# MEXICO'S PHARMACEUTICAL PATENT DILEMMA AND THE LESSON OF INDIA

Juan Bacalski*

"Intellectual property 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."[1]

## I. INTRODUCTION

Patent protection is necessary for the development of any technology-based industry.[2] This is especially true of the pharmaceutical industry, which depends on the enormous investment of resources in the development of new drugs.[3] In fact, the patent system is considered essential to the business model of the pharmaceutical industry.[4] First, patent protection allows a pharmaceutical company that develops a new drug to sell it at a price that better reflects the true cost of producing it. Second, that company then has the potential to realize a profit from sales of the drug, and, thus, there is the incentive for the company to continue investing in drug discovery. In 2003, for example, the average cost of bringing a new drug to market was more than $900 million.[5] The bulk of this cost goes into research and development (hereinafter referred to simply as "R&D"), including extensive testing for safety and efficacy.[6] In the United States, only one of five drugs that reach the clinical trials stage will get Food and Drug Administration (FDA) approval, and, of these, only three of ten will earn back the average cost of R&D.[7] R&D costs contribute a significant portion to the prices

* J.D., University of Arizona James E. Rogers College of Law, 2007; B.S., Animal Physiology and Neuroscience, University of California, San Diego, 1993. Thanks first to my parents for their continuing support. I also extend my deepest gratitude to Christina Wu, Jonathan Millet, May Lu, Sally Bassett, and Tyler Abrahams for their great editorial contributions and to Professor David Adelman for his valuable advice and suggestions.

1. Susan Finston, Essay, *India: A Cautionary Tale on the Critical Importance of Intellectual Property Protection*, 12 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 887, 888 (2002).

2. *See id.*

3. *See* PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (PHRMA), PHARMACEUTICAL INDUSTRY PROFILE 5 (2005), *available at* http://www.phrma.org/2005_industry_profile [hereinafter PHRMA].

4. John H. Barton, *TRIPS and the Global Pharmaceutical Market*, HEALTH AFF., May/June 2004, at 146, 146.

5. Alex Berenson, *Blockbuster Drugs Are So Last Century*, N.Y. TIMES, July 3, 2005, § 3, at 1.

6. PHRMA, *supra* note 3, at 5-6.

7. *Id.*

set by pharmaceutical firms for their products.[8] Drug prices are initially high for consumers because patents give companies the power to set prices that are reflective of the massive R&D costs for new products.[9]

In contrast, pharmaceutical companies in countries with low patent protection have considerably lower costs associated with bringing a product to market. These companies capitalize on the inventions of others by reverse engineering[10] an existing product whose structure is not protected under local patent laws, and then manufacturing a generic version with lower production costs and no R&D costs.[11] These unauthorized generic versions of existing products are then sold at prices that undercut the original inventor's prices.[12]

It has been suggested that "pirates" of intellectual property sometimes conspire together to set higher prices for their counterfeit products than would be expected for imitations.[13] As a patent reaches the end of its term, the threat of competition from other companies selling their own versions of the product often results in price reductions.[14] Thus, there is the potential for better price control and competition within a strong patent system. These price reductions generally reflect the "future marketing considerations" of the patent holder.[15] Further, a patent only excludes the use of a particular invention, not the participation in a particular market.[16] Therefore, in the case of pharmaceuticals, competing firms may develop different drugs to treat the same conditions, i.e., to serve the same market.[17] Competition among the drugs will benefit the market by forcing the producers to keep prices at competitive, and generally lower, levels.[18]

Patents also encourage innovation. They spur the pace of technology creation and development by providing both financial incentive and property protection to patentees.[19] The basic idea, central to all patent systems, is that by

---

8. *See* Shanker A. Singham, *Competition Policy and the Stimulation of Innovation: TRIPS and the Interface Between Competition and Patent Protection in the Pharmaceutical Industry*, 26 BROOK. J. INT'L L. 363, 388-89 (2000).

9. *See* Robert M. Sherwood, *The TRIPS Agreement: Implications for Developing Countries*, 37 IDEA 491, 500 (1997) (arguing that because patents have a fixed duration, marketing considerations will effect price reductions as the patent terms near expiration).

10. When an existing drug is reverse engineered, a company analyzes it carefully to reproduce it exactly, rather than developing a new product. *See* MERRIAM-WEBSTER'S COLLEGIATE DICTIONARY 1067 (11th ed. 2003).

11. *See generally* Rebecca Mayer, *A Passage for India*, 24 MED AD NEWS 4, Feb. 1, 2005, *available at* 2005 WLNR 3520883 (describing Indian pharmaceutical companies' practice of reverse engineering).

12. *Id*.

13. Sherwood, *supra* note 9, at 500.

14. *Id.*

15. *Id*.

16. *See id.*

17. *See id.*

18. *See id.*

19. Sherwood, *supra* note 9, at 500.

rewarding the creator for an invention, there will be incentive for the creation of more inventions, thus benefiting society.[20] This concept dates back to the time of Aristotle in Ancient Greece.[21] In turn, patents serve the public by ensuring that useful public goods will be created and made available.[22] Inventors are incentivized to maximize the value of their patents by improving on their technologies without fear that competitors will steal their ideas.[23]

The purpose of patents is not only to incentivize the creation of novel technologies, but also to encourage the dissemination of knowledge.[24] A patent generally provides protection for a limited period during which the inventor may exclude or restrict the production or use of the invention.[25] When this limited period terminates, the details of the invention become openly available for anyone's use.[26] Publication of a patent ensures that the invention will continue to be accessible to others after the period of protection ends.[27] Information that is disclosed in patent applications may be used by other researchers to accelerate their own R&D, thus accelerating the advance of technology.[28] Under a patent system, the inventor is essentially agreeing to publicize the invention in exchange for an initial period during which use of the invention is under the inventor's exclusive control. These two functions of patents, to incentivize creation and to disseminate information, ideally serve to advance the development of technology.[29]

Although patent protection serves a beneficial function to society, some argue that patent systems are harmful to developing nations whose citizens are

---

20. *See* ROBERT PATRICK MERGES & JOHN FITZGERALD DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS 2 (3d ed. 2002).

21. *Id.* at 1 ("According to Aristotle [in his *Politics*], Hippodamus of Miletos calls for a system of rewards to those who discover things useful to the state.").

22. *See* Singham, *supra* note 8, at 365.

23. *Id.* at 366; *see also* Sherwood, *supra* note 9, at 500 ("The role of patents in many industries is not price enhancement but primarily to defend against immediate copying.").

24. Singham, *supra* note 8, at 366-67.

25. The U.S. Constitution, for example, authorizes Congress "[t]o promote the Progress of Science and useful Arts, by *securing for limited Times* to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." U.S. CONST. art. I, § 8, cl. 8 (emphasis added). Most major industrial nations follow a "twenty-year-from-filing" rule, which limits the patent term to twenty years from the date the patent application is filed. MERGES & DUFFY, *supra* note 20, at 59.

26. Singham, *supra* note 8, at 366-67.

27. In fact, information about the invention is generally made available to the public only eighteen months after an application is filed due to an eighteen-month publication rule that is standard in most industrial nations. MERGES & DUFFY, *supra* note 20, at 62. The reason for this rule is to inform other researchers of new technological developments so as to avoid duplication of effort and to increase "the storehouse of publicly available knowledge sooner." *Id.* at 63.

28. Singham, *supra* note 8, at 366-67.

29. *See id.*

unable to gain access to life-saving drugs due to prohibitive costs.[30] The argument is that stringently enforcing patents in developing countries keeps drug prices artificially high in those countries.[31] This argument is misleading, however. "Most of the medicines on the 'essential medicines list' of the World Health Organization are not under patent . . . and for a range of medical conditions affecting the poor in developing countries, patent protection is not the principal obstacle to treatment."[32] Thus, factors other than patent issues affect the availability of drugs in developing countries.

The issues facing developing countries with regard to the protection of pharmaceutical patent rights involve not only the interests of the domestic and international pharmaceutical industries, but also the protection of public health.[33] These competing interests must be balanced.[34] Pharmaceutical producers must be given the incentive to innovate, but, at the same time, life-saving drugs should be accessible and affordable to the people who need them.[35] The position of the World Intellectual Property Organization (WIPO) is that all people have a right to a certain standard of living, including adequate medical care, but that this right does not conflict with the inventor's right to enjoy the material rewards that come from creating useful inventions.[36] Indeed, providing the right of reward to the inventor, by encouraging innovation and progress in medical science, adds to the level of medical care that may be enjoyed by the world public.[37]

Mexico and India are two developing countries facing similar issues regarding patent law policy and its effect on their respective pharmaceutical industries. This Note will examine the current state of Mexico's nascent pharmaceutical industry and will demonstrate how Mexico can improve that industry through the application of reasonable patent protections. The more mature Indian pharmaceutical industry will also be examined as a model to which Mexico's industry may be compared and from which important lessons may be drawn. Part II of this Note will provide a general perspective on the current state

30. *See* 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, 345 (2001).

