

# TRIPS COMPLIANCE: DEALING WITH THE CONSEQUENCES OF DRUG PATENTS IN INDIA

*Rishi Gupta\**

I. INTRODUCTION.....	600
II. RESPONDING TO THE THREAT OF INCREASED DRUG PRICES .....	606
A. <i>Will Drug Prices Actually Rise?</i> .....	606
B. <i>Drug Price Controls</i> .....	608
C. <i>Governmental Purchasing Power</i> .....	611
D. <i>Compulsory Licenses</i> .....	612
E. <i>Lax Enforcement of Patent Rights</i> .....	615
F. <i>Public-Sector Drug Development</i> .....	618
G. <i>Summary</i> .....	621
III. RESPONDING TO THE THREAT TO INDIAN INDUSTRY.....	624
A. <i>India Possesses Local Capacity</i> .....	624
B. <i>Presence of a Skilled Scientific Workforce</i> .....	626
C. <i>Anticipatory Behavior of Indian Pharmaceutical     Firms</i> .....	629
D. <i>Alignment of Regulatory Regimes</i> .....	633
E. <i>Development of a Venture Capital Industry</i> .....	636
F. <i>Summary</i> .....	643
IV. CONCLUSION .....	645

---

\* J.D., Yale Law School, 2004; A.B., Harvard College, 1999. I am grateful to Owen Fiss, Amy Kapczynski and George Priest for insightful comments. I would also like to thank Cassandra Jeu and other student editors at the Houston Journal of International Law for timely and helpful editorial assistance.

This paper received the James Baker Hughes Prize Writing Award.

## I. INTRODUCTION

“The idea of a better-ordered world is one in which medical discoveries will be free of patents and there will be no profiteering from life and death.”<sup>1</sup>

The sentiment expressed by Indira Gandhi some twenty years ago has come to the fore of the public consciousness in recent months. Skyrocketing healthcare costs in the United States have been attributed to the rising prices of prescription drugs.<sup>2</sup> Stories of senior citizens who must make daily choices between food and life-saving medicines are commonly reported in the media,<sup>3</sup> and the debate about the legality of drug reimportation from Canada continues to rage.<sup>4</sup> The high costs of HIV/AIDS drugs in countries of sub-Saharan Africa—some of which have HIV infection rates that approach or exceed twenty-five percent among their adult populations—mean that people are suffering and dying despite the fact that medicines have been developed against this modern scourge.<sup>5</sup> The villains in all

---

1. Indira Gandhi, Address Before the World Health Assembly, Geneva (May 1982) in INTELLECTUAL PROPERTY RIGHTS, GLOBAL CENSUS, GLOBAL CONFLICT? 186 (R. Michael Gadbow & Timothy J. Richard eds., 1988).

2. The average annual percentage growth in prescription drug spending increased from 10.2% in 1993 to 19.7% in 1999, and expenditure for prescription medications constituted the fastest-growing component of healthcare spending during much of that period. Stephen Heffler et al., *Health Spending Projections Through 2013*, HEALTH AFFAIRS—WEB EXCLUSIVE, Feb. 11, 2004, at W4-79, W4-81, at <http://content.healthaffairs.org/cgi/reprint/hlthaff.w4.79v1.pdf>. While the growth slowed to 15.3% in 2002 and is expected to slow even further to 13.4% in 2003 and 12.4% in 2005, prescription drug spending remains the fastest-growing health sector. *Id.* at W4-90.

3. See, e.g., Sen. Patrick Leahy, Editorial, *Congress' Scorecard for Seniors*, THE ESSEX REP., Oct. 4, 2000 (“I have heard stories of Vermont seniors cutting pills in half or not taking the drugs at all because the cost is just too high. Many seniors must make the choice between putting food on the table and purchasing medicine. No one in this country should have to forgo the life-saving drugs they need.”), available at <http://leahy.senate.gov/issues/seniors/essex.htm>.

4. See, e.g., Roger Parloff, *The New Drug War*, FORTUNE, Mar. 8, 2004, at 144.

5. See *UNFPA Response 2003*, at <http://www.unfpa.org/hiv/2003/3a.htm> (“In four Southern African countries, national adult HIV prevalence has risen higher than thought possible: Botswana (38.8 per cent), Lesotho (31 per cent), Swaziland (33.4 per

2004] *TRIPS COMPLIANCE: DEALING WITH DRUG PATENTS IN INDIA* 601

of these stories are the firms that produce drugs—pharmaceutical and biotechnology companies—and the system of intellectual property rights (in particular, patent rights) that enables the companies to charge what some consider to be exorbitant prices for their products for an extended period of time.

A patent, as embodied in American law, is a government-issued grant that confers upon the patent owner “the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States” for a period of twenty years beginning from the filing date of the patent application.<sup>6</sup> A patent effectively grants the patent owner a limited monopoly on the patented invention.<sup>7</sup> While the inventor can collect monopoly rents on sales of her product until the time of patent expiration, this inefficiency is justified on utilitarian or consequentialist grounds—that is, without patent protection, inventors would not invent, or would invent only to a level that would be considered sub-optimal. This concern is particularly salient in the world of medicines, where a substantial capital investment is required to bring products to market.<sup>8</sup> Significant funds are needed for drug research for two reasons: first, new drugs are exposed to extensive regulatory scrutiny and must be tested in expensive clinical trials in order to prove their safety and efficacy; and second, medical research is inherently uncertain and risky in nature, with a number of failures typically preceding any valuable breakthroughs.<sup>9</sup> Without the prospect of a limited

---

cent) and Zimbabwe (33.7 per cent.)” (last visited Jun. 15, 2004).

6. 35 U.S.C. § 154 (2000).

7. Some argue that a patent grant is *not* a monopoly grant because patents by themselves do not confer market power; other substitute products can still be marketed. JEAN O. LANJOUW, *THE INTRODUCTION OF PHARMACEUTICAL PRODUCT PATENTS IN INDIA: HEARTLESS EXPLOITATION OF THE POOR & SUFFERING?* 4 (Nat’l Bureau of Econ. Research, Working Paper No. 6366, 1998). However, there are often no effective alternatives in the case of pharmaceuticals, and patients may be in the position of *needing* the drugs in order to survive.

8. *See id.* at 5.

9. *See* PHARM. RESEARCH AND MFRS. OF AM., *WHY DO MEDICINES COST SO MUCH?*, at <http://www.phrma.org/publications/publications/brochure/questions/whycostmuch.cfm>. According to the Pharmaceutical Research and Manufacturers of America, drug

monopoly, it appears unlikely that many investors would be willing to place tens or even hundreds of millions of dollars at risk on early-stage biomedical research.

The trade-off with drug patents, then, involves weighing the creation of incentives for research and development against the temporary high costs for consumers and the associated economic inefficiency that result. The granting of patents, to be sure, comes at a price. The central question is: When does that price become too high? The Indian government decided some thirty years ago that the price is *always* too high. The 1970 Patent Act simply prohibited the granting of patents on pharmaceutical products (in other words, on drug compounds themselves).<sup>10</sup> However, patents on manufacturing processes are permitted and indeed enforced.<sup>11</sup> The upshot of this is that Indian pharmaceutical firms undertake little original research and development. Rather, a large and fragmented generic pharmaceuticals industry has developed in India, with some sixteen thousand firms.<sup>12</sup> These firms have become quite adept over time at starting with a drug compound that has been approved in a foreign market and reverse-engineering it—that is, determining how the compound is made and devising a novel manufacturing process for producing it in great quantities.<sup>13</sup> As a result of this expertise, and because reverse-engineering entails minimal research costs that need to be recouped, drugs are often available in India at a fraction of their price in the United States and Europe.<sup>14</sup>

---

companies spend an average of 12 to 15 years to discover and develop a new drug at an average cost of \$500 million. *Id.* Only five in 5,000 compounds that enter preclinical testing make it to human clinical trials, and only one of these five tested in people is ultimately approved for marketing. *Id.*

10. LANJOUW, *supra* note 7, at 3.

11. Susan Finston, *India: A Cautionary Tale on the Critical Importance of Intellectual Property Protection*, 12 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 887, 889 (2002).

12. See SEAN ERIC SMITH, OPENING UP TO THE WORLD: INDIA'S PHARMACEUTICAL COMPANIES PREPARE FOR 2005 13 (Asia/Pacific Research Ctr., Inst. For Int'l Studies, Working Paper, May 2000).

13. Finston, *supra* note 11, at 889.

14. For example, ranitidine (for the treatment of ulcers and gastroesophageal reflux disease) is 56 times more expensive in the United States and 26 times more expensive in the United Kingdom than in India. LANJOUW, *supra* note 7, at 39. Similarly,

2004] *TRIPS COMPLIANCE: DEALING WITH DRUG PATENTS IN INDIA* 603

However, India has begun to pass legislation that will over time turn this relative pricing advantage and the robustness of the Indian generics industry into distant memories. As a result of the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) and India's membership in the World Trade Organization (WTO), India is required to make significant changes to its drug patent laws by 2005.<sup>15</sup> In particular, to comply with Trade Related Aspects of Intellectual Property Rights (TRIPS)<sup>16</sup> agreements, India, along with many other developing countries, must adopt an intellectual property regime that mimics the system of much of the developed world, complete with twenty-year patent rights on pharmaceutical products.<sup>17</sup> Such a system, it is believed, will have many positive effects in the long run, including the stimulation of risky and expensive research and development activity. Specifically, patents in developing countries such as India are likely to fuel research into diseases such as malaria and tuberculosis that are specific to those areas and that have not previously drawn much attention from industry because of the unavailability of patent protection.<sup>18</sup>

---

ciprofloxacin (an antibiotic) costs 15 times more in the U.S. and 10 times more in the U.K. than in India. *Id.*

15. See SMITH, *supra* note 12, at 13.

16. See Agreement on Trade Related Aspects of Intellectual Property Rights, Apr. 15, 1991, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments—Results of the Uruguay Round vol. 31, 33 ILM 81, 93 (1994) [hereinafter TRIPS Agreement].

17. *Id.* at 18.

18. A 1996 study found that \$42 per malaria death was spent on research; the comparable figures for asthma and HIV/AIDS were \$840 and \$3,360, respectively. Donald G. McNeil, Jr., *New Drug for Malaria Pits U.S. Against Africa*, N.Y. TIMES, May 28, 2002, at F6. This was the result despite the fact that malaria still exists in 90 countries (almost exclusively in developing ones), with more than 300 million cases a year, and over 1 million deaths. *Id.* Similarly, tuberculosis, which has been largely eradicated from the developed world, accounts annually for nearly 1.7 million deaths worldwide, WORLD HEALTH ORGANIZATION, THE WORLD HEALTH REPORT 2001 144–45 (2001), available at <http://www.who.int/whr2001/2001/main/en/pdf/whr2001.en.pdf> [hereinafter THE WORLD HEALTH REPORT 2001], thirty percent of which occur in India, *DOTS Coverage and Treatment Success Rate Soars in India*, in WORLD HEALTH ORG., HEALTH A KEY TO PROSPERITY 38 (November 14, 2003), at <http://www.who.int/inf-new/tuber3.htm>. These two diseases together claim almost as many lives in any given year as HIV/AIDS. THE WORLD HEALTH REPORT 2001, *supra*, at 144–45. Moreover, the

Despite the potential benefits, however, critics have rightly pointed to two major difficulties of compliance with TRIPS. First, product patents will mean that generic companies will no longer be able to market a drug simply by developing a new manufacturing method. As such, there will be no competitive pressures on a drug until its patent expires; drug prices are therefore almost certain to increase. This is objectionable in a country like India, where only a small percentage of the population can afford prescription drugs even at currently depressed prices.<sup>19</sup> Second, there is a strong argument to be made that the new laws in 2005 will benefit multinational pharmaceutical companies at the expense of Indian industry and jobs.<sup>20</sup> The multinational corporations (MNCs) have been conducting drug discovery programs for many years, and are therefore likely to benefit significantly from the ability to patent their promising drug candidates in India. Indian generic manufacturers, on the other hand, have very little experience discovering and developing their own drugs; as noted above, they are in the business of imitating already-approved drugs that can then be sold cheaply. Thus, it seems possible that Indian generic firms may be driven out of business unless they can find a way to compete effectively in drug discovery with MNCs. If they are unable to do so, Indian pharmaceutical

---

organisms that cause both malaria and tuberculosis are rapidly developing resistance to currently available treatments, making additional research even more urgent. WORLD HEALTH ORG., WHO GLOBAL STRATEGY FOR CONTAINMENT OF ANTIMICROBIAL RESISTANCE 1 (2001), available at [http://www.who.int/csr/resources/publications/drugresist/en/EGlobal\\_Strat.pdf](http://www.who.int/csr/resources/publications/drugresist/en/EGlobal_Strat.pdf).

19. Spending on drugs in India amounted to only \$3 per capita in 1994, Trade and Development Centre, *Trade and Development Case Studies: India*, at <http://www.itd.org/issues/india5.htm> (last visited Jun. 15, 2004), and examining present drug price levels makes clear that affordability is a problem even today. For instance, 10 tablets of Voveran, a chronic pain medication, cost more than 15 cents, and 10 tablets of Dolonex, an anti-inflammatory medication used to treat arthritis, among other ailments, cost over 60 cents. See LANJOUW, *supra* note 7, at 39 tbl. 2. Given that these drugs are used to treat chronic conditions, they must be taken continuously, meaning that their cost per year, even in India, is many multiples of \$3. Thus, the current spending level suggests that a sizeable number of Indians do not have access to the drugs they need.

