Kentucky Law Journal

Volume 91 | Issue 4 Article 7

2003

Pharmaceutical Patents and TRIPS: A Comparison of India and South Africa

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NOTES

Pharmaceutical Patents and TRIPS: A Comparison of India and South Africa*

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I. INTRODUCTION

Patent protection is directly connected to the world's economy. The international patent system has a powerful effect upon the industries and economies of individual nations. The international patent system and individual domestic patent structures play a central role particularly in the areas of science and technology. In several industries across the globe, patent law heavily influences research, manufacturing, and marketing. By extension, patent law influences price and access to products.

One of the complex issues involving patent law is that of pharmaceutical development. Pharmaceuticals are special products that have a profound significance in people's lives. Especially in the modern era, with the AIDS crisis growing year by year, the demand for life-saving medications is extremely high. When compared with the interests of suffering patients, the profits of a corporate patent-holder seem an insignificant and even vulgar concern. The development of effective medicines, however, is an expensive and time-consuming business that requires massive amounts of capital. Without patent protection, pharmaceutical development would lose its profitability and ultimately its momentum. Additionally, effective dis-

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* This Note was originally written as a seminar paper for Professor Mary J. Davis' Comparative Law Seminar.

** J.D. expected 2003, University of Kentucky. The author wishes to dedicate this Note to Barbara Dean Barnes (1940-2002), teacher, doctor, and beloved mother. The author would like to thank Angela Elizabeth Minella for her constant love and support, and would like to thank his family and friends. Last, and most certainly least, the author wishes to thank Kurt Vonnegut, Jr., for teaching us that the secret to life is loving whoever is around to be loved.

tribution of medicines at the local and personal level is an important concern largely unrelated to patent protection. Thus, the issue is an extremely complex one.

This Note focuses on the issue of pharmaceutical development in two countries: India and South Africa. A recent intellectual property treaty, over which the World Trade Organization ("WTO") has authority, has become the focal point for disputes between these two countries and within the international community. The intellectual property treaty, Trade-Related Aspects of Intellectual Property ("TRIPS"),[1] provides potent patent protection, and, until recently, conflicted with certain Indian and South African patent laws.

First, this Note discusses the history of medical research, the American pharmaceutical industry, and the historical and philosophical underpinnings of various patent laws.[2] Second, this Note compares Indian and South African patent laws in the context of the TRIPS drug disputes, including a discussion of the history of each law, the philosophy upon which it is based, and the relevance of the provisions to the issue of pharmaceuticals.[3]

A. Pharmaceutical Research

While new medicines are produced at an astounding rate, effective medicines are a relatively recent phenomenon. "Less than two dozen effective drugs were known before the year 1700."[4] In a world with pervasive superstition, lack of widespread communication, and no scientific method, most medicines were worthless. "The few effective drugs that were known were used alongside many other substances that were either valueless or downright poisonous."[5]

Physicians prescribed various medicines without a full understanding of their effects. In ancient Egypt, for example, baldness was treated with "a mixture of writing ink and cerebrospinal fluid."[6] Robert Boyle, a noted

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[1] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994 [hereinafter TRIPS], *reprinted in* THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS—THE LEGAL TEXTS 6-19, 365-403 (GATT Secretariat ed., 1994).

[2] *See* discussion *infra* Part I.A.-C.

[3] *See* discussion *infra* Parts II, III.

[4] HARRY F. DOWLING, MEDICINES FOR MAN: THE DEVELOPMENT, REGULATION, AND USE OF PRESCRIPTION DRUGS 14 (1970) (These drugs included aloe, figs, caster oil, alcohol, opium, quinine, iron, strychnine, and iodine. Several of these early medicines were derived from plants and animals.).

[5] *Id.* at 15.

[6] *Id.*

seventeenth-century chemist, "treated his patients with powdered cow dung for infection of the eyes."[7] Other examples of subsequently discredited medicines were "ants, earthworms, grasshoppers, the excrements of pigeons, the tails of lizards, [and] the eyes of crayfish."[8] Expressing his disgust with nineteenth-century medical science, Justice Oliver Wendell Holmes wrote that "if the whole *materia medica*, as now used, could be sunk to the bottom of the sea, it would be all the better for mankind—and all the worse for the fishes."[9]

During and after the Renaissance, however, science began developing rapidly. In the eighteenth and nineteenth centuries, chemical compounds were isolated, purified, and measured so that "the therapeutic properties of [a] drug could be studied accurately and any adverse effects could be clearly attributed to it."[10] By the early twentieth century, chemists had developed a method of "extracting from the natural product the portion having the pharmacological effect."[11] Improved "chemical invention and clinical observation"[12] and the combination of drugs discovered in "compounds [ ] that were effective in a larger group of diseases and caused fewer adverse effects"[13] were other significant steps in the development of modern pharmaceutical research.

This foundation led to the development of more sophisticated techniques, including synthesizing chemicals found in nature and manipulating the chemical composition of drugs.[14] Modern pharmaceutical research is well-organized, efficient, and prolific.

A massive multi-national drug industry, which devotes a great deal of its energies to research, now exists. Government regulatory agencies and sophisticated industry research departments work together to develop medicines safely and rapidly. "Currently, the [American] pharmaceutical industry has more than 1,000 medicines in development—either in human clinical trials or at FDA awaiting approval."[15] Each year, medicines are developed, approved, and distributed at an increasing rate. "During the

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[7] *Id.* at 16.

[8] *Id.* at 24.

[9] *Id.* at 17 (quoting OLIVER WENDELL HOLMES, MEDICAL ESSAYS (1891)).

[10] *Id.* at 16-17.

[11] *Id.* at 25.

[12] *Id.* at 17.

[13] *Id.* at 22.

[14] *Id.* at 25.

[15] PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, 2001-2002 ANNUAL REPORT *1, *at* http://www.phrma.org/publications/publications/annual report/2002/innovation.cfm [hereinafter PHRMA ANNUAL REPORT].