31. *Id.*

32. Frederick M. Abbott, *The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health*, 99 AM. J. INT'L L. 317, 322-23 (2005).

33. *Id.* at 318.

34. The World Intellectual Property Organization (WIPO) has emphasized the importance of striking a balance between patentees' interests and issues of public health but states that this balance is already present within the current international patent system, which allows member states to modify their own systems as needed to ensure that balance. World Intellectual Prop. Org. [WIPO], *Striking a Balance: The Patent System and Access to Drugs and Health Care*, http://www.wipo.int/freepublications/en/patents/491/wipo_pub_491.pdf (last visited Sept. 10, 2006).

35. *See* Abbott, *supra* note 32, at 318.

36. WIPO, *supra* note 34.

37. *Id.*

of Mexico and India with regard to their respective economies, populations, and pharmaceutical industry prospects in light of current international treaties and agreements. Part III of this Note will outline the historical development of patent law in Mexico and India. Part IV will examine the pharmaceutical industry, its dependence on patent rights, and the current state of the industry in both Mexico and India. Part V will analyze the factors that have affected the pharmaceutical industry in India, compare them with factors facing the Mexican pharmaceutical industry, and draw conclusions regarding Mexico's best course of action for the future. Part VI of this Note will address humanitarian concerns and will consider issues such as compulsory licensing, costs of innovation, and accessibility of drugs to people in poor and developing countries.

## II. OVERVIEW: MEXICO VS. INDIA

### A. Mexico

Mexico is a developing country,[38] but its economy is actually fairly robust compared to other developing and even some developed countries, as the following statistics indicate. Although a high percentage of Mexicans lives below the poverty level,[39] the gross domestic product (GDP)—a measure of economic strength—has recently been estimated to be about $1 trillion with an annual growth rate of 3%.[40] In comparison, Mexico's southern neighbor, Guatemala, has a GDP of just under $60 billion and an annual growth rate of 3.2%.[41] Mexico's economy ranks nearly even with Canada's in terms of GDP (total gross, not per capita) and Mexico's GDP is growing faster than Canada's.[42] Mexico's population is young; the median age is approximately twenty-five years, and there is a relatively high literacy rate of 92.2%, roughly equivalent between males and

38. Geoffrey Kransdorf, Note, *Intellectual Property, Trade, and Technology Transfer Law: The United States and Mexico*, 7 B.C. THIRD WORLD L.J. 277, 295 (1987).

39. This was estimated in 2003 to be 40% of Mexico's population. CENTRAL INTELLIGENCE AGENCY [CIA], THE WORLD FACTBOOK (2006), *available at* https://www.cia.gov/cia/publications/factbook/geos/mx.html#Econ.

40. In 2005, the GDP of Mexico was estimated at $1.064 trillion. *Id.* Note that the GDP values used are calculated using purchasing power parity (PPP) exchange rates and represent the sum value of all goods and services produced in the country valued at prices prevailing in the United States. *Id.* at https://www.cia.gov/cia/publications/factbook/docs/notesanddefs.html#2003. This method of calculating the GDP is especially useful for comparing the economic strength of different countries. *Id.*

41. GDP was calculated to be $56.86 billion in 2005. *Id.* at https://www.cia.gov/cia/publications/factbook/geos/gt.html#Econ.

42. Canada's GDP is estimated to be $1.111 trillion and growth rate is estimated at 2.9% as of 2005. *Id.* at https://www.cia.gov/cia/publications/factbook/geos/ca.html#Econ.

females.[43] In addition, Mexico has close economic ties to the United States, the result of both geographic proximity and the common market created by the North American Free Trade Agreement (NAFTA).[44] Given these factors—a young, literate work force, a growing economy, and a powerful trading partner in the United States—Mexico has an excellent opportunity to expand its position in the high technology industries, including the pharmaceutical industry.[45] The estimated value of the market for pharmaceuticals in Mexico is $7 billion with a projected annual growth rate of 10%.[46] By developing its own pharmaceutical industry, Mexico will be able to serve this market and potentially even expand to supply pharmaceutical products to markets in other countries as well. To accomplish these objectives, Mexico must implement and enforce patent protections in a way that balances the interests of drug companies with the Mexican public's need for affordable and accessible medicines.

## B. India

India, a developing country with a relatively large and successful pharmaceutical industry,[47] provides a useful model for comparison to Mexico. India's pharmaceutical industry is powerful and independent, and is "a formidable international competitor."[48] These are qualities to which the Mexican pharmaceutical industry should aspire. On the issue of patent protection, however, India provides a better example of a course Mexico must avoid.[49]

---

43. *Id.* at https://www.cia.gov/cia/publications/factbook/geos/mx.html#People. The literacy rate in Guatemala is approximately 70%. *Id.* at https://www.cia.gov/cia/publications/factbook/geos/gt.html#People. The literacy rate in India is approximately 59.5% (with a high discrepancy of literacy rate between the sexes: 70.2% for men versus 48.3% for women). *Id.* at https://www.cia.gov/cia/publications/factbook/geos/in.html#People.

44. *See* Ryan H. Flax, Comment, *NAFTA & the Patent Systems of Its Members: Is There Potential for Unification of the North American Patent Systems?*, 5 NAFTA: L. & BUS. REV. AM. 461, 478 (1999).

45. *See generally* Kransdorf, *supra* note 38, at 295 (arguing that Mexico needs new technology and that cooperation with the United States on intellectual property protection issues would lead to increased trade and technology transfer to the benefit of both nations).

46. *Ranbaxy To Set Up JV in Mexico*, BUS. STANDARD 9 (New Delhi), Feb. 21, 2005, at *1, *available at* 2005 WLNR 2649041.

47. *N.J. Drug Makers See Future in India*, N.J. RECORD, Oct. 21, 2004, at A01, *available at* 2004 WLNR 3246457.

48. Stephen Barnes, Note, *Pharmaceutical Patents and TRIPS: A Comparison of India and South Africa*, 91 KY. L.J. 911, 924 (2002-2003).

49. *See* Finston, *supra* note 1, at 888 ("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.").

India's pharmaceutical industry is as strong as it is today partly because it benefited from patent laws that protected only specific manufacturing processes but not the actual drug compounds.[50] Thus, a drug fully protected in the United States could be legally manufactured by an unlicensed competitor in India provided the drug was produced using a novel process. By this law, India encouraged the mass production of low-cost drugs at the expense of innovation.[51] The rationale behind this law was that medicines were so important that the drugs themselves should not be patented.[52] Given this aspect of India's patent law, Indian pharmaceutical companies devoted themselves primarily to producing generic versions of name-brand drugs by reverse engineering those drugs and then modifying the production process to avoid patent issues.[53] By "free riding" on others' inventions, Indian companies avoided most R&D costs other than the small amount needed to analyze existing products.[54] By focusing on existing drugs, Indian pharmaceutical companies were able to offer generic alternatives at a fraction of the patented name-brand drugs and thus enter the pharmaceutical market quickly.[55] While this allowed the pharmaceutical industry to grow quickly in India, in the long run, the practice may prove detrimental now that India is in the process of adopting stricter patent regulations.[56]

The Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement is closing the door through which India was able to enter the pharmaceutical market so quickly.[57] India signed the World Trade Organization's (WTO) General Agreement on Tariffs and Trade (GATT) in 1995.[58] Under that agreement, India agreed to adopt the requirements of TRIPS, which requires India to implement patent protections that conform to international standards.[59] The implementation of the TRIPS standards will have a significant effect on Indian

50. *Compare* Embassy of India, *Intellectual Property Rights in India*, http://www.indianembassy.org/policy/ipr/ipr_2000.htm (last visited Sept. 10, 2006) (2000 policy statement) *with* Embassy of India, *Intellectual Property Rights in India*, http://www.indianembassy.org/special/ipr/ipr.htm (last visited Sept. 10, 2006) (current policy statement).

51. *See* Barton, *supra* note 4, at 147.

52. *Id.*

53. David K. Tomar, Note and Comment, *A Look into the WTO Pharmaceutical Patent Dispute Between the United States and India*, 17 WIS. INT'L L.J. 579, 582 (1999).

