

AIDS AS A DETRIMENT TO INDIA SHINING: THE NEW GOVERNMENT'S FOCUS ON  
PATENTS

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India Shining – the campaign rejected by the Indian public in 2004, did not discuss an important shadow looming over the country and threatening its population. Even Congress – I, the party now in power and then, desperate to take over the *desh* despite its *videshi* leader, could not bring itself to address the one issue that Indians continue to hope would be outshined by the current economic trend - AIDS. There are several angles to the AIDS crisis – the most important being the human angle, the most consequential being the legal economics of patents affecting the price of pharmaceuticals and thus, accessibility to medication. Unfortunately, the AIDS issue is most likely to haunt the Indians and question the country's political ability to handle sensitive issues. India cannot, given the current projections of the disease, do away with compulsory licensing and price control of generic medication, particularly the AIDS medication.

The mechanism of compulsory licensing forces the patentee to license the patent to the government. Compulsory licenses, as “involuntary contract[s] between a willing buyer and an unwilling seller imposed and enforced by the state,”<sup>1</sup> affect market exclusivity directly and market price indirectly. Price control, being government-induced interferences with the market, restricts the maximum market price.<sup>2</sup> Prices can be controlled either directly or indirectly. Direct price control is where the government restricts the market price of a product from exceeding a certain percentage above the cost of production. Indirect price control is where the government uses an incentive, a deterrent, or both, to prevent the manufacturer from realizing the highest marginal profit. The issue of compulsory licensing or price control holds unique significance in the area of pharmaceuticals. Unlike consumer products, where the elasticity of individual human-need varies with affordability, the demand for pharmaceuticals is independent of affordability. A medication's cost efficiency minimally affects demand due to the continued needs of patients, given the lack of alternatives. In low per capita income markets, like India, increasing the cost reduces affordability, causes disease conditions to worsen thus increasing the demand for medication and raising the need to use tools like compulsory licensing to balance trade with welfare. Hence, use of the appropriate intellectual property and health care policies has a direct bearing on economic development.

In contrast, the higher per capita income in the developed nations virtually

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<sup>1</sup>. Gianna Julian-Arnold, *International Compulsory Licensing: The Rationales and the Reality*, 33 IDEA 349, 349 (1993) (quoting PAUL K. GORECKI, REGULATING THE PRICE OF PRESCRIPTION DRUGS IN CANADA: COMPULSORY LICENSING, PRODUCT SELECTION, AND GOVERNMENT REIMBURSEMENT PROGRAMMES (Economic Council of Canada 1981)).

<sup>2</sup>. See Mary T. Griffin, *AIDS Drugs & the Pharmaceutical Industry: A Need for Reform*, 17 AM. J.L. & MED. 363, 402 n.260 .

eliminates the use of compulsory licensing except when the economy slows down. Hence patentees generally enjoy a total monopoly during the patent term. Patents serve as market incentives enabling patentees to derive maximum economic efficiency irrespective of maximization of consumer welfare. Since competition is curtailed, patent owners charge the highest price that the market can bear, typically far exceeding the marginal cost.<sup>3</sup> Presumably, the increased cost covers the investor's past and future investments on research and development. Consumers, in turn, associate the higher cost for patented products with the privilege of using the invention. Developed nations, particularly the United States, believe that patent owners with valuable products will market them and hence, discourage government interference with patent monopolies. Thus, the United States disfavors patent restrictive mechanisms like compulsory license and price control as disincentives to inventors and patent holders. On this basis, the developed nations persist that the international trade obligations in the Agreement on Trade Related to Intellectual Property Rights (TRIPS) to which India is a party, necessitates a level of patent protection that eliminates the option of exercising compulsory licensing and price control mechanisms even under a threat to public health.

Unlike the emphasis by developed nations on inventor incentives, India should continue to emphasize the public accessibility of the invention. The low per capita income within India affects the government's ability to fulfill basic requirements and thus increases the probability of occurrence of health exigencies. Given the higher population and illiteracy rates, India should prioritize increased consumer maximization, especially for products like medication catering to basic requirements. Such a move will enable India to effectively balance intellectual property rights with consumer welfare. In a global sense, this is the balance between trade and welfare. India should choose this option because of several reasons. First, the developed nations' argument that increased trade would positively impact per capita income and ultimately benefit the marginalized by trickling down does not convincingly account for the welfare obligations during the interim period. Conventional prudence suggests that deteriorating economic conditions cannot serve as a means to improve the economy over a period of time. Second, TRIPS, even before the Doha amendment, implied that compulsory licensing could be used to preserve public health. Article 31 provides the right to compulsory licensing subject to certain conditions as a means for developing nations to enable marginalized people to access pharmaceuticals. The Doha amendment further secures for the developing world, the right to read the TRIPS commitments flexibly to proactively avoid health exigencies. India should fully use the opportunity provided by the Doha Declaration of 2001. Third, developed nations themselves avoid increasingly marginalizing the poor knowing that it will worsen economic conditions before stabilizing them. For example, even as late as in 2000s, an economic crisis within the states moved the Supreme Court of the United States, in *Pharmaceutical Research and Manufacturers of America ("PhRMA") v. Walsh*,<sup>4</sup> to validate indirect price control over pharmaceuticals. The threat of an anthrax crisis moved the United States and Canada towards compulsory licensing as discussed below.