20. See, e.g., Richard Gerster, *How WTO/TRIPS Threatens the Indian Pharmaceutical Industry*, at <http://www.twinside.org.sg/title/twr120h.htm> (last visited Jun. 15, 2004).

2004] *TRIPS COMPLIANCE: DEALING WITH DRUG PATENTS IN INDIA* 605

workers will no doubt lose jobs, and they will not necessarily be absorbed by MNCs, who can set up their manufacturing operations anywhere in the world and are unlikely to open new facilities in India because of relatively poor infrastructure.<sup>21</sup> Moreover, large amounts of wealth that previously remained within India to be re-invested domestically will likely leave the country via the MNCs.

These criticisms are legitimate and suggest results that are quite problematic for a country like India. How, then, can the nation live with the consequences of TRIPS compliance? I argue here that there are many factors already in place and several relatively straightforward policy choices that the Indian government can make that will mitigate the drawbacks of granting pharmaceutical product patents. In Part II, I address the real possibility that patents will result in increased prices of essential medicines. While this possibility is likely to materialize, it is apt to occur only gradually, and the Indian government can make use of price controls, its bargaining power as a large purchaser, and compulsory licenses in the meantime to ensure that the process does not proceed more quickly than is desirable. However, such strategies should only be undertaken when absolutely necessary; resorting to them too liberally would only serve to undermine the very incentives that drug patents are intended to create. Part III of this Article takes up the concern that Indian pharmaceutical firms will suffer and that Indian jobs will be lost in the post-2005 world. This fear is by no means far-fetched, but there are reasons to believe that Indian industry will be able to compete with global players. Among these are an educated, well-trained scientific workforce and evidence of successful drug development in the past. Moreover, by passing reforms that will encourage the development of venture capital, India's government can make certain that funding will be available for the country's nascent biotechnology industry, an industry that holds the promise of making significant contributions to India's economic growth and public

---

21. See, e.g., Assif Shameen, *The Future of Manufacturing*, ASIA INC., Feb. 2004, available at [http://www.asia-inc.com/February04/coverstory\\_feb.htm](http://www.asia-inc.com/February04/coverstory_feb.htm) (citing the "[h]igh cost of power, and delays in road and port transportation" as examples of India's infrastructure problems) (last visited Jun. 15, 2004).

health needs. Part IV concludes with some thoughts about the importance of experimentation and context-specificity with regard to the strengthening of intellectual property rights in the developing world, and with a word of caution about an over-reliance on patents to solve the difficult problems of drug research and economic development.

## II. RESPONDING TO THE THREAT OF INCREASED DRUG PRICES

### A. *Will Drug Prices Actually Rise?*

As described earlier, patents give the patent holder the right to exclude others from making, using or selling the patented invention for a specified period of time.<sup>22</sup> The effective result of this grant is a limited monopoly, which yields lower output and higher prices than would result in a competitive market situation.<sup>23</sup> Hence, there is a worry that prices of medicines in India will rise post-2005, and that life-altering or life-saving drugs will be available to even fewer people, even though access is already severely limited at the currently low price levels.<sup>24</sup> Indeed, the rhetoric often used by critics of the TRIPS requirements would suggest that on January 1, 2005, millions of sick people suddenly will not be able to afford the drugs on which they had been relying to improve or prolong their lives. For example, the non-governmental organization Oxfam in late 2002 staged a protest outside of the WTO headquarters in Geneva in which an African woman with pneumonia who was taking a generic medicine intravenously had her “generic lifeline” cut by suited trade delegates representing industrialized countries and drug companies.<sup>25</sup> Such tactics no

---

22. See 35 U.S.C. § 154 (2000).

23. See JOHN H. JACKSON ET AL., LEGAL PROBLEMS OF INTERNATIONAL ECONOMIC RELATIONS: CASES, MATERIALS AND TEXT 922 (4th ed. 2002) (stating that “a patent holder . . . will tend to charge a monopoly price over the life of the patent, thus introducing the distortion of monopoly pricing into the economy.”).

24. See, e.g., S. Venu, *The IPR Effect on Drug Prices*, THE HINDU BUSINESS LINE, Oct. 28, 2002, at <http://www.thehindubusinessline.com/bline/2002/10/28/stories/2002102801140800.htm>.

25. *Oxfam Stages Theatrical WTO Protest Over Access to Medicines for Poor*, AGENCE FRANCE PRESSE, Nov. 25, 2002, available at 2002 WL 23657634.

doubt raise public awareness of the downsides of drug patents in developing countries, but they are misleading. To pin down with some certainty what is likely to happen to the prices of pharmaceutical drugs after the new patent provisions are in place, we must consider how exactly the law will change.

The patent requirements of TRIPS are contained in Articles 27–34 of the WTO Agreement.<sup>26</sup> Patents must be made available for both products and processes and must last for at least twenty years from the date of filing of a patent application.<sup>27</sup> When the TRIPS agreement was passed in 1994, however, its rules did not have immediate effect in the developing world; instead, transition periods were put in place.<sup>28</sup> Developing nations that did not provide patent protection for a particular area of technology (such as pharmaceuticals, in the case of India)<sup>29</sup> were given until January 1, 2005 to implement and enforce patent rights in that area.<sup>30</sup> While India has not yet provided for product patents, it has passed an Act allowing for exclusive marketing rights for new products from 2000–2005. This statute permits India to be in compliance with Articles 70.8 and 70.9 of TRIPS, although the law does not prevent the marketing of generic copies under a different name.<sup>31</sup> The Indian government has also put in place a mailbox provision for the filing of product patent applications during the transitional period from 1995–2005; such applications may be filed during this time, but patents will not be granted on these inventions until 2005.<sup>32</sup> What is key in all of this, however, is that India's laws do not have to be and will not be retroactive<sup>33</sup>—in other words, drugs

---

26. See TRIPS Agreement, *supra* note 16, at 93.

27. *Id.* at 93, 96.

28. *Id.* at 107.

29. See SMITH, *supra* note 12, at 5. India has historically granted product patents in other areas, such as software and information technology (IT). This is part of the reason for the IT boom that India experienced in the 1990's. Donald G. McNeil, Jr., *Selling Cheap 'Generic' Drugs, India's Copycats Irk Industry*, N.Y. TIMES, Dec. 1, 2000, at A1.

30. See TRIPS Agreement, *supra* note 16, at 107.

31. The Patents (Amendment) Act, §24A (1999) (India) (amending The Patents Act, 1970, Co. 39 (India)).

32. *Id.*

33. *Id.*

that have already been patented elsewhere and that are already being produced generically when the legislation goes into effect will not be protected by patent in India. As a result, the prices of drugs already for sale are not likely to change,<sup>34</sup> and the consumer with pneumonia will not abruptly be denied the generic medication that she has been taking. It is only those drugs that are newly discovered that will be afforded patent protection and whose prices will remain high during the period of the patent.<sup>35</sup> Thus, overall spending on pharmaceutical drugs will rise only gradually over time as new drugs are patented in India and then approved for sale; the country will not suffer a sudden shock from immediate price increases. This timing issue often gets obscured in the heated debates about drug patents, but it is an important one because it means that the biggest drawback of granting product patents will be phased in slowly over time.

### *B. Drug Price Controls*

Even though drug prices will increase only gradually, they are sure, in the aggregate, to rise. Fortunately, there are other, more active steps that the Indian government can take to deal with the inevitability of higher drug prices. The first of these involves the use of price controls.<sup>36</sup> When India passed its Patent Act in 1970, it also instituted a Drug Price Control Order (DPCO).<sup>37</sup> The legislation had a threefold purpose: to ensure public access to essential drugs, to provide a reasonable rate of return to companies, and to ensure quality.<sup>38</sup> In its initial form, the DPCO was quite wide-ranging and stringent, but it was weakened by amendment in 1995, as nearly half of the drugs

---

34. Finston, *supra* note 11, at 894.

35. It is worth mentioning that because it takes many years to get a drug approved for marketing, the effective patent period for prescription drugs is often shorter than twenty years—it frequently amounts to ten years or less. James C. Mason, *FDA Approval of Generic Drugs: Instituting a First Successful Defense Requirement for Generic Exclusivity*, 22 BIOTECHNOLOGY L. REP. 97, 98 (2003).

36. See SMITH, *supra* note 12, at 17.

37. *Id.*

38. *Id.*

2004] *TRIPS COMPLIANCE: DEALING WITH DRUG PATENTS IN INDIA* 609

that were covered by the legislation were dropped from the list.<sup>39</sup> Thus, it is true that India has been moving away from price controls in recent years, particularly since it began its program of economic liberalization in 1991.<sup>40</sup> Nonetheless, the prices of some seventy-five compounds are still subject to strict controls,<sup>41</sup> and there is no reason why this regulation cannot be extended to new drugs that are patented and approved for sale after 2005. Such a move would protect both consumers and local companies from the potentially destabilizing effects of India's obligations under TRIPS, at least in the short term. It would be a powerful means by which to keep prices down and would no doubt send a strong message to the industry.

However, the use of price controls would come at the risk of deterring some would-be drug discoverers from entering the business. As such, this is one of the tools at the government's disposal that must be used with utmost care and caution. If it is used repeatedly, even in situations when it is of questionable necessity, and if prices are capped far below market rates, Indian and international pharmaceutical and biotechnology companies alike will be put on notice that the prices at which they will be able to sell their products will likely be artificially depressed, thereby muting the incentives to commercialize therapies for diseases specific to the Indian subcontinent. If, however, price controls are used sparingly and only in truly emergency circumstances, drug discovery firms will know they can charge market rates in most cases, and will have to discount potential profits only slightly when deciding whether to conduct research into various therapeutic areas.

Another related concern is that if price controls are imposed, MNCs may decide to keep their patented products out of India entirely, and local companies will be prohibited from producing them on a generic basis, thereby depriving consumers of access to those drugs altogether. However, in the case of drugs for diseases like malaria and tuberculosis, it would be foolish for MNCs to pull out of India, as India is one of the larger markets

---

39. *Id.*

40. VIJAY JOSHI AND I.M.D. LITTLE, *INDIA'S ECONOMIC REFORMS 1991-2001*, (Oxford University Press 1996).

41. SMITH, *supra* note 12, at 17.

for such products.<sup>42</sup> As long as the threat of price controls *ex ante* did not dissuade a firm from developing these drugs in the first place, it would not make sense for a firm to decide *ex post*, after the research and development investment had been made—a sunk cost, in economic terms<sup>43</sup>—to withdraw from the Indian market, unless the controlled price was below the marginal cost of production. The worry about pullout is much stronger in the case of drugs for diseases that have significant markets in the United States and Europe. Here, the firm may more plausibly wield the threat of withdrawal, since it will be making the bulk of its profits outside of India in any case. Nonetheless, the public relations backlash that would result may be sufficient to deter firms from pursuing such strategies.<sup>44</sup> Even if image concerns did not preclude such tactics, however, taking steps to prevent the export and resale of drugs at higher prices abroad likely would. The primary reason that pharmaceutical companies oppose the idea of selling drugs in developing countries at low cost is the fear that such drugs will find their way back to developed nations, to be resold at a large profit.<sup>45</sup> Sadly, this worry is grounded in reality, as cases have recently come to light of cheap HIV/AIDS drugs destined for Africa being resold in Europe at huge markups.<sup>46</sup> Thus, the Indian government may

---

42. See Finston, *supra* note 11, at 891–92.

43. See Defense Economic Analysis Council, *Economic Analysis Handbook*, at <http://www.nps.navy.mil/drmi/definition.htm> (defining a sunk cost as a “cost incurred in the past” that “should be ignored in determining whether a new investment is worthwhile”) (last visited Jun. 15, 2004).

44. For example, thirty-nine drug companies sued the South African government in 1997 after it passed a law allowing the country to ignore their patents and import cheaper generic drugs, but global protests embarrassed the companies into dropping their lawsuit in April 2001. Daryl Lindsey, *Amy and Goliath*, SALON, May 1, 2001, at <http://archive.salon.com/news/feature/2001/05/01/aids/>.

45. See Samantha Shoell, Comment, *Why Can't the Poor Access Lifesaving Medicines? An Exploration of Solving the Patent Issue*, 4 MINN. INTELL. PROP. REV. 151, 162–68 (2002) (discussing the effects of parallel imports on the profits of pharmaceutical manufacturers).

46. See Gregory Crouch, *Europeans Investigate Resale of AIDS Drugs*, N.Y. TIMES, Oct. 29, 2002, at W1. Deeply discounted HIV/AIDS drugs manufactured by GlaxoSmithKline arriving on flights from Africa were intercepted at airports in Paris and Brussels in mid-2002. *Id.* GlaxoSmithKline claimed to have lost nearly \$16 million that year from the illegal resale of its products. *Id.* Moreover, investigators discovered evidence that some of the humanitarian organizations responsible for distributing the

2004] *TRIPS COMPLIANCE: DEALING WITH DRUG PATENTS IN INDIA* 611

need to couple its use of price controls with methods to stop such illegal reselling, perhaps via special registration and labeling for drugs that are at-risk for such activity. Putting such safeguards in place would make drug price controls a viable approach for keeping prices of new drugs in check in situations where the public health need was genuinely desperate, while simultaneously reducing the probability that firms will exit the Indian market completely.

### *C. Governmental Purchasing Power*

There exists an alternative to price controls that would accomplish similar results and that might be more palatable to pharmaceutical companies. It involves governmental use of its substantial buying power to bargain with drug companies for lower prices. Private health insurance is extremely undeveloped in India, with less than four percent of drug purchases paid for by private insurance companies.<sup>47</sup> Another seventy-five percent of prescription drug spending is out-of-pocket.<sup>48</sup> The remaining twenty or so percent of drug spending is paid for by the Indian government.<sup>49</sup> While it is not the sole buyer of medicines, the government is by far the single largest purchaser of prescription drugs in the country. The Department of Health in the Ministry of Health and Family Welfare could comfortably use its significant bargaining power to negotiate with pharmaceutical companies for more favorable drug prices. Such a strategy would probably be seen as less offensive than price controls by industry, for it would simply be an instance of the market at work. Moreover, it would involve pharmaceutical firms in the process, which would also contribute to acceptability over schemes that entail unilateral decisions by government entities.