54. *See* Finston, *supra* note 1, at 889 (discussing how Indian manufacturers have "perfected the art of copying existing products developed by foreign firms and developing different processes for making these compounds").

55. Barnes, *supra* note 48, at 924.

56. *See* Finston, *supra* note 1, at 888.

57. *See* Mayer, *supra* note 11, at *1-4; *see also infra* note 124 and accompanying text.

58. Mayer, *supra* note 11, at *2.

59. *Id.* at *1.

pharmaceutical companies.[60] Some industry experts predict that many Indian companies will fail as a result and those that survive will have to become innovative and develop novel drugs, possibly through partnering with Western companies.[61]

Indian drug manufacturers benefited from a system that allowed them to manufacture and sell drugs patented elsewhere without the patent-holders' permission. Mexican companies, on the other hand, will face a governmental policy that upholds rather than subverts international standards of patent protection since they must contend with the requirements of both TRIPS and NAFTA. As a result, Mexico will not have the luxury of free riding and instead must be innovative from the very beginning.[62] In the long run, this will make for a stronger pharmaceutical industry at the present cost of strict patent controls and, unfortunately, higher drug costs.

## III. HISTORICAL ANALYSIS

### A. The Development of Patent Law in Mexico

The Mexican government's authority to grant intellectual property protection, including patents, is based in the Mexican Constitution.[63] The Mexican Constitution of 1917 grants the government broad authority to regulate the economic development of Mexico.[64] Monopolies are prohibited under the constitution with certain government monopolies excepted.[65] One such monopoly that is reserved to the government is that of providing intellectual property privileges to inventors and authors.[66] Although intellectual property protection in Mexico has legal precedent in previous constitutions,[67] certain aspects may in fact have been based on Soviet law.[68] This would be consistent with the strong

60. *See id*. at *2 ("Industry experts say in anticipation of the [TRIPS] agreement, a number of Indian pharmaceutical companies adopted survival tactics.").

61. *Id.*

62. *See* Edwin S. Flores Troy, *The Development of Modern Frameworks for Patent Protection: Mexico, a Model for Reform*, 6 TEX. INTELL. PROP. L.J. 133, 142 (1998) (citing the Mexican Senate's reasons for expanding the scope of intellectual patent protection, including the belief that doing so would support "a permanent process of improving innovation and technology within productive sectors").

63. *See id.* at 137.

64. *Id*.

65. *Id*.

66. *Id*.

67. Specifically, they are the Political Constitution of the Spanish Monarchy of 1812 (Article 335) and the Mexican Constitution of 1857. *Id.*

68. Troy, *supra* note 62, at 137-38.

governmental role and the relatively weak individual rights delineated in the 1917 Constitution.[69]

Mexico first instituted a formal patent system in 1976 by enacting the Law on Inventions, promoted by President Luís Echeverria and Secretary of Industry Jose Sainz.[70] The Law on Inventions was not designed to benefit the inventor, as a more traditional patent system would, and it did not offer much protection to the patent-holder.[71] Rather, the purpose of the law was to eliminate the inventor's rights based on the belief that the rights to an invention should belong to the government to use for the collective interest.[72] The law gave the government the right to require an inventor to exploit the invention by producing and selling it within a certain timeframe.[73] If the inventor failed to do so, the government then had the right to exploit the invention itself, by licensing the invention to a competitor of the inventor, for example. This is a form of "compulsory licensing."[74] A patent owner had three years to exploit the patent or else risk compulsory licenses being granted to third parties.[75]

The Law on Inventions was heavily influenced by the Calvo Doctrine, which gives a high priority to nationalism in the drafting of laws.[76] Among other things, the Calvo Doctrine, named after Argentine jurist, Carlos Calvo (1824–1906), "maintains that the grant of intellectual property rights by one nation does not force other nations to grant the same rights."[77] Mexico was among the majority of Latin American nations to implement the Calvo Doctrine into its laws in the nineteenth and twentieth centuries in an effort to create a "new international order" giving those nations' governments stronger rights at the expense of individual citizens and foreigners.[78] Behind this political backdrop, Mexico passed the Law on Inventions. This law provided very little protection to patent-holders yet burdened them with duties to exploit their inventions at the risk of losing exclusivity.[79]

Motivated by a need to modernize its industries, increase employment opportunities, and improve the quality of products and services, Mexico chose to

---

69. *See id.* at 137.
70. Flax, *supra* note 44, at 466-67.
71. *Id.*
72. *Id.*
73. Arlene Nolan Farolan, *Harmonization of the Patent Systems of NAFTA Nations*, CURRENTS: INT'L TRADE L.J., Summer 2001, at 54, 57.
74. *Id.*; *see also infra* Part VI.A.
75. Farolan, *supra* note 73, at 57.
76. *Id.*
77. Edgardo Buscaglia & Clarisa Long, *U.S. Foreign Policy and Intellectual Property Rights in Latin America*, HOOVER INSTITUTION, Apr. 1997, http://www.hoover.org/publications/epp/2846756.html?show=essay.
78. Flax, *supra* note 44, at 466-67.
79. Farolan, *supra* note 73, at 57.

change the structure of its intellectual property laws.[80] In 1987, Mexico began to align its patent system with the international community by amending the Law on Inventions to conform with some of the standards of the International Convention for the Protection of Industrial Property (generally referred to as the "Paris Convention").[81] Among the effects of the Calvo Doctrine on the Law on Inventions was the reduction of the term of patent protection from fifteen years to ten.[82] This change greatly diminished the value of patents.[83] The amendment to the Law on Inventions in 1987 increased the term of patent protection from ten to fourteen years.[84]

In 1991, the Salinas administration continued the reformation of the Mexican patent system by pushing forward the Industrial Property Law (IPL).[85] In order to pass the IPL, Salinas had to contend with the entrenched nationalism of the legislative branch.[86] To sell the proposed law to the legislature, the executive promoted it as a means to improve the quality of goods and services for the benefit of consumers.[87] In addition, it was touted as serving the social goals of recovery of job growth and the entry of Mexico into the world economy.[88] In 1991, the IPL was formally enacted, making Mexican patent law conform more closely to U.S. patent law.[89] Under this law, patent terms were extended to twenty years from the fourteen mandated by the 1987 amendments, with a three-year extension available for pharmaceutical patents.[90] Current U.S. law likewise grants a patent term of twenty years.[91] In 1991, the U.S. patent term was only seventeen years but was measured from the date of issuance, not filing.[92] In 1994, the GATT was signed, resulting in the change to a twenty-year term measured from the filing date, in line with other industrialized nations.[93] There is also a provision in U.S. law for term extensions to pharmaceutical patents in the event of delay of FDA approval.[94]

In 1993, Mexico created the "Instituto Mexicano de la Propiedad Industrial" (IMPI).[95] The IMPI's stated purpose is to stimulate creativity to the

80. *Id*.
81. *Id*.
82. *Id.*
83. *Id.*
84. *Id*.
85. Troy, *supra* note 62, at 138.
86. *See id.* at 139 (arguing that to pass legislation, the executive had to appeal to "a paternalistic attitude toward the public and demagogic nationalism").
87. *Id*.
88. *Id.* at 139-40.
89. Flax, *supra* note 44, at 478.
90. *Id.* at 479.
91. 35 U.S.C. § 154 (2002).
92. *See* MERGES & DUFFY, *supra* note 20, at 59.
93. *See id.*
94. 35 U.S.C. § 156 (2002).
95. Farolan, *supra* note 73, at 57.

benefit of society and to foster and protect intellectual property rights.[96] Unlike its counterpart in the United States, the U.S. Patent and Trademark Office (USPTO), the IMPI has a role in actively developing technology and enforcing patents.[97] The IMPI has considerably more power than the USPTO.[98] The IMPI may conduct investigations, hold hearings, impose administrative sanctions on patent infringers, and even investigate possible criminal violations.[99] In addition, the IMPI has the responsibility to provide information on intellectual property to the public, including counseling those involved in technological research about their rights.[100] In contrast, the USPTO primarily functions to examine and issue patents.[101]

The enactment of NAFTA in 1994 by the United States, Canada, and Mexico had profound effects on Mexico's patent system.[102] NAFTA requires that each member nation provide "effective, fair and equitable enforcement of intellectual property rights under its own laws."[103] NAFTA encourages the harmonization of the patent laws of the three countries and the accordance of respect to international standards.[104] By 1994, when NAFTA went into effect, the Mexican government had changed its philosophy regarding intellectual property rights, transferring more rights to the inventor and away from the government, as evidenced by the extensive overhaul of the patent system described above.[105] One crucial change that came directly as a result of the NAFTA requirements was the recognition of intellectual property protection for pharmaceutical products and general medicines, which had not received protection under the 1976 law or the 1987 amendments.[106]

## B. The Development of Patent Law in India

When India became an independent nation in 1947, following over one hundred years of British rule,[107] its patent system was still governed by the Indian

96. *See* Instituto Mexicano de la Propiedad Industrial, *¿Qué es el IMPI?*, *available at* http://www.impi.gob.mx/impi/jsp/indice_all.jsp?OpenFile=docs/bienvenida/main_quees_impi.html (last visited Sept. 10, 2006).
97. Farolan, *supra* note 73, at 58.
98. *Id.*
99. *Id.*
100. *Id.*
101. *Id.*
102. *Id*. at 59.
103. Farolan, *supra* note 73, at 59.
104. *Id.*
105. *See id.* at 57.
106. Troy, *supra* note 62, at 140.
107. Tomar, *supra* note 53, at 580.

