of the WIPO in Geneva. *See* Patent Cooperation Treaty, art. 3, June 19, 1970, 28 U.S.T. 7652, available at http://www.wipo.int/pct/en/texts/articles/a3.htm#_3 (last visited June 6, 2006). Through designation of any or all of the PCT contracting states, including India, the international application will have the effect of a national patent application in each designated contracting state. *See id.* art. 4, 28 U.S.T. 7652-54, available at http://www.wipo.int/pct/en/texts/articles/a4.htm#_4; *id.* art. 11, 28 U.S.T. 7656-57, available at http://www.wipo.int/pct/en/texts/articles/a11.htm#_11. The PCT applicant generally must file a copy of her international application and translation (if required) with each designated national patent office (e.g., the Indian Patent Office) within 30 months of the application’s priority date. *See id.* art. 22, 28 U.S.T. 7667-68, available at http://www.wipo.int/pct/en/texts/articles/a22.htm#_22. This latter step represents entry into the “national phase” of the PCT procedure.

772. For FY 2004-05, 10,671 PCT national phase applications were filed out of 17,466 total applications filed, or 61.1 percent. ANNUAL REPORT 2004-2005, *supra* note 14, App. C at 27. Out of the remaining 6,795 non-PCT applications, 2,396 were “convention applications” which claimed the priority date of a corresponding application filed within the previous twelve months in another country under the Paris Convention’s right of priority, and 4,399 were “ordinary applications” not claiming any foreign priority. *See id.* app. B at 26. For further explanation of the designations “ordinary application,” “convention application,” and “PCT national phase application,” see MPPP, *supra* note 374.

773. *See* World Intellectual Property Organization, *Treaties Database-Contracting Parties—PCT—India—Details*, *supra* note 51 (noting India’s accession to the Patent Cooperation Treaty (PCT) on September 7, 1998, and the entry into force of the PCT in India on December 7, 1998).

fiscal year, the number of PCT-filed applications entering the national phase in India nearly equaled the number of applications filed directly.⁷⁷⁴ In each of the most recent four fiscal years, the percentage of PCT national phase filings has remained constant at around 60-61 percent.⁷⁷⁵ Applicants from the U.S. were the most prevalent filers of PCT national phase applications in India during 2004-05, followed by applicants from Germany, France, Japan, and the Netherlands.⁷⁷⁶

It is unclear to what extent Indian patent examiners, during the course of their examination of PCT national phase applications, rely on or consult the International Searching Authority (ISA) report and prior art previously generated for these applications by foreign patent offices.⁷⁷⁷ An examiner can require an applicant "to furnish details . . . relating to the processing of the application in a country outside India,"⁷⁷⁸ but reliance on the ISA-generated materials is neither automatic nor conclusive.⁷⁷⁹

Foreign entities are not solely responsible for the dramatic increase in India's patent filings. The number of patent applications filed by Indian entities has also increased dramatically during the ten-year period depicted in Figure 3. In 1995-96, Indians filed 1,606 patent applications in the Indian Patent Office.⁷⁸⁰ By 2004-05, that number had increased by 126 percent to 3,630.⁷⁸¹ The largest number of Indian filers were from the state of Maharashtra (which includes Mumbai) and the Union Territory of Delhi.⁷⁸²

774. For FY 2000-01, 4,164 national phase applications under the PCT were filed out of a total of 8,503 applications filed, or 49.0%. See ANNUAL REPORT 2004-2005, *supra* note 14, App. C at 27.

775. In FY 2002-03, 7,049 national phase applications under the PCT were filed out of a total of 11,466 applications, or 61.5%. In FY 2003-04, 7,717 PCT applications were filed out of 12,613, or 61.2%. In FY 2004-05, 10,671 PCT applications were filed out of 17,466, or 61.1%. See *id.* app. C at 27.

776. Out of a total of 10,671 PCT national phase applications filed in the Indian Patent Office in FY 2004-05, 4,053 were filed by U.S. applicants, 1,292 were filed by German applicants, 671 were filed by French applicants, 626 were filed by Japanese applicants, and 520 were filed by applicants from the Netherlands. See *id.* app. B at 24-26.

777. See Patent Cooperation Treaty, *supra* note 771, art. 15, 28.U.S.T. 7660-61, available at http://www.wipo.int/pct/en/texts/articles/a15.htm#_15 (last visited June 6, 2006).

778. The Patents Act, No. 39 of 1970, § 8(2) (Universal 2005) (amended 2005).

779. Interview with K.S. Kardam, *supra* note 175.

780. ANNUAL REPORT 2004-2005, *supra* note 14, App. C at 27.

781. *Id.* These 3,630 applications filed in 2004-05 are "ordinary applications" as defined above; i.e., filed by Indians for the first time with the Indian Patent Office. See *id.* app. B at 24. In addition, Indian entities in 2004-05 filed 26 convention applications and 345 PCT national phase applications. See *id.*

782. See *id.* Out of the 3,630 ordinary applications filed by Indian entities in 2004-05, 1,093 filers were from Maharashtra state (which includes Mumbai) and 935 were from Delhi (Union Territory). *Id.* The third-highest state of origin for Indian patent filers was Tamil Nadu (which includes Chennai). *Id.* (showing 397 filers from Tamil Nadu state). Both Mumbai and Chennai are centers of Indian industry and home to many chemical and biotech firms.

Despite the significant increase in filings by Indian citizens, their applications made up only 23 percent of the total filed in India in FY 2004-05, as opposed to the remaining 77 percent filed during that period by foreigners.⁷⁸³ At the end of the day, India's patent system is still utilized largely by foreigners rather than its own citizens.