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<sup>3</sup>. See Mark A. Lemley, *The Economics of Improvement in Intellectual Property Law*, 75 TEX. L. REV. 989, 1065–66 (1997) (noting that “producers will price at marginal cost only if they are forced to by the existence of competition. A producer who controls a market will cut output and raise prices, increasing its profits but reducing both consumer and aggregate social welfare”).

<sup>4</sup>. 123 S. Ct. 1855 (2003) (to be filed at 538 U.S. 644).

When the economy in the United States slowed in 2001, it resulted in a deficit from tax revenues in several states. Simultaneously, the cost of the most frequently used prescription drugs rose at four times the rate of inflation.<sup>5</sup> The declining tax revenues left states with the choice of either reducing the state funds for Medicaid or confronting the cost of drugs.<sup>6</sup> Owing to the economic slowdown, state governments sought what the federal government advocated against in developing nations—balancing the rights of manufacturers and consumers by interfering with the market price of pharmaceuticals. Efforts were taken to reduce state expenditures on prescription drugs without affecting accessibility of drugs to the needy. State governments wanted to indirectly influence the price of branded pharmaceuticals to reduce the cost of patented Medicaid pharmaceuticals.

The State of Maine took the first step by passing the Fairer Pricing for Prescription Drugs Act of 2000, which created the “Maine Rx Plus Program” (“Program”).<sup>7</sup> The Program dealt with pharmaceutical drug pricing and profits—terms, incidentally, used in several third world nations, including India, to refer to price control. Under the Program, the state government acting as a market player negotiated a discounted rebate for drugs with the pharmaceutical manufacturers. Sales made by manufacturers who did not “voluntarily” enter into rebate agreements with the Commissioner of Maine Care were subject to the *prior authorization requirements* of Maine Care, the state Medicaid administrator. The procedural burdens imposed by the prior authorization requirement shifted patient and physician loyalty to competing drugs of manufacturers not subject to the authorization. Soon drug companies voluntarily negotiated rebates reducing the cost of drugs meant for Medicaid. Encouraged by the success of Maine, other states including Florida, Vermont *etc.*, introduced similar programs. Michigan, however, made the bold move of seeking rebates for non-Medicaid drugs. Michigan’s Best Practices Initiative (“Initiative”) identified drugs bearing negotiated rebates as “best in class.” Drugs not so identified were subject to the *prior authorization* requirement. Manufacturers could avoid the *prior authorization* procedure by either matching the price of the lowest priced “best in class” drug in the “relevant therapeutic class,” or, by discounting prices of certain non-Medicaid drugs. PhRMA challenged the programs on different grounds in each of the states in question. In Maine, the First Circuit refused to agree with PhRMA’s argument that the program was federally preempted on the basis that the substantial local benefit outweighed any effect on

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<sup>5</sup>. The rising prescription drug costs became a larger factor in the total health expenditures of states, and led to an increase of 16%, or \$142 billion, on prescription medication. Ron Winslow et al., *States, Insurers Find Prescriptions for High Drug Costs*, WALL ST. J., Sept. 11, 2002, at A1 (explaining that the total spending in the U.S on prescription drugs accounts for 10% of American health care spending. The rate of inflation for prescription drug prices exceeded the rate of general inflation.). See generally Whitney Magee Phelps, Comment, *Maine’s Prescription Drug Plan: A Look into the Controversy*, 65 ALB. L. REV. 243, 245 (2001) (reporting that total drug expenditures are expected to double from 1999 to 2004). Between 1982 and 1988, prescription drug costs increased at an average annual rate of 9.5% . . . , more than any other component of the health care sector. “Between 1998 and 2000, Medicaid’s average annual spending on prescription drugs grew by 19.7%.” Sarah Lueck, *States Efforts To Cut Drug Prices Get Boost From Medicaid Chief*, WALL ST. J., May 30, 2003, at A1; see Sara M. Ford, *Congressional Research Service Report to Congress, Medicaid: Reimbursement for Outpatient Prescription Drug*, CRS- 15 (Mar. 7, 1991). From 1980 to 1989, payments for Medicaid prescription drugs increased 179%. Medicaid expenditures for all other services increased by only 134%.