Patents and Design Act of 1911, originally instituted by the British.[108] Jawaharlal Nehru, India's first Prime Minister, was concerned about the influence and control that he feared foreign companies would exert over the Indian economy.[109] Two government committee reports validated Nehru's concern.[110] The 1948 Tek Chand Committee and the 1957 Ayyangar Committee both concluded that foreign interests were exploiting Indian patent protection to monopolize various markets, including the pharmaceutical market.[111] At the time of the reports in the 1940s and 1950s, India was dependent on foreign sources for drugs, both the bulk chemicals and the completed medicines.[112] The great majority, some 90%, of the Indian pharmaceutical market was controlled by foreign companies.[113] Indian drug prices at that time were among the highest in the world.[114] Initially, India sought to solve this problem by instituting high tariffs and price controls on pharmaceuticals.[115] It would be a number of years, however, before the patent laws were changed.[116]

The change finally came with the passage of the Patents Act of 1970.[117] Like the 1976 Mexican Law on Inventions, the Indian Patents Act of 1970 was strongly nationalistic and protectionist, making it difficult for foreign patent holders to enjoy protection of their inventions in India, particularly in the pharmaceutical field. Under the Act, the specific chemical formulations of medicines and drugs could not be patented.[118] Only their manufacturing processes were protected.[119] Furthermore, foreign patents were granted no recognition or respect.[120] One commentator has stated that this resulted in India creating "perverse incentives for local Indian manufacturers to reinvent the wheel rather than to innovate."[121] Despite the lack of incentive for innovation, the Patents Act of 1970 achieved its intended effects of stimulating the Indian pharmaceutical

108. Barnes, *supra* note 48, at 920.

109. *Id.*; *see also* Tomar, *supra* note 53, at 582 (discussing how Nehru "attacked the de-industrialization of India by the British Raj" and how India at the time feared continuing foreign control of its industries and resources).

110. Barnes, *supra* note 48, at 920.

111. *Id.*

112. *Id.*

113. Tomar, *supra* note 53, at 582.

114. *Id.*

115. *Id.*

116. Barnes, *supra* note 48, at 920.

117. The Patents Act, No. 39 of 1970; India Code (1970), *available at* http://indiacode.nic.in/fullact1.asp?tfnm=197039; *see also* Barnes, *supra* note 48, at 920 (noting the irony of the fact that the 1970 Act is actually a weaker version of the English Patent Act of 1949).

118. Barnes, *supra* note 48, at 921.

119. *Id.*

120. *See* Tomar, *supra* note 53, at 582.

121. Finston, *supra* note 1, at 889.

industry, capturing control of the market for domestic companies, and lowering drug prices in India.[122]

In 1995, India signed the GATT/WTO agreement giving India a decade in which to adopt TRIPS-mandated patent protections.[123] The purpose of the TRIPS agreement is to promote technological innovation and to disseminate technology "to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations."[124] Patents are discussed in section 5, articles 27-34, of the TRIPS agreement.[125] Article 27 defines as patentable subject matter, "any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application."[126] The agreement lists particular exceptions to patentability.[127] Pharmaceuticals as a class does not fall within these exceptions and is therefore presumptively patentable.[128] Thus, under TRIPS, India must end the practice of reverse-engineering pharmaceuticals.[129] Also, prior to 1999, Indian law provided for relatively short patent terms for pharmaceutical processes.[130] The term was only five to seven years[131] versus the twenty-year term mandated by TRIPS.[132] Finally, Indian patent law at the time placed the burden of proof on the plaintiff in infringement cases.[133] Under TRIPS, the defendant must prove noninfringement in cases where a patented product is produced by a new method or where a new product is made using a patented process.[134]

In 1999, India took a step towards TRIPS compliance by adopting the Patents (Amendment) Act of 1999, which brought the nation into compliance with recommendations made by the WTO Dispute Settlement Body.[135] Among the significant provisions of this Act are ones allowing for the recognition of foreign patents for pharmaceuticals.[136] In January 2005, the deadline for full TRIPS compliance was reached and India's drug companies became subject to the patent

122. Tomar, *supra* note 53, at 582-83.

123. Mayer, *supra* note 11, at *2.

124. Agreement on Trade-Related Aspects of Intellectual Property Rights art. 7, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. (1994) [hereinafter TRIPS Agreement].

125. *See id.* arts. 27-34.

126. *Id.* art. 27(1).

127. *Id.* arts. 27(2)-(3).

128. *See id.*

129. Mayer, *supra* note 11, at *1.

130. Barnes, *supra* note 48, at 921.

131. Tomar, *supra* note 53, at 592.

132. TRIPS Agreement, *supra* note 124, art. 33.

133. Tomar, *supra* note 53, at 593.

134. *See* TRIPS Agreement, *supra* note 124, art. 34.

135. Tomar, *supra* note 53, at 590.

136. *See id.*

protection laws mandated by the TRIPS agreement.[137] India amended its patent laws by presidential decree in January 2005.[138] The Patents (Amendment) Act of 2005 was published in the Official Gazette on April 4, 2005, but the majority of provisions of the Act were deemed to have come into effect as of January 1, 2005, the date of the presidential decree as well as the TRIPS deadline.[139] The 2005 amendments allow for the full recognition of foreign patents and for the patenting of drugs and chemicals, not just the processes used in making them.[140]

To prevent a sudden increase in prices as a result of the changes to the patent regime, India's new patent structure contains certain prophylactic measures.[141] For example, the government can issue compulsory licenses or revoke patents for the public interest.[142] The 2005 amendments do not apply to drugs patented in India before 1995.[143] These changes are expected to have significant effects on the pharmaceutical industry in India, including greater investment in R&D and greater outsourcing by foreign drug companies.[144] The large manufacturers of generic pharmaceuticals in India will certainly be affected as well and may continue to challenge patents in other countries by continuing to produce generic versions of drugs.[145] These companies may also, or alternatively, try to contract as suppliers of drug ingredients to foreign firms.[146]

## IV. THE PHARMACEUTICAL INDUSTRY

The business of developing and manufacturing pharmaceuticals is very risky in terms of the success rate of finding new drugs.[147] Every new drug that arrives on the market represents a company's enormous investment of time and resources in discovering and testing compounds.[148] Because so many compounds turn out to be dead ends, pharmaceutical companies rely on the few successful drugs to fund continued R&D.[149] It has been shown that more than 55% of

137. Mayer, *supra* note 11, at *2.

138. Eric Agovino, *India Amends Law to Allow Drug Patents*, INTELL. PROP. STRATEGIST, Feb. 2, 2005, at 7.

139. *See* The Patents (Amendment) Act, No. 15 of 2005; India Code (2005), *available at* http://indiacode.nic.in/fullact1.asp?tfnm=200515.

140. *Id.*; *see also* Agovino, *supra* note 138, at 7.

141. Agovino, *supra* note 138, at 7.

142. *Id.*; *see also* The Patents (Amendment) Act, No. 15 of 2005; India Code (2005), *available at* http://indiacode.nic.in/fullact1.asp?tfnm=200515.

143. Agovino, *supra* note 138, at 7.

144. *Id.*

145. *Id.*

146. *Id.*

147. *See* Singham, *supra* note 8, at 373-74.

148. *See id.* at 373.