Data are not yet available that would provide a clear picture of India's patent examination pendency; i.e., the average time lag between application filing and ultimate disposition (allowance or final rejection). Both the Patent Office and the applicant may contribute to this time lag. For example, because the applicant must file a Request for Examination following publication of her application, any delay in making that request would extend application pendency to some degree. The Indian Patent Office does not yet publish average pendency figures.⁷⁸⁴ Secondary literature suggests that average pendency ranges from three to six years.⁷⁸⁵ The pendency issue is of potential concern to the pharmaceutical industry, where a patent may be as much or more economically valuable at the end of its life than at the beginning. Notably, and in contrast with U.S. patent laws,⁷⁸⁶ the Indian Patents Act currently does not make any provision for patent term adjustment due to Patent Office delay.⁷⁸⁷

Despite the significant annual increase in both number of applications filed and applications examined in India since FY 1999-2000, the number of

783. See 2005-06 GOV'T OF INDIA, MINISTRY OF COM. & INDUSTRY, DEP'T OF INDUS. POL'Y & PROMOTION ANNUAL REPORT 78, available at http://www.dipp.nic.in/anrepo_e/annual_report_eng_2005-06.pdf (reporting that a "total of 17,466 applications, including 13,452 from other countries, were filed during 2004-05"). In contrast, approximately 55 percent of applicants for U.S. patents in FY 2005 were U.S. residents. See 2005 USPTO PERFORMANCE AND ACCOUNTABILITY REP. tbl. 7, available at http://www.uspto.gov/web/offices/com/annual/2005/060404_table7.html (reporting 225,152 filings for FY 2005); *id.* at tbl. 9, available at http://www.uspto.gov/web/offices/com/annual/2005/060409_table9.html (reporting 184,380 filings for FY 2005).

784. In contrast, pendency figures for U.S. applications are available at 2005 USPTO PERFORMANCE AND ACCOUNTABILITY REP. tbl. 4, available at http://www.uspto.gov/web/offices/com/annual/2005/060404_table4.html.

785. *Around the World—India Modifies Patent Rules to Boost Innovation and Attract Investment*, WORLD INTEL. PROP. REP., June 2006, at 9 (reporting comments of Akash Taneja of the National Intellectual Protection Organization that due to Indian government's modernization efforts and recent hiring of new patent examiners, "the average time taken to secure a patent in India could come down from the current three to six years to about a year and one-half to three years").

786. See Uruguay Round Agreements Act, Pub. L. No. 103-465, 108 Stat. 4983-85 (1994) (codified as amended at 35 U.S.C. § 154(b) (2000)).

787. See The Patents Act, No. 39 of 1970, § 53 (Universal 2005) (amended 2005). See also Mirandah, *supra* note 733, at 28 (noting that Singapore is the only one of the South and South East Asian countries (i.e., India, Malaysia, Indonesia, Singapore, Vietnam, Thailand, and the Philippines) that presently allows term extensions for unreasonable patent office-caused delays).

patents granted annually by the Indian Patent Office has barely changed. Comparing the number of patents granted versus those examined in Figure 3, one can only conclude that the Indian Patent Office has taken a very restrictive approach to patentability. For example, the ratio of patents granted in FY 2004-05 to applications examined during that year is only about thirteen percent.⁷⁸⁸ The low numbers are consistent with the observations of Shamnad Basheer, who has noted the Indian “Patent Office’s deep entrenchment with the Ayyangar report and a consistently conservative approach to the issue of patentability.”⁷⁸⁹ Because in Basheer’s view the Indian Patent Office is “rooted in a system that stressed the virtues of a weak patent system,”⁷⁹⁰ it is “likely that the Patent Office w[ill] continue with a conservative approach to the issue of patentability, even with regard to pharmaceutical inventions (that are patentable under the 2005 Act).”⁷⁹¹

More specifically, Basheer suggests that the new Patents Act’s “several patent eligibility exclusions such as the ‘new use’ exclusion, method of medical treatment exception, and the ‘product of nature’ exclusion [] could be interpreted in a fairly liberal manner to limit the scope of protection to pharmaceutical inventions.”⁷⁹² In addition, Basheer suggests, “the traditional patentability criteria of novelty, non-obviousness, or utility could be strictly construed to limit the scope of such patent grants.”⁷⁹³ If these restrictive views towards patentability represent the philosophical viewpoint of the majority of India’s patent examining corps, as Basheer suggests, they soon will be subject to the review of a newly-formed appellate body within the Patent Office, as next discussed.

5. *Creation of Patent Appellate Board*

Under the Patents Act, 1970, decisions of the Indian Controller of Patents were appealable to the Indian High Courts,⁷⁹⁴ which occupy in India’s judicial

788. Based on 14,813 applications examined in 2004-2005 versus 1,911 applications granted in the same period. See ANNUAL REPORT 2004-2005, *supra* note 14, at 8.

789. Basheer, *supra* note 688, at 316. See also Ragavan, *supra* note 87, at 281 n.53 (observing that the “Ayyangar Report, as modified by the Report of the Joint Committee of Parliament in 1966, forms the backbone of the Indian patent system”).

790. Basheer, *supra* note 688, at 310.

791. *Id.*

792. *Id.* at 323.