<sup>6</sup>. Medicaid is a federal and state approved health insurance program designed to provide access to health services for persons below a certain income level. See also *Miracle. On Ice*, ECONOMIST, May 17, 2003, at 29 (arguing that despite consistent ranking among the top in health care, education, and quality of life, a two-year deficit of \$4.2 billion threatens Minnesota’s programs).

<sup>7</sup>. ME. REV. STAT. ANN. tit. 22 § 2681 (West. Supp. 2003).

interstate commerce.<sup>8</sup> In Florida, the Eleventh Circuit disagreed with PhRMA's argument that the prior authorization aspect of the program violated the federal Social Security Act ("SSA") requirement that *all* drugs be available to Medicaid beneficiaries.<sup>9</sup> Similarly, the United States District Court for the District of Columbia validated the indirect price reduction for both Medicaid and non-Medicaid drugs in Michigan after hearing PhRMA's argument under the SSA challenging the authority of the Secretary of Health and Human Services ("Secretary") to approve the program.<sup>10</sup> The court, however, agreed with PhRMA's contention against a similar Vermont program that the SSA required the Medicaid program to pay the cost of medication under a "state plan."<sup>11</sup> PhRMA contended that the state programs shifted the burden of funding Medicaid on the pharmaceutical companies, requiring them to cover 18% of the cost of prescription drugs. The Circuit conflicts resulted in the Supreme Court of United States granting certiorari to decide whether there was an abuse of discretion in allowing Maine to implement the Program. The Supreme Court in *PhRMA v. Walsh*<sup>12</sup> held that the Maine Program did not impose a disparate burden on out-of-state manufacturers in violation of the Commerce Clause. Interestingly, the Supreme Court never considered whether indirect price controls violated TRIPS. The Court, however, favored indirect price controls for non-Medicaid drugs. Referring to public health obligations, the Court ruled that a state's "interest in protecting the health of its uninsured residents also provides a plainly permissible justification" for imposing the indirect price control, including coercing manufacturers to reduce prices of all drugs. The Court in fact, dismissed the impact on profit margins of manufacturers as irrelevant so long as "transfer of business to less expensive products produce[d] savings for the Medicaid program." Notably, the United States precluded developing nations' efforts to make medical services affordable to the poor by emphasizing on manufacturer profits. Justice Thomas appreciated the state governments' attempts as an essential, if not commendable, "delicate balance" of health care with cost. The "delicate balance" Justice Thomas refers to is precisely what the price control measures of all developing countries seeks to achieve. If such a "delicate balance" is envisaged in a nation with a higher per capita income to assist the poor, the exercise of balancing between economic and social welfare in developing countries is bound to be dire and less delicate. The issue of "balancing" has a greater relevance in developing nations since the cost of medication is borne by patients. Developing countries wanted to "balance" for the noble and economically sound objective, promoted in the United States, of avoiding more expensive treatment if AIDS became an epidemic. Instead, United States opposed efforts by developing nations, by prioritizing manufacturers' profits dismissing the factor of cost-effectiveness for the respective governments. The proposals of the developing world have repeatedly been touted as economically unsound initiatives with noting more than the human rights angle.

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<sup>8</sup>. See *Pharm. Research & Mfrs. of Am. v. Concannon*, 249 F.3d 66, 75.

<sup>9</sup>. See *Pharmaceutical Research & Mfrs. of Am. v. Meadows*, 304 F.3d 1197, 1208 n.9 (11th Cir. 2002). See also Conrad F. Meier, *PhRMA Asserts Itself in Court Action*, HEALTH CARE NEWS, Oct. 2001, at 2. Because manufacturers refused to enter into such agreements, fifty percent of the branded drugs in the Medicaid program were not on the preferred list. *Meadows*, 184 F. Supp. 2d at 1189.

<sup>10</sup>. See *Pharm. Research & Mfrs. of Am. v. Thompson*, 259 F. Supp. 2d 39, 45 (D.D.C. 2003);

<sup>11</sup>. See *Pharm. Research & Mfrs. of Am. v. United States*, 135 F. Supp. 2d 1, 4 (D.D.C. 2001), *rev'd*, 251 F.3d 219 (D.C. Cir. 2001).

<sup>12</sup>. 123 S.Ct. 1855 (2003).