149. *See id.* at 373-74.

industry profits may come from as few as 10% of marketed drugs.[150] For this reason, a lack of patent protection is more damaging to the pharmaceutical industry than to most other industries.[151] The medicines that are currently available came about because the pharmaceutical companies that developed them were able to rely on the patent systems in the developed world.[152] What this means for developing countries is that a failure by them to provide adequate patent protection will result in diminished research into necessary drugs.[153]

For pharmaceutical companies, more than other types of companies, patent protection is vital to their willingness to pursue R&D in a given country.[154] A weak patent system hurts local research and reduces the technological growth of a country.[155] Innovative firms will not risk doing research in a country where copycat companies can easily steal the fruits of their endeavors.[156] Native inventors will leave the country to pursue their research in nations that offer them greater protection, a phenomenon commonly referred to as "brain drain."[157] Furthermore, foreign firms will not be willing to share their technology with companies in a country with weak patent laws.[158]

R&D is a vital part of the world economy.[159] In the international arena, a pharmaceutical company's most valuable asset is its patent portfolio.[160] Companies build portfolios of closely related patents by employing inventors and having the patent rights to new inventions assigned by the inventors to the corporation.[161] Companies in developed nations spend a great deal on R&D to assemble competitive patent portfolios.[162] In order to compete effectively in the world market, pharmaceutical companies in developing nations, such as Mexico and India, need to invest in R&D and build their own patent portfolios or else they risk competing essentially empty-handed against Western firms that have had years to develop their own portfolios.[163]

To evaluate the current condition of the pharmaceutical industries in Mexico and India, especially in regard to the effects of globalization, it is important to consider how they are structured and the policies behind those structures.

---

150. *See id.* at 373.
151. *Id.*
152. *See id.* at 374.
153. Singham, *supra* note 8, at 374.
154. *See id.* at 373-74.
155. *See id.* at 378.
156. *See id.* at 374.
157. *Id.* at 378.
158. *Id.* at 379.
159. *See* Singham, *supra* note 8, at 372.
160. *See* Finston, *supra* note 1, at 895.
161. *See* MERGES & DUFFY, *supra* note 20, at 1255.
162. *See* Singham, *supra* note 8, at 372.
163. *See* Mayer, *supra* note 11, at *2-3.

## A. Mexico's Opportunity

### 1. Mexico's Pharmaceutical Industry

The Mexican pharmaceutical industry is among the most developed in Latin America.[164] In 2002, there were approximately 390 companies, both domestic and multinational, manufacturing pharmaceutical products in Mexico.[165] As in India, indigenous Mexican firms have traditionally manufactured generic drugs, including those for which the patents have expired.[166] Novel drugs are also produced in Mexico but generally by foreign firms using imported technology.[167] This beneficial flow of technology into the country is actually attributable to specific health regulations; Mexican health regulations are nearly as stringent as those in the United States and include measures to ensure the safety of pharmaceuticals.[168] One such measure provides that in order to register a drug for sale in Mexico, the drug must be locally inspected and the producing company must have a sanitary license issued by the responsible local health agency.[169] For this reason, many multinational pharmaceutical companies maintain subsidiaries in Mexico to facilitate the process of inspection in order to obtain the sanitary license needed for the registration of pharmaceutical products for import into Mexico.[170] As a result of such health regulations and, particularly, their effect of bringing foreign technology into Mexico, the majority of pharmaceutical manufacturers in Mexico are considered to be world-class in terms of their ability to produce quality pharmaceuticals.[171]

The presence of world-class pharmaceutical manufacturers in Mexico combined with strict health regulations gives Mexico an advantage that was missing from India in 1970 when India began to build up its own pharmaceutical industry.[172] If Mexico can encourage greater commitment to R&D by local

164. JESUS S. GONZALEZ, U.S. DEP'T OF COMMERCE, INDUSTRY SECTOR ANALYSIS: DRUGS AND PHARMACEUTICALS, MEXICO 2 (2002), http://www.ita.doc.gov/td/health/phRMA/Mexico%20Pharms%20ISA.pdf.

165. *Id.* at 1.

166. *Id.* at 2.

167. *Id.*

168. *Id.* at 6.

169. *See id.*

170. GONZALEZ, *supra* note 164, at 6.

171. *See id.* at 2.

172. *See* Tomar, *supra* note 53, at 583-84.

companies, there is a high probability that Mexico will truly enter the world economy as a competitive producer of name-brand pharmaceuticals.[173]

2. Mexico's Pharmaceutical Market

The Mexican pharmaceutical market is split between the private sector and the public sector.[174] Each sector has different requirements mandated by the Mexican government, and each therefore affects the pharmaceutical industry differently.[175] The public sector, in which drugs are purchased through government agencies, is larger in terms of people served—60% to 70% of the population—but accounts for only about 15% of the total financial value of the pharmaceutical market.[176] The reason for this disparity is the difference in prices between the two sectors.[177] Prices in the public market are often one-fifth the price of comparable drugs sold in the private sector.[178] The public-sector group of buyers is comprised of specific institutions: primarily, the IMSS (Instituto Mexicano del Seguro Social), the ISSSTE (Instituto de Seguridad y Servicios Sociales de los Trabajadores del Estado), and the SSA (Secretaría de Salud);[179] and secondarily, the Red Cross and various state-owned institutions.[180] The IMSS, the ISSSTE, and the SSA are the main public-sector institutions and account for the majority of the market.[181] These public institutions make bulk purchases from the suppliers according to specific regulations;[182] the drugs purchased by the public sector must be labeled with the "generic denomination," not the brand name.[183]

---

173. *See* Troy, *supra* note 62, at 168 (concluding that the goals of the new industrial property laws include the internationalization of Mexico's economy and an increase in Mexico's participation in the globalization of the world's economies).

174. GONZALEZ, *supra* note 164, at 6-7.

175. *Id.*

176. *Id.* at 7.

177. *Id.* at 3.

178. *Id.*

179. *Id.* at 7; *see also* El Instituto Mexicano del Seguro Social, http://www.imss.gob.mx/imss (last visited Sept. 10, 2006); El Instituto de Seguridad y Servicios Sociales de los Trabajadores del Estado, http://www.issste.gob.mx/issste (last visited Sept. 10, 2006); Secretaría de Salud, http://www.salud.gob.mx (last visited Sept. 10, 2006).

180. GONZALEZ, *supra* note 164, at 7.

181. *Id.*

182. These regulations cover such things as the amount of money that may be spent on purchases, how many providers must be involved, and compliance with NAFTA when applicable. *Id.*; s*ee also* Compranet, *Sistema Electrónico de Contrataciones Gubernamentales*, http://www.compranet.gob.mx (last visited Sept. 10, 2006) (for a listing of transactions made by public tender).

183. GONZALEZ, *supra* note 164, at 7.

The private sector of the Mexican pharmaceutical market serves a smaller segment of the population but accounts for about 85% of the total financial value of the market.[184] It is similar to the U.S. drug market in that companies, mainly large multinational firms, go to considerable expense to advertise and promote their products.[185] Unlike the public sector, both name-brand and generic drugs may be sold in the private sector.[186] However, generic drugs must comply with certain bioavailability[187] standards to show that they are equivalent to the name-brand versions.[188]

## B. India's Current Troubles

India's pharmaceutical industry grew from a weak industry dependent on foreign support in the 1940s to a strong and largely independent producer of bulk generic drugs for both domestic and international markets by the 1990s.[189] The ascent of this industry to its current position of power could not have been achieved so quickly without the protectionist Patents Act of 1970.[190] However, fast growth does not guarantee continued success. "In 1970, India turned its back on Western models for development, and despite the development of a small number of world-class pharmaceutical exporters . . . it has paid a high price."[191] Currently, India is faced with problems rooted in its protectionist past.[192]

One problem is that India is now a real player in the world pharmaceuticals market and must therefore play by the same rules as the more developed countries of the West.[193] The TRIPS agreement requires India to bring its patent laws into alignment with the laws of developed nations. As noted above, India must end the practice of reverse engineering pharmaceuticals.[194] Yet, reverse engineering of pharmaceuticals has effectively been the basis for India's successful generic drug industry since the enactment of the Patents Act of 1970.[195]

---

184. *Id.*

185. *Id.*

186. *See id.* at 8.

187. Bioavailability is defined as "the degree and rate" at which an active ingredient of a drug is absorbed into the body or is actively available at the appropriate physiological site. WEBSTER'S MEDICAL DESK DICTIONARY 74 (1986).

188. *See* GONZALEZ, *supra* note 164, at 7. Interestingly, these standards are not applied to generic drugs sold in the public sector. *Id.*

189. Barnes, *supra* note 48, at 925.

190. *See id.* at 924.

191. Finston, *supra* note 1, at 895.

192. *See id.*

193. *Id.*

194. Mayer, *supra* note 11, at *1.

195. *See* Barnes, *supra* note 48, at 924.