793. *Id.*

794. The Patents Act, No. 38 of 1970, § 116(2), available at <http://indiacode.nic.in> (providing that “an appeal shall lie to a High Court from any decision, order or direction of the Controller under any of the

hierarchy a position comparable to the state supreme courts of the U.S.⁷⁹⁵ Patent Office appeals to the courts were initiated by written petitions that had to be filed within three months from the date of the Controller's decision, order or direction.⁷⁹⁶ The appeals were typically heard by a single Judge of the High Court, who was to "endeavour . . . to decide the appeal within a period of twelve months" of its filing.⁷⁹⁷

The jurisdiction of the Indian High Courts to hear Patent Office appeals is soon to be removed and transferred to a new, specialized administrative tribunal known as the Intellectual Property Appellate Board (IPAB). The India Patents (Amendment) Act, 2002, expanded the jurisdiction of the existing IPAB, previously established for trademark matters by India's Trade Marks Act, 1999, to encompass patent appeals.⁷⁹⁸ The legislation's intent is to remove appellate jurisdiction over Patent Office matters from a non-specialized forum with a notorious backlog of cases⁷⁹⁹ and relocate it under the auspices of a specialized, patent-focused administrative tribunal.⁸⁰⁰

As of early 2006, however, the Patent Appellate Board was not yet operational⁸⁰¹ because the Indian government had not yet named a Technical Member to the Board.⁸⁰² Section 116 of the current Patents Act provides that the Appellate Board shall have power to hear appeals from decisions of the Controller provided that the Board includes a Technical Member.⁸⁰³ The Technical Member must be either a former Controller of Patents, or an

following provisions, that is to say, section 15, section 16, section 17, section 18, section 19, section 20, section 25, section 27, section 28, section 51, section 54, section 57, section 60, section 61, section 63, sub-section (3) of section 69, section 78, section 84, section 86, section 88(3), section 89, section 93, section 96 and section 97").

795. *See infra* Part V.B.1.

796. *See* The Patents Act, No. 38 of 1970, §§ 116(3), 117(1), *available at* <http://indiacode.nic.in>.

797. *See id.* §§ 117(2), 117(3).

798. *See* The Patents Act, No. 38 of 1970, § 116(1), *available at* <http://indiacode.nic.in> (providing that "[s]ubject to the provisions of this Act, the Appellate Board established under section 83 of the Trade Marks Act, 1999 shall be the Appellate Board for the purposes of this Act and the said Appellate Board shall exercise the jurisdiction, power and authority conferred on it by or under this Act . . .").

799. *See infra* Part V.B.1.

800. *See* E-mail from Manoj Pillai (June 28, 2006), *supra* note 530.

801. *See id.*; Basheer, *supra* note 688, at 321 n.73 ("Although the Intellectual Property Appellate Board ('IPAB') has been established and has already rendered some important decisions in the area of trade marks, no rules have been finalised so far for the purposes of hearing appeals under the Patents Act. The IPAB has therefore not started functioning with respect to patents.").

802. Interview with Krishna Sarma, *supra* note 126.

803. The Patents Act, No. 39 of 1970, § 116(1) (Universal 2005) (amended 2005).

individual with a scientific or technical degree and at least ten years experience as a Registered Patent Agent.⁸⁰⁴

Once the Patent Appellate Board is in operation, its decisions in appeals from Patent Office matters will be for all practical purposes final. No further direct review of Patent Appellate Board decisions will be available through the Indian court system, and then-pending proceedings before the High Courts will be transferred to the Appellate Board.⁸⁰⁵ Nevertheless, the High Courts retain constitutional powers to entertain “writ petitions” against decisions of an administrative body such as the Patent Appellate Board.⁸⁰⁶ Typically the High Courts will entertain such a petition only if it establishes a *prima facie* case of “patent illegality in the decision rendered,” “miscarriage of justice,” or a “question of law that merits attention.”⁸⁰⁷ Having had their heavy caseload reduced by the creation of the Patent Appellate Board, it seems highly unlikely that the High Courts will entertain writ petitions challenging Board decisions with any frequency.

B. Judicial Capacity: India’s Court System

In addition to the Patent Office (including the Patent Appellate Board), the other key actor in the implementation of India’s new patents regime is the judiciary, which decides issues of patent enforcement. As pharmaceutical product patents begin to issue in India, their potential economic worth can be expected to catalyze a rapid increase in volume of patent infringement litigation. The Indian courts will face challenging statutory interpretation issues when they are asked to apply the new patentability provisions of the Patents Act, 1970 (2005), such as the anti-evergreening provision of Section 3(d).⁸⁰⁸ The Indian courts can also expect to confront a rising number of

804. *See id.* § 116(2).

805. *See id.* § 117G (providing that “[a]ll cases of appeals against any order or decision of the Controller and all cases pertaining to revocation of patent other than on a counter-claim in a suit for infringement and rectification of register pending before any High Court, shall be transferred to the Appellate Board from such date as may be notified by the Central Government in the Official Gazette and the Appellate Board may proceed with the matter either *de novo* or from the state it was so transferred”).

806. *See* INDIA CONST., art. 226, *available at* [http://lawmin.nic.in/legislative/Art1-242%20\(1-88\).doc](http://lawmin.nic.in/legislative/Art1-242%20(1-88).doc), at 79.

807. E-mail from Manoj Pillai (June 28, 2006), *supra* note 530. *See also* L. Chandrakumar v. Union of India, A.I.R. 1997 SC 11265 (decision of Indian Supreme Court holding that while the High Court cannot hear appeals from the orders of an administrative tribunal, it nevertheless retains jurisdiction to entertain writ petitions under Art. 226 of the Constitution).

808. *See supra* Part IV.A.3.a.

patent claim interpretation and infringement issues, at a time when those issues remain very much in flux even in developed-country patent systems.⁸⁰⁹

Prior to implementation of the new pharmaceutical product patents regime, few patents were granted each year in India and even fewer were litigated.⁸¹⁰ As a result, there is a relative paucity of Indian patent case law from which to predict how the Indian courts will rule in future cases. Moreover, accessing and searching the reported Indian patent decisions is not straightforward.⁸¹¹

Early indicators of the Indian courts' treatment of pharmaceutical product patents do not bode well for uniformity. Two recent and conflicting High Court decisions in preliminary injunction proceedings involving the same patent application and EMR, described below, may well be harbingers of future forum shopping and inter-High Court conflicts in patent cases.