1990s, the [American] industry developed 370 new medicines—up from 239 in the previous decade."[16]

More than most other industries, the pharmaceutical industry devotes a great deal of its resources to research and development ("R&D"). "During the past two decades, the [American] industry's percentage of sales allocated to R&D has jumped from 11.9 percent in 1980 to 18.5 percent in 2001. This compares to an average of less than 4.0 percent for all U.S. industries."[17] In the modern era, medicine can no longer be "sneeringly referred to as the withered arm of science."[18]

B. What is the Justification for Patent Protection?

Drug innovation and intellectual property protections go hand-in-hand. The prolific research by the pharmaceutical industry requires billions of dollars of investment, and patent protections assure that drug companies will earn the resulting profits. Theoretically, a country's patent system "provides key incentives to inventive work and its related investment cost[ ] by ensuring that the inventor derives certain economic benefits from his or her work for a fixed period of time, generally 20 years."[19] The patent system requires a description of the compound to be patented, which in turn allows the compound to be manipulated and improved upon—one of the essential techniques of medicinal development. "[K]ey information on the invention is made available to the public and to other researchers, thus adding to the general body of accessible technical knowledge in the world. . . . Medical researchers rely heavily on previous work in developing better drugs to treat diseases."[20] According to Abraham Lincoln, "[t]he patent system added the fuel of interest to the fire of genius."[21]

A patent is a "publicly available document[ ]"[22] that describes an invention in terms "sufficiently full, clear, concise, and exact to enable any person skilled in the art to which the invention pertains to be able to make

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[16] *Id.*

[17] *Id.*

[18] DOWLING, *supra* note 4, at 17.

[19] World Intellectual Property Organization (WIPO), *Striking a Balance: Patents and Access to Drugs and Health Care*, *at* http://www.wipo.org/about-ip/en/studies/publications/health_care.htm (last visited Apr. 2, 2003).

[20] *Id.*

[21] HERBERT F. SCHWARTZ, PATENT LAW AND PRACTICE 3 (3d ed. 2001) (quoting Abraham Lincoln, Speech in Springfield, Illinois (Feb. 5, 1859)).

[22] Edmund W. Kitch, *The Patent Policy Of Developing Countries*, 13 UCLA PAC. BASIN L.J. 166, 169 (1994).

and use the invention."[23] Patents give inventors the right to "exclude others from making, using, offering for sale, or selling the patented invention . . . for the life of the patent."[24] Thus, on the rare occasions that patents cover profitable inventions, they can be extremely valuable to their holders. The drafters of a 1791 French patent law took the position that "it would be a violation of the rights of humanity in their very essence if an industrial invention were not regarded as the property of its creator,"[25] presumably due to the personal value of the patent to its holder and the societal value in innovation.

The relationship between patents and innovation has long been apparent, and it is often argued that strong patent protection is a catalyst for innovation. "As early as 500 B.C., the Greek colony of Sybaris granted [patent-like] rights."[26] In Renaissance Italy, the general patent statute of the Venetian Republic in 1474 included the following language:

> We have among us people of great genius, apt to invent and discover ingenious devices; and in view of the grandeur and virtue of our City, more such people come to us every day from divers parts. Now, if provision were made for the works and devices discovered by such persons, so that others who may see them could not build them and take the inventor's honor away, more people would then apply their genius, would discover, and would build devices of great utility and benefit to our Commonwealth.[27]

Statutory and constitutional language may include the idea that patents "promote" innovation. According to the United States Constitution, Congress may "promote the Progress of Science and useful Arts, by

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[23] SCHWARTZ, *supra* note 21, at 14 (citing 35 U.S.C. § 112, ¶ 1 (1988)). "For an invention to be patentable, it must be (1) of patentable subject matter, (2) useful, (3) new, and (4) nonobvious." *Id.* at 61.

[24] *Id.* at 2-3.

[25] A. Samuel Oddi, *TRIPS—Natural Rights and a "Polite Form of Economic Imperialism,"* 29 VAND. J. TRANSNAT'L L. 415, 421 (1996) (citing 2 LOIS & ACTES DU GOVERNMENT (1790-91), reprinted in part and translated in Frank D. Prager, *A History of Intellectual Property From 1545-1787*, 26 J. PAT. & TRADEMARK OFF. SOC'Y 711, 756-57 (1944)).

[26] SCHWARTZ, *supra* note 21, at 1.

[27] Oddi, *supra* note 25, at 419 (quoting Giulio Mandich, *Venetian Patents (1450-1550)*, 30 J. PAT. & TRADEMARK OFF. SOC'Y 166, 176-77 (1948) (*translated by* F.D. Prager from Giulio Mandich, *Le Privative Industriali Veneziane (1450-1550)*, 34 RIVOSTA DI DIRITTO COMMERCIALE 511 (1936))).

securing for limited Times to . . . Inventors the exclusive Right to their respective . . . Discoveries."[28] The fact that this provision was included in the Constitution shows a strong belief of the drafters that scientific development was closely related to patents and that science would prove important to the young nation.

While modern international patent legislation is often criticized as being influenced by wealthy innovators,[29] it was societal interest rather than the interest of the innovator that prompted the Founding Fathers to include this provision in the Constitution. "The patent monopoly was not designed to secure to the inventors . . . natural rights in their discoveries. Rather it was a reward, an inducement, to bring forth new knowledge."[30]

The theory that stronger patent laws promote innovation influences domestic and international law. During the early 1980s, judicial decisions and legislation helped make patents more valuable,[31] including the creation of the Federal Circuit in 1982, which, among other functions, is a national patent court of appeals.[32] The belief that strong, uniform patent protection is a motivating factor for innovation has deeply influenced the United States government and the international community.

C. TRIPS

Powerful members of the international community come together to create uniform international standards for patent legislation. These standards were codified in 1994 in the TRIPS[33] Agreement of the General

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[28] U.S. CONST. art. I, § 8, cl. 8.

[29] *See infra* notes 36-37 and accompanying text.

[30] Oddi, *supra* note 25, at 420 (quoting Graham v. John Deere Co., 383 U.S. 1, 8-9 (1965), in which the United States Supreme Court described Thomas Jefferson's philosophy of patents). Patents grant the holder the right to the exclusive use of an invention, and Professor Oddi notes that "Jefferson and other notable U.S. citizens abhorred monopolies." *Id.* at n.14.

[31] *See* SCHWARTZ, *supra* note 21, at 4-5. In support of his proposition that the patent system was "buttressed" in the late 1970s and early 1980s, Professor Schwartz cites a 1980 "reexamination statute" (35 U.S.C.A §§ 301-307 (West 1984 & Supp. 2000)) that "allowed patent owners to strengthen their issued patents by having the PTO reexamine them in light of certain types of 'prior art.'" *Id.* at 5. The judicial branch also played a role. Schwartz cites *Diamond v. Chakrabarty*, 447 U.S. 303 (1980) and *Diamond v. Diehr*, 450 U.S. 175 (1980), which recognized microorganisms and computer programs, respectively, as within the "broad scope of patentable subject matter." *Id.* at 5 & nn.25-26).