India has some 20,000 drug companies, and many of these are expected to fail as a direct result of TRIPS.[196]

Another problem India must confront is the "brain drain" issue.[197] Patent protection stimulates basic research.[198] Local companies will not invest in R&D, much less employee training, unless there is a certain level of protection for their inventions.[199] When an industry is based solely on copying, there is no incentive to innovate.[200] Companies that invest in copying divert resources away from basic research.[201] Thus, companies spend money to produce drugs that are already available instead of investing in the development of sorely needed new drugs.[202] Indian companies simply do not invest enough on R&D to discover novel drugs of their own.[203] While Western companies typically spend 15% or more of sales on R&D, Indian companies spend only 1%.[204] As a result, there is a significant lack of research opportunities in India. Many of the best technological minds have left the country in search of opportunities elsewhere, largely to the benefit of American and European laboratories.[205] India desperately needs quality researchers to reinvigorate the pharmaceutical industry and to work on cures for endemic diseases that are not a priority for foreign firms.[206]

## V. ANALYSIS: WHAT CAN MEXICO LEARN FROM INDIA?

### A. Western Models of Development and the Need for Strong Patent Protection

In 1970, India abandoned Western standards of patent protection, allowing an entire industry of "copycat" pharmaceuticals to develop.[207] As a result of copycatting, thirty-six years later India's pharmaceutical industry still does not have a viable research sector and is losing valuable scientists to the very Western companies with which it sought to compete.[208] This is not to say the

196. *Id.*
197. *See* Finston, *supra* note 1, at 890.
198. *Id.*
199. Sherwood, *supra* note 9, at 504.
200. Finston, *supra* note 1, at 891.
201. *Id.* at 890.
202. *Id.*
203. Barnes, *supra* note 48, at 926.
204. *Id.* U.S. pharmaceutical firms are estimated to spend up to 20.8% of revenue on R&D, which is higher than the worldwide average. Singham, *supra* note 8, at 373.
205. It is estimated that more than 15% of the scientists in the United States doing pharmaceutical R&D are of Indian origin. Finston, *supra* note 1, at 890.
206. *Id.*
207. *Id.* at 890, 895.
208. *Id.*

Indian pharmaceutical industry is in imminent danger of complete collapse. Indeed, the major Indian companies may actually benefit from a rise in domestic drug prices as the TRIPS standards are implemented.[209] A general increase in drug prices will allow domestic companies to raise prices for generics based on off-patent products.[210] However, as noted above, the application of stronger patent protection and the recognition of foreign patents will likely cause a significant number of Indian drug companies to fail.[211] If India had provided stronger patent protection earlier in the development of its industry, there would have been greater foreign investment and a more viable research sector than that which currently exists.[212]

Like India, Mexico has focused on the manufacture of generic drugs rather than investing in R&D.[213] Unlike India, Mexico is incorporating stronger patent protection at an earlier stage in the development of its pharmaceutical industry.[214] This is a crucial difference that will give a significant advantage to Mexico as it will force Mexican companies to invest in R&D in order to remain competitive both locally and in the world market.

In the 1990s, with the adoption of NAFTA, Mexico entered into a trade partnership with two considerably more developed nations: the United States and Canada.[215] Prior to NAFTA, Mexico's patent laws attempted to increase the transfer of technology into Mexico while minimizing the cost to Mexico.[216] These laws had the unfortunate effect of actually impeding international trade and foreign investment, resulting in *less* transfer of technology.[217] Under NAFTA, Mexico is instituting reforms to its patent system. As Mexico's system offers more protection and is modeled more closely on the U.S. and Canadian models, foreign investment will increase and so will technology transfer.[218]

### B. What Should Mexico Do Next?

Mexico needs to continue strengthening and enforcing its patent laws. There is a direct relationship between the level of intellectual property protection and the development of technology and technology transfer into developing countries.[219] The greater the patent protection Mexico offers, the more foreign

209. Mayer, *supra* note 11, at *2.
210. *See id.*
211. *Id.*
212. *See* Finston, *supra* note 1, at 895.
213. *See* GONZALEZ, *supra* note 164, at 8.
214. Farolan, *supra* note 73, at 57.
215. *Id*.
216. *See* Flax, *supra* note 44, at 466.
217. *Id*. at 469.
218. *Id.*
219. Singham, *supra* note 8, at 375.

investors will be willing to invest in the country.[220] Mexico must offer protection equivalent to the protection offered in the developed world if it wishes to effectively compete for foreign investment.

NAFTA has facilitated the harmonization of Mexican law with international standards and, more particularly, with U.S. standards.[221] The importance of the United States' role in the future of the Mexican pharmaceutical industry cannot be overemphasized. The United States is currently the largest supplier of pharmaceutical products to Mexico.[222] In 2001, for example, U.S. exports accounted for 24% of Mexico's total import market.[223] Yet, at the same time, many in the U.S. pharmaceutical industry see Mexico as a pharmaceutical "black market" loaded with counterfeit products.[224] To combat these perceptions, Mexico must continue both to remove nationalistic barriers to trade and to implement stronger patent protection.[225]

The crucial area in which Mexico can improve its patent regime is enforcement. Mexico has already implemented important changes to its patent law, but, though these changes look good on paper, they are meaningless without proper enforcement.[226] Currently, enforcement of patent rights is the exclusive responsibility of the IMPI.[227] The IMPI has broad jurisdiction that includes policing power and even pseudo-judicial powers.[228] The Mexican government endowed the IMPI with these broad powers as a means of complying with chapter 17 of NAFTA (enforcement of intellectual property rights).[229] This arrangement differs from that of the United States and other industrialized countries, where the enforcement of patent rights and other intellectual property rights falls to the courts.[230] In Mexico, an injured party must submit a request to the IMPI for an administrative declaration of infringement.[231] The IMPI may also choose to issue such a declaration *ex officio*.[232] The problem with using an administrative agency like the IMPI to enforce, examine, and issue patents is that it creates the potential

220. *See id.* at 375-76.

221. Farolan, *supra* note 73, at 59.

222. GONZALEZ, *supra* note 164, at 5.

223. *Id.*

224. *Id.* at 6.

225. Flax, *supra* note 44, at 480.

226. *See* Buscaglia & Long, *supra* note 77 (noting that intellectual property enforcement in Latin America is weak to non-existent). "The failure to enforce formal laws is as bad as the absence of laws altogether." *Id.*

227. Alejandro Perez Serrano, *Overview of Intellectual Property Enforcement in Mexico*, NAT'L L. CENTER FOR INTER-AMERICAN FREE TRADE, 1998, http://natlaw.com/interam/mx/ip/sp/spmxip13.htm.

228. Farolan, *supra* note 73, at 58.

229. *Id.* at 59.

230. Serrano, *supra* note 227.

231. *Id.*

232. *Id.*

for conflicts of interest.[233] Such a situation would inevitably occur whenever the IMPI is asked to invalidate a patent the IMPI itself granted.[234] When an administrative agency registers patents and civil courts enforce patents, this conflict is avoided.

There are several administrative remedies the IMPI may apply under a declaration of infringement, including inspection, impoundment of articles and machinery, fines, closure of facilities, and administrative arrest.[235] The IMPI has the discretionary power to use any of these singly or in combination with each other.[236] Additionally, the IMPI may use certain provisional measures.[237] Provisional measures offer a relatively weak form of injunctive relief for the patentee and include such actions as ordering the withdrawal of infringing goods from the market and ordering the violator to cease infringing actions.[238] In general, however, there is no private right for a claimant to injunctive relief for patent infringement.[239] This is quite different from the case in industrialized nations such as the United States.[240] If one views patent infringement as a tort, then it is the role of a patent system to make the cost of infringing prohibitive.[241] To raise the cost of infringing, Mexico must allow patent-holders to sue for injunctions against infringers.