Of course, bargaining for lower prices will be most effective for drugs in therapeutic areas for which there are reasonable treatment alternatives and for drugs in disease areas that are

---

drugs in Africa at least knew of the reselling, and may have been involved with it. *Id.*

47. LANJOUW, *supra* note 7, at 10.

48. Trade and Development Centre, *supra* note 19.

49. See LANJOUW, *supra* note 7, at 10; Trade and Development Centre, *supra* note 19.

specific to India and other developing countries, where the seller needs the market as much as the people of the country need the drug product. The government's negotiating leverage will be much weaker with regard to new drugs in disease indications that have sizable markets overseas. Here, price controls—coupled with resale prevention mechanisms—may be necessary to keep prices at levels that are acceptable for consumers while at the same time profitable for manufacturers. Thus, while bargaining over price is in some ways limited, it can be effective for certain categories of drugs, and can keep prices low for at least the twenty percent of Indian consumers for whom the government acts as the medical insurer.

#### *D. Compulsory Licenses*

A third affirmative step that the government of India can take to ensure that the new intellectual property regime of 2005 does not result in extreme difficulties for Indian consumers is the granting of compulsory licenses.<sup>50</sup> Compulsory licenses are granted by a government and allow a party to use a patent without the consent of the patent holder.<sup>51</sup> At the WTO talks in Doha in late 2001, the delegations from India and a number of other developing countries secured a significant concession regarding compulsory licenses, embodied in the Doha WTO Ministerial Declaration on TRIPS and Public Health.<sup>52</sup> Section

---

50. In addition to the very direct measures described in Parts II.B, II.C and II.D, there may be more indirect means at the government's disposal as well. Gideon Parchomovsky and Peter Siegelman have recently argued that the existence of trademark protection allows a patent holder to extend her protection even after the patent expires, thereby receiving greater profits than she would without the possibility of such coupling. See Gideon Parchomovsky & Peter Siegelman, *Towards an Integrated Theory of Intellectual Property*, 88 VA. L. REV. *passim* (2002). What is more, Parchomovsky and Siegelman show theoretically and empirically (using several case studies, including some from the pharmaceutical industry) that this coupling (or "leverage," as they call it) is efficient because it results in patent holders pricing and producing less monopolistically than they would if they were to lose all protections once the patent expired. See *id.* Thus, if India were to introduce strong trademark laws together with patent laws in 2005, it may create incentives for future patent holders to price their drugs at a level that would eliminate some of the deadweight loss that consumers suffer in a pure monopoly situation.

51. BLACK'S LAW DICTIONARY 931 (7th ed. 1999).

52. Declaration on the TRIPS Agreement and Public Health, Nov. 14, 2001, World

2004] *TRIPS COMPLIANCE: DEALING WITH DRUG PATENTS IN INDIA* 613

5b of the Doha Declaration provides that “[e]ach Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.”<sup>53</sup> The WTO now recognizes that in national emergencies or other circumstances of extreme urgency, which are explicitly defined to include public health crises, nations are permitted to grant compulsory licenses on patented compounds to generic manufacturers who will produce the drug at low cost.<sup>54</sup>

Since countries are authorized to decide for themselves what constitutes an emergency within their borders, India could make use of this “emergency out” as liberally as is necessary to reduce the costs of medications for certain conditions. HIV/AIDS, tuberculosis and malaria are mentioned explicitly in the Doha Declaration,<sup>55</sup> so it has always been clear that compulsory licenses for drugs that treat these diseases will be permitted. However, while several developed countries contested whether the text of the document limits such licenses strictly to these conditions or whether other diseases fall within its scope as well, an agreement reached on August 30, 2003 clarified the situation.<sup>56</sup> Specifically, trade representatives from India and other developing countries negotiated a deal that effectively sets no limit on the range of ailments for which compulsory licenses may be issued.<sup>57</sup> The Indian government may therefore utilize such licenses for any public health matter as it sees fit.

It deserves mention that compulsory licenses are not without precedent in North America and Europe. Canada and the United Kingdom both made extensive use of them in the 1970’s,<sup>58</sup> and the United States itself recently threatened Bayer,

---

Trade Organization—Doha Ministerial 2001, WT/MIN(OI)/DEC/2.

53. *Id.* at §5(b).

54. *Id.* at §5(c).

55. *Id.*

56. Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Decision of 30 August 2003, WT/L/540 (Sep. 1, 2003) [hereinafter Decision of 30 August, 2003]; see also *Symptomatic Relief*, THE ECONOMIST (Sept. 6, 2003); see also *CPTech Statement on WTO Deal on Exports of Medicines*, at <http://www.cptech.org/ip/wto/p6/cptech08302003.html> (last visited Jun. 15, 2004).

57. See Decision of 30 August, 2003, *supra* note 56.

58. COMMISSION ON INTELLECTUAL PROPERTY RIGHTS, INTEGRATING INTELLECTUAL PROPERTY RIGHTS AND DEVELOPMENT POLICY 42 (3rd ed. 2003) [hereinafter COMMISSION

telling the company that if it did not supply Cipro cheaply the government would procure generic versions of the drug to deal with the consequences of anthrax attacks.<sup>59</sup> Still, what many developing countries (including India) lack is a simple administrative process for issuing compulsory licenses. The process must be transparent and quick, and it must allow for appeal without suspending the execution of the license.<sup>60</sup> Furthermore, unambiguous guidelines for setting royalty rates on such licenses are a necessity.<sup>61</sup> Fortunately, India possesses a fairly capable governmental bureaucracy that should be able to put such procedures in place. In addition, the existence of a generic pharmaceutical industry intimately familiar with the process of reverse-engineering drugs means that governmental threats to grant compulsory licenses will be credible. Other nations without similar domestic capabilities may not be so lucky.<sup>62</sup>

Finally, the same caveats that apply to the use of price controls apply to the use of compulsory licenses. Great restraint should be exercised when deciding whether to issue such licenses, and they should be granted only in cases of dire need. Of course, when we are dealing with the health requirements of millions of people, many situations can be classified as urgent. Nonetheless, the government needs to maintain a long-term perspective—not necessarily an easy thing to do in a parliamentary democracy with elections every few years—and it should not allow short-term pressures to eliminate completely the research and commercialization incentives that the patent

---

ON IPR], available at [http://www.iprcommission.org/graphic/documents/final\\_report.htm](http://www.iprcommission.org/graphic/documents/final_report.htm).

59. *Id.*

60. Carlos M. Correa, *TRIPS and Access to Drugs: Toward a Solution for Developing Countries Without Manufacturing Capacity*, 17 EMORY INT'L L. REV. 389, 400 (2003).

61. James Love, *Compulsory Licensing: Models for State Practice in Developing Countries*, Jan. 21, 2001, at [http://www.cptech.org/ip/health/cl/recommended\\_statepractice.html](http://www.cptech.org/ip/health/cl/recommended_statepractice.html) (last visited Jun. 15, 2004).

62. COMMISSION ON IPR, *supra* note 58, at 42. However, an agreement was recently reached at the WTO to permit such nations to import cheap copies of patented drugs from countries like India and Brazil that have a generic pharmaceutical industry. *WTO Votes To Bypass Patents on Medicines: Cheap Generics Go To Poor Nations*, THE WASH. POST, Aug. 31, 2003, at A16.

system is designed to create. Certainly the sick and poor of today need to be assisted, but this is better accomplished through the solicitation of international aid to pay for medicines and via negotiation with patent holders themselves for lower prices for necessary drugs.<sup>63</sup>

#### *E. Lax Enforcement of Patent Rights*

Aside from the use of price controls, bargaining power and compulsory licenses, another factor remains that may help to keep down the prices of certain patented drugs. This factor has to do with the Indian government's willingness and ability to enforce patent rights. As Indira Gandhi's statement reproduced at the outset indicates, India has had for a long time strong anti-patent beliefs, and these will take some time to overcome. It is not insignificant that, over the past two decades, India has led other developing countries in opposing developed countries' efforts to implement global intellectual property standards.<sup>64</sup> Moreover, it was India's Parliament that in 1995 insisted on a ten-year transition period to pass new legislation that would comply with TRIPS.<sup>65</sup> Such historical aversion to patents is not easily reversed. At a minimum, it is reasonable to assume that the government is not fully and absolutely committed to increased patent protection.

There is a trade group in India called the Organisation of Pharmaceutical Producers of India (OPPI) that is roughly analogous to the Pharmaceutical Research and Manufacturers of America (PhRMA) in the United States.<sup>66</sup> OPPI represents the

---

63. Additionally, as I will argue in Part II.F, governments should focus their energies on economic development so that they can subsidize drug purchases for their citizens in the future.

64. Nadia Natasha Seeratan, *The Negative Impact of Intellectual Property Patent Rights on Developing Countries: An Examination of the Indian Pharmaceutical Industry*, 3 SCHOLAR 339, 359 (2001).

65. SMITH, *supra* note 12, at 21.

66. See Fact Sheet, Organisation of Pharmaceutical Producers of India (OPPI), About OPPI, at <http://www.indiaoppi.com/about.htm> (stating that OPPI, established in 1965, is an organization of pharmaceutical manufacturers that represents primarily research based companies in India) (last visited Jun. 15, 2004); Fact Sheet, The Pharmaceutical Research and Manufacturers of America (PhRMA), Who We Are, at <http://www.phrma.org/whoweare> (last visited Jun. 15, 2004).

interests of branded pharmaceutical companies that engage in substantial research and development of their own, and who therefore support strong patent laws.<sup>67</sup> This group has worked hard to convey its members' interests to influential politicians, and it is largely because of OPPI's labors that India has made incremental steps toward meeting its TRIPS obligations by 2005.<sup>68</sup> However, OPPI has been vehemently opposed in its efforts by the Indian Drug Manufacturers' Association (IDMA). IDMA is a powerful and vocal lobby for the generics industry,<sup>69</sup> which, as noted earlier, is quite large, and certainly much larger than the branded industry in India. Such a dynamic does not exist in the United States because of the lack of a cohesive generic pharmaceuticals industry, but in India IDMA serves as a strong counterweight to those special interests that favor robust patent laws. In fact, IDMA published a book several years ago devoting five full chapters to a description of the adverse effects of patents.<sup>70</sup> In addition to its work to make certain that patent legislation is not as stringent as OPPI would like, IDMA is sure, after 2005, to apply political pressure to guarantee that patent enforcement is not as unforgiving as it might be.

Finally, a consideration of the Indian patent office and the Indian judiciary also reveals that lax enforcement of patents is a distinct possibility. India's version of the Patent & Trademark

---

67. See generally Organisation of Pharmaceutical Producers of India (OPPI), at <http://www.indiaoppi.com> (last visited Jun. 15, 2004).

68. OPPI has an influential collection of members, and part of the membership criteria is acceptance of OPPI's stand on intellectual property rights (IPR) issues. See Fact Sheet, Organisation of Pharmaceutical Producers of India (OPPI), OPPI Members, at <http://www.indiaoppi.com/membership.htm> (last visited Jun. 15, 2004). OPPI has lobbied for immediate compliance with the TRIPS requirement since signing the GATT Agreement on April 15, 1994. See Fact Sheet, Organisation of Pharmaceutical Producers of India (OPPI), Pharmaceutical Industry in India, at <http://www.indiaoppi.com/intelprop.htm> (last visited Jun. 15, 2004).

69. See Fact Sheet, Indian Drug Manufacturers' Association (IDMA), The Voice of the National Sector, at <http://www.idma-assn.org> ("IDMA represents the national sector of the Indian manufacturers engaged in producing and providing high quality bulk actives and pharmaceuticals to the Nation and to the world at a very reasonable price") (last visited Jun. 15, 2004).

70. N.B. ZAVERI, PATENTS FOR MEDICINE: BALANCED PATENT LAW—THE NEED OF THE HOUR 8–37 (1998).

2004] *TRIPS COMPLIANCE: DEALING WITH DRUG PATENTS IN INDIA* 617

Office (PTO) in 1993–94 spent about \$330,000, whereas the United States PTO in the late 1980's spent approximately \$300 million a year.<sup>71</sup> Given such minimal resources, it is conceivable that patent examination and approval will be a slow process and that patent holders will discount their expected profits for such delays.<sup>72</sup> However, additional funds are gradually being devoted to the development of an intellectual property administration infrastructure;<sup>73</sup> this problem is therefore likely to fade away over the next decade. What is much more suspect is the question of how India's judges will enforce patents. There exists evidence to suggest that India's judiciary is, as a rule, not well versed in economic theory and often makes decisions that are hostile to good economic judgment.<sup>74</sup> Thus, whereas the negative aspects of patents, in the form of higher prices, are immediate and easy to see, their upsides, in terms of increased research incentives, are more long-term and therefore more obscure, and this may affect judicial decision-making. Moreover, judges in India, as elsewhere, are not immune to public opinion,<sup>75</sup> and they may have a difficult time making decisions that will ostensibly raise drug prices and cost their fellow citizens jobs. All of these observations, taken together, hint that there simply may not exist in India the political will to strictly enforce patent rights,<sup>76</sup>

---

71. LANJOUW, *supra* note 7, at 19.

72. In addition to delays, there may also be additional expenses related to patent filing if the Indian patent office decides to charge user fees to remain within budget, as the U.S. PTO does. *See, e.g.*, Debra Robertson, *U.S. Patent Office Strategic Plan May Penalize Biotech*, 21 *NATURE BIOTECH.* 345–46 (2003).