[32] *Id.* at 5.

[33] TRIPS, *supra* note 1.

Agreement on Tariff and Trade ("GATT") treaty.[34] TRIPS is the section of GATT that contains international patent obligations, and provides an extremely high standard of patent protection.[35] To join the WTO, a nation must agree to become subject to the broad GATT treaty, which includes the TRIPS patent provisions.

Different theorists give varying reasons for what they consider the driving force behind the most recent treaty. Professor A. Samuel Oddi, an authority on international patents, explained the adoption of TRIPS in the following critical manner:

> Industry groups (lobbyists) in developed countries, particularly in the United States, found a receptive government ear to their plea that their intellectual property was being "counterfeited," "pirated," "stolen," and "infringed" to their detriment and to the detriment of intellectual property-exporting countries by a generally bad lot in certain countries.[36]

This criticism of TRIPS is common. Another more spirited criticism included the following language: "[T]he TRIPS Agreement, in its current form, acts as a vehicle for Western imperialism over developing countries . . . [and, as administered by the WTO, an instrument] for forcing open markets to United States corporations at any cost, including the destruction of livelihoods, the environment, and human health."[37] Critics conclude that the strong patent protection in TRIPS was enacted to benefit private industry at the expense of poorer nations, rather than to promote innovation and benefit society as a whole.

Another argument is that TRIPS is part of the natural and economically sensible continuation of a post-World War II attempt to create a suitable framework for the international economy. This argument holds that TRIPS is part of the important process that included the adoption of GATT and the WTO treaties. Many of the post-war world leaders considered the breakdown of international trade during the Great Depression as a major contributor to the instability that led to World War II, which was one

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[34] General Agreement on Tariffs and Trade, Oct. 30, 1947, 61 Stat. A-11, T.I.A.S. 1700, 55 U.N.T.S. 194.

[35] Matthew Kramer, Comment, *The Bolar Amendment Abroad: Preserving the Integrity of American Patents Overseas After the South African Medicines Act*, 18 DICK. J. INT'L L. 553, 559 (2000).

[36] Oddi, *supra* note 25, at 424.

[37] Nadia Natasha Seeratan, Comment, *The Negative Impact of Intellectual Property Patent Rights On Developing Countries: An Examination of the Indian Pharmaceutical Industry*, 3 SCHOLAR 339, 347, 365 (2001).

impetus for the establishment of GATT in 1947.[38] GATT was a forerunner to the WTO treaty and includes the TRIPS Agreement.[39] Matthew Kramer, a graduate of the Dickinson School of Law, describes the adoption of TRIPS as one aspect of the gradual move towards economic globalization and a step in a multi-national effort spanning half a century.[40] "[T]he push for more secure and stable international trading systems, and the emergence of the hyper-connected international economy, have necessitated strict intellectual property protections."[41] Thus, this modern theory focuses on the idea that strong patent protection is essential to a stable international economy, but not necessarily because it promotes innovation.

The Director of the Intellectual Property and Investment Division of the WTO, Adrian Otten, describes the philosophical basis for the TRIPS Agreement as follows:

> [N]egotiation of the TRIPS Agreement was prompted by the perception that inadequate standards of protection and ineffective enforcement of intellectual property rights were often unfairly depriving the holders of such rights of the benefits of their creativity and inventiveness, and, as a result, prejudicing the legitimate commercial interests of their respective countries. . . . [It was perceived] that a major agreement on intellectual property was a necessary component . . . to the maintenance and strengthening of the multilateral trading system as a whole.[42]

There is probably some element of truth in each of the various descriptions of TRIPS.

II. INDIA AND SOUTH AFRICA

Factors other than a powerful drug industry and the development of the international community have influenced patent law in India and South Africa. Protectionism has shaped patent legislation in India.[43] South Africa, on the other hand, altered its patent legislation in response to the catastrophic public health situation caused by AIDS.[44] This Note discusses these two countries in detail below.[45]

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[38] Kramer, *supra* note 35, at 557.

[39] *Id.* at 556-57.

[40] *See id.* at 556-60.

[41] *Id.* at 557.

[42] Adrian Otten & Hannu Wager, *Compliance With TRIPS: The Emerging World View*, 29 VAND. J. TRANSNAT'L L. 391, 393 (1996).

[43] *See* discussion *infra* Part II.A-C.

[44] *See* discussion *infra* Part II.D-E.

[45] These two countries are discussed in detail in this Section.

The strong patent protection of TRIPS has brought the United States into conflict with Indian and South African patent laws. Considering the philosophical underpinnings of the different legal systems leads to a better understanding of why each country adopted particular policies. The United States, as discussed above, strongly believes that patents promote innovation. Conflicting interpretations exist as to what prompted the adoption of the TRIPS Agreement, but fears about "pirating" inventions, lobbying by powerful private industry, and a desire to maintain a stable international economic framework may have been part of the equation. Concerns about the future of India's pharmaceutical industry and domestic health concerns prompted India to adopt weak patent laws, especially with respect to pharmaceuticals. South Africa's disastrous public health situation led to the passage of its controversial patent legislation.

A. India's History and Patent System

This section will discuss the historical and philosophical bases for India's weaker patent model, as well as some of its more relevant provisions. India engages in what is known as *free-riding*, which is the practice of disregarding a foreign patent and manufacturing the product that the patent protects.[46] "[S]ome countries may decide that they can win by free-riding on the patented technology developed elsewhere without substantially slowing the march of technological development."[47] For instance, an American pharmaceutical company may research, develop, test, and after an extensive testing and approval process, manufacture a certain drug. This process may span several years and cost the company millions of dollars. Finally, the company must apply for a patent in each country in which it wishes to market the product. The free-riding occurs when a foreign company takes the product and manufactures it, disregarding the patent protection afforded the American company. An Indian company will manufacture products, particularly pharmaceutical products, that have been developed elsewhere without concern for whether the products are patented.

India, an English Colony until 1947, had pre-independence patent laws based upon those of England.[48] India was under British rule for over 100

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[46] Martin J. Adelman & Sonia Baldia, *Prospects and Limits of the Patent Provision in the TRIPS Agreement: The Case of India*, 29 VAND. J. TRANSNAT'L L. 507 (1996).