In reality, the provisional measures available to the IMPI are rarely used.[242] The standard practice under a declaration of infringement is for inspectors to visit the suspected infringer and investigate the claim.[243] If they determine that an offense has been committed, the inspectors then confiscate the infringing goods as well as the equipment used for making those goods.[244] This system thus hampers the infringers but fails to provide meaningful relief to the inventor whose patent was infringed. "Holders of intellectual property rights would presumably be more eager to transfer technology to Mexico or invest in its development if a private right to injunctive relief were readily available to private parties wishing to enforce their patent, copyright, trademark, or trade secret rights."[245] Mexico should consider transferring enforcement of patents and other

---

233. *Id.*
234. *Id.*
235. *Id.*
236. Serrano, *supra* note 227.
237. *Id.*
238. *Id.*
239. *Id.*
240. *Id.*
241. Mariano Municoy, *Allocation of Jurisdiction on Patent Disputes in the Models Developed by the Hague Conference in Private International Law: Asymmetric Countries and the Relationship of Private Parties*, 4 CHI.-KENT J. INTELL. PROP. 342, 389-90 (2005).
242. Serrano, *supra* note 227.
243. *Id.*
244. *Id.*
245. *Id.*

intellectual property rights to the judicial system or at least to a separate agency independent of the IMPI. Enforcement by the courts presumably would avoid the IMPI's current conflict of interest as well as provide a more objective forum for patent holders to pursue infringement actions.[246]

## VI. HUMANITARIAN CONCERNS

### A. Compulsory Licensing

A major challenge facing Mexico in regard to its pharmaceutical industry and patent regime, in addition to the economic issues discussed above, is how to guarantee the availability of medicines to its people.[247] This concern, on a global level, is reflected in the Declaration on the TRIPS Agreement and Public Health, which was adopted at the 2001 Ministerial Conference of the World Trade Organization meeting in Doha, Qatar.[248] The Doha Declaration, as it is called, holds that the TRIPS agreement provides flexibility for member nations to protect public health and to procure medicines for their people.[249] One contentious provision of the Declaration instructs the TRIPS council to find a way to make compulsory licensing available to benefit nations with insufficient pharmaceutical manufacturing capacities.[250] Compulsory licensing is a procedure whereby a government forces a recalcitrant patent-holder, who has declined to license the use of an invention, to contract with a buyer who desires such a license.[251] Developing countries believe compulsory licenses improve access to patented drugs and prevent over-pricing of those drugs by foreign firms.[252] In practice, compulsory licenses are rarely formally granted.[253] Instead, the threat of compulsory licenses is used by governments as leverage in the negotiation of prices with the pharmaceutical companies.[254]

The United States was unwilling to accept the Doha Declaration out of a fear that countries would use compulsory licensing to cover a broad variety of

246. *See id.*

247. *See* Seeratan, *supra* note 30, at 347 (discussing the issue as it applies to India).

248. Abbott, *supra* note 32, at 317.

249. *Id.*

250. *Id.* The Declaration disappointed parties on both sides of the issue. *Id.* Nongovernmental organizations (NGOs) and generic pharmaceutical producers in the developing world were concerned that the arrangement was too complex and not realistically feasible. *Id.* The pharmaceutical industry initially accepted the Declaration but later lobbied to restrict its implementation. *Id.* at 317-18.

251. Singham, *supra* note 8, at 390.

252. *Id.*

253. Barton, *supra* note 4, at 147.

254. *Id.*

products beyond those critically needed to address public health concerns.[255] The issue was resolved to the satisfaction of the United States by compromise in 2003 when the Declaration was amended by a statement from the chairperson of the WTO General Council emphasizing that the use of compulsory licensing be in good faith for the protection of public health and not for the pursuit of commercial objectives.[256]

The Doha Declaration addresses but does not resolve what is known as the 31(f) problem, referring to article 31(f) of the TRIPS agreement. Article 31 discusses the conditions under which a member government may allow the use of a patented invention without the patent-holder's authorization.[257] Subsection (f) limits compulsory licensing to countries with the capability to produce pharmaceutical products internally.[258] Specifically, it states that if a government uses or allows the use of an invention without the inventor's consent, "any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use."[259] Thus, article 31(f) does not allow a country with an established infrastructure for manufacturing pharmaceuticals, such as India, to produce patented drugs without the patent-holder's permission if those drugs are to be exported rather than sold locally. The Doha Declaration fails to provide guidance or clarity but instead merely instructs the TRIPS council to find a way to provide support to underdeveloped nations that need pharmaceuticals but cannot produce them.[260]

Compulsory licensing is available in Mexico under current patent law.[261] Article 70 of the IPL provides for the grant of a compulsory license (*licencia obligatoria*) under certain conditions.[262] NAFTA, like the TRIPS agreement, allows for the granting of such compulsory licenses.[263] Article 1709(10) sets forth conditions under which a compulsory license may be granted, including the requirement that the license applicant have previously requested authorization from the patent-holder.[264] Among the NAFTA nations, Canada and Mexico have compulsory licensing while the United States does not.[265]

Compulsory licensing is useful to increase access to patented pharmaceuticals. It is generally accepted that a strong patent regime increases the

---

255. *Id.* at 149.

256. *Id.*

257. TRIPS Agreement, *supra* note 124, art. 31.

258. Barton, *supra* note 4, at 149.

259. TRIPS Agreement, *supra* note 124, art. 31(f).

260. *See* Barton, *supra* note 4, at 149.

261. *See* Ley de la Propiedad Industrial [L.P.I.] [Industrial Property Law], *as amended,* Diario Oficial de la Federación [D.O.], 26 de Diciembre de 1997 (Mex.), *translated in & available at* http://www.wipo.int/clea/docs_new/en/mx/mx016en.html.

262. *Id.*

263. Farolan, *supra* note 73, at 60.

264. *Id.*

265. *Id.*

price of new drugs.[266] However, these changes in drug prices, relatively small and less significant to people in developed nations, can be a considerable strain on people in developing nations.[267] It is arguable that compulsory licensing is necessary because pharmaceutical patent protection provides little benefit to those in extreme poverty and limits access to essential medicines by pricing those medicines out of reach for those who need them most.[268] In fact, at least in the case of India, the new TRIPS-mandated patent regime may not even have as significant an impact on drug prices as most people expect.[269] This is because the laws will apply only to new drugs introduced after the laws were enacted.[270] The existing generic drugs already on the market will still be available, presumably without any significant price change.[271]

The pharmaceutical industry disfavors compulsory licensing.[272] Patent rights are weakened by compulsory licensing.[273] It has been asserted that such licensing is a policy contradiction.[274] The argument is that property rights, in the form of patents, are granted in the first place to stimulate innovation for the public good.[275] Introducing compulsory licensing, also in the name of the public good, reduces the value of the patent rights that were considered desirable in the first place.[276] Companies in developing countries are often accused of using compulsory licensing to free ride on the expensive R&D done by the firms in the developed world and then profiting from sales of generic versions of drugs developed by those other firms.[277]

Compulsory licensing may adversely impact world health because it reduces the incentive to research and develop new drugs.[278] As noted above, a lack of R&D spending in India has been associated with "brain drain" as talented researchers leave that country in search of opportunity elsewhere.[279] Additionally, drug manufacturers around the world will not spend resources searching for cures for diseases that affect primarily developing countries, such as tropical diseases, if

---

266. *See* Abbott, *supra* note 32, at 325. *But see* Singham, *supra* note 8, at 385 (arguing that "[d]rug prices will not necessarily increase if countries shift to a patent enforcing system").

267. Seeratan, *supra* note 30, at 388.

268. *Id.*

269. Finston, *supra* note 1, at 894.

270. *Id.*

271. *Id.*

272. *See* Seeratan, *supra* note 30, at 406.

273. Singham, *supra* note 8, at 390.

274. *Id.* (quoting Robert M. Sherwood, *Intellectual Property Systems and Investment Stimulation: The Ratings of Systems in Eighteen Developing Countries*, 37 IDEA 261, 275 (1997)).

275. *Id.*

276. *Id.*

277. *Id.*

278. *Id.* at 384.

279. *See* Finston, *supra* note 1, at 890.

there is no financial incentive to do so and there is no hope of recouping the investment costs.[280] One anticipated effect of TRIPS is that pharmaceutical firms will be more interested in pursuing tropical-disease research.[281] In addition, it has been observed that domestic research is stimulated in countries that strengthen intellectual property rights.[282] The usefulness of compulsory licensing as it is intended to be used and as it actually is put into practice must be carefully evaluated.