73. *See* Sudha Nagaraj, *IP Offices to Come Up in Four Metros*, *THE ECON. TIMES*, July 12, 2002, available at <http://economictimes.indiatimes.com/cms.d11/articleshow?msid=15698158>. Recently, the Indian government announced that it is funding the opening of fully integrated intellectual property offices in Kolkata, Delhi, Mumbai, and Chennai. *Id.* These offices will house 230 patent examiners, who will be supported with technical assistance from the World Intellectual Property Organisation. *Id.*

74. *See, e.g.*, T.C.A. Srinivasa-Raghavan, *Of Law, Justice and Markets*, *BUS. STANDARD*, Oct. 9, 2000, WL 25808976.

75. *See, e.g.*, G. Edward White, *The Constitutional Journey of Marbury v. Madison*, 89 *VA. L. REV.* 1463, 1573 (2003) (reviewing the influences and limitations of the U.S. Supreme Court's decision making process and concluding that "there will always be limits on the legitimacy of the Court's expositions if they fail to resonate with enough members of the public").

76. Stanford law professor John Barton, who recently chaired the Commission on

and that may help to mitigate some of the adverse effects of patents in the short run.

*F. Public-Sector Drug Development*

Some who criticize the planned expansion of intellectual property rights in the developing world argue that there are better ways in which to spur drug discovery activity. One oft-repeated suggestion is for government to directly fund research.<sup>77</sup> Indeed, studies have found a substantial return to public investments in basic biomedical research.<sup>78</sup> In the United States, the National Institutes of Health (NIH) consists of twenty-seven institutes and centers that conduct their own medical research, and the NIH also provides funding for much of the basic and clinical research activity that takes place in university labs and hospitals.<sup>79</sup> The NIH has a significant budget—for fiscal year 2003 it was approximately \$27 billion<sup>80</sup>—and it has been successful in advancing its mission, which includes the improvement and development of strategies for the diagnosis, treatment, and prevention of disease.<sup>81</sup> In fact, several currently available drugs were developed to a large extent by NIH dollars. For instance, d4T, marketed by Bristol-Myers Squibb for the treatment of HIV/AIDS, was developed primarily by grant money from the NIH before being licensed to Bristol-Myers Squibb for clinical trials.<sup>82</sup>

---

Intellectual Property Rights in the United Kingdom, is particularly pessimistic about the capacity of the Indian government to implement new patent legislation. See SMITH, *supra* note 12, at 22.

77. See, e.g., Dean Baker, *The Real Drug Crisis* (Jul. 25, 1999), at <http://www.cepr.net/wto/realdrugcrisis.htm>; COMMISSION ON IPR, *supra* note 58, at 34.

78. See, e.g., IAIN COCKBURN & REBECCA HENDERSON, PUBLIC-PRIVATE INTERACTION AND THE PRODUCTIVITY OF PHARMACEUTICAL RESEARCH 1 (Nat'l Bureau of Econ. Research, Working Paper No. 6018, 1997).

79. See Fact Sheet, Nat'l. Institutes of Health, U.S. Dep't of Health and Human Servs, About NIH, at <http://www.nih.gov/about/> (last reviewed May 17, 2004).

80. *Id.*

81. See Fact Sheet, Nat'l. Institutes of Health, U.S. Dep't of Health and Human Servs, The NIH Almanac, at <http://www.nih.gov/about/almanac/index.html> (last reviewed May 13, 2004).

82. See *Stavudine (d4T)*, at <http://www.cptech.org/ip/health/d4T.html> (last visited Jun. 15, 2004).

2004] *TRIPS COMPLIANCE: DEALING WITH DRUG PATENTS IN INDIA* 619

Unfortunately, however, the argument for government-funded research—where the government would then own the patent on the drug and ensure that any licensees would market it at reasonably affordable rates—does not hold up well in a context such as India. First, there is no institution comparable to the NIH, and it would be extremely costly to build the infrastructure to get such a research center up and running. As noted above, the NIH has some twenty-seven centers and institutes, including the National Cancer Institute, the National Institute of Mental Health, and the National Center for Complementary and Alternative Medicine.<sup>83</sup> The NIH's annual budget is approximately one-nineteenth the entire gross domestic product (GDP) of India.<sup>84</sup> India simply could not afford to fund an agency of that quality and magnitude.

Of course, the Indian government could start small and grow the agency over time, but even that does not appear to be an attractive alternative. In India, it makes eminently more sense for the government to pay on the back-end in the form of higher drug prices than to shell out funds up-front to subsidize research that could just as effectively be undertaken by the private sector. India has been running massive fiscal deficits the last several years, which are threatening its macroeconomic stability; the combined central and state government deficit exceeds ten percent of GDP, and this is on top of an already excessive debt-to-GDP ratio of nearly sixty percent.<sup>85</sup> Not only are such deficits unsustainable, but they also crowd out private sector investment.<sup>86</sup> Clearly, the time is not ripe for additional

---

83. See Fact Sheet, Nat'l. Institutes of Health, U.S. Dep't of Health and Human Servs., The NIH Almanac—Organization, at <http://www.nih.gov/about/almanac/organization/index.htm> (last reviewed May 13, 2004).

84. Compare U.S. Department of Health and Human Services, National Institutes of Health, About NIH, at <http://www.nih.gov/about/> (last reviewed May 17, 2004), with *India at a Glance*, at [http://www.worldbank.org/data/countrydata/aag/ind\\_aag.pdf](http://www.worldbank.org/data/countrydata/aag/ind_aag.pdf) (last visited Jun. 15, 2004). India's GDP in 2002 was \$510 billion, up from \$195 billion in 1982 and \$244 billion in 1992. *Id.*

85. ARVIND PANAGARIYA, INDIA'S ECONOMIC REFORMS 3–4 (Asian Dev. Bank, ERD Policy Brief No. 2, 2002).

86. *Id.*; see also T.N. SRINIVASAN, INDIA'S FISCAL SITUATION: IS A CRISIS AHEAD? 6 (Ctr. for Research on Econ. Dev. & Policy Reform, Stanford Univ., Working Paper No. 92, 2001).

borrowing. Assuming that stability can be maintained, the economy is growing rapidly—nearly six percent annually for the past couple of decades<sup>87</sup>—and should continue to do so under an economic program advocated by Jeffrey Sachs and Nirupam Bajpai.<sup>88</sup> Indeed, the government of India has declared this to be the “Decade of Development,” and has set the aggressive but achievable goal of doubling the country’s per capita income by the year 2010.<sup>89</sup> This would require growth in the per capita gross national product of seven percent per year for the ten years from 2000–2010, not appreciably higher than what India has attained in the recent past.<sup>90</sup> If this target is reached, India will be a significantly richer nation in the year 2010, and will be better positioned to increase spending on prescription drugs at that time, when the government is likely to be on stronger financial footing.

Finally, it would be wise for the Indian government to focus on the things that it *can* do well, such as investing in primary education and public health services, and to leave the more

---

87. *Id.*

88. See JEFFREY D. SACHS & NIRUPAM BAJPAI, THE DECADE OF DEVELOPMENT: GOAL SETTING AND POLICY CHALLENGES IN INDIA *passim* (Ctr. for Int’l Dev., Harvard Univ., Working Paper No. 62, 2001) (emphasizing that economic development requires a combination of both human development, involving commitments to health, education and political participation, and economic growth, including improved infrastructure and technological upgrading).

89. *Id.* at 1.

90. *Id.*; see SRINIVASAN, *supra* note 86, at 3. It is notable that stronger intellectual property rights are likely to attract foreign direct investment, which can contribute to economic growth and help India reach its goals. See Finston, *supra* note 11, at 888. A country’s stance on intellectual property is often treated as a signal of its business climate more generally. See, e.g., James Love, *Business Groups Urge Zoellick to Resist Reopening TRIPS Agreement* (Aug. 15, 2003), at <http://lists.essential.org/pipermail/ip-health/2003-August/005102.html>. For instance, China’s foreign direct investment inflows are believed to be more than ten times those of India, James Gordon, *Foreign Direct Investment and Exports*, Sept. 20, 2002, *passim* at <http://www.imf.org/external/country/IND/rr/2002/pdf/092002.pdf> (last visited Jun. 15, 2004), in spite of India’s superior conditions regarding the rule of law, democracy and the widely spoken English language. See Jeffrey D. Sachs et al., *Foreign Direct Investment in India: How Can \$10 Billion of Annual Inflows Be Realized?* 7 (Jan. 11, 2000) (unpublished Report to the Honorable Murasoli Maran, Minister of Commerce and Industry, Government of India), at <http://www2.cid.harvard.edu/india/pdfs/FDI.pdf>. Part of the reason (though certainly not the whole story) is that China provides stronger intellectual property protection in many areas, including product patents for pharmaceuticals. *Id.* at 36.

2004] *TRIPS COMPLIANCE: DEALING WITH DRUG PATENTS IN INDIA* 621

arcane activities involved in the drug discovery process to those who have more experience with them and who therefore can perform them more efficiently. Moreover, new drug development is a pursuit that can be left to the private sector, particularly if patent protection is in place, whereas education and health services are goods whose provision can only adequately be met by public spending because they create positive externalities that are not fully captured by the supplying entity. Regrettably, the Indian government's previous record in education and public health, particularly the former, is extremely dubious.<sup>91</sup> Fortunately, however, amid the many failures are a handful of stories of success from which the central and state governments can draw as they make policy decisions in the coming years. In particular, several southern states, including Kerala and Tamil Nadu, score far better than the rest of the country in certain important indicators such as life expectancy, infant mortality, and literacy,<sup>92</sup> demonstrating that government can make a difference in education and health if it makes the appropriate choices. There is no doubt that the government has the capability to make a greater impact with greater ease in these areas than it can in the highly technical and risk-laden world of medical research.

### *G. Summary*

As we have seen, there are good reasons to believe that the passage of a TRIPS-compliant intellectual property regime in India will not have a significant adverse impact on consumers in the short run *vis-à-vis* drug prices. Prices of already-approved drugs being produced by generic manufacturers should be utterly unaffected by the legislation. As far as the prices of drugs that are newly patented and approved after 2005, there are mechanisms in place that the Indian government can use to

---

91. See generally JEAN DRÉZE & AMARTYA SEN, *INDIA: ECONOMIC DEVELOPMENT AND SOCIAL OPPORTUNITY* *passim* (1995) (noting that Jawaharlal Nehru's goal of "the ending of poverty and ignorance and disease and inequality of opportunity" is largely unaccomplished).

92. *Id.* at 53, 60, 62–64; see also PIA MALANEY, *HEALTH SECTOR REFORM IN TAMIL NADU: UNDERSTANDING THE ROLE OF THE PUBLIC SECTOR* 3 (Ctr. for Int'l Dev., Harvard Univ., 2000).

keep them low. It can utilize drug price controls, its significant bargaining power, and compulsory licenses, though it should employ these tools only in cases of extreme necessity. Moreover, patent rights are not likely to be enforced stringently, further applying downward pressure on prices. Thus, fears of unconscionably high drug prices are exaggerated,<sup>93</sup> and such predictions ignore the considerable benefit that the granting of product patents is likely to have on research and development activity.

Diseases like malaria, tuberculosis, leishmaniasis and sleeping sickness, rarely given much attention in the United States and Europe, are terrible scourges in places like India and similarly situated developing countries.<sup>94</sup> Intellectual property rights are apt to spur drug discovery programs and provide some relief in these therapeutic areas.<sup>95</sup> Those who do not believe that

---

93. Even if prices remain too high to be affordable after steps are taken to reduce them, the Indian government can then subsidize drug spending, which will be a more realistic possibility in the future if the government focuses on and achieves its goals for economic growth. See discussion *supra* Part II.F. One study found that in Italy between 1978 and 1995 (patent protection for drugs was introduced in the former year), the price index for specialty drugs increased from 103.3 to 277.1, while the general price inflation index rose from 131.2 to 535.1. See Richard P. Rozek & Ruth Berkowitz, *The Effects of Patent Protection on the Prices of Pharmaceutical Products—Is Intellectual Property Protection Raising the Drug Bill in Developing Countries?*, 1 J. WORLD INTELL. PROP. 179, 180 n.3 (1998) (citing George Korenko, *Intellectual Property Protection and Industrial Growth: A Case Study* (April 1995) (unpublished manuscript)). Another analysis of pharmaceutical products in nine developing countries concluded that improving patent rights did not have a measurable impact on real or nominal prices of existing drugs, and little, if any, impact on price changes of new drugs under patent. *Id.* at 215.

94. See LANJOUW, *supra* note 7, at 25. See also WORLD HEALTH ORG., THE WORLD HEALTH REPORT 2000: HEALTH SYSTEMS: IMPROVING PERFORMANCE 170–71 annex tbl.4 (2000), available at [http://www.who.int/health-systems-performance/whr2000\\_annex4.pdf](http://www.who.int/health-systems-performance/whr2000_annex4.pdf).