[47] *Id.* at 510.

[48] *See id.* at 518.

years before its independence.[49] Before that, the Indian subcontinent was home to a collection of varied cultures and tribes with only fragile cohesion. It was the independence movement that brought modern-day India into existence. At the time of India's independence, the Indian Patents and Design Act of 1911 was the existing patent law.[50] The newly independent nation wanted to revamp its British patent system to make it more Indian and more in line with national goals.[51] The first Prime Minister of India, Jawaharlal Nehru, was concerned that foreign companies would control the Indian economy.[52] In 1948 and again in 1957, two government committees were formed to evaluate the patent system. The reports of these two committees, the Tek Chand Committee in 1948 and the Ayyangar Committee in 1957, led to an overhaul of Indian patent law.[53]

> The committees found that *between eighty and ninety percent of the Indian patents were held by foreigners* and more than ninety percent of them were not worked [i.e. used by manufacturers] in India. The committees asserted that the system was being exploited by foreigners to achieve monopolistic control over the market. In regard to vital industries like food, chemicals, and pharmaceuticals, the data for patents was similar for the period 1947 through 1957. Medicines were arguably unaffordable to the general populace, and the drug-price index was rising. . . .[54]
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> . . . In the early 1940s and 1950s, ninety percent of the [Indian] drug market was under the control of foreign companies, and the country was totally dependent on imports for both bulk drugs (the active ingredients) and formulations (the medicines made from bulk drugs). As a result, Indian drug prices were then among the highest in the world.[55]

After extensive debate and delay, the Indian parliament passed the Patent Act of 1970,[56] which, ironically, is "a copy of the English Patent Act of 1949,"[57] except that it provides much less patent protection.

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[49] David K. Tomar, *A Look into the WTO Pharmaceutical Patent Dispute Between the United States and India*, 17 WIS. INT'L L.J. 579, 580 (1999).

[50] Adelman & Baldia, *supra* note 46, at 518.

[51] *Id.*

[52] Tomar, *supra* note 49, at 581.

[53] Adelman & Baldia, *supra* note 46, at 518.

[54] *Id.* (emphasis added).

[55] *Id.* at 526.

[56] *Id.* at 518.

[57] *Id.* at 518-19.

The objectives of the Act included the following: "[T]o encourage inventions and to secure that [they] are worked *in India*, . . . [to ensure that] they are *not* granted merely to enable patentees to enjoy a *monopoly for the importation* of the patented article, . . . [and to prioritize the] public interest over the private interest of the inventor."[58] The objectives of the Act as listed in its text are unapologetically protectionist, which is not surprising in view of the Committee's findings. Modern India had set a goal to free itself from foreign monopolies and establish strong domestic industries.

Indian patent law is particularly weak for certain inventions. While medicines and drugs may not be patented, "process claims covering methods of their manufacture are patentable."[59] These patents expire much more rapidly than those of other countries. "The term for inventions involving the method or process of the manufacture of a substance to be used as a food, medicine, or drug is five years from the date of sealing or seven years from the filing date of the complete specification, whichever is shorter."[60] The minimum term under the TRIPS Agreement, however, is twenty years.[61]

The term "sealing" refers to the grant of a patent upon the applicant's request after termination of the examination and opposition procedures.[62] Opposition procedures may take a great deal of time. A "complete specification" is included in the original application for the patent.[63] "Its claims define the boundaries of the patentee's property rights. The complete specification should fully describe the invention and the method by which it is to be carried out and disclose the best mode of performing the invention known to the applicant."[64]

In other words, five years from the grant of a medicine "process" patent which has overcome opposition and passed examination, it will expire. Seven years from the time of application for one of these patents, it will expire. "[I]t is possible that a patent which is opposed will expire before the opposition is concluded. Hence, for processes that come within this special definition, patent protection is plainly minimal"[65] when compared to that of other countries. As noted above, TRIPS requires member countries to

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[58] *Id.* at 519 (citing The Patents Act, No. 39, § 83(a) (1970) (India) [hereinafter India Patents Act]).

[59] *Id.* at 520 (citing India Patents Act, § 5(a), (b)).

[60] *Id.* at 523 (citing India Patents Act, §§ 53(1)(a), 45).

[61] TRIPS, *supra* note 1, art. 33.

[62] Adelman & Baldia, *supra* note 46, at 523 n.77.

[63] *Id.* at 520.

[64] *Id.* at 521 (citing India Patents Act §10(4)(a), (b)).

[65] *Id.* at 523.

establish a minimum of twenty years of patent protection.[66] India, a signatory to GATT, "has resisted altering its weak patent law system, thereby violating the agreement it so recently signed."[67]

Another weak aspect of the Indian patent system is its licensing system. The Indian "government has required that all private manufacturing enterprises be licensed."[68] All foreign technology licenses must obtain approval from the government, and their terms are also very short.[69] Once a license agreement expires, the patent holder has neither patent protection nor any right to collect royalties.[70]

One of the most potent protectionist tools in the Indian patent system is its compulsory licensing system.

> "Compulsory licensing" allows a nation to select a firm in their nation to make the drugs and sell them at . . . [low] cost. The patent holder is given a small royalty. . . .
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> . . . .
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> Before a nation may use compulsory licensing, the nation must attempt to get a voluntary license for the drug. The nation must also make payments for the use of the patented drug, and its decision to use the drug must be subject to some form of independent or judicial review.[71]

In any patent system, compulsory licenses serve the important purpose of forcing greedy patent holders to allow production of their products at reasonable prices. If a patent holder does not attempt to work the patent in the relevant country, a compulsory license will force them to do so. Unless they are used rarely, however, compulsory licenses can significantly erode patent protection. Under the TRIPS Agreement, for example, "[c]ompulsory licensing and government use without the authorization of the right holder are allowed, but are made subject to fifteen conditions aimed at protecting the legitimate interests of the right holder."[72] Compared with

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[66] *See supra* note 61 and accompanying text.

[67] Tomar, *supra* note 49, at 579.

[68] Le-Nhung McLeland & J. Herbert O'Toole, *Patent Systems in Less Developed Countries: The Cases of India and the Andean Pact Countries*, 2 J.L. & TECH. 229, 236 (1987).

[69] *Id.*

[70] *Id.* at 237.