1. Court Structure and Backlog Concerns

Unlike the U.S., India does not have a dual state and federal court system. Rather, India's unitary court system comprises a Supreme Court based in Delhi and eighteen High Courts, each having jurisdiction over at least one state of India.⁸¹² Beneath the High Courts in the judicial hierarchy are the

809. In the U.S., for example, trial courts are just beginning to grapple with the implications of the watershed claim interpretation decision, *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (*en banc*). In India, the High Courts are already being asked in pharmaceutical patent cases to apply British claim construction approaches such as the older "pith and marrow" doctrine and the more recent "purposive construction" principle. See *Novartis AG v. Adarsh Pharma*, 2004 (29) P.T.C. [India Patent and Trade Marks Cases Reporter] 108, 132 (Mad[ras]). See *infra* Part V.B.3 for further detailed discussion of the *Novartis* litigation.

810. See *supra* Part V.A.4 for statistics on Indian patent grants.

811. Decisions of the Indian High Courts are reported in the ALL-INDIA REPORTER (A.I.R.), which is part of the collection of a few U.S. law school libraries such as that of Columbia University. A specialized PATENT, TRADEMARK AND COPYRIGHT (P.T.C.) REPORTER also exists for Indian intellectual property cases. Subscriptions to the content of these reporters on CD-ROM can be purchased, see <http://www.allindiareporter.com/ahc.php> (last visited June 12, 2006), but that content is not accessible via the Internet. In the U.S., Lexis provides Indian Supreme Court decisions from 1999 onwards, but neither Lexis nor Westlaw currently provides Indian High Court decisions. Recently, several of the High Courts began making their opinions available for free via the Internet, see <http://indiancourts.nic.in/sitesmain.htm> (last visited June 12, 2006), but text search capabilities are varied. The best free Internet site for locating Indian case law is the World Legal Information Institute site for India, available at <http://www.worldlii.org/catalog/2179.html> (last visited June 12, 2006).

812. See Theodore A. Mahr, *An Introduction to Law and Law Libraries in India*, 82 LAW LIBR. J. 91, 121 (1990) (noting that "[t]he High Courts in India correspond to the state supreme courts in the United States, although there is not a dual federal and state court system"). A list of India's eighteen High Courts, their territorial jurisdiction and seats is available at http://indiancourts.nic.in/indian_jud.htm ("Annexure

District Courts.⁸¹³ The High Courts were first implemented in 1861 by the British, who bequeathed to India their common law system including *stare decisis* principles.⁸¹⁴ After India gained its independence in 1947, leaders such as Nehru and Gandhi “chose to maintain the adversary court system with its rule of law, individualistic rights, and ideas of equality.”⁸¹⁵

India’s independent judiciary and adherence to the rule of law are well regarded, but the fundamental weakness of the Indian judicial system is the immense backlog of cases it faces. Indian courts are said to be “the most crowded of any in the world”⁸¹⁶ and the Indian judiciary “overburdened to the point of dysfunction.”⁸¹⁷ A recent USAID study reported that the Indian judicial backlog may be “as high as 28 million cases” and that exceedingly long case processing times “effectively deny[] justice to those who need the system’s protection.”⁸¹⁸

The Indian government appears to be concerned that the courts’ backlog will negatively impact the nation’s desired image as one of new-found respect for intellectual property rights. Keynoting the November 2005 annual meeting of the Asian Patent Attorneys Association, the Chief Justice of the Indian Supreme Court, Y.K. Sabharwal, proposed fast-tracking of IP cases through the Indian courts.⁸¹⁹ The Chief Justice “promised to include IPR cases in his priority list, which he had unveiled as Chief Justice designate, to be put on fast

A”) (last visited June 12, 2006). A list of various High Court websites is available at <http://indiancourts.nic.in/sitesmain.htm> (last visited June 12, 2006).

813. A list of District Court websites is available at <http://indiancourts.nic.in/sitesmain.htm> (last visited June 12, 2006).

814. *See Mahr, supra* note 812, at 100-02.

815. *See id.* at 107. Other Indian legal cultures co-exist with the adversarial court system. *See id.* (describing “traditional panchayat village councils, which use customary law and procedure to settle disputes and maintain social control” and the social norms of Brahmin “high culture” law).

816. Jayanth K. Krishnan, *Social Policy Advocacy and the Role of the Courts in India*, 21 AM. ASIAN REV. 91, 92-93 (2003).

817. Jishnu Guha, *Time For India’s Intellectual Property Regime to Grow Up*, 13 CARDOZO J. INT’L & COMP. L. 225, 240 (2005).

818. USAID India, *Strategy 2003-2007*, § 1, available at http://www.usaid.gov/in/our_work/strategy/strategy1.htm (last visited Oct. 20, 2005). The USAID report states in pertinent part:

One of India’s most recognizable strengths is its independent and well-regarded judiciary. However, the legal system is hampered by critical problems that often affect the poor most. Backlogs total as high as 28 million cases. Case processing times are exceedingly long, effectively denying justice to those who need the system’s protection. Too many citizens charged with minor crimes spend lengthy periods in jail awaiting trial. Legal literacy is low, and there are few mechanisms for legal aid.

Id.

