

OF THE INEQUALS OF THE URUGUAY ROUND

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INTRODUCTION

Ten years ago, the Agreement on Trade-Related Aspects of Intellectual Property Rights¹ (TRIPs) took the high road to intellectual property harmonization to create equal trading partners among the World Trade Organization (WTO) Members. At that time, the TRIPs Agreement contemplated that all member countries would establish the agreed-upon minimum standards and prioritize international trade obligations as a means to achieve national goals.² The TRIPs Agreement accounted for differing levels of national development by permitting no more than ten years of derogation from international obligations.³ Only five years later, at Doha, the AIDS crisis highlighted that compromising pressing national responsibilities—like a looming public health crisis—to fulfill international obligations may, in fact, detrimentally affect international trade.⁴ Thus, the separate Declaration on the TRIPs Agreement and Public Health adopted at Doha⁵ made concessions to balance international trade obligations with national welfare issues, focusing especially on creating accessibility to medication in the least developed nations.⁶ Despite the efforts, an acceptable framework of solutions allowing those least developed nations to benefit from Doha is yet forthcoming.⁷ Meanwhile, this year marks the

1. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments—Results of the Uruguay Round, 33 I.L.M. 1125, 1197 (1994) [hereinafter TRIPs Agreement]. See generally J. H. Reichman, *Compliance with the TRIPs Agreement: Introduction to a Scholarly Debate*, 29 VAND. J. TRANSNAT'L L. 363 (1996).

2. See TRIPs Agreement, *supra* note 1, art. 7.

3. *Id.* arts. 65, 70(8)–(9).

4. See World Trade Organization, Declaration on the TRIPs Agreement and Public Health of 14 November 2001, WT/MIN(01)/DEC/2, 41 I.L.M. 755 (2002) [hereinafter Doha Declaration on TRIPs and Public Health].

5. *Id.*

6. See *id.*

7. See Trade Negotiations Committee, *Report by the Chairman of the Trade Negotiations Committee to the General Council*, TN/C/5 (July 28, 2005), available at http://www.wto.org/english/news_e/news05_e/gc_tnc5_e.pdf. The Director General of the WTO, Supachi Panchipakadi, has hoped to find a solution for the issues raised at Doha. Although the WTO has attempted to address the issue of implementation of paragraph 6, the results have been unsatisfactory. See World Trade Organization General Council, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPs Agreement and Public Health*, WT/L/540 (Sept. 2, 2003), available at <http://docsonline.wto.org> (follow “Simple Search” hyperlink; and enter document symbol in search field) [hereinafter *Implementation of Paragraph 6*]; Frederick M. Abbott, *The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health*, 99 AM. J. INT'L L. 317 (2005) (discussing in detail

tenth anniversary of TRIPs and the end of the transitional period.⁸ The future success of TRIPs increasingly depends on its ability to address *national* responsibilities⁹ that may impede member countries from successfully fulfilling international obligations.

This Article suggests that policy options embraced by countries like India, which prioritized national responsibilities in its quest to appear on the global trade map, should be revisited as possibilities for jump-starting ailing economies. After all, even the developed nations themselves embraced such options before occupying the moral high ground as promoters of intellectual property rights.¹⁰ This Article also suggests that although such policy options may be legally vulnerable to WTO challenges, they can be instrumental in achieving the objectives of the TRIPs Agreement.

Part I outlines the issues impeding access to medication in least developed nations. Part II discusses the national issues that India faced, which led to the genesis of the Indian patent policy in the Ayyangar Committee Report. The Ayyangar Report remains significant even today for its analysis of patent regimes and conclusions on what each aspect of the patent regime represents in terms of national ambitions. Part III outlines how India used its patent statute and drug policy to achieve the national goal of developing an indigenous pharmaceutical industry. Part IV discusses how the Indian experience can be replicated in other nations. The conclusion asserts that to create accessibility to medication, the contemporary experiences of the developed nations alone will provide an inadequate menu of choices for the least developed nations to emulate. The objective of paragraph 6 of the Doha Declaration is not to create a theoretically perfect patent regime

the implementation of paragraph 6 and concluding that it is not capable of fully addressing the AIDS crisis).

8. TRIPs Agreement, *supra* note 1, art. 65. This date also coincides with the Sixth WTO Ministerial Conference held in Hong Kong in December 2005. See World Trade Organization, The Sixth WTO Ministerial Conference, http://www.wto.org/english/thewto_e/minist_e/min05_e/min05_e.htm (last visited Jan. 8, 2006). “The countries make their decisions through various councils and committees, whose membership consists of all WTO Members. Topmost is the ministerial conference which has to meet at least once every two years. The Ministerial Conference can take decisions on all matters under any of the multilateral trade agreements.” WORLD TRADE ORGANIZATION, UNDERSTANDING THE WTO 101 (3d ed. 2005), available at http://www.wto.org/english/res_e/doload_e/inbr_e.pdf.

9. National responsibilities are issues—like poverty, health care, and local economic conditions affecting intellectual property implementation—that have a stake in development, democracy, and *public order*.

10. See generally Srividhya Ragavan, *Can't We All Get Along? The Case for a Workable Patent Model*, 35 ARIZ. ST. L.J. 117 (2003).

in least developed nations, but to enable accessibility to affordable medication. Viewed from that perspective, the Indian experience can be a useful tool in the hands of the TRIPs Council.