[71] Herman Reinhold, *Patients v. Patents*, NO. 4 INTELL. PROP. L. NEWSL. (A.B.A. Publ'n), Summer, 2001, at 4.

[72] Otten & Wager, *supra* note 42, at 401 (citing TRIPS, art. 31). Article 31 contains the following requirements:

developed nations, the Indian compulsory licensing scheme is much more likely to be used.

In India, the government grants compulsory licenses for patents if the patents have not been worked by the patentee or are not available to the people of India at a low enough cost.[73] The large amount of discretion in the decisions makes the patent application process especially susceptible to the corruption pervading the Indian bureaucracy. Under the compulsory licensing rules, patents on food and medicines may be overridden three years from the time of sealing, whether or not the patent holder has attempted to "work" the invention.[74] Thus, even when the patent holder makes a good faith effort to work the drug locally, and even if the technology is a type that can be patented, "the patents are only effective for a period of three years from sealing."[75] India's compulsory licensing system

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(a) authorization for compulsory licensing must be considered on the merits;
(b) the licensee must have attempted to obtain authorization from the patent holder on reasonable commercial terms and that such efforts remained unsuccessful after a reasonable period of time had passed;
(c) the scope and duration of the compulsory license shall be limited to the purpose for which it was originally authorized;
(d) the use of the compulsory license shall not be exclusive;
(e) the use shall not be assignable;
(f) the compulsory license shall be authorized predominantly for the use of the domestic market of the Member authorizing the compulsory license;
(g) authorization for the compulsory license shall cease when the circumstances that necessitated its implementation no longer exist;
(h) the patent holder shall receive appropriate compensation for the use of the patent and such compensation shall be determined by taking into account the economic value of the license;
(i) the legal validity of any compulsory license scheme shall be subject to judicial review;
(j) the determination of appropriate compensation to be paid to the patent holder shall be subject to judicial review;
(k) anti-competitive practices by the patent holder shall be taken into consideration; and
(l) additional conditions shall apply where use is authorized to exploit the second patent which cannot be exploited without infringing another patent.

[73] Adelman & Baldia, *supra* note 46, at 524 (citing India Patents Act § 84(1)).

[74] McLeland & O'Toole, *supra* note 68, at 235.

[75] Adelman & Baldia, *supra* note 46, at 524 (citing India Patents Act § 87(1)(a)).

is clear evidence of the protectionist philosophy underlying its patent system. After the passage of the 1970 Act,[76] foreign patent applications declined significantly. "[I]n the area of chemical processes, drugs, and food articles, the statistics show that the world at large believes India provides little patent protection."[77]

B. The Indian Pharmaceutical Industry

India's protectionist patent system has shown remarkable results. Although India was totally dependent on foreign companies for drugs in 1947,[78] it has a powerful independent pharmaceutical industry today.[79]

> Weak patent laws allowed India to quickly enter into pharmaceutical markets, both domestic and foreign, by allowing Indian-owned pharmaceutical companies to copy existing pharmaceuticals cheaply without the expenditures of time and money that foreign pharmaceutical companies spent on research and development. Also, Indian-owned pharmaceutical companies feared neither legal infringement against pharmaceutical developers nor the accompanying litigation expenses. Thus, by building up Indian-owned pharmaceutical companies, India was able to reverse the earlier trend and prevent large foreign multinational corporations from dominating India's pharmaceutical sector, giving India autonomy which affected both India's economic and political sectors.[80]

In 1947, Indian drug prices were among the highest in the world.[81] At the time of independence, Indian pharmaceutical companies did little more than process ingredients imported from other companies. Now, however, the reverse is true. As of the 1990s, "Indian companies control[led] seventy percent of the domestic formulations market and eighty-five percent of the bulk drugs market."[82] At least in the area of drug production, Nehru's concern about Indian industry dependence on foreign nations has been avoided.

Not only is the Indian drug industry free from foreign domination with respect to domestic markets, it is also a formidable international competi-

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[76] The Patents Act, 1970, No. 39 (India).
[77] McLeland & O'Toole, *supra* note 68, at 237.
[78] *See supra* notes 54-55 and accompanying text.
[79] *See infra* note 82 and accompanying text.
[80] Tomar, *supra* note 49, at 582.
[81] Adelman & Baldia, *supra* note 46, at 526.
[82] *Id.* at 527.

tor. Use of generic drugs is now common in the West, and "Indian companies compete in the international race to exploit the huge market for generic drugs."[83] Compared to the weak, dependent industry of the late 1940s, the modern drug industry is almost unrecognizable. "Indian industry has emerged as a world leader in the production of bulk drugs[, and] . . . India has become a net exporter of drugs and has earned a considerable reputation in the international market as a dependable bulk drug manufacturer."[84]

This success was achieved, in large part, through the protectionist patent legislation described above.[85] In view of India's history as a subservient colony, fears about foreign domination must have been particularly compelling. It is not clear, however, that this justification is acceptable fifty years after independence. In view of the fact that the Indian drug industry is now a powerful international competitor, it seems especially inappropriate to argue that there is imminent danger of foreign domination.

C. Does Public Health Justify India's Weak Patent System?

There is no health concern to justify India's weak patent protection. The health problems that Indian citizens face are unrelated to patent laws. It is important to note that India's AIDS crisis, while serious, is not as catastrophic as that of South Africa where a similar protectionist patent system was in place. The adult rate of HIV/AIDS infection in India is 0.8%, which is only slightly higher than the 0.6% rate in the United States. Such a comparison is misleading, however, because India has a total population of over 1 billion people.[86] The author does not wish to underemphasize the

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[83] *Id.* at 525.

[84] *Id.* at 525-26.

[85] *See supra* notes 59-77 and accompanying text.

[86] *See* UNAIDS, REPORT ON THE GLOBAL HIV/AIDS EPIDEMIC 2002, 190, 194, 198, *at* http//:www.unaids.org/barcelona/presskit/barcelona%20report/table.html [hereinafter UNAIDS REPORT] (HIV/AIDS statistics are from this publication's detailed "Table of Country-Specific HIV/AIDS Estimates and Data" section. These estimates indicate that roughly 3.97 million people in India are living with AIDS, which means India has the second highest amount of HIV infected people in the world after South Africa. *Id.* at 194. Without discounting the seriousness of the Indian epidemic, however, the author wishes to clarify the difference between South Africa's epidemic and India's epidemic. Fewer than 1% of Indian adults have HIV/AIDS, compared to about twenty percent of South African adults. *Id.* at 190, 194.).

crucial importance of an HIV or AIDS epidemic in any region, but it is important to realize that as horrible as India's epidemic is, it is simply not on the scale of South Africa's. Thus, a national health issue as a justification for free-riding is now largely economic and not founded on imperialism or public health concerns.