819. *See* Dhananjay Mahapatra, *Intellectual rights cases to get top priority, says CJI*, TIMES OF INDIA, Nov. 13, 2005, at 19.

track trial.”⁸²⁰ Along similar lines, the Law Commission of India has proposed the creation of a high-tech commercial court.⁸²¹ The commercial court’s docket would include patent cases, with resolution in a one-to-two year time frame.⁸²²

2. *Litigating Patent Infringement and Revocation in India*

Lawsuits alleging infringement of Indian patents are filed before the District Courts, but if the accused infringer files a counter-claim for revocation (or in U.S. parlance, invalidity) of the patent, the case will be transferred to the appropriate High Court for hearing and decision.⁸²³ Those defending a patent infringement action may raise as a defense any ground set forth in Section 64 (“Revocation of patents”) of the Patents Act,⁸²⁴ which enumerates an extensive list of bases for revocation including lack of novelty,⁸²⁵ utility⁸²⁶ and inventive step;⁸²⁷ failure to provide an enabling disclosure;⁸²⁸ failure to disclose the best mode;⁸²⁹ lack of claim clarity,⁸³⁰ non-patentable subject matter;⁸³¹ and failure to disclose the source or geographical origin of biological material used for the invention.⁸³²

Affirmative actions are also permitted by those seeking a judicial declaration of non-infringement,⁸³³ but unlike U.S. declaratory judgment actions, such actions in India cannot assert patent invalidity.⁸³⁴ The party seeking to revoke a patent outside the context of defending an infringement

820. *Id.*

821. See 188 L. COMMISSION OF INDIA REP. ON PROPOSALS FOR CONST. OF HI-TECH FAST-TRACK COM. DIVISIONS IN HIGH CTS, Dec. 2003, available at <http://www.commonlii.org/in/other/INLC/2004/188.pdf> (visited Oct. 21, 2005).

822. *See id.*

823. See The Patents Act, No. 39 of 1970, § 104 (Universal 2005) (amended 2005).

824. *See id.* § 107.

825. *See id.* §§ 64(1)(a), (e), (l), and (q).

826. *See id.* § 64(1)(g).

827. *See id.* § 64(1)(f).

828. See The Patents Act, No. 39 of 1970, § 64(1)(h) (Universal 2005) (amended 2005).

829. *See id.* (application “does not disclose the best method of performing [the invention] which was known to the applicant for the patent and for which he was entitled to claim protection”).

830. *See id.* § 64(1)(i).

831. *See id.* § 64(1)(d) (subject of any claim “is not an invention within the meaning of this Act”); § 64(1)(k) (subject of any claim “not patentable under this Act”).

832. *See id.* § 64(1)(p).

833. See The Patents Act, No. 39 of 1970, § 105 (Universal 2005) (amended 2005).

834. *See id.* § 105(3) (stating that “[t]he validity of a claim of the specification of a patent shall not be called in question in a suit for a declaration brought by virtue of this section”).

suit must file a petition for revocation with the Indian Patent Office.⁸³⁵ The revocation petitioner must be a “person interested,” suffering tangible commercial harm from the continued pendency of the challenged patent.⁸³⁶

Unlike the U.S., India does not recognize a presumption of validity for issued patents.⁸³⁷ A leading treatise explains thus:

The [India Patents] Act provides for search among the records of the Patent Office for anticipation based on published material. Such a search, however, can never be exhaustive or final. . . . Besides, the question of obviousness or inventiveness has to be judged from the point of view of a man skilled in the art which requires evidence of experts. This question can be resolved only in opposition or revocation proceedings. But many patents are granted unopposed. The Act therefore does not guarantee the validity of the patent which can finally be decided only by the High Court in infringement or revocation proceedings.⁸³⁸

In contrast, the U.S. does recognize a presumption (though not a warranty or guarantee) of validity for issued patents,⁸³⁹ based at least in part on an assumption of administrative correctness on the part of the USPTO.⁸⁴⁰ Federal Circuit case law further mandates that the quantum of a challenger’s burden of proof in invalidating an issued patent is clear and convincing evidence (a higher standard than the preponderance of the evidence typically required to prevail in a civil case).⁸⁴¹ Because this evidentiary standard is not applied in

835. *See id.* § 64(1) (providing that “a patent, whether granted before or after the commencement of this Act, may be revoked on a petition of any person interested or of the Central Government by the Appellate Board or on a counter-claim in a suit for infringement of the patent by the High Court”).

836. The Delhi High Court has held that “[a] ‘person interested’ within the meaning of section 64 must be a person who has a direct, present and tangible commercial interest which is injured or affected by the continuance of the patent on the register.” The Patents Act, No. 39 of 1970, § 64 (Universal 2005) (amended 2005), cmt. (i) (citing *Ajay Industrial Corp. v. Shiro Kanao of Ibaraki City*, A.I.R. 1983 (Del.) 496), reprinted in UNIVERSAL’S THE PATENTS ACT, 1970, AS AMENDED BY THE PATENTS (AMENDMENT) ACT, 2005, at 41 (Universal Law Publishing Co. Pvt. Ltd. 2005). *See also* The Patents Act, No. 39 of 1970, § 2(1)(t) (Universal 2005) (amended 2005) (defining “person interested” to “include[] a person engaged in, or in promoting, research in the same field as that to which the invention relates”).

837. *See* The Patents Act, No. 39 of 1970, § 13(4) (Universal 2005) (amended 2005) (“The examination and investigations required under section 12 [“Examination of application”] and this section [“Search for anticipation by previous publication and by prior claim”] shall not be deemed in any way to warrant the validity of any patent, and no liability shall be incurred by the Central Government or any officer thereof by reason of, or in connection with, any such examination or investigation or any report or other proceedings consequent thereon.”).

838. *See* NARAYANAN (PATENT LAW), *supra* note 50, ¶ 1-19.

839. *See* 35 U.S.C. § 282 (2006) (providing that “[a] patent shall be presumed valid”).

840. *See* *Applied Materials, Inc. v. Advanced Semiconductor Materials Am., Inc.*, 98 F.3d 1563, 1569 (Fed. Cir. 1996); *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1139 (Fed. Cir. 1985).

