

## Essay

# India: A Cautionary Tale on the Critical Importance of Intellectual Property Protection

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*It would have been wonderful if at this stage of the golden jubilee of India's independence, an example could have been cited of how through basic research conducted . . . on a widespread tropical disease endemic to India, . . . a novel concept for treatment of the disease was taken up by the Indian pharmaceutical industry, and a novel product was discovered, adequately secured through product, process, and use patents, . . . resulting in a cure for the patients having the disease. It would have been a shining example . . . of industry's willingness to venture into areas unlikely to be highly remunerative, as long as there is government support of the endeavor to provide benefits to the nation's people.<sup>1</sup>*

### INTRODUCTION

As the above quote from a prominent Indian researcher indicates, protecting innovation is far from a zero-sum North/South game. Technological advances flow among states that protect the intellectual capital of their citizens, and therefore all of the countries that respect the right of the individual to profit from creativity and innovation can benefit from the full breadth of their human capital.

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<sup>1</sup> Dr. Noel J. de Souza, *Overview of the Indian Pharmaceutical Industry: Imperatives for the Next Millennium*, 5 PHARMACEUTICAL NEWS 6 (1998), available at <http://www.gbhap.com/magazines/pharmanews/5-b-article.htm>.

Intellectual property (hereinafter “IP”) protection is an increasingly important tool for countries at every stage of development, and nations that fail to protect intellectual property will be left behind. As the United States government has documented, protection of intellectual property is a launching pad for domestic and foreign investment, technology transfer, economic growth, and high-paying jobs in every region and area of technology.<sup>2</sup> Unfortunately, India cannot be counted among the large number of developing countries that have sought to obtain the economic and social benefits of IP protection for pharmaceutical products.<sup>3</sup>

The case of India demonstrates that there are high opportunity costs associated with the failure to provide adequate and effective protection for pharmaceutical products and the confidential, commercially valuable data produced during product development and marketing. Because India had no domestic constituency to oppose copyright protection, it has developed a thriving information technology and software sector employing in excess of 250,000 in India, and tens of thousands of people overseas.<sup>4</sup> In the patent area, however, entrenched domestic interest groups lobbied hard in 1970 against patent protection for pharmaceuticals; as the *New York Times* noted, “In fact, India recognizes Western-style intellectual property rights on most products, including computer software, in which it has a thriving industry. But it does not recognize them on chemicals for medicine or agriculture, a position that dates back to its Patents Act

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<sup>2</sup> See Stuart E. Eizenstat, *Intellectual Property Rights Protection and Emerging Economies*, U.S. Department of State, July 21, 1999, available at <http://usinfo.state.gov/topical/econ/ipr/ipr-eizenstat/htm>.

<sup>3</sup> The 34th Annual Report 1999 – 2000 of the Organization of Pharmaceutical Producers of India (OPPI) notes that since the late 1980s, “The following developing countries extensively changed and improved their patent systems: Korea (1987), Czech and Slovak Republics (1990), Mexico, Bulgaria, Indonesia, Chile, Belarus (1991), Romania Taiwan, Russia Ukraine, Thailand (1992), China, Yugoslavia, Philippines, Poland, Slovenia, Macedonia (1993), Andean Pact, Hungary (1994), Brazil (1996) and Jordan (2000). All of them introduced product patents for pharmaceuticals.” 34 ORG. OF PHARMACEUTICAL PRODUCERS OF INDIA, 1999-2000 ANNUAL REP., at 6 (2000).

<sup>4</sup> Donald G. McNeil, Jr., *Selling Cheap ‘Generic’ Drugs, India’s Copycats Irk Industry*, N.Y. TIMES, Dec. 1, 2000, at 1, available at <http://www.nytimes.com/library/national/science/health/pharmaceuticals-health.html> (last visited Feb. 28, 2002).