In fact, one negative effect upon Indians caused by the free-riding system is that the drug industry does not have an adequate research sector. Because the weak patent system allowed the industry to take the inventions of others, the industry devoted very little energy to developing its own drugs. "[S]cientific research in India, mainly a government-run activity, has been conducted under a few governmental or quasi-governmental agencies"[87] which have been ineffective at developing new drugs. "Indian-owned companies typically spend 1% of sales on R&D, compared to an average of 15% by Western pharmaceutical companies."[88] The common sight of Indian scientists at American universities is misleading for two reasons. First, "a large percentage of Indian scientists are engaged in teaching and academic research and not industrial research."[89] Second, many of the Indians who study in Western countries are lured by the lucrative job opportunities and wealthy lifestyle and do not go back to India.[90] This lack of research capability is attributable, in part, to the patent system.

Additionally, India has its own health concerns which deserve attention and focused research. Drug companies in the West have no incentive to develop treatments for many of the health problems that affect India. Diseases like malaria and leprosy are not major concerns in the West, so pharmaceutical companies lack an incentive to research possible cures. "The technological needs of [India] are not the same as the technological needs of a developed country."[91] If a Western drug company does not invent a treatment, Indian companies, while adept at copying, will not have the capability to invent the drugs.[92] Thus, not only may the Indian patent system be justified on the basis of public health concerns, its stunting effect on the Indian pharmaceutical industry's research capability has a negative impact on Indian public health.

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[87] Adelman & Baldia, *supra* note 46, at 528.

[88] Tomar, *supra* note 49, at 583; *see also* PHRMA ANNUAL REPORT, *supra* note 15.

[89] McLeland & O'Toole, *supra* note 68, at 238.

[90] *Id.*

[91] Kitch, *supra* note 22, at 176.

[92] Adelman & Baldia, *supra* note 46, at 511.

Recently, in response to TRIPS, as well as to disputes with the United States and the WTO, there has been a movement towards amending Indian patent laws and creating research capabilities. On March 26, 1999, the Indian government adopted the Patents Amendment Act of 1999, bringing it into compliance with recommendations by the WTO.[93] These amendments include provisions aimed specifically at "the reception of [foreign] patents for pharmaceuticals."[94] Additionally, Indian "pharmaceutical companies [have begun] trying to build technology muscle. A prime example is Ranbaxy Lab, Inc... [which] signed a $90 million joint venture with Eli Lilly & Co. to collaborate for drug research and development."[95] Within ten to twenty years, the Indian drug industry and patent system could be distinctively different from the way it is today. It may be that India, recognizing the problems with its patent system, is attempting to modernize and join the developed world.

D. South Africa's History and Patent System

South Africa had a patent system that was similar in many respects to the pre-1999 Indian system. The philosophy underlying the South African system is much different, however. While India structured its patent system in an attempt to free itself from foreign economic control and later maintained the system to bolster its pharmaceutical industry, South Africa altered its patent system for public health reasons.

Like India, South Africa was under British Rule until the mid-twentieth century. South Africa gained partial independence from England in 1910 and complete independence in 1932.[96] Unlike the situation in India, however, South African independence from Britain did not end racial oppression. Africans have been dominated in South Africa from 1658, when slaves were first imported into the new Dutch colony, until 1993 when Apartheid was abolished.[97]

The period between independence from Britain and the abolition of Apartheid was marked by some particularly nasty legislation that kept

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[93] Tomar, *supra* note 49, at 590.

[94] *Id.*

[95] Adelman & Baldia, *supra* note 46, at 528. *But see* Jean-Francois Tremblay, *C&EN Talks with an Indian Iconoclast*, CHEMICAL AND ENGINEERING NEWS, May 6, 2002, at 19 (discussing India's Chipla company, which sends AIDS medications to Africa for dramatically less than Western drug companies).

[96] *See* Emily Bourdeaux Smith, *South Africa's Land Reform Policy and International Human Rights Law*, 19 WIS. INT'L L.J. 267, 269 (2001).

[97] *See id.*

blacks from owning land, created numerous criminal offenses directed only at blacks, and consolidated the power of the white minority.[98] The "Three Pillars of Apartheid," the Blacks Land Act 27 of 1913, the Blacks (Urban Areas) Act 21 of 1923, and the Black Administration Act 38 of 1927 resulted in the "complete subjugation of blacks in South Africa."[99] These laws allowed the government to relocate individuals and even entire tribes without compensation, limit the areas in which blacks could live and work, alter tribal groups, and keep blacks from owning land.[100] The "legislation created and thereafter sustained 'another world' wherein black persons have been forced to live, work and raise their families under rules and conditions which do not apply to other races in South Africa."[101] For example, Section 5 of the Black Administration Act 38 of 1927 gave the Governor-General (i.e., the State President) the power to "divide existing tribes into one or more parts, or amalgamate tribes or parts of tribes into one tribe, or constitute a new tribe . . . [and] order the removal of any tribe or portion thereof or any Native from any place to any other place within the Union."[102] Blacks in South Africa were the most abject of second-class citizens.

As a partial attempt to redistribute the stolen land, two new constitutions have been enacted since the abolition of Apartheid: the 1993 interim constitution and the 1996 final constitution.[103] One year after the adoption of the final constitution, the patent legislation addressed in this Note was passed. The patent legislation came on the heels of the newly drafted constitutions, which themselves came immediately after the liberation from Apartheid. It is important to be clear that public health, not economic independence as it had been in India, was the impetus behind the passage of the law.

E. The South African AIDS Crisis

One-fifth of the adult population in South Africa is infected with HIV.[104] Of a total population of thirty-nine million people, five million have

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[98] *See* Judge Justice Moloto, *South African Legal Reform After April 1994*, 26 N.C. J. INT'L L. & COM. REG. 653, 653-64 (2001).

[99] *Id.* at 655.

[100] *Id.*

[101] *Id.* at 656.

[102] *Id.* at 655 (citing Black Administration Act 38 of 1927, § 5(1), 6 BSRSA pt. 28 (2000)).