841. *See* *Buildex Inc. v. Kason Indus., Inc.*, 849 F.2d 1461, 1463 (Fed. Cir. 1988).

India, it would appear relatively easier to obtain revocation of an Indian patent than to invalidate the corresponding patent in the U.S.

Chapter XVIII of India's Patents Act, titled "Suits Concerning Infringement of Patents,"⁸⁴² does not provide a provision explicitly enumerating acts of direct infringement along the lines of Section 271(a) of the U.S. Patent Act.⁸⁴³ Elsewhere, however, India's Patents Act specifies that a product patentee has "the exclusive right to prevent third parties, who do not have his consent, from the act of making, using, offering for sale, selling or importing for those purposes that product in India."⁸⁴⁴ This definition is entirely consistent with the TRIPS Agreement, which mandates the identical exclusive rights.⁸⁴⁵

No provision exists in the India Patents Act regarding indirect liability under a theory of joint tortfeasance, e.g., for acts by entity X that aid and abet or materially contribute to the direct infringement of entity Y, such as by intentionally providing a non-staple component or starting material for the manufacture of a directly infringing product.⁸⁴⁶ In contrast with its treatment of direct infringement, the TRIPS Agreement does not mandate recognition of (nor even mention) indirect infringement liability.⁸⁴⁷ Because TRIPS sets forth only minimum standards, member countries have the option of expanding a patentee's rights.⁸⁴⁸ The U.S., which has statutorily recognized liability for acts of contributory⁸⁴⁹ and inducing⁸⁵⁰ infringement since the 1952 Patent Act, is a case in point. India, by contrast, has chosen not to statutorily implement this expanded protection for patentees, consistent with TRIPS' silence on the point.⁸⁵¹

842. The Patents Act, No. 39 of 1970, §§ 104-15 (Universal 2005) (amended 2005).

843. *See id.*

844. *Id.* § 48.

845. TRIPS, *supra* note 3, Art. 28.

846. *See* The Patents Act, No. 39 of 1970 (Universal 2005) (amended 2005) (not mentioning contributory infringement or inducing infringement).

847. *See* TRIPS, *supra* note 3, Art. 28 (enumerating only acts of direct infringement); Cynthia M. Ho, *Patents, Patients, and Public Policy: An Incomplete Intersection at 35 U.S.C. § 287(c)*, 33 U.C. DAVIS L. REV. 601, 663-64 (2000) ("TRIPS does not require members to recognize contributory infringement. The exclusive rights that each member country must provide under TRIPS are limited to direct infringement, although each nation is free to provide additional rights, such as contributory infringement.") (citations omitted).

848. *See* Ho, *supra* note 847, at 664.

849. *See* 35 U.S.C. § 271(c) (2006).

850. *See id.* § 271(b).

851. Although the Patents Act does not specifically refer to liability for inducing or contributory infringement, a form of protection therefrom is available indirectly through the statutorily-codified remedy of seizure. *See* The Patents Act, No. 39 of 1970, § 108(2) (Universal 2005) (amended 2005) (providing

Remedies for infringement of an Indian patent include injunctive relief, “subject to such terms, if any, as the court thinks fit.”⁸⁵² The primary distinction between infringement remedies available in the U.S. and India is that in India (in addition to injunctive relief) the plaintiff may elect to receive either damages *or* an “account of profits.”⁸⁵³ The former refers to damages suffered by the patentee, e.g., profits lost by the patentee on sales that it would have made but for the infringement, while the latter refers to disgorgement of the accused infringer’s wrongly-obtained profits. Congress eliminated the accounting remedy in the U.S. in 1946.⁸⁵⁴

3. *High Court Patent Conflicts*

During 2004, two Indian High Courts reached opposite conclusions concerning whether Swiss pharmaceutical manufacturer Novartis AG, holder of an Indian EMR on the anti-cancer drug marketed as Glivec (sometimes spelled Gleevec), and its Indian subsidiary Novartis India Ltd. (jointly “Novartis”) were entitled to an interlocutory injunction against infringement of the EMR by generic competitors. The facts common to both cases are these:⁸⁵⁵ Novartis AG filed in 1998 an Indian patent application claiming the “beta crystalline form of imatinib mesylate,” having the previous day filed a patent application claiming the same drug in Australia.⁸⁵⁶ The Australian government granted marketing approval in 2001 and issued an Australian patent in 2002.⁸⁵⁷ On the basis of the Australian approvals, Novartis AG in 2002 filed its application for an EMR with the Kolkata branch of the Indian Patent Office.⁸⁵⁸ The EMR was granted in November 2003, conferring on Novartis an exclusive right to sell Glivec in India for up to five years or until Novartis’ pending product patent claim was disposed of, whichever was earlier.⁸⁵⁹ The Drug Controller of India also gave Novartis India marketing

that, in addition to seizure of infringing goods, “materials and implements, the predominant use of which is in the creation of infringing goods shall be seized, forfeited or destroyed, as the court deems fit under the circumstances of the case without payment of any compensation”).

852. *Id.* § 108(1).

853. *Id.*

854. *See* *Aro Mfg. v. Convertible Top Replacement Co.*, 377 U.S. 476, 505 (1964).

855. *See* *Novartis AG v. Adarsh Pharma*, 2004 (29) P.T.C. [India Patent and Trade Marks Cases Reporter] 108, 113-14 (Mad[ras]) (citing plaintiff Novartis’ statement of facts as set forth in its pleadings).

856. *Id.* at 114.

857. *Id.*

858. *Id.* *See supra* Part II.C.2 for a discussion on the various requirements for obtaining an EMR.