95. See LANJOUW, *supra* note 7, at 25. An argument often made by those who disfavor the expansion of strong patent rights to the developing world is that such rights will not increase research incentives for diseases—diabetes and cardiovascular disease, for instance—that already have sizable markets in developed countries. See, e.g., Seeratan, *supra* note 64, at 386. However, this argument misses a critical subtlety. As we continue to understand more and more about the genetic basis of disease, we are learning that while a particular drug may be effective for some people, it is not likely to be effective for everyone. In particular, people whose genetic makeup is different may respond differently to the same medication. See, e.g., Allen D. Roses, *Pharmacogenetics*

2004] *TRIPS COMPLIANCE: DEALING WITH DRUG PATENTS IN INDIA* 623

such relief will result contend that patents cannot generate innovation where there is no money in the market, and that neglected diseases in poor countries will therefore remain neglected.<sup>96</sup> Why, the argument goes, would any businessperson, with the option to invest either in a baldness cure that would sell in the United States or in a new parasite medicine that would sell only to the most destitute in rural India, choose the latter? In fact, there may be many reasons for doing so. Not every businessperson enters, or more importantly, can enter, the most profitable venture she can conceive. Often, capital constraints preclude this possibility. A small pharmaceutical company, for instance, may not have available to it the funds necessary to conduct the more rigorous, more expensive testing required by the United States Food and Drug Administration (FDA),<sup>97</sup> but may be able to move a drug through the relatively less demanding approval process in India.<sup>98</sup> Other concerns—some business-oriented, such as diversification, and some personal—may also drive businesspeople to conduct research into historically neglected diseases and conditions. Without patent protection, they are sure to lose money on their investment; with it, they may get a positive return, and, even if it is small, there is a chance that they will go forward with the project, especially if anticipated returns are higher than earnings on the low-margin generic drugs they currently make, as is the case with many Indian companies. Furthermore, while the “patents do not provide incentives where there are no

---

*and the Practice of Medicine*, 405 NATURE 857 (2000). Thus, the implementation of product patents in India, for example, may create incentives to produce and commercialize drugs that are most effective for the Indian population.

96. Keith E. Maskus, *Ensuring Access to Essential Medicines: Some Economic Considerations*, 20 WIS. INT'L L.J. 563, 568 (2002).

97. See, e.g., Rosemarie Kanusky, *Pharmaceutical Harmonization: Standardizing Regulations Among the United States, the European Economic Community, and Japan*, 16 Hous. J. INT'L L. 665, 668–675 (1994) (discussing the regulation of the pharmaceutical market and the introduction of new drugs in the United States and the FDA's role); PHARM. RESEARCH AND MFRS. OF AM., *supra* note 9 (noting that it costs \$500 million, on average, to get a drug approved by the FDA); see also FOOD AND DRUG ADMINISTRATION, STRATEGIC ACTION PLAN: PROTECTING AND ADVANCING AMERICA'S HEALTH, 10 (2003), available at <http://www.fda.gov/oc/mcclellan/FDAstrategicPlan.pdf> (stating that by some estimates, it costs more than \$800 million to develop a new drug).

98. See LANJOUW, *supra* note 7, at 3–4.

markets” line of reasoning may have significant validity in many developing nations, it is less compelling in a country such as India, with a population of over one billion people<sup>99</sup> and some of the world’s biggest burdens of malaria,<sup>100</sup> tuberculosis and leprosy.<sup>101</sup> The Indian pharmaceutical market is one of the largest in the world in terms of volume, and Indian consumers have exhibited extraordinary pharmaceutical purchasing habits in spite of their low incomes; the aggregate market size in 2002 was approximately \$4.5 billion, constituting the thirteenth largest pharmaceutical market in the world.<sup>102</sup> Indeed, there are some pharmaceutical companies that are betting that incomes in India will continue to rise and that market demand will support the higher prices likely to result from patent protection.<sup>103</sup> Accordingly, while no one can say with certainty what will happen after January 1, 2005, it seems plausible that drug prices can be kept in check in the short-term while the new patent regime increases the flow of research dollars into, at a minimum, the most widespread of India’s neglected diseases.

### III. RESPONDING TO THE THREAT TO INDIAN INDUSTRY

#### A. *India Possesses Local Capacity*

Even if the concerns about drug prices are overblown and can be set aside, what of the apprehension regarding MNCs and

---

99. See Office of the Register General, India, *Census of India* (Apr. 5, 2001), at <http://www.censusindia.net/results/resultsmain.html> (last visited Jun. 15, 2004).

100. See World Health Organization South-East Asia Regional Office, *Distribution of Malarious Population at Risk in Who SEA Region*, 1999, at <http://w3.whosea.org/malaria/distribmalrpop.htm> (last modified Oct. 15, 2003). An event study found evidence of increased research activity in malaria in the 1980’s and 1990’s, when patent protections in developing countries were beginning to strengthen. JEAN O. LANJOUW & IAIN COCKBURN, DO PATENTS MATTER?: EMPIRICAL EVIDENCE AFTER GATT 5–13 (Nat’l Bureau of Econ. Research, Working Paper No. 7495, 2000).

101. See World Health Organization South-East Asia Regional Office, *Leprosy*, at <http://w3.whosea.org/leprosy/burden.htm> (last modified Jul. 2, 2003). India has two-thirds of the world’s leprosy cases, with 1.2 million cases expected to be detected by 2003. *Id.*

102. Ranbaxy Laboratories Limited, *Investor FAQ’s (December 31, 2002)*, at <http://www.ranbaxy.com/irfaqs2.htm>.

103. SMITH, *supra* note 12, at 19–20.

the harm that will befall Indian domestic industry and workers?<sup>104</sup> Will not the MNCs, with their experienced research and development arms, capture all of the benefits to be gained from patents and drive Indian firms out of business?<sup>105</sup> How can India live with this second major consequence of the new patent laws being thrust upon it?

It is clear that this concern is persuasive for many developing countries where local systems of innovation, particularly of the kind established in developed nations, are flimsy.<sup>106</sup> There, the dynamic benefits from intellectual property protection are likely to be inoperative for local firms because the patent system may provide appropriate incentives but there will be limited local capacity to use them.<sup>107</sup> It is the MNCs in such cases who will be able to take advantage of the incentive scheme and earn profits by producing drugs of interest to the domestic market. While consumers will benefit via introduction of new pharmaceuticals over time (though they will have to contend with temporarily high prices), domestic industry will receive little or no benefit, and, in fact, significant amounts of wealth may leave the country in the form of MNC profits.<sup>108</sup>

However, India is different in this regard in that it possesses sizeable scientific and technological capacity within its borders.<sup>109</sup> One common assumption of those who favor wide-ranging intellectual property rights is “that there is a latent supply of innovative capacity in the private sector [that is] waiting to be unleashed by the grant of the protection that [patents] provide[].”<sup>110</sup> This is more likely to be true of India than of any other developing country in the world, with the possible exception of China. Still, there are historical examples where MNC supremacy did come about following the introduction of patents. For example, in Italy in the late 1970’s and early 1980’s, MNCs “took over many local companies . . . and imports

---

104. See discussion, *supra* Part I.

105. See discussion, *supra* Part I.

106. COMMISSION ON IPR, *supra* note 58, at 15.

107. *Id.*

108. *Id.* at 36.

109. *Id.* at 2.

110. *Id.* at 15.

of patented drugs increased.”<sup>111</sup> Nonetheless, several factors are in place in India that indicate that the worry about MNC hegemony is overstated, including a large number of trained scientists and a sizeable domestic pharmaceutical industry that is already preparing for the 2005 changeover.<sup>112</sup> To be sure, some, perhaps many, Indian firms will not be able to handle the competitive pressures and will be forced to shut down or sell their companies in the patent era, but it is also likely that a number of Indian firms will become significant global players, in the process creating jobs and wealth, generating significant tax revenues for the central and state governments, and re-investing substantial funds back into the domestic economy.

### *B. Presence of a Skilled Scientific Workforce*

The first critical factor to note is that India possesses a large pool of well-educated, English-speaking scientists and engineers, many of whom are willing to work for wages that are relatively low on the world scale.<sup>113</sup> While elementary education has been sadly ignored in India,<sup>114</sup> Jawaharlal Nehru’s vision of creating a world-class university system has largely been realized,<sup>115</sup> particularly in the areas of science, medicine, and technology.<sup>116</sup> Indeed, India generates even more university graduates than does the United States, and some forty percent of them have

---

111. *Id.* at 37.

112. See generally SMITH, *supra* note 12.

113. ANNALEE SAXENIAN, BANGALORE: THE SILICON VALLEY OF ASIA? 22 (Ctr. for Research on Econ. Dev. and Policy Reform at Stanford Univ., Working Paper No. 91, 2001).

114. An indication of this is the amazingly low rate of literacy in India (64% for males and 37% for females in 1995). These rates are much lower than in China, lower than rates in many east and southeast Asian countries thirty years ago, lower than the average literacy rates for ‘low-income countries’ other than India or China, and no higher than estimated literacy rates in sub-Saharan Africa. See DRÉZE & SEN, *supra* note 91, at 114.

115. See, e.g., Achal Mehra, *IIT Tooms: The IITs Turn 50*, LITTLE INDIA, Nov. 2000 at <http://www.littleindia.com/India/Nov02/tooms.htm> (last visited Jun. 15, 2004). India had 19 universities at the time of independence in 1947, and had 219 by 1997. Ahron Daniel, *India Since Independence: Education in India*, at <http://adaniel.tripod.com/education.htm>, 1999–2000.

116. See, e.g., High Commission of India, *Study in India*, at <http://www.highcommissionofindia.com/Ifc/Html/study.htm> (last visited Jun. 15, 2004).

2004] *TRIPS COMPLIANCE: DEALING WITH DRUG PATENTS IN INDIA* 627

degrees in either science or engineering.<sup>117</sup> Moreover, it is not just quantity of which India can boast, but of quality as well. Over a half-century ago, for example, then-Prime Minister Nehru founded the Indian Institutes of Technology (IIT), envisioning them as 'Pillars of Modern India' that would train a corps of techno-elites who would power the nascent country's industrial revolution.<sup>118</sup> Today, graduates of IIT are among the most highly sought after students in the world by graduate schools and employers.<sup>119</sup> Part of the reason for this is that the IITs are quite possibly the most selective educational institutions anywhere, admitting only about 2,500 of the over 100,000 students who take the entrance exam each year.<sup>120</sup> This ensures that they enroll only the top students from an Indian educational system that already has a heavy math and science focus.

India's comparative advantage in highly skilled, relatively low-wage engineers has been cited as one of the primary reasons that the country experienced an information technology (IT) boom in the 1990's.<sup>121</sup> The performance of the industry was impressive in that decade, particularly in comparison to other sectors of the Indian economy. The compound annual growth rate of IT for 1994–1999 exceeded forty percent, compared to

---

117. JOHN NAISBIT, *MEGATRENDS ASIA: EIGHT ASIAN MEGATRENDS THAT ARE RESHAPING OUR WORLD* 191 (1996). 61,000 students graduate annually with computer engineering degrees in India, as compared with 30,000 in the United States. RAFIQ DOSSANI, *ACCESSING VENTURE CAPITAL IN INDIA* 9 (Asia/Pacific Research Ctr. at Stanford Univ., 1999). Additionally, nearly 1.5 million Indian students graduate annually with degrees in other science or engineering fields. *See id.*; National Science Foundation, *Science and Engineering Indicators 2000*, at <http://www.nsf.gov/sbe/srs/seind00/access/c4/c4s3.htm> (last visited Jun. 15, 2004).

118. Mehra, *supra* note 115.

119. Manjeet Kripalani, *Whiz Kids: Inside the Indian Institutes of Technology's Star Factory*, *BUS. WEEK*, Dec 7, 1998, at 117. Indeed, IIT graduates have had tremendous success in the worlds of business and technology. The more prominent alums include: Victor J. Menezes, Senior Vice Chairman of Citigroup; Rajat Gupta, former CEO of McKinsey & Co.; Rakesh Gangwal, former President & CEO of US Airways; and Vinod Khosla, Co-Founder of Sun Microsystems and Partner at Kleiner, Perkins, Caufield & Byers. *Id.* at 118.

120. *Id.* The Indian government pays nearly all of the \$3,000 annual cost of educating each student. *Id.*

121. Devesh Kapur, *The Causes and Consequences of India's IT Boom*, *INDIA REVIEW* 1(2), Apr. 21, 2002, at 5–6.

less than seven percent for the economy as a whole.<sup>122</sup> The growth was most pronounced in the software sector, which in 1999 accounted for two-thirds of India's total IT revenues and employed over 200,000 workers.<sup>123</sup> What is more, the software industry's growth was driven primarily by exports; exports increased at an annual rate of more than fifty-five percent in the late 1990's.<sup>124</sup>

This explosion in IT created an enormous amount of wealth for India. Companies like Wipro, Infosys and Satyam became among the most valuable on the Indian stock market, achieving market capitalizations upwards of \$15 billion at their peak.<sup>125</sup> The founders of these three firms, Azim Premji of Wipro, K.R. Narayana Murthy of Infosys, and B. Ramalinga Raju of Satyam, were all among the twenty richest people in India in 2000.<sup>126</sup> This money was made—and taxed, contributing to the public fisc—largely because India produces an abundance of highly skilled engineers and programmers each year; it was these individuals who helped propel Indian software firms to tremendous success. As noted above, just as engineers and programmers graduate from Indian universities at an astonishing rate, so too do scientists, including biochemists, pharmacists and molecular biologists.<sup>127</sup> This suggests the possibility that, once the patent regime is implemented, the Indian pharmaceutical industry might experience the same type of explosive growth that the software industry has undergone. Biomedical engineers who decide to shift promptly upon graduation and become computer engineers—this is not uncommon, because IT is widely perceived as the area where jobs, money and prestige lie—may not make that choice

---

122. SAXENIAN, *supra* note 113, at 3.

123. *Id.*

124. *Id.*

125. The stocks of these companies have taken less of a beating than the stocks of many other high technology companies over the past couple of years. As of June 15, 2004, Wipro and Infosys were still valued at \$10.4 billion and \$11.5 billion, respectively. *Wall Street Journal* (online edition), at <http://online.wsj.com/public/us> (last visited Jun. 15, 2004).