[103] *See id.* at 664-68. S. AFR. CONST. (1993); S. AFR. CONST. (1996).

[104] UNAIDS REPORT, *supra* note 86, at 190.

HIV.[105] Two hundred and fifty thousand of those infected are children.[106] "[Former] U.S. Surgeon General David Sacher has compared the current African AIDS crisis to the Black Death that swept Europe five hundred years ago."[107] South Africa's total HIV-infected population is the highest in the world, and its percentage of adult HIV infection is the seventh highest in the world, behind Botswana, Zimbabwe, Swaziland, Lesotho, Namibia, and Zambia.[108] Lesotho and Swaziland are landlocked inside South Africa, while Botswana, Zimbabwe, and Namibia share borders with South Africa. The average percentage of adults infected with HIV in sub-Saharan African countries is 9%, compared with 1.2% world-wide.[109] Sub-Saharan Africa in general, and particularly the southern tip of Africa, are being devastated by AIDS.

In addition to the dramatically high numbers of HIV-infected South Africans, the passage of the 1997 patent law attributed to South Africa's poverty and inability to afford high-priced AIDS medicines from the West. Although AIDS is an incurable disease, modern research has shown that life may be prolonged by various medicinal therapies and that certain treatments may also prevent transmission from mother to the fetus altogether.[110] "This treatment plan has reduced AIDS-related mortality by over seventy percent in developed countries."[111] Drugs that are neither expensive nor difficult to manufacture "such as Retrovir, which can halt the

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[105] *Id.*

[106] *Id.*

[107] Kramer, *supra* note 35, at 565 (quoting Africa Policy Information Center, *AIDS Drug Policy*, AFRICA NEWS SERVICE, Sept. 7, 1999, *available at* 1999 WL 25944377).

[108] UNAIDS REPORT, *supra* note 86, at 190. The adult infection rates as of the end of 2001 are as follows: Botswana: 38.8%, with 330,000 total infected adults and children of a population of 1.5 million; Zimbabwe: 33.7%, with 2,300,000 total infected adults and children of a population of 12.8 million; Swaziland: 33.4%, with 170,000 total infected adults and children of a population of 938 thousand; Lesotho: 31%, with 360,000 total infected adults and children of a population of 2 million; Namibia: 22.5%, with 230,000 total infected adults and children of a population of 1.7 million; and Zambia: 21.5%, with 1,200,000 total infected adults and children of a population of 10.6 million. *Id.*

[109] *Id.*

[110] Mary K. Schug, *Promoting Access to HIV/AIDS Pharmaceuticals in Sub-Saharan Africa Within the Framework of International Intellectual Property Law*, 19 LAW & INEQ. 229, 235 (2001).

[111] *Id.*

transmission of AIDS from mothers to their unborn children,"[112] are very expensive. The famous "triple-drug cocktail," which "includes two nucleoside analogs and a protease inhibitor," is fantastically expensive, even by American standards.[113] "In 1992, seven AIDS treatment drugs ranged in monthly price from $160 to $1,740, with yearly costs of $1,920 to $20,882."[114] Although the prices have dropped,[115] these drugs are simply out of reach for the people of South Africa. According to The World Almanac, the South African Per Capita Gross Domestic Product was $5,400 in 1999.[116] Regardless of which is more accurate, it is clear that the average South African could never afford AIDS medications at the prices quoted above.

In 1997, the South African Parliament, recognizing the public health catastrophe on its hands, passed the Medicines and Related Substances Control Act, Act No. 90 of 1997.[117] "Included in this bill, specifically [sections 15(c) and 22(c)], were provisions for parallel importing, compulsory licensing, and a clause that overrules patent rights that prevent South African companies from developing local versions of effective treatments."[118] As explained above, "compulsory licensing" is the practice where a nation picks a domestic company to make the drug protected by a foreign patent and then sells the drug for less than the patent holder would charge.[119] " 'Parallel importation' is reselling goods that were first sold in another country. A nation would buy the drugs on the world market wherever they are cheapest, and then import them for its own people."[120]

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[112] Kramer, *supra* note 35, at 565 (AZT stands for "azidothymidine" which is actually an older name. It is now also called "RETROVIR," which is a brand name for the chemical drug "zidovudine." THOMPSON PDR, 2003 PHYSICIANS' DESK REFERENCE 1625 (57th ed. 2003)).

[113] Reinhold, *supra* note 71, at 4.

[114] *Id.*

[115] *See* UNAIDS FACT SHEET: ACCELERATING ACCESS TO TREATMENT AND CARE (2002), *at* http//:www.w3.unaids.org/en/media/fact+sheets.asp. "In early 2000, the price of Highly Active Antiretroviral Therapy (HAART, also referred to as triple therapy) for one patient for a year was US $10,000-US $12,000. By the end of 2000, prices had dropped to US $500-US $800 per person per year for first-line antiretroviral treatment in low-and middle-income countries. By December 2001, certain combinations of medicines cost US $350 per person per year." *Id.*

[116] *Id.*

[117] Kramer, *supra* note 35, at 565.

[118] *Id.*

[119] *See supra* note 71 and accompanying text.

[120] Reinhold, *supra* note 71, at 4.

The Minister of Health in his individual discretion may use these tools to override patent protections. "Specifically, [section 22(c) of] the amendment grants the Minister of Health the power to allow for compulsory licensing, provided the drug was initially marketed by the patentee or with the patentee's consent and the drug does not have other expressed restrictions."[121]

> The minister [of Health] may prescribe conditions for the supply of more affordable medicines . . . so as to protect the health of the public, and . . . may
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> . . . .
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> [allow the importation of a medicine] which is imported by a person *other* than the person who is the holder of the [patent].
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> . . . .
>
> [T]he council may . . . issue . . . a license to manufacture or act as a wholesaler of or distribute . . . such medicine or medicinal device.[122]

This Act is similar to the compulsory licensing scheme of the Indian Patent Act of 1970.[123] India and South Africa have implemented the tools of compulsory licensing and weak patent protection for two different ends.

The international community, led by the United States, was infuriated by the amendments. "Forty major drug companies sued, countering the . . . Act in an attempt to protect pharmaceutical patent rights and corporate profits. The United States [government] added more fuel to the fire and waged an aggressive campaign to reverse the South African law."[124] It is unclear whether the law was in violation of TRIPS or not, because, as noted above, TRIPS allows compulsory licensing under certain circumstances.[125]

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[121] Rosalyn S. Park, *The International Drug Industry: What the Future Holds for South Africa's HIV/AIDS Patients*, 11 MINN. J. GLOBAL TRADE 125, 136 (2002).