859. *Novartis AG*, 2004 (29) P.T.C. 108.

approval (i.e., an import license) to sell Glivec for the three-year period of January 1, 2003 through December 31, 2005.⁸⁶⁰

In *Novartis AG v. Adarsh Pharma*,⁸⁶¹ Judge Balasubramanian of the High Court of Madras (Chennai) on April 28, 2004 confirmed Novartis' earlier-granted *ex parte* injunction against further infringement of its Glivec EMR. The Madras court refused to consider the defendant's arguments that the EMR was invalid on grounds of anticipation by virtue of the claimed invention having previously been disclosed in earlier-filed U.S. and Canadian applications and patents assigned to Novartis and in earlier-published journal articles. The Madras court interpreted the statutory provisions pertaining to the granting of EMRs as strictly limited to consideration of whether the covered product was or was not considered patentable subject matter under sections 3 and 4 of the Indian Patents Act.⁸⁶² At least at the interlocutory injunction stage, it would not be proper to challenge an EMR based on sections 12 and 13 of the Patents Act, under which a patent examiner in the course of examining a conventional patent application would be required to conduct a search for "anticipation by previous publication and by prior claim."⁸⁶³ In the Madras court's reading of the statute, anticipation "by previous publication or by prior claim has no relevancy while examining the patent claim in the context of deciding to grant or not to grant an 'EMR.'"⁸⁶⁴ The Madras court's interpretation is thus fully consistent with the notion that the grant of an EMR (a legal instrument that existed solely as an interim measure during India's TRIPS transition period) is fundamentally premised on recognition that other countries have already awarded patent rights to the EMR applicant on the same technology.

Nor was the Madras court troubled by the fact that Novartis AG, the Swiss parent company, had applied for the Indian patent and EMR, while it was Novartis India, the Indian subsidiary, that held the marketing approval; the two entities, although legally separate, were fairly treated in this context

860. *Id.*

861. *Id.*

862. *See id.* at 119 (concluding that "there is no scope, in my considered opinion, for examining the said patent claim on the basis of any of the other provisions of the Act, which may stand attracted when the patent claim is taken up for consideration on merits after 31.12.2004").

863. The Patents Act, No. 39 of 1970, §§ 12, 13 (Universal 2005) (amended 2005). *See also Novartis AG*, 2004 (29) P.T.C. at 119 (reading section 24-A(1) of Act as "inevitabl[y]" meaning that "examination under section 12(1) of the Act stands postponed till 31.12.2004").

864. *Novartis AG*, 2004 (29) P.T.C. at 120.

as “one economic unit.”⁸⁶⁵ The very high price charged for Glivec⁸⁶⁶ did not persuade the Madras court to deny an injunction; any potential harm to the public’s interest through the maintenance of the injunction was fully allayed by the Indian government’s statutory power to fix the price at which Novartis could sell Glivec under the EMR.⁸⁶⁷ Noting that the accused infringer began marketing its product in India after Novartis did,⁸⁶⁸ the Madras court also rejected the defendant’s argument that an injunction was improper because the Novartis EMR was of merely “recent origin.”⁸⁶⁹ Although such a rule might have been applicable in earlier cases involving issued patents, in the Madras court’s view it was not properly applied to limit enforcement of an EMR, a unique legal right which by definition could last at most five years.⁸⁷⁰

The Madras court’s reasoning was rejected in *Novartis AG v. Mehar Pharma*,⁸⁷¹ wherein Judge Deshmukh of the High Court of Bombay (Mumbai) on December 23, 2004 denied Novartis’s motion for a temporary injunction against infringement of the same Glivec EMR by different defendants. Contrary to the Madras court’s view,⁸⁷² the Bombay court concluded that the “recent origin” of Novartis’ EMR justified a substantive analysis of the novelty of the invention claimed in the Novartis patent application on which the EMR was based.⁸⁷³ The court concluded that the teachings of Novartis’ 1993 Canadian patent application raised “a serious question as to whether the product in relation to which [the] EMR has been granted is really a new product or not.”⁸⁷⁴ Also weighing against Novartis was the Bombay court’s

865. *Id.* at 129.

866. *See id.* at 115 (stating defendant’s assertion that the cost per patient per year of Glivec is Rs. 25 lakh). The Indian “lakh” refers to a quantity of 100,000. Thus Rs. 25 lakh means 2,500,000 rupees. At an exchange rate of about 46 rupees per U.S. dollar this amount converts to approximately \$54,000. *See Yahoo Finance Currency Converter*, available at <http://finance.yahoo.com/currency>.

867. *See Novartis AG*, 2004 (29) P.T.C. at 133 (citing The Patents (Amendment) Act, No. 29 of 2002, § 24D(2) (giving Indian government the right, “in the public interest,” to set the price of an EMR-covered drug “at a price determined by an authority specified by it in this behalf”)). As a creature of the TRIPS transition period, Section 24D(2) (along with all other statutory provisions pertaining to EMRs) has now been repealed. *See the Patents (Amendment) Act*, No. 15 of 2005, § 21 (Universal 2005).

868. *See Novartis AG*, 2004 (29) P.T.C. at 135.

869. *See id.* at 134.

870. *See id.* at 134-35.

871. *Novartis AG v. Mehar Pharma*, 2005 (30) P.T.C. [India Patent and Trade Mark Cases Reporter] 108 (Bom[bay]).

872. *See id.* at 174 (concluding that Madras court had “not properly considered the settled law in the matter of grant of temporary injunction in relation to a patent of recent origin”).

873. *See id.* at 172-73.