126. Die Hard Indian, *Success Stories*, at <http://www.diehardindian.com/ntertain/success.htm> (last visited Jun. 15, 2004).

127. *See supra* note 117 and accompanying text.

2004] *TRIPS COMPLIANCE: DEALING WITH DRUG PATENTS IN INDIA* 629

anymore, instead devoting themselves to drug and medical device discovery and development. The possibility of obtaining product patents may well set free the undeveloped supply of human scientific capacity that is clearly present in India. Once enough trained scientists determine that it is worth their while to work for Indian pharmaceutical firms, the chances increase that those firms will be able to compete effectively with MNCs, thereby creating wealth that will not quickly escape India's borders. Fortunately, just as the new patent system is being put in place, many Indian firms are taking steps that are likely to make them more attractive places to work for creative and motivated scientists and engineers.

### *C. Anticipatory Behavior of Indian Pharmaceutical Firms*

After 2005, Indian pharmaceutical companies will no longer be able to rely on their time-tested strategy of immediately reverse-engineering and marketing generic versions of new drugs that are approved in India and other countries. Instead, the patent laws will require them to wait twenty years before any such imitation may occur.<sup>128</sup> However, it is important to note that despite this obstacle, most firms are not likely to face insolvency, as eighty percent of their business in the aggregate comes from drugs that are off patent.<sup>129</sup> These, and other drugs whose patents expire by 2005, will continue to be available to Indian companies for generic production, meaning that more than four-fifths of the industry's revenues will remain steady and in place.

Nonetheless, to fully take advantage of the post-2005 environment and grow in the future, these companies realize that they will need to develop novel drugs of their own. Interestingly, while the new patent laws are likely to provide Indian firms with reasons to perform research into disease areas specific to India, they are not likely to provide much added incentive for research into drugs for diseases that are prevalent

---

128. SMITH, *supra* note 12, at 18.

129. Additionally, as observed earlier, even for those drugs that are on patent, if one company begins to market a generic version before the new laws go into effect, India will not grant a patent on those drugs, resulting in presumably unchanged prices and market dynamics post-2005. *Id.*

all over the world, because Indian companies can already patent such drugs in the world's largest markets. Rather, as Jean Lanjouw notes, perhaps the best reason to think that the introduction of product patents in India will increase the amount of innovative research and development done by Indian firms is simply that they will be precluded from continuing their profitable copying strategy and will need to switch to something else in order to survive and grow.<sup>130</sup> In other words, it is not the "pull" effect of patents and enhanced returns that will be operative, but rather the fact that firms are being "pushed" out of their traditional line of business.

A considerable number of Indian companies are indeed re-tooling and re-evaluating their strategies in anticipation of the 2005 changeover. Many, including Lupin Laboratories and Sun Pharmaceuticals, have decided to embark upon a gradual program of increased technological competence, including developing innovative line extensions and novel drug delivery systems.<sup>131</sup> Others, however, have aggressively begun drug discovery by recruiting people with the right types of skills for those activities and by investing in technologies that facilitate early stage research.<sup>132</sup> This is made easier by the fact that many of the same competencies and characteristics that foster high quality reverse-engineering are transferable to drug discovery. "Reverse-engineering requires [scientists] to screen molecules, to use complex analytical equipment, and to create standardized test conditions," all of which are applicable to the discovery process.<sup>133</sup> One indication that Indian companies are making

---

130. LANJOUW, *supra* note 7, at 30.

131. See Lupin, *Novel Delivery Systems*, at [http://www.lupinworld.com/r\\_d/novel\\_delivery.htm](http://www.lupinworld.com/r_d/novel_delivery.htm) (last visited Jun. 15, 2004); Aparna Krishnan, *Sun Pharma to Focus on Exports, R&D*, THE HINDU BUSINESS LINE (Internet Edition) (May 13, 2003), at <http://www.thehindubusinessline.com/bline/2003/05/13/stories/2003051302310200.htm>.

132. See LANJOUW, *supra* note 7, at 27.

133. SMITH, *supra* note 12, at 29. The following is proof that Indian firms have significant expertise in these reverse-engineering activities: GlaxoSmithKline "tried to be the first in the Indian market with their anti-ulcer drug Zantax, but were met by seven local competitors on the launch day" and "[a]t the time of its world launch of Viagra, Pfizer already faced Indian competition: three Indian firms were developing the active ingredient with five more expected to request marketing approval." LANJOUW & COCKBURN, *supra* note 100, at 5.

2004] *TRIPS COMPLIANCE: DEALING WITH DRUG PATENTS IN INDIA* 631

aggressive moves into drug discovery is that as of 1998 a handful of firms had already begun increasing their total investment in research and development from one to two percent of sales to five to six percent of sales, a significant portion of which was allocated to the search for new molecules rather than to imitative process development research.<sup>134</sup> This has begun to yield results for some Indian firms. For instance, Dr. Reddy's Laboratories (DRL) and Ranbaxy Laboratories each have multiple products in clinical trials, some under the auspices of the FDA, and these companies also possess research and development pipelines that are sufficiently robust to move at least one product from preclinical testing into human clinical trials every year.<sup>135</sup>

In addition to increased new drug research, significant consolidation—through merger and acquisition activity, as well as partnerships and alliances—has already begun to occur within the industry.<sup>136</sup> Firms that have complementary capabilities are determining that combining their operations is the optimal way to position themselves to compete with MNCs in the years to come.<sup>137</sup> In recent years, DRL acquired Cheminor, and Ranbaxy, Sun and DRL all engaged in hefty purchases of assets from other firms.<sup>138</sup> This consolidation has led to tremendous increases in productivity in both sales and research activities.<sup>139</sup> Moreover, only a small portion of such productivity gains is attributable to staff reductions, which are difficult to achieve in India because of stringent labor laws.<sup>140</sup> Such acquisitive growth is sure to enable Indian firms to attain the scale they need to contend with much larger MNCs.

Some have argued that this anticipatory activity is

---

134. LANJOUW, *supra* note 7, at 27–28.

135. Dr. Reddy's Laboratories, *Discovery Pipeline*, at [http://www.drreddys.com/view\\_content.asp?div=Div\\_2&id=SF\\_56&fid=F\\_77](http://www.drreddys.com/view_content.asp?div=Div_2&id=SF_56&fid=F_77) (last visited Jun. 15, 2004); Ranbaxy *New Drug Discovery Research*, at [http://www.ranbaxy.com/rnd\\_nDDR.htm](http://www.ranbaxy.com/rnd_nDDR.htm) (last visited Jun. 15, 2004); see also SMITH, *supra* note 12, at 8.

136. SMITH, *supra* note 12, at 27.

137. *See id.*

138. *Id.* at 8.

139. *Id.* at 27.

140. *Id.*

insignificant, that Indian firms are certain to lose out to more experienced MNCs as far as developing novel drugs is concerned.<sup>141</sup> However, there exists anecdotal evidence of Indian companies being able to conduct drug discovery extremely effectively. A few large firms have managed to get compounds from the laboratory and into clinical trials in less than a decade, at costs substantially lower than global benchmarks, and with higher rates of success.<sup>142</sup> A case in point is DRL, whose chairman, Anji Reddy, estimates his research costs to be one-eightieth of those of his MNC competitors, with a better ratio of hits to failures.<sup>143</sup> Indeed, as far as costs are concerned, not only do Indian firms typically have low labor costs, but they also often have capital costs that are fifty to seventy-five percent lower than those in developed countries, and this further contributes to their competitiveness.<sup>144</sup>

Thus, the sizeable labor pool, the preparatory activities of firms, and the prior experience of the industry combine to hint that prospects may not be so bleak for Indian pharmaceutical companies in the future.<sup>145</sup> As more and more firms begin to make the transition from imitation to innovation, they are more and more likely to be able to draw on India's pool of talented scientists, for a couple of reasons. First, drug discovery work is generally more creative and intellectually engaging than is the vocation of reverse-engineering,<sup>146</sup> meaning that the best minds in the field will be drawn to the industry in greater numbers.

---

141. See discussion *supra* Parts I, III.A.

142. SMITH, *supra* note 12, at 25–26.

143. *Id.* at 26.

144. LANJOUW, *supra* note 7, at 17.

145. See *id.* at 26–29. In addition to contributing to economic growth, a vibrant pharmaceutical industry would potentially help to stem the brain drain from which India suffers because of the lack of lucrative domestic opportunities. SAXENIAN, *supra* note 113, at 12. Many Indian scientists and engineers escape to the United States or Europe for access to better training and jobs. *Id.* IIT graduates have been referred to as the 'hottest export' that India has ever produced; of 2,000 startups in Silicon Valley, an estimated forty percent were started by Indians, and of those, half were founded by IIT alums. Kripalani, *supra* note 119. Additionally, "OPPI estimates that more than 15 percent of the scientists engaged in pharmaceutical [research and development] in the [United States] are of Indian origin." Finston, *supra* note 11, at 890.

146. See SMITH, *supra* note 12, at 16.

2004] *TRIPS COMPLIANCE: DEALING WITH DRUG PATENTS IN INDIA* 633

Second, the development of new drugs, while entailing more risk, holds out the prospect of greater financial rewards, and this is sure to attract gifted researchers as well.<sup>147</sup> With the assistance of such capable employees, some Indian firms, rather than being driven out of business, may develop into internationally competitive MNCs in their own right.

*D. Alignment of Regulatory Regimes*

In addition to steps already being taken by private actors, there are active measures that the government of India can employ to facilitate the development of a robust drug discovery industry within the nation's borders. One of these is to bring the Indian drug approval process in line with those of the United States and Europe. Currently, Indian regulatory requirements are more lenient than those in the developed world, creating a disincentive for Indian firms to export their products to those countries.<sup>148</sup> If they are able to market their drugs domestically and earn a decent profit, Indian pharmaceutical companies may be less likely to attempt the more expensive and more burdensome approval process required, for example, by the United States FDA.<sup>149</sup> In fact, empirical evidence shows that "many Indian firms have opted to limit their operations to domestic sales and exports to other countries with approval standards similar to India's."<sup>150</sup>

However, while the Indian market alone once provided sufficient profitability for Indian pharmaceutical companies, this has recently changed.<sup>151</sup> The market has become more crowded, and the costs of producing new products, while still low on the world scale, have slowly risen.<sup>152</sup> As a result, "it is increasingly necessary for [Indian firms] to look for customers beyond India and the developing world."<sup>153</sup> Indeed, for diseases that are common globally, including cancer, cardiovascular disease and

---

147. *Id.* at 17.

148. *Id.*

149. *Id.*

150. *Id.*

151. SMITH, *supra* note 12, at 16.

152. *Id.*

153. *Id.*

diabetes, exports are where Indian companies will have the most room for rapid growth. The government should push this overseas focus. By holding firms at home to a more rigorous standard, not only will the safety and efficacy of approved drugs be enhanced, but companies will not have to expend additional efforts to run further studies that will satisfy the FDA and the relevant European authorities, making it easier and more cost-effective for them to market their products internationally. Some firms, including Cipla, Ranbaxy, DRL, and Lupin, have already begun to export more to developed markets and less to emerging ones,<sup>154</sup> but they often have to resort to alliances, such as joint ventures, partnerships, and other contractual arrangements, with companies in those markets in order to do so.<sup>155</sup> A modification of the regulatory process to align it with those of the United States and Europe would compel Indian companies to develop the expertise to enable them to gain approval in overseas markets. This is desirable because it would facilitate the growth of Indian firms and permit them to compete more effectively with MNCs.<sup>156</sup>

There is a concern that a revision of the regulatory regime, as suggested, would result in Indian firms producing almost exclusively for export,<sup>157</sup> meaning that treatments for India-specific diseases such as malaria and tuberculosis would continue to be underdeveloped. Some may argue that even without such a revision, Indian firms will produce primarily for export, because developed country markets are where the real returns lie. However, if the regulatory process was not altered, there would remain a significant cost difference between gaining approval in India and gaining approval in, say, the United

---

154. *Id.* at 24.

155. *Id.* at 26.

156. Such a modification would not give MNCs any advantage they do not already possess. By collecting data for approval in the United States and Europe, they typically already have enough information to file for approval in India as well. Aligning the approval processes would leave MNCs in the same position in which they find themselves currently *vis-à-vis* marketing approval in India.

157. This issue is particularly worrisome if the experience of the software industry is instructive; more than two-thirds of Indian software sales are to customers abroad. See SAXENIAN, *supra* note 113, at 31.

2004] *TRIPS COMPLIANCE: DEALING WITH DRUG PATENTS IN INDIA* 635

States.<sup>158</sup> Thus, while the market for tuberculosis drugs in India may be much smaller in dollar terms than the market for breast cancer drugs in the United States, it will be much cheaper to properly test a tuberculosis drug and have it approved for marketing. Many Indian companies—particularly those that do not have the capital to conduct the costly clinical trials required by the FDA—would continue to produce for the domestic market, including the development of drugs for previously neglected diseases.<sup>159</sup>

In contrast, if the regulatory procedure were aligned with that of the United States, the cost of getting *anything* approved for sale in India would rise. This would make investing in a leprosy treatment, for example, less attractive and might change some firms' decisions from development to non-development.<sup>160</sup> In order to combat this result, the convergence of approval processes should be phased in slowly over time and should, perhaps, not occur for drugs for developing country diseases. For such illnesses, there are no markets in developed countries, and there is therefore no need to encourage Indian firms to seek approval in those countries.<sup>161</sup> An added wrinkle to this is that over time, as effective treatments are produced for developing country diseases, the balance may shift. Once an effective drug is available for leprosy, regulatory alignment may be desirable because the increased safety and efficacy resulting from a more stringent review process may then outweigh the need to keep costs low to maintain sufficient incentives for research. In the

---

158. In contrast, this is not true of the software industry; the costs to produce software are similar regardless of where it is marketed, because there are not any significant market-specific regulatory hurdles that need to be cleared before software products may be sold.