2002] *INDIA AND INTELLECTUAL PROPERTY PROTECTION* 889

of 1970, for which Mr. Hamied [managing director of CIPLA, one of India's leading pharmaceutical producers] heavily lobbied Prime Minister Indira Gandhi."<sup>5</sup>

By protecting only the manufacturing process of pharmaceutical products, rather than the chemical entities themselves, India has created perverse incentives for local Indian manufacturers to reinvent the wheel rather than to innovate. Indian pharmaceutical companies have perfected the art of copying existing products developed by foreign firms and developing different processes to for making these compounds. Some 20,000 manufacturers operate in India, producing multiple copies of the same products.<sup>6</sup> The result is little or no social benefit to Indian consumers. As the Indian government and industry alike recognize, "*Spurious, substandard and irrational products have become plentiful.*"<sup>7</sup> As with most protectionist trade policies, this policy has benefited a few larger Indian drug producers, but that benefit has not trickled down to the vast majority of the Indian population, as discussed below.<sup>8</sup>

## II. THE ABSENCE OF BASIC RESEARCH LEADS TO MASSIVE "BRAIN DRAIN"

India is the fourth leading supplier of bulk pharmaceutical products and active ingredients, but expends precious little of its profits on basic research and/or original product development.<sup>9</sup> As noted by the Organization of Pharmaceutical Producers of India (hereinafter "OPPI"), "The R&D [Research & Development] investment in India's Pharmaceutical Industry is a mere 0.001 [percent] of world's pharmaceutical R&D."<sup>10</sup> Further, limited R&D

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<sup>5</sup> *Id.*

<sup>6</sup> *Supra* note 3, at 9 (describing the prevalence of large number of infringing copies as "an effect of lack of IPR").

<sup>7</sup> *Id.* at 9 (emphasis added); *see also* INDIAN DRUG MFRS.' ASS'N, VOL. 31, IDMA BULLETIN, 777 (Sept. 7, 2000) (citing similar conclusions of Union Minister of Health and Family Welfare Dr. C.P. Thakur, and Secretary, Health, Shri Javed Ahmed Choudhury, and Shri S.P. Agarwal, Director General of Health Services).

<sup>8</sup> *See infra* Parts II & III.

<sup>9</sup> *See supra* note 1.

<sup>10</sup> *Supra* note 3, at 8.

resources are diverted to a search for yet another equally efficient or even less efficient means of producing an already available product.<sup>11</sup> Lack of patent protection has eliminated any incentive for India's best scientific minds to develop cures for tropical diseases endemic to India, or even to remain in India to work in the domestic industry. "[T]he high-caliber scientific and technological brains that have drained into the laboratories of companies in the United States, Europe, and elsewhere"<sup>12</sup> constitute a loss of incalculable proportions to India.<sup>13</sup> The OPPI estimates that more than 15 percent of the scientists engaged in pharmaceutical R&D in the U.S. are of Indian origin. One of these scientists, Dr. Ananda Chakrabarty, born and educated in Calcutta, emigrated from India to the United States and became the first inventor to receive a patent for a novel bioengineered microorganism,<sup>14</sup> and continues to work on groundbreaking research towards a cure for cystic fibrosis<sup>15</sup> and cancer.<sup>16</sup>

Until India begins to provide patent protection for pharmaceutical products, as well as data exclusivity for the commercially valuable and confidential data developed in the research and development process, India will continue to lose many of its most talented minds. These leading Indian scientists are desperately needed in India to conquer endemic diseases. As one segment of the Indian pharmaceutical industry recognizes, "India has now entered the millennium of knowledge. The Information Technology (IT) Industry has already carved out a place of its own on the global map.

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<sup>11</sup> See generally CONSUMER UNITY & TRUSTS SOC'Y, BRIEFING PAPER, TRIPS AND PHARMACEUTICALS: IMPLICATIONS FOR INDIA 8 (Aug. 1997), available at <http://www.cuts-india.org/1997-8.htm> (last visited Jan. 14, 2002); see also *supra* note 1.

<sup>12</sup> *Supra* note 1.

<sup>13</sup> Sarita Sarvate, *India Fights the Brain Drain*, REDHERRING (Jan. 11, 2000), at <http://www.redherring.com/insider/2000/0111/news-salon-drain.html> (last visited Jan. 14, 2002); see also *Ralph Nader Deplores 'Brain Drain' from India to US*, PRESS TRUST OF INDIA LTD., Oct. 31, 2000, available at 2000 WL 27415239.