[122] Medicines and Related Substances Control Amendment Act of 1997, Act No. 90, §§ 15(c), 22(c) (BSRSA 1997).

[123] *See supra* notes 73-77 and accompanying text.

[124] Bess-Carolina Dolmo, Note, *Examining Global Access to Essential Pharmaceuticals in the Face of Patent Protection Rights: The South African Example*, 7 BUFF. HUM. RTS. L. REV. 137, 138 (2001).

[125] *See supra* note 72 and accompanying text; *see also* TRIPS, *supra* note 1, art. 31; *see also* Naomi A. Bass, *Implications of the TRIPS Agreement for Developing Countries: Pharmaceutical Patent Laws in Brazil and South Africa in the 21st Century*, 34 GEO. WASH. INT'L L. REV. 191, 199 (2002) (citing the TRIPS art. 31 conditions that must be achieved before a signatory nation may grant compulsory licenses).

The United States chose not to contest the law using the WTO mediation process as it had in the case of the Indian Patent Act, perhaps because it feared that the WTO mediators would find that South African law was not in violation of TRIPS.[126] This issue remains unsettled.

Regardless of whether the South African law conflicted with TRIPS, the dispute resulted in both sides backing away from the issue. The drug companies withdrew their suit in April 2001, and the South African Parliament passed the "South African Medicines and Medical Devices Regulated Authority Act (SAMMDRA), which rescinded the Medicines and Related Substances Amendment Act and the amendment."[127] South Africa has not attempted to grant compulsory licenses, and the international community has lifted its pressure.

The South African parliament saw reforming its patent laws as the solution to the AIDS crisis. Even if South Africa were to have access to the drugs it seeks, it is doubtful that the people would receive them. "South Africa does not have the infrastructure to effectively provide the drugs now."[128] Treatment of AIDS is a complex, expensive, and long-term process. Patents on AIDS medications are only a minor part of the health crisis. A report prepared for the World Intellectual Property Organization ("WIPO") found that the necessary medical infrastructure will be costly to develop, and foreign assistance is currently inadequate.[129] The report also provided that

> . . . [T]he intellectual property rights of pharmaceutical companies and the TRIPS agreement are not, in themselves, impediments to the availability of HIV/AIDS therapies in sub-Saharan Africa; and it is clearly incorrect to assume that without restrictions imposed by the WTO through TRIPS and without patents, HIV/AIDS patients would have access to drugs crucial to their survival.[130]

It is doubtful that even if South Africa had attempted to implement its patent law it would have significantly helped the AIDS crisis.

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[126] *See* Dolmo, *supra* note 124, at 146 (claiming that former Vice President Gore and other United States officials believed that the South African law was not in violation of the TRIPS Agreement).

[127] Park, *supra* note 121, at 137.

[128] Reinhold, *supra* note 71, at 5.

[129] The Intellectual Property Institute, *Patent Protection and Access to HIV/AIDS Pharmaceuticals in Sub-Saharan Africa* (2000), *at* http://www.wipo.int/about-ip/en/pdf/iipi_hiv.pdf (last visited Apr. 2, 2003) (Report prepared for the World Intellectual Property Organization (WIPO)).

[130] *Id.* at 54.

The medical community has not been convinced that strong patent laws have exacerbated the African AIDS crisis, or that patent laws have been the main impediment to drug access. A 2001 study published in the *Journal of the American Medical Association* disclosed the following findings:

> [It appears that] patents and patent law are not a major barrier to treatment access in and of themselves. We conclude that a variety of de facto barriers are more responsible for impeding access to antiretroviral treatment, including but not limited to the poverty of African countries, the high cost of antiretroviral treatment, national regulatory requirements for medicines, tariffs and sales taxes, and, above all, a lack of sufficient international financial aid to fund antiretroviral treatment.[131]

Clearly, the West has a duty to attack the African AIDS crisis and must do so soon. Several factors must be addressed, including funding, medical infrastructure, education, and, of course, drug patents. It is also clear, however, that blaming pharmaceutical companies and patent laws for the AIDS crisis is excessively simplistic.

III. COMPARISONS

The histories of the United States, Western Europe, India, and South Africa are all related to their modern patent laws. In the West, governments have long understood the important connections between scientific research and patent laws, as well as the powerful economic effects of patent laws. The Indian government, with its goal of freedom from foreign control, understood that weak patent laws could build up its economy. The South African government, busy remedying the effects of Apartheid, had a major epidemic on its hands and saw weak patent laws as the solution for its troubles. The WTO looks to strong patent laws as a means to the goal of an efficient and stable international economy.

Socially and culturally, the parties at issue here are very different. While it is always difficult to make generalizations about hundreds of millions of people, there are certain common themes relevant to this topic.

Western nations reap the benefits of strong patent laws through the development of numerous medicines. Additionally, efficient medical infrastructures make new medicines available to ordinary citizens, and quality medical care is a realistic expectation for a large percentage of

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[131] Amir Attaran & Lee Gillespie-White, *Do Patents For Antiretroviral Drugs Constrain Access To AIDS Treatment In Africa?*, 286 JAMA 1886 (2001).

Western people. It is the West that determines the course of the international community, and strong patent law is seen as another way to secure the prosperity of the global economy.

In India, the foreign domination of the two previous generations must be fresh in the minds of many people. Weak patent laws have been essential to the Indian economy for many years. Because it is a nation with many poor people, any threat to the Indian economy must seem severe.

South Africa, with its horrendous AIDS crisis, has a terrified population. It is likely that every person in South Africa has been affected by the epidemic in some way. It is easy to see how the national and regional AIDS panic influenced the South African legislature into passing its weak patent legislation.

The reasons underlying Indian and South African refusal to implement strong patent protection, while superficially appealing, appear unsatisfactory. India, with its massive population, powerful economy, and competitive drug industry, is not at risk of foreign control. South Africa's struggle with AIDS can only be a success through a Herculean effort, which includes improving its medical infrastructure and receiving substantial help from the rest of the world. Access to AIDS drugs is only part of the solution.

As the economy of the world becomes more interconnected, treaties like TRIPS will become increasingly important. As time passes and the benefits of compliance become apparent, resistance by countries such as India and South Africa may decrease.