It should be noted that patent protection is by no means the only obstacle to access to medical care in the developing world.[283] With respect to the issue of use of patented drugs, the Doha Declaration and the subsequent clarifying statement[284] represent significant improvements in the promotion of access to medicine in the developing world, but obstacles still remain.[285] Factors that may affect access to medical care include regulatory requirements, tariffs, sales taxes, infrastructure for delivery of drugs, and even the base costs of producing drugs notwithstanding any patent protection issues.[286]

## B. Allocation of the Costs of Innovation vs. Accessibility of Pharmaceutical Products

One of the problems encountered when the international community seeks to bring uniformity to the world body of patent law is that different nations occupy distinct positions within the global market and, therefore, have markedly different goals vis-à-vis the regulation of their patent regimes.[287] In cases where countries are especially asymmetric, as between a developed country such as the United States and a developing country such as Mexico, the regulatory aims may in fact be opposite to each other.[288] The result of this asymmetry is that developed countries, as exporters of technology, tend to prefer high levels of patent protection, while developing countries, as importers of technology, generally prefer lower levels of patent protection.[289] Differences between countries in the regulation of intellectual property were traditionally tolerated under the concept of

280. Singham, *supra* note 8, at 384.
281. *Id.*
282. *Id.*
283. Abbott, *supra* note 32, at 322-23.
284. *See* Barton, *supra* note 4, at 149.
285. *Id.*
286. *See* Barnes, *supra* note 48, at 932-33 (discussing barriers to treatment for AIDS in South Africa).
287. Municoy, *supra* note 241, at 343.
288. *See id.*
289. *See id.* at 347.

territoriality.[290] This is changing, however, as developing countries grow economically and the flow of technology on a global level increases.[291]

Mexico, as noted above, created a patent system in the 1976 Law on Inventions that gave relatively low protection to patent rights.[292] Mexico's Law on Inventions and India's Patents Act of 1970 both reflected a then-current model of economic development, involving import-substituting industrialization, known as ISI.[293] ISI is a closed-market strategy that places high tariffs on imported goods in order to force consumers to buy locally-produced products.[294] This policy was once popular in both Latin America and India but has since been discredited due to economic stagnation and debt crises in those countries.[295] More recently, developing countries have moved away from such nationalistic policies and have begun to liberalize their markets and to open them up to foreign investors.[296] This move to an export-led model of growth has resulted in developing countries seeking access to larger, more developed markets.[297] This in turn has given developed countries, such as the United States, the needed leverage to negotiate for greater patent protections and, ultimately, the acceptance of the TRIPS agreement.[298]

The problem with TRIPS and greater patent protection in developing countries is that despite recent changes, a fundamental asymmetry remains.[299] The basis of this asymmetry is the disparity of financial resources that are available to fund R&D.[300] Taken as a group, developing countries are estimated to account for only 4% of global R&D spending.[301] As a result, strong patent protection mainly benefits developed countries with greater R&D spending.[302]

Similarly, TRIPS and greater patent protection cannot require pharmaceutical companies to create drugs needed in developing countries because the cost of producing those drugs cannot be recovered if only consumers in those

---

290. *Id.* at 347-48. Territoriality is the principle of a nation's right to sovereignty within its own borders. BLACK'S LAW DICTIONARY 1483 (8th ed. 2004).

291. *See* Municoy, *supra* note 241, at 347-48.

292. Flax, *supra* note 44, at 466-67.

293. *See* Susan K. Sell, *What Role for Humanitarian Intellectual Property? The Globalization of Intellectual Property Rights*, 6 MINN. J. L. SCI. & TECH. 191, 195 (2004).

294. *See* Amelia M. DeAngelis, Note, *Coffee, Mexico's Other Bean: An Examination of the Globalization of the Coffee Industry, Its Impact on Mexican Villages, and the Possibility of Surviving the Grind*, 3 WASH. U. GLOBAL STUD. L. REV. 887, 891 (2004).

295. Sell, *supra* note 293, at 195.

296. *Id.*

297. *Id.*

298. *See id.*

299. *See* Municoy, *supra* note 241, at 371.

300. *Id.*

301. *Id.*

302. *See generally id.* at 371-72 (discussing patents as economic-welfare instruments and how this is affected by the asymmetry between developed and developing nations).

countries buy them.[303] There is significant expense associated with developing pharmaceuticals.[304] Regardless of who the consumer is, the manufacturers must recoup these costs or they will not produce new drugs. In the global marketplace, these costs have to be distributed over countries with different economies.[305] Ultimately, this means that patients in the developed world will pay a larger share per person than patients in the developing world.[306]

Under a strict free trade theory, prices for goods equalize near their lowest marginal cost.[307] Patent rights create an economic misallocation because the period of exclusivity allows patented inventions to be priced considerably above the lowest marginal cost.[308] The question is "whether the intellectual property right produces a favorable trade-off between the short-term cost to consumers through higher prices and long-term benefit to consumers through increased innovation."[309]

## VII. CONCLUSION

Technology thrives when it is protected by strong intellectual property rights.[310] This is as true for developing countries such as Mexico and India as it is for developed countries such as the United States. Strong patent rights backed by effective enforcement encourage investment in R&D.[311] R&D benefits not only the company that pursues it but also the country that supports it.[312] It has even been suggested that the social benefits are *greater* than the private benefits.[313] Greater R&D investment leads to greater technology development, which then increases competition as firms adapt to take advantage of the new technologies.[314] The effect reaches the general population as new technologies result in the creation of new jobs, especially jobs requiring skilled workers.[315] As intellectual property protection increases, companies become more willing to invest in

303. John H. Barton, *The Economics of TRIPs: International Trade in Information-Intensive Products*, 33 GEO. WASH. INT'L. L. REV. 473, 490 (2001).

304. *See* Berenson, *supra* note 5.

305. *See* Barton, *supra* note 303, at 489.

306. *Cf. id*. at 490.

307. *Id*. at 487.

308. *Id*.

309. *Id*.

310. Singham, *supra* note 8, at 375.

311. *See id.* at 378.

312. *Id*. at 375.

313. *Id*. at 375-76; *see also* MERGES & DUFFY, *supra* note 20, at 302 ("[E]conomic historians consistently find that investments in R&D pay a higher 'social dividend'—i.e., have larger spillover benefits that are not captured by the investor—than almost any other type of investment.").

314. *See* Singham, *supra* note 8, at 376.

315. *See id.*

training employees at ever higher skill levels.[316] As more skilled workers become available in a country, the effect begins to snowball because private investment increases, resulting in a larger technology industry and the creation of even more jobs.[317] In terms of industrial development, particularly in the pharmaceutical sector, patent protection is of primary importance.[318]

The history of India's Patents Act shows that it is possible for a nation with weak patent laws to build a pharmaceutical industry based on copying rather than innovating, but, in the long run, this comes at a high price.[319] Furthermore, such an industry, without intellectual property of its own, finds itself at a serious disadvantage in the age of globalization when the international community seeks to uphold intellectual property standards worldwide.[320] As India adapts to new standards, its pharmaceutical industry will change, and this will affect India's economy and the Indian people as consumers of pharmaceuticals.[321]

Mexico has a relatively well-developed pharmaceutical industry compared to the rest of Latin America.[322] Mexico's patent system, once very similar to India's, has been in a state of revision since 1987.[323] The purpose of this revision has been to increase patent protection and to thereby stimulate industry.[324] By creating a strong patent regime, one with adequate protections backed by effective enforcement, Mexico may avoid the pitfalls with which India must now contend.

Of course, many are concerned that high patent protection results in poor access to medicines.[325] A reasonable fear exists that as developing countries strengthen their patent regimes, there will be a concomitant rise in drug prices that will disproportionately affect the poorest people.[326] While valid, this concern is mitigated in part by a general rise in the overall economic well-being that will accompany the institution of stronger patent protection as industry grows and unemployment falls.[327] It must be recognized that many other factors besides patents affect drug prices and availability. This is particularly true in the developing world, where the healthcare infrastructure may be deficient and prone to corruption.[328]

---

316. Sherwood, *supra* note 9, at 504.
317. Singham, *supra* note 8, at 376.
318. *Id.* at 372-73.
319. *See* Finston, *supra* note 1, at 889.
320. *See id*.
321. *See* Mayer, *supra* note 11, at *1-4.
322. *See* Gonzalez, *supra* note 164, at 2.
323. *See* Farolan, *supra* note 73, at 57.
324. *Id*.
325. *See* Seeratan, *supra* note 30, at 345.
326. *See id.*
327. *See* Singham, *supra* note 8, at 376.
328. *See* Abbott, *supra* note 32, at 322-23.

Ultimately, a strong patent regime provides substantial benefits to a developing country and to the world at large. Pharmaceutical innovation must be encouraged if there are to be new drugs and cures for the diseases that still infect and kill so many people every year, especially the many diseases endemic to developing countries. Pharmaceutical companies in developed nations engage in substantial R&D but lack the economic incentive to develop cures for diseases that do not affect people in the developed world. Innovative pharmaceutical industries in developing countries will be able to treat their own people and contribute to the pharmaceutical field at large through discoveries made by their scientists. International agreements like TRIPS and NAFTA show that "courts, legislators and international diplomats now seem determined to make patent rights strong, enforceable incentives for innovation."[329] Mexico is on the right course by strengthening its patent laws but must give those laws teeth and make stringent enforcement part of the patent regime. Mexico has abundant potential, and by fostering technological growth in the pharmaceutical industry as well as other industries, it can become an important and competitive player in the world market.

329. MERGES & DUFFY, *supra* note 20, at 13.