<sup>14</sup> *Diamond v. Chakrabarty*, 447 U.S. 303 (1980) (containing the factual background to Dr. Chakrabarty's patent, which was the subject of this landmark case).

<sup>15</sup> See Ananda Chakrabarty, at <http://www.uic.edu/depts/mcmi/chakrabarty.html> (describing Dr. Chakrabarty's current work) (last visited Apr. 6, 2002).

<sup>16</sup> *Interview with Dr. Ananda Chakrabarty*, BUSINESS TIMES, Jan. 2002, at 31.

*Patenting actually aids the spread of knowledge. When a 'copying culture' prevails there is no incentive to innovate. The lack of IPR is a double-edged sword. Our own scientists require protection for the knowledge they create.*"<sup>17</sup>

### III. THE DOMESTIC MARKET AND DISEASES ARE NEGLECTED BY PROFITABLE INDIAN INDUSTRY

It is not surprising that the Indian pharmaceutical industry has not focused its efforts on development of novel treatments for the diseases that challenge India the most. Although the Indian government and some in the pharmaceutical industry present the Indian industry in the noble role of Robin Hood, stealing patented products from the rich (Western pharmaceutical companies) for the benefit of the poor in India,<sup>18</sup> this image does not reflect reality. Instead, numerous sources confirm that "modern medicine reaches barely 30 percent of the country's population. This means there is no coverage for 600 to 700 million people, a number more than the population of United States and all of Europe put together."<sup>19</sup> Despite the sophistication and success of the Indian pharmaceutical sector,

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<sup>17</sup> *Supra* note 3, at 9 (emphasis added); see also *The Unanticipated Benefits of IPRs*, THE ECONOMIC TIMES MUMBAL, Jan. 19, 2000 (concluding that "strong IPR has helped developing countries in two ways. First, it has accelerated the shift of material-intensive manufacturing to into developing countries. Second, it has helped some countries like India to leapfrog into the brain-intensive sectors. This has unquestionably be good for world trade, and ensured a two-way flow of benefits between rich and poor countries. Exactly what the WTO should be about.").

<sup>18</sup> India's current drug laws ignore that reasoning, on the ground that saving Indian lives is more important than profits to inventors. And Parliament, with the country's drug industry lobbying hard to protect its ability to copy molecules, is taking its time on compliance legislation. "We don't need to be apologetic about it," said Dr. Javid A. Chowdhury, the Indian minister of health. "We're a self-contained, developing economy. We live on little, but we survive. Outside of the third world, there's very little realization of how little money the poor live on. The per-capita health expenditure in India is \$10 a year." *Supra* note 4.

<sup>19</sup> *Supra* note 1, at 3; see also *supra* note 3, at 8 (stating that access to pharmaceutical products is "negligible" for over 70% of the Indian population).

[d]iseases like tuberculosis, malaria, leprosy, plague, AIDS, dengue fever, schistosomiasis, rheumatic fever, and rheumatic heart [disease] continue to pose serious problems and take millions of lives each year. The concentration of efforts is on developing the world market rather than on meeting the needs of the Indian population. As returns in the export market are much more than in the domestic area, *there has been negligible additional investment in production facilities for the domestic sector in the last 15 years.*<sup>20</sup>

As if to underscore the benefits of a workable patent system, the Council of Scientific and Industrial Research of India filed applications for nearly 200 patents abroad during 1999-2000.<sup>21</sup>

Ironically, while some Western media tout India's role as savior to the developing world and potential source of low-cost copies of the West's own inventions, Indian industry does not even attempt to serve the vast majority of the Indian population, at any price. Instead, local Indian manufacturers focus their efforts primarily on lucrative foreign markets and in reality Indian industry thrives by leveraging its free-rider advantages in "pariah" markets that do not respect intellectual property rights,<sup>22</sup> not by providing pharmaceutical products to India's poor.