159. Currently, in the absence of a change in the approval system but in anticipation of the new patent laws, Indian firms are undeniably focused on products for the worldwide market, but have allocated a non-negligible portion of their research and development budgets to illnesses specific to developing countries. See LANJOUW & COCKBURN, *supra* note 100, at 20.

160. The decision to invest in a hypertension treatment, however, should not change because the drug would be marketed globally, meaning that the bulk of the costs would already have to be incurred to gain approval in the United States and Europe.

161. As noted previously, Indian firms will achieve their greatest growth by exporting drugs for internationally prevalent diseases to developed country markets. See discussion *supra* Part III.D.

meantime, however, while efficacious treatments remain unavailable for historically neglected illnesses, the discovery and commercialization of effective therapies continues to be of primary importance.<sup>162</sup> Whereas an alignment of regulatory regimes makes sense for drugs for global disease areas in which Indian companies can experience significant growth, it appears to be less compelling in the case of drugs for developing country diseases.

### *E. Development of a Venture Capital Industry*

Another step, and perhaps the most important step, that the Indian government can take to facilitate drug discovery by Indian firms is to nurture the development of a venture capital industry.<sup>163</sup> Drug discovery is an extremely perilous enterprise; it requires sizeable capital investments (because many failures often precede any successes) and the assumption of substantial amounts of risk.<sup>164</sup> As a result, it has historically been large pharmaceutical companies that have carried out most discovery research.<sup>165</sup> However, India has only a dozen or so large drug companies,<sup>166</sup> and even those are a great deal smaller than the leading MNCs.<sup>167</sup> For Indian industry to be competitive with the

---

162. LANJOUW, *supra* note 7, at 15.

163. Venture capital firms are typically organized as follows. They raise capital from institutions (such as pension funds and endowments) and wealthy individuals. The venture capitalists are professionals, often with industry experience, and the investors are limited partners in one or more of the firm's funds. Each of the funds generally operates for a specified number of years (often seven to ten) and is then terminated. Venture capital firms will invest in recently established companies believed to have the potential to provide very large returns, and most become actively involved with their portfolio companies to help them achieve that goal. Venture capital firms normally exit their investments either via a public offering or a sale to a strategic or financial buyer. See WILLIAM L. MEGGINSON, TOWARDS A GLOBAL MODEL OF VENTURE CAPITAL?, at 12-13, at <http://www.milkeninstitute.org/pdf/Megginson.pdf> (Dec. 31, 2001).

164. SMITH, *supra* note 12, at 15.

165. *Id.*

166. Some of India's influential pharmaceutical companies include DRL, Ranbaxy Laboratories, Sun Pharmaceutical Industries, Wockhardt, Lupin, and Nicholas Piramal. See *id.* at 31-38.

167. For example, Ranbaxy Laboratories, India's largest pharmaceutical company, had revenues in 2003 of \$969 million. Ranbaxy Laboratories, Ltd., 2003 Global Profits Before Tax (PBT) Cross Rs 1000 Crores (PBT:Rs. 10.2 Billion, Up 22%), Jan. 23, 2004, at

2004] *TRIPS COMPLIANCE: DEALING WITH DRUG PATENTS IN INDIA* 637

likes of Pfizer, Merck and GlaxoSmithKline, there must be an additional locus of drug discovery activity outside of large Indian firms such as DRL and Ranbaxy. Unfortunately, as observed previously in Part II.F., India lacks quality public research institutions such as the NIH, which would be able to serve as a center for such pursuits. One notable exception is the Indian Institute of Science, but even its expertise lies in the area of clinical trials and not in discovery research.<sup>168</sup> Given this reality, it would seem that a private biotechnology sector composed of small companies focused on drug discovery would be best suited to fill the void.

In the United States, for example, such a sector was spawned over two decades ago, and today, nearly 1,500 biotechnology firms work primarily on the discovery of new drugs.<sup>169</sup> To be sure, some companies have sufficiently matured over the past twenty years to the point where they now conduct their own clinical trials and market their own products.<sup>170</sup> However, most firms develop promising drug candidates and conduct pre-clinical testing before out-licensing the compounds to big pharmaceutical companies for clinical development.<sup>171</sup> In

---

<http://www.ranbaxy.com/irfinancialresults.htm>. In contrast, Pfizer, the largest pharmaceutical company in the United States and in the world, had 2003 revenues of \$45.2 billion. Pfizer, Inc., PFIZER INC. SEGMENT/PRODUCT REVENUES TWELVE MONTHS 2003 (UNAUDITED) (2003), available at [http://www.pfizer.com/download/news/2004Q4\\_earnfin4.pdf](http://www.pfizer.com/download/news/2004Q4_earnfin4.pdf).

168. SMITH, *supra* note 12, at 26.

169. Biotechnology Industry Org., *Biotechnology Industry Statistics*, at <http://www.bio.org/er/statistics.asp> (last visited Jun. 15, 2004) ("There are 1,457 biotechnology companies in the United States, of which 342 are publicly held").

170. Over the years, more than 150 biotechnology drugs and vaccines have been approved by the FDA. *Id.* Examples of leading American biotechnology companies are Genentech, Amgen and Genzyme. Each has several approved products, as well as a number of others in development. See Fact Sheet, Genentech, Investor Fact Sheet, Mar. 2004, available at <http://www.gene.com/gene/ir/fact-sheet/factsheet.pdf>; Amgen, *Market Products* (current as of Mar. 23, 2004), at [http://wwwext.amgen.com/news/TA\\_marketedProducts.html](http://wwwext.amgen.com/news/TA_marketedProducts.html); Press Release, Amgen, Amgen's First Research and Development Day Highlighted 24 of the Approximately 40 Programs in its Pipeline (Mar. 23, 2004), available at <http://wwwext.amgen.com/news/news04/pressRelease04323a.odf>; Genzyme, *Our Business*, at [http://www.genzyme.com/research/pipeline/pipe\\_home.asp](http://www.genzyme.com/research/pipeline/pipe_home.asp).

171. See Bioseeker Group, *Biotech Business Perspectives in the Oncology Arena—Optimizing Deal Values*, at <http://www.bioseeker.com/viewProduct.do?productID=801> (last visited Jun. 15, 2004).

exchange, they typically receive an up front fee, milestone payments, and royalties if the drug is ultimately approved for sale.<sup>172</sup> This discovery function for the biotechnology industry has taken on increasing importance in recent years, as the patents on many of the pharmaceutical industry's major products are expiring and there is little in their pipelines to compensate.<sup>173</sup> Indeed, many feel that "big pharma" faces a major productivity problem; it is investing more money than ever into research and development, but the rate of new product approval has slowed substantially.<sup>174</sup>

Biotechnology companies would play a similar role in India to the one they perform in the United States. They would conduct early-stage discovery research and generate lead compounds that would then be fed up to the larger pharmaceutical firms for development, approval and marketing. Small biotechnology companies would undoubtedly attract ambitious entrepreneurs and top scientists because of their significant upside potential. Such possibilities for huge financial payoffs do not, however, come without an enormous amount of risk. Indeed, most startup biotechnology firms worldwide have their entire future tied up in a single compound; if it fails, the company will fail with it.<sup>175</sup> Raising capital is consequently not an easy task, and venture capitalists are often the only ones who have the appropriate risk tolerance to make such investments.<sup>176</sup> This is because they focus on the economic viability of their overall portfolios; by investing in a large number of companies, technologies, and therapeutic areas, they can approximate the

---

172. See, e.g., Anna Yau-Young & Marilyn Ziemer, *Biotechnology Licensing*, 4 J. ASS'N U. TECH. MANAGERS (1992) at <http://www.autm.net/pubs/journal/92/biotech92.html>.

173. Amy Barrett & Michael Arndt, *No Quick Cure*, BUS. WEEK, May 6, 2002, at 30-31.

174. *Id.*

175. See Chris Martenson et al., *Cornell Equity Research—ArQule, Inc.*, at 4 (Nov. 17, 1997), at [http://parkercenter.johnson.cornell.edu/docs/other\\_research/1997\\_fall/arql.pdf](http://parkercenter.johnson.cornell.edu/docs/other_research/1997_fall/arql.pdf). This is because such companies—unlike 'big pharma'—lack the resources to pursue a wider range of projects that would reduce their risk to ideal levels. See SMITH, *supra* note 12, at 15.

176. See SMITH, *supra* note 12, at 15.

2004] *TRIPS COMPLIANCE: DEALING WITH DRUG PATENTS IN INDIA* 639

risk characteristics of a large pharmaceutical company.<sup>177</sup> Promoting venture capital is therefore critical to the proliferation of a robust biotechnology industry that would add considerably to the drug discovery work done by the major pharmaceutical firms.

The availability of venture capital has increased dramatically in India in recent years. In fact, according to some estimates, the amount of money flowing into India-dedicated venture capital funds increased from about \$20 million in 1996 to over \$1 billion in 2001.<sup>178</sup> Moreover, the consultancy McKinsey & Co. believes “that India will attract \$10 billion in [venture capital] money annually by 2008.”<sup>179</sup> Nevertheless, there remain significant barriers to the continued expansion of the Indian venture capital industry, and the Indian government would be wise to reconsider these.

First, it is important to note that venture capital can thrive only if there are relatively straightforward means by which venture capitalists can exit their investments.<sup>180</sup> A public offering of stock is an extremely common exit mechanism,<sup>181</sup> and Bernard Black and Ronald Gilson have therefore argued that an active stock market is likely to be a precondition for a successful venture capital industry.<sup>182</sup> Fortunately, India has an active stock market in place. In fact, there are twenty-two stock exchanges in the country, the largest of which is the Bombay

---

177. *Id.*

178. Justin Doebele, *What Bubble?*, FORBES, Apr 2, 2001. While biotechnology companies have been ignored in the past by venture capitalists in India (who have focused instead on IT), more and more have received funding in recent years. For example, Bharat Serums and Vaccines, Strand Genomics, Avestha Gengraine Technologies, Gangagen, Bangalore Genie Diagnostics, Bhat Biotech, and XCyton Diagnostics all received infusions of venture capital in 2001. Josey Pulienthuruthel, *Indian VCs Look Beyond Traditional Outlets*, THE DEAL.COM, Mar. 22, 2002, at <http://www.thedeal.com> (on file with author).

179. Doebele, *supra* note 178.

180. Bernard S. Black & Ronald J. Gilson, *Does Venture Capital Require an Active Stock Market?*, 11 J. APPLIED CORP. FIN. 36, 41 (Winter 1999).

181. I define ‘exit mechanism’ broadly to refer to any means by which an investor, such as a venture capitalist, disposes of her investment. Bankruptcy, therefore, is included in this definition.

182. Black & Gilson, *supra* note 180, at 36.

Stock Exchange (BSE), with over 7,000 companies listed.<sup>183</sup> However, the difficulty is that the stock markets are not as open or as transparent as they should be.<sup>184</sup> In fact, in 1998 the BSE produced a list of 600 untraceable companies that were listed at the time.<sup>185</sup> Stories of bankers floating shell companies with sets of phony prospectuses, income tax returns and profit statements are not uncommon.<sup>186</sup> Such occurrences scare off investors and make it more difficult for venture capitalists to take their promising private companies public.<sup>187</sup> Additional government regulation can strengthen the requirements for firms that issue publicly traded securities,<sup>188</sup> thereby increasing confidence in stock markets and encouraging asset managers to invest in venture capital. Other exit mechanisms must be reformed as well. In particular, Indian venture capital firms should be allowed to own equity in companies overseas, something that is presently not permitted.<sup>189</sup> Not only does this preclude synergistic investments in offshore firms that collaborate with Indian companies, but it also limits the number of exit opportunities available to venture capitalists, such as sales of portfolio companies to foreign entities.<sup>190</sup> Because Indian venture capital firms cannot own offshore shares, foreign firms wishing

---

183. Manjeet Kripalani, *Now You See 'Em, Now You Don't*, BUS. WEEK, Feb. 8, 1999, at 48.

184. *Id.*

185. *Id.*

186. *Id.*

187. *Id.*

188. The United States Congress, for instance, recently passed the Sarbanes-Oxley Act, which encompasses a broad range of corporate reform, Pub. L. No. 107-204, 116 Stat. 745 (codified in scattered sections of 11, 15, 18, 28 and 29 U.S.C.), and the Securities and Exchange Commission (SEC) has taken steps to increase disclosures by companies to investors, as well as the accuracy of such disclosures. Nasdaq and the New York Stock Exchange also proposed regulations that would impose new structural requirements (including some regarding the composition of Boards of Directors and various committees of the Board) on their listed companies. These proposals were approved by the SEC in November 2003. U.S. Securities and Exchange Commission, *NASD and NYSE Rulemaking: Relating to Corporate Governance*, (Nov. 4, 2003) at <http://www.sec.gov/rules/sro/34-48745.htm>.

189. See RAFIQ DOSSANI & MARTIN KENNEY, CREATING AN ENVIRONMENT: DEVELOPING VENTURE CAPITAL IN INDIA 31 (Berkeley Roundtable on the Int'l Econ., Working Paper No. 143, 2001).