The anthrax crisis is another example to demonstrate how the United States, in the wake of a mere threat to public health, relegated the importance of branded prices and future generations to a secondary position and considered the compulsory licensing option to ensure access to drugs. When the anthrax crisis was reported, the United States determined that public affordability of the medication was a priority—signifying a change from its traditional disregard to public affordability of medication in developing nations. The United States considered reducing the cost of Cipro, the recommended anthrax medication, by either compulsorily licensing Bayer’s patent on Cipro, or purchasing Cipro from generic sources. Both options restricted Bayer’s ability to price the drug above marginal cost. Compulsorily licensing Cipro interfered with Bayer’s right to exploit its patent. The second option of procuring generic ciprofloxacin from third world countries like India restricted Bayer’s market share as a patent owner and cut into the profits allocated for research and development. Incidentally, the United States government opposed the use of both options by developing countries as violating TRIPS. Presumably, the United States government reasoned that the increased sales of Cipro—generated by the high-volume need for the drug—would offset Bayer’s profits from a higher market price with comparatively limited sales. This is the reasoning the government repeatedly rejected when put forward by third-world governments seeking AIDS medication at lower prices for millions of poverty stricken citizens. Finally, the United States Department of Health and Human Services (“DHHS”) forced Bayer to reduce the price of Cipro by threatening to compulsorily license Bayer’s patent.<sup>13</sup> Thus, although the DHHS did not compulsorily license the patent, it indirectly controlled the price of Cipro at ninety-five cents a pill. Importantly, under a threat to local public health, much like how TRIPS was not considered in *PhRMA v. Walsh*, the issue of compliance with TRIPS was not even raised internally by the United States government.

That the United States, despite TRIPS, was able to prioritize its national responsibilities while compelling third world countries to do otherwise demonstrates that the inability of TRIPS to secure equivalent behavior from all parties. Developed nations are seemingly exempt from obligations developing nations are forced to fulfill. Thus, poorer nations like India uniquely suffer a “poverty penalty.” The “poverty penalty” refers to the cost poorer nations suffer from fulfilling international obligations that require prioritizing trade interests to the detriment of welfare. The “poverty penalty” can cause dangerous economic consequences in a developing country. For example, within developing nations, AIDS-infected people with limited access to testing and medication have spread the infection. Lack of medication affects standards of living, sometimes permanently, either from loss of loved ones or loss of good health. Any epidemic increase of AIDS reduces life expectancy, affects labor and economic output, as the younger casualties increase. The decline of national productivity from loss of labor is proportionate to the value of output of each life lost. That is, assuming that a person’s productivity is derived from several indicators, such as: living conditions; earning potential; or per capita income, the loss of each adult life in his/her most productive age represents an equivalent deprivation of productivity to the economy. The cumulative loss of productivity will be further enhanced by the losses from other factors of productivity—“total factor productivity”—from costs affecting the economy. Examples of other costs range from

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<sup>13</sup>. See Charles Schumer, Editorial, *The Cipro Circus*, WALL ST. J., Oct. 25, 2001, at A20;

the increasing cost of employee medical benefits to the deterrence such costs create for foreign investments.<sup>14</sup> For example, the increased incidence of AIDS in South Africa raised the cost of employee medical benefits from 7% of income in 1995 to 19% by 2005. The increased cost of employee benefits impacted overall economic productivity and output, especially since the additional costs were incurred at the same time that productivity was declining.<sup>15</sup> Considering that labor has been, and continues to remain, the main factor of productivity in several poor nations, including India, TRIPS can cause unfortunate effects on labor productivity without supplementing or substituting the loss of labor productivity with other sources of economic development. The diminishment of the main factor of productivity—labor, in this case, due to increased disease conditions—will detrimentally affect other sources of economic development, like foreign investments. Thus, the deterrence of the AIDS epidemic to foreign investors is higher than the incentive to investment from signing TRIPS. For example, AIDS affected the profitability of Anglo American, a mining conglomerate with operations in Africa, by causing absenteeism, deaths, and increased medical costs for AIDS-related illnesses. The Economist recently reported that the company was on the verge of losing 30,000 members of its South African workforce to AIDS. Thus, each developing nation can potentially suffer economic losses unless adequate steps are taken to protect national health at the appropriate juncture.

Countries like India should highlight such economic and legal issues arising from TRIPS. After all, the game at WTO is a game played in turf of developed nations given their bargaining power in trade. Hence India should tailor its arguments in a manner that developed nations understand. Developed nations understand the language of legal economics better than emotional and philosophical issues of patenting, which India seems to emphasize. India's achievements at the Doha Summit are impressive. However, as the emerging leader of the developing nations, India should recognize the potentially looming national crisis if health care deteriorates, particularly from AIDS, and take steps towards fully and convincingly arguing its case to the international community.

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<sup>14</sup>. See, e.g., LORI BOLLINGER & JOHN STOVER, THE POLICY PROJECT, U.S. AGENCY FOR INT'L DEV., THE ECONOMIC IMPACT OF AIDS IN SOUTH AFRICA 3 (1999).

<sup>15</sup>. *AIDS Toll on Regional Economies*, SOUTHERN AFRICAN ECONOMIST, May 15, 1997.