#### IV. THE LACK OF DOMESTIC ACCESS TO HIV/AIDS DRUGS

The above is particularly true in the area of HIV/AIDS therapies. Estimates of the number of Indians who are HIV-positive or infected

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<sup>20</sup> See *supra* note 3, at 8 (emphasis added).

<sup>21</sup> *CSIR Files 200 Patents Abroad*, THE INDIA SERVER BUSINESS LINE INTERNET EDITION, Nov. 3, 2000, available at <http://www.ibionet.com/businessline/2000/11/03/stories/010367s4.htm> (last visited Mar. 4, 2002).

<sup>22</sup> "Mr. Hamied makes sildenafil citrate, the active ingredient in Viagra, for 2 cents a pill. He exports it to Yemen and Sudan, where it sells under the Erecto name." *Supra* note 4.

with AIDS ranges from just under five million to over ten million,<sup>23</sup> of which only a few thousand have access to Western HIV/AIDS therapies.<sup>24</sup> The drug manufacturer CIPLA first offered extremely low-priced HIV/AIDS therapies for export markets (where they are able to make a profit even at the fire-sale price of \$350 per year, per patient due to their lack of R&D expenses),<sup>25</sup> and made these concessionary prices available in India only later. Early in 2001, cheap HIV/AIDS drugs were not available in India, and the media reported that, “[t]he cheapest AIDS drug combination in India costs more than the average per capita annual income. For example, a two-drug combination sells for \$1,320 annually, plus testing and doctor fees. Yet [CIPLA] made its outstanding offer of \$350 per year for a three-drug combination to Doctors Without Borders.”<sup>26</sup> Since the time that statement was published, CIPLA came under domestic political pressure to extend the offer to the government of India, and eventually did so, but even this has had little impact on treatment in India.<sup>27</sup>

<sup>23</sup> Dr. Rajan Gupta, *Risk Factors and Societal Response to HIV/AIDS in India*, available at <http://t8web.lanl.gov/people/rajan/AIDS-india/MYWORK/hivindia2001.html> (last visited Mar. 5, 2002); see also *AIDS in India: The NewsHour with Jim Lehrer* (PBS television broadcast, June 26, 2001) (quoting Dr. Ishwar Gilada: “Currently, it is doubling at the rate of eighteen months, or the rate of every twenty-four months. And I’m estimating something like ten to 12 million HIV infections today.”).

<sup>24</sup> While it is difficult to estimate the exact number of Indian patients receiving HIV/AIDS therapies, there is no dispute that “only the wealthiest few thousand have full access to treatment and there is no comprehensive strategy to increase this number.” Ranjit Devraj, *India’s Dilemma: Should It Put AIDS First?*, Panos Institute, July 11, 2000, at <http://www.panos.org.uk/news/00-07-11/india.html> (last visited Mar. 4, 2002).

<sup>25</sup> See P. A. Francis, *CIPLA’s Charity Begins in Africa!*, Pharmabiz.com, available at <http://www.pharmabiz.com/edit/edit39.asp> (last visited Jan. 14, 2002).

<sup>26</sup> Acton Institute, *Pricing of Drugs for Pandemics*, at <http://www.acton.org/ces/issue1.html> (last visited Jan. 14, 2002) (noting that “[CIPLA] has participated with other Indian drug companies in asking the government to put a 35 [percent] import duty on an AIDS drug called 3TC that [CIPLA] also makes. When the Indian government ordered [CIPLA] to reduce prices of some drugs under India’s price control regulations, the company sued instead.”).

<sup>27</sup> Dr. Rajan Gupta, *Risk Factors ad Societal Response to HIV/AIDS in India*, June 2001, at <http://t8web.lanl.gov/people/rajan/AIDS-india/MYWORK/hivpolicy.html> (last visited Jan. 14, 2002) (“Even with CIPLA’s offer there are still remain problems of implementation for which there seems to be no political will. At \$350 [sic] per year, the cost to Indian Government to treat the roughly 4 million infected would be over two billion dollars per year once delivery and test costs are included. This amount is roughly eight times the