190. *Id.*

2004] *TRIPS COMPLIANCE: DEALING WITH DRUG PATENTS IN INDIA* 641

to purchase Indian companies must pay the venture capital investors in cash, which is believed to limit the number of deals that are proposed and that actually close.<sup>191</sup> Removing such restrictions would enhance the availability of exit options and would encourage venture capitalists to enter the Indian market.

An additional change the Indian government should consider is a relaxation of the rules having to do with compensating employees with stock options. It used to be that equity could not be used to reward employees of startup companies in India.<sup>192</sup> However, in 1998, the Securities and Exchange Board of India (SEBI) issued guidelines allowing founders and employees of privately held firms to participate in employee stock option programs (ESOPs).<sup>193</sup> Nevertheless, these guidelines remain fairly restrictive. For example, firms, even private ones, with more than fifty shareholders have little flexibility under Indian corporate law to issue stock options or other forms of equity to employees.<sup>194</sup> While this may not be a problem for early stage investments made by venture capitalists, it is likely to be an obstacle for later round venture capitalists who would like to invest as part of a consortium.<sup>195</sup> Not being able to make use of stock options as compensation deprives venture capital firms of the two-fold benefits of ESOPs. First, if used properly, equity provides a mechanism for motivating employees because of the vast upside potential that it embodies.<sup>196</sup> Second, stock or options to purchase stock can be used as a substitute for scarce cash in the early stages of a startup company's experience.<sup>197</sup> If they have this tool at their

---

191. *Id.* at 31–32.

192. Jayant M. Thakur, *Employee Stock Options and SEBI Guidelines*, FIN. EXPRESS (Net Edition), July 13, 1999, at <http://www.financialexpress.com/fe/daily/19990713/fex13045.html>.

193. *Id.*

194. *Id.*

195. DOSSANI & KENNEY, *supra* note 189, at 31.

196. Paul Oyer & Scott Schaefer, *Why Do Some Firms Give Stock Options To All Employees?: An Empirical Examination of Alternative Theories* 1 (Feb. 2004), at <http://faculty-gsb.stanford.edu/oyer/wp/options.pdf>.

197. Dave Bracken, *Benchmark Your Tech or Web Salary*, at <http://www.wetfeet.com/asp/article.asp?aid=82&atype=Compensation> (last visited Jun. 15, 2004).

disposal, venture capitalists are able to deploy less money to fund a company for a given period of time, because the cash portion of employee salaries may be reduced. If they cannot utilize equity, on the other hand, venture capitalists are less likely and less able to make investments at all.

Yet another consideration, and a major one, concerns tax issues. The Indian government agreed in the 1990's to give venture capital firms the advantage of a tax rate lower than the corporate tax rate and equal to the individual tax rate.<sup>198</sup> However, the government has on numerous occasions refused to allow tax-free pass-through of capital gains income to investors, as is the norm internationally.<sup>199</sup> In other words, in most other countries with significant venture capital industries, the investors are taxed when they receive funds representing the return on their investment, but in India the venture capital firm also gets taxed for making the distribution. Thus, venture capital firms operating in India have to make a higher internal rate of return in order for their investors to receive an after-tax rate of return equivalent to what they would receive by investing in venture capital in another country. This places an unfair and unnecessary burden on the industry and makes it much more difficult to raise money to be invested in India. Moving this segment of India's tax laws in line with those of other countries would put investing in venture capital in India on an equal footing with investing in venture capital elsewhere.

A final alteration that would facilitate the development of venture capital in India would be an amendment to the country's corporate law to provide for certain corporate forms that do not currently exist, such as the limited partnership, the limited liability partnership (LLP), and the limited liability corporation (LLC).<sup>200</sup> Indeed, in most countries venture capital firms are organized as LLPs or LLCs.<sup>201</sup> The firm is then the general partner of each of the funds it manages, which are individually structured as LLPs, and the investors are limited

---

198. DOSSANI & KENNEY, *supra* note 189, at 28–29.

199. *Id.* at 29.

200. *See id.* at 31.

201. MEGGINSON, *supra* note 163, at 8–9.

2004] *TRIPS COMPLIANCE: DEALING WITH DRUG PATENTS IN INDIA* 643

partners.<sup>202</sup> The funds operate for only a specified number of years.<sup>203</sup> Indian regulations, however, do not recognize limited life funds.<sup>204</sup> As a result, each venture capital fund has to be organized as a separate trust or company, which is administratively and legally time consuming. Furthermore, terminating each fund requires court approval on a case-by-case basis.<sup>205</sup> Such transaction costs can be a significant deterrent to the formation and operation of venture capital funds. Allowing them to be configured as LLPs or LLCs would vastly reduce these costs, and in so doing would make venture capital investing in India more attractive.

#### *F. Summary*

Given the preceding discussion, it seems unlikely that MNCs will take over the Indian pharmaceutical industry after the new product patent laws are implemented in 2005. The key to success in a world with drug patents will be the ability to discover and develop new drugs, an enterprise in which many Indian firms are not at a major disadvantage. They have access to a skilled and low-cost pool of labor, and several have already taken steps to prepare themselves for the new regime. For example, some are devoting an increasing portion of their budgets to the research and development of novel compounds,<sup>206</sup> and others are consolidating with companies that have complementary capabilities.<sup>207</sup> In fact, there exists evidence that a few Indian firms have already been able to perform new drug discovery in a manner that is more efficient than what is typical for MNCs.<sup>208</sup> Rather than falling victim to MNCs, then, it appears that a number of Indian companies will be able to compete effectively with global players for business both within and beyond India's borders.

Moreover, the Indian government can make certain

---

202. *Id.*

203. *Id.* at 12–13.

204. DOSSANI & KENNEY, *supra* note 189, at 31.

205. *Id.*

206. *See* discussion *supra*, Part III.C.

207. *Id.*

208. *Id.*

straightforward legal and regulatory changes that would smooth the progress of the pharmaceutical industry and enable it to experience rapid growth. Such changes include a strengthening of the requirements for drug approval in India for globally important diseases, which would encourage Indian firms to export products to larger, more lucrative markets, and a number of reforms—such as allowing ownership in foreign companies, more liberal ESOPs, and pass-through taxation for capital gains—that would go a long way toward expanding the venture capital industry in India. This would in turn assist in the creation of biotechnology companies that would fill the drug discovery void and allow Indian pharmaceutical firms to compete more effectively with MNCs. Government commitment to these types of adjustments in law and policy would not only facilitate the creation of wealth for those Indian firms and the individuals involved with such organizations that have success, but would also broaden the tax base and increase tax revenues that could be put to use for various public health and education initiatives.

It is important to mention that there is a concern that the mechanisms identified in Part II that may help to keep drug prices in check after 2005 might also operate to impede the development of a pioneering pharmaceutical industry in India.<sup>209</sup> This concern is undoubtedly a valid one, as it is possible, perhaps even likely, that factors that in effect place a cap on drug prices would render policies designed to promote the growth of the pharmaceutical industry largely ineffectual. However, there are two responses to this worry. First, Indian firms are certainly already aware that price controls, compulsory licenses, and informal resistance to the enforcement of patents are real possibilities that may come into play once product patents are granted. Even so, Indian firms are allocating funds to the research of new drugs for both global illnesses and developing country diseases. This suggests that the companies have made calculations that they will be able to earn acceptable returns on their investments even after discounting

---

209. E-mail from Owen Fiss, Sterling Professor of Law at Yale Law School, to Rishi Gupta (May 22, 2002, 15:56:27 EST) (on file with author).

2004] *TRIPS COMPLIANCE: DEALING WITH DRUG PATENTS IN INDIA* 645

for the possibility that they will be forced to charge lower prices than they would in the absence of caps. Second, given that methods to contain prices may inhibit the growth of the pharmaceutical industry, the Indian government should make use of such methods cautiously.<sup>210</sup> This caveat was discussed in Part II. If price controls and compulsory licenses are utilized frequently and in cases where the public health need is not critical, the incentive for Indian firms to conduct innovative research will be muted, and the development of the industry will be stunted. However, if these devices are employed only when the state of affairs genuinely dictates their use, they are likely to have only a minimal negative effect on incentives and the domestic industry's growth.<sup>211</sup> The government entity that is charged with their implementation must therefore conduct long-term cost-benefit analyses before making its decisions, and the entity should ideally be structured in a way that enables it to avoid the myopia that afflicts much political decision-making in today's world. Additionally, the Indian government may consider some form of training for its judiciary that would make judges more keenly aware of the economic trade-offs involved with patents. This would help to ensure that case law evolves in a way that is consistent with smart economic policy, and that judges do not unjustifiably hamper the prospects of what could be the next major growth industry for the Indian economy.

#### IV. CONCLUSION

As we have seen, it appears plausible that critics of the WTO requirement that India implement a developed country-style intellectual property system are overstating their case. To be sure, complying with TRIPS brings with it some serious drawbacks. However, there are factors in place that will to some

---

210. See discussion, *supra* Part II.B.

211. Michael Kremer has argued that governments must make credible commitments to purchase vaccines in order for any significant level of private sector research activity to occur. See RACHEL GLENNERSTER & MICHAEL KREMER, *A WORLD BANK VACCINE COMMITMENT* 1, 3 (The Brookings Inst., Policy Brief No. 57, 2000). A similar argument would apply to pharmaceutical drugs, and the advocacy of limited, occasional uses of price controls and compulsory licenses does not stand in contradiction to Kremer's basic contention.

extent mitigate the difficulties involved with granting product patents, and there are relatively simple, active steps that the Indian government can take to ameliorate the problems even further. While no one can say with certainty what the result will be once the new laws are put into operation, the goals of research into developing country illnesses, reasonable drug prices and a continued healthy Indian pharmaceutical industry seem achievable.

I should note that the conclusions and policy recommendations I have advanced in this Article are restricted to the Indian context. It is important to keep in mind when considering these kinds of issues that 'developing country' is a category containing a tremendous amount of diversity. Social and economic structures, and scientific and technical capacities vary widely among developing nations, and as such, a one-size-fits-all approach is unlikely to be productive.<sup>212</sup> Where the capability to build a domestic pharmaceutical industry is absent, the threat of MNC domination is more real. In nations where the drug market is small, patent laws will do little to stimulate research into disease areas specific to that environment. In countries without capable government bureaucracies, the use of price controls and compulsory licenses to keep drug prices low will be only marginally effective. We must therefore be open to the notion of different schemes for different countries, but TRIPS unfortunately allows for little flexibility in this regard.

It is indisputable that patent protection is of considerable importance to pharmaceutical companies, which often view their patent portfolios as their most valuable business asset and which generally regard patent protection as a necessary precondition to their technological innovation.<sup>213</sup> However, what is not clear is whether a twenty-year patent life is needed to spur a level of research that society would consider optimal. Let us not forget that the U.S. pharmaceutical industry has been immensely profitable,<sup>214</sup> suggesting that the incentive to invent

---

212. COMMISSION ON IPR, *supra* note 58, at 2.

213. *Id.* at 22, 29.

214. See, e.g., *Health Care Dilemma: The Politics of Pills*, S.F. CHRON., Apr. 7, 2002, at D4 (noting that since 1998, the five largest U.S.-based drug makers have outperformed most of the companies in the Standard & Poor's 500 stock index); Robert

and commercialize new drugs would be present even with a truncated patent period. It would seem that there is a wonderful opportunity at our doorstep to allow nations that are soon to be implementing intellectual property laws to experiment with the patent term. This would allow us to collect data on the results that are obtained with various patent lives, after controlling for other factors. Such experimentation makes particular sense in India because if it turns out that Indian companies are indeed especially efficient at discovering novel drugs, then a shorter patent term would likely be sufficient to induce substantial innovation. Regrettably, these types of modifications are also out of bounds under TRIPS.<sup>215</sup>

Patents are no panacea. They cannot, by themselves, solve terribly complicated problems. Additional measures will, in all probability, be needed in India to provide sufficient incentives for drug research, particularly for certain India-specific illnesses. For example, though “the managing director of Cipla stated his belief that a company could make a profit from malaria treatments,” the medical director at Lupin has commented “that leprosy [has] a smaller estimated market . . . than the cost of developing a drug,” and that leprosy is therefore not an interesting disease area for pharmaceutical companies.<sup>216</sup> Thus, something akin to the United States Orphan Drug Act,<sup>217</sup> which provides market exclusivity and clinical trial subsidies for drugs with potential markets below a certain size, may be needed. This type of legislation would supply more targeted encouragement for work in disease areas with extremely small

---

Pear, *Michigan Senator Who Ran on Drug Issue Will Lead Democrats in Debate*, N.Y. TIMES, July 15, 2002, at A12 (observing that in 2001 the pharmaceutical industry topped the Fortune 500 list of the most profitable industries, providing investors with an 18.5 percent return on revenues).

215. The tools at the disposal of the Indian government described in Part II may have some of the same effects as a shorter patent life. The use of price controls or compulsory licenses would reduce profits by the patent holder, as would an abridged patent term (by shortening the period of time over which monopoly profits could be made). Nonetheless, not all of the effects of these various tactics are comparable, and it would be most informative to directly compare the outcomes obtained with varying patent lives in the range of approximately ten to twenty-five years.

216. LANJOUW & COCKBURN, *supra* note 100, at 19.

217. Orphan Drug Act of 1983, Pub. L. No. 97-414, 96 Stat. 2049, 2049-56 (codified as amended in scattered sections of 21, 26 and 42 U.S.C.).

profit potential, such as parasite illnesses that affect only the rural poor of India. This is but one idea, and many more will be required before we can realize the right balance between the equally significant but sometimes competing goals of creating incentives for research, providing drug access for patients, and achieving economic growth. Still, the coming of pharmaceutical product patents is a start, and is likely to do more good than bad, at least in India.