874. *Id.* at 173. The Bombay court thus rejected Novartis’ contention that while its Indian patent application and EMR are directed to a particular (beta-crystalline) form of imatinib mesylate, its Canadian application filed in 1993 disclosed only “imatinib *per se*, and not [] imatinib mesylate, let alone the beta

observation that the company imports Glivec into India from Switzerland, where it is manufactured, creating risk associated with “rely[ing] entirely on the international transport system” for ensuring availability in India of a “life-saving drug.”⁸⁷⁵ Lastly, the Bombay court observed that “the aspect of the difference in price of the product of plaintiffs and the defendants also cannot be ignored, especially at the stage of considering the question whether the plaintiffs are entitled to any interim relief.”⁸⁷⁶

That the Madras and Bombay High Courts relied on diametrically opposed reasoning to reach opposite conclusions about the propriety of injunctive relief for infringement of the same EMR does not bode well for uniformity and certainty in Indian patent litigation. These decisions portend future patent law conflicts between the various High Courts that could catalyze rampant forum shopping in Indian patent litigation. One approach to dealing with pronounced variations in judicial philosophy concerning patents is to hope for Supreme Court resolution; given the immense backlog facing India’s courts as discussed above, that solution does not seem particularly palatable. Another approach would involve creating a specialized appellate tribunal with nationwide jurisdiction to resolve patent cases, as the U.S. did by establishing the Court of Appeals for the Federal Circuit in 1982. India may want to consider the latter approach.

VI. CONCLUSION AND RECOMMENDATIONS

Viewed after its first eighteen months in operation, India’s new pharmaceutical product patents regime is neither the fully-Westernized panacea hoped for by its pro-TRIPS advocates nor the unmitigated disaster for the Indian public predicted by its fiercest critics. Innovation in India’s pharmaceutical sector is slowly on the rise and patent application filings are increasing dramatically. At the same time, the price of most medicines has not been affected by the newly expanded availability of product patent protection. Longer-term effects of patent protection on drug pricing in India are not yet known, but the government has a number of tools at its disposal to deal with that concern. As this article has demonstrated, India’s new patents regime is still evolving and a great deal remains to be clarified through implementation.

crystalline form of imatinib mesylate.” *Id.* at 162.

875. *Id.* at 174.

876. *Id.* According to the defendants’ submission, “the drug of the plaintiffs costs Rs. 1000 [per tablet] whereas the drug as sold by the defendants costs about Rs. 90.” *Id.* at 170.

What has already become clear, however, is that India's generic drug manufacturers, along with NGOs, public interest groups, and patient advocacy organizations will not be passive observers of the new regime. Rather, they are already making active use of available statutory flexibilities to challenge pharmaceutical product patents and will likely continue to push the envelope in an attempt to obtain favorable precedents.

Those advocating stronger patent protection will also find ample basis for challenging the new Patents Act. Significant questions of TRIPS compliance remain to be settled, especially with regard to the Act's provision of prior user rights for those infringing patents issuing from mailbox applications and the Act's maintenance of domestic working requirements as a trigger for compulsory licensing. The Indian Patent Office has a great deal of discretion in applying these provisions and in setting the terms and conditions of government-compelled licenses. The manner in which it exercises that discretion will have much to do with whether another WTO TRIPS dispute proceeding is initiated against India.

Although a number of the new Patent Act's provisions provide the Indian government with legitimate means for balancing innovation incentives against the social costs of pharmaceutical product patents, other provisions should be re-thought. In reaching eleventh-hour compromises to appease concerns about patent-driven drug price increases, India's lawmakers may also have triggered unintended negative consequences for indigenous innovation. If retained in their current form, the Act's broad prohibitions on new use patents and its obviousness-plus standard emphasizing commercial success will likely prevent deserving local innovators from obtaining the benefits of patent protection.

The Indian Patent Office and Indian judiciary face a formidable learning curve in interpreting and applying the new Patent Act's ambiguous patentability requirements, compulsory licensing conditions, and the like. Although opponents of stronger patent protection may exploit the current uncertainties to their advantage, in the long term the lack of confidence in the availability of patent protection for legitimate advances could prevent both increased foreign direct investment by MNCs and a greater degree of indigenous innovation. Rapid implementation of the new Patent Appellate Board is important to give the Patent Office examiners guidance in these matters as well as to alleviate High Court delays in Patent Office appeals.

As the world watches India to see how its unique and still unsettled patent system matures, greater transparency is needed from the Indian Patent Office. To begin with, the Patent Office would perform a valuable public service by posting on its website a consolidated version of the current Patents Act and Rules, incorporating all amendments that have been made to date to the

principal (1970) Act and principal (2003) Rules. Additionally, the full text of patent applications should be published electronically at eighteen months after filing, along with current versions of the Patent Office's *Annual Reports*. Notification of the filing of both pre- and post-grant oppositions should be made public, as should written decisions in oppositions that involve interpretation and application of new and ambiguous patentability criteria. When the Patent Appellate Board becomes operational, its decisions should be in writing and made publicly available. The four branch offices of the Indian Patent Office should adopt uniform standards for patent application data reporting.

If the recent trend of dramatic increases in patent application filings continues, the current Indian Patent Office staffing inadequacy will soon escalate to crisis proportions. The Indian government's exemplary funding of new and improved physical facilities for its Patent Office branches needs to be matched by significant funding commitments for the hiring, training and retention of scientifically skilled patent examiners, especially in the chemical and biotechnological arts. Computerization of Patent Office functions should also be prioritized.

Lastly, fast-tracking of patent infringement cases will be required if patent enforcement in India's clogged court system is to have any real meaning. Preliminary indications of inter-High Court conflicts in patent cases may also foster forum shopping and disparate doctrinal development, problems that spurred creation of the Court of Appeals for the Federal Circuit in the U.S. If such conflicts and inconsistencies continue to fester, India should consider establishing a specialized patents court with nationwide jurisdiction at the High Court level.