## V. PRICE REMAINS A RED HERRING

India has justified its lack of patent protection on the basis that its policy results in lower drug prices. Indeed, Indian pharmaceutical prices are lower than drugs in neighboring Pakistan and significantly lower than in other world markets. The introduction of patent protection consistent with The Agreement on Trade-Related Aspects of Intellectual Property Rights (hereinafter “TRIPS”) will in no way require an increase in the price of drugs that are already on the market.<sup>28</sup> Particularly in the area of essential medicines, as defined by the World Health Organization (hereinafter “WHO”), the OPPI testified to the Indian Parliament’s Joint Committee on Patents in May, 2000 that, “[e]very single drug in the WHO Essential List is available in India today in Generic Form, and will continue to be available in 2005 in Generic Form.”<sup>29</sup> As an Indian expert’s review concludes, “even under the new patent regime (compatible with the TRIPS Agreement), the availability and prices of generic drugs will largely be unaffected.”<sup>30</sup> Product patent protection will apply to new drugs introduced to the market after the law is enacted, a small percentage of the total market. Prices for the next generation of drugs are likely to be restrained by lively competition in the large Indian domestic market.<sup>31</sup>

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FY2001 yearly budget of the Ministry of Health, Central government. As a result, I do not foresee the Indian government acting on the CIPLA offer in the near future unless the price drops by another factor of ten. Their concern may be that if they provide free drugs for HIV, then they will have to provide free drugs for all life-threatening communicable diseases.”)

<sup>28</sup> See generally Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization [hereinafter WTO Agreement], Annex 1C, LEGAL INSTRUMENTS – RESULTS OF THE URUGUAY ROUND, vol. 31, 33 I.L.M. 81 (1994), available at [http://www.wto.org/english/docs\\_e/legal\\_e/27-trips.pdf](http://www.wto.org/english/docs_e/legal_e/27-trips.pdf) (last visited Mar. 8, 2002).

<sup>29</sup> Presentation to the Joint Committee on Patents (Second Amendment) Bill, 1999, OPPI, Mumbai, May 24, 2000 (not paginated).

<sup>30</sup> See *supra* note 9, at 13.

<sup>31</sup> HEINZ REDWOOD, NEW HORIZONS IN INDIA: THE CONSEQUENCES OF PHARMACEUTICAL PATENT PROTECTION 59-74 (1994) (citing as three factors that will hold prices in check the low purchasing power of the Indian medical consumer, the Government of India’s continuing price control powers, and interbrand competition within therapeutic classes).

## CONCLUSION

In 1970, India turned its back on Western models for development, and despite the development of a small number of world-class pharmaceutical exporters (out of over 20,000 entrants), it has paid a high price.<sup>32</sup> Unlike South Korea and Italy, two countries that adopted protection for pharmaceutical products in the 1970s, India has no viable research industry and therefore India has been unable to meet the public health requirements of its own population, even in such rudimentary areas as provision of potable water,<sup>33</sup> off-patent generic antibiotics, anti-malarial treatments, and/or tuberculosis therapies.<sup>34</sup> Further, the absence of protection for pharmaceuticals and other chemical products has led directly to an exodus of American and other international research-based pharmaceutical firms,<sup>35</sup> the greatest single example of dis-investment of the twentieth century.<sup>36</sup> This departure of Western pharmaceutical firms has led the best and brightest scientific minds trained by Indian universities to apply their genius in Western laboratories, a situation that will only be reversed if and when India adopts reasonable IP protection for pharmaceutical products.

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<sup>32</sup> *Supra* note 1.

<sup>33</sup> "52% of Indian villages have no protected source of drinking water," according to OPPI's Presentation to the Joint Committee on Patents (second Amendment) Bill, 1999, OPPI, Mumbai, May 24, 2000 (not paginated).

<sup>34</sup> *Illfare*, THE ECONOMIST, Jan. 21, 1995, at 23, available at 1995 WL 9568017.

<sup>35</sup> *See supra* note 9, at 7.

<sup>36</sup> In contrast, virtually all of the largest research-based pharmaceutical companies in the world maintain a presence in China, which provides product patent protection, despite a difficult political and business environment that includes a significant language barrier. *See supra* note 9, at 7-8.