I. THE EXISTENCE OF INEQUALS

The Doha Declaration on TRIPs and Public Health epitomizes the failed attempt at Uruguay to create equality amongst inequals by signing the TRIPs Agreement. In granting concessions to the inequals, paragraph 6 of the Doha Declaration acknowledges the extent of that inequality by stating that “WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPs Agreement.”¹¹ Paragraph 6 categorizes the less-equal Members of the WTO, that is, the non-developed nations, into two classes: (1) Members with *insufficient* manufacturing capacities in the pharmaceutical sector that *may be able* to benefit from compulsory licensing; and (2) Members with *no* manufacturing capacities in the pharmaceutical sector and, thus, *cannot* benefit from compulsory licensing.¹² Paragraph 6 encourages the more fortunate of the less-equals, Members that fall into the former class (like India and Brazil), to manufacture generic drugs to tackle prevailing or potential public health needs and, thus, benefit from the concessions.¹³ Members belonging to the latter class, in which inadequate development impedes production of generic drugs, cannot benefit from the concessions.¹⁴ Development in these countries is so poor that not even generic drugs can be manufactured in these nations.

Unfortunately, the logical option of importing life-saving generic medication to the countries lacking manufacturing capabilities is thwarted by the operation of Article 31(f) of TRIPs.¹⁵ By requiring Members to locally produce the compulsorily licensed patents, Article 31(f) prevents least-developed countries from importing generic drugs from nations, like India, that produce them.¹⁶ Thus, the high point of

11. Doha Declaration on TRIPs and Public Health, *supra* note 4, ¶ 6.

12. *Id.*

13. *See id.*

14. *Id.*

15. TRIPs Agreement, *supra* note 1, art. 31(f).

16. *Id.* See generally Carlos M. Correa, *Implications of the Doha Declaration on the TRIPs Agreement and Public Health* (2002), available at http://www.who.int/medicines/areas/policy/WHO_EDM_PAR_2002.3.pdf.

the TRIPs tenure—the introduction in the Doha Declaration on TRIPs and Public Health of public interest safeguards in the form of the right to compulsorily license patented medication¹⁷—will remain useless where it is most needed.

In effect, the paragraph 6 problem vis-à-vis the least developed nations is two-fold: (1) the lack of immediate access to low-cost medication; and (2) the absence of local industrialization, which impairs the countries' abilities to fully benefit from the Doha Declaration on TRIPs and Public Health.¹⁸ Conscious of the problem, the framers of the Doha Declaration delegated the task of finding an expeditious solution to the TRIPs Council and instructed it to “report to the General Council before the end of 2002.”¹⁹ The ambitious agenda notwithstanding, the TRIPs Council continues to work towards finding an appropriate solution before the conclusion of the Sixth Ministerial Meeting.²⁰ Meanwhile, out of an estimated three million people scheduled to receive treatment for HIV, the virus that causes AIDS, barely one million are being treated.²¹ To address this problem realistically, this Article suggests that the TRIPs Council should examine how nations like India succeeded in establishing an indigenous pharmaceutical industry.

The Indian experience is remarkable in its ability to address health care issues with a keen appreciation of practical national impediments.²² Notably, at the time of independence in 1947, Indians' accessibility to medication was comparable to what currently exists in several least developed nations.²³ By the end of the 1980s, India had developed its own indigenous pharmaceutical industry.²⁴ During the South African

17. Doha Declaration on TRIPs and Public Health, *supra* note 4, ¶ 6.

18. *See generally id.*

19. *Id.* ¶ 6. *See generally* Gardiner Harris & Rachel Zimmerman, *Drug Makers Say WTO Setback Will Not Have Significant Impact*, WALL ST. J., Nov. 15, 2001, at B5.

20. *See Implementation of Paragraph 6, supra* note 7; *see also* Abbott, *supra* note 7 (criticizing the August 2003 resolution of the General Council).

21. *Leaders: Too Much Morality, Too Little Sense: AIDS*, ECONOMIST (London), July 30, 2005, at 13.

22. *See e.g.*, Ramesh Govindaraj & Gnanaraj Chellaraj, *The Indian Pharmaceutical Sector: Issues and Options for Health Sector Reform 1* (World Bank, Discussion Paper No. 437, 2002) (“A detailed assessment of the pharmaceutical sector in developing countries, therefore, is an essential input into the formulation of viable policies to simultaneously promote pharmaceutical competitiveness, and mitigate the impact of rising drug prices while ensuring quality assurance.”).

23. *See infra* notes 33–43 and accompanying text.

24. *See* Govindaraj & Chellaraj, *supra* note 22, at 6 (discussing the extent of development).

AIDS crisis, and even during the anthrax crisis in the United States, India emerged as a reliable supplier of generic drugs.²⁵ Therefore, India's experience in developing a working patent policy may be of significant help in determining solution options to create a manufacturing capacity in least developed nations.

II. INTRODUCING A PATENT REGIME IN INDIA

A. *The Background*

The East India Company introduced patent laws in India.²⁶ The first Indian Patents Act was enacted in 1856 as a result of the recommendations of the Lord Macaulay Law Commission.²⁷ This Act was followed by a series of amendments, such as the 1859 amendment to introduce exclusive privileges for making, selling, licensing, and using inventions.²⁸ The Patterns and Designs Protection Act of 1872²⁹ introduced legislation for the protection for industrial designs and was followed by the Protection of Inventions Act of 1883.³⁰ The 1872 and 1883 legislations were combined into the Inventions and Designs Act in 1888.³¹ Finally, in 1911, the Indian Patents and Designs Act was enacted, repealing all these earlier enactments.³² The various

25. See generally Manu Joseph, *Indian Cipro Copies Don't Pay Off*, WIRED NEWS, Nov. 8, 2001, available at <http://www.wired.com/news/conflict/0,2100,48153,00.html>; Andrew Tanzer, *Pill Factory to the World*, FORBES, Dec. 10, 2001, at 70. Indian generic drug companies like Cipla Ltd. and Dr. Reddy's Laboratories were willing to sell reverse-engineered copies of Bayer's anthrax-fighting Cipro for less than twenty cents per pill. *Id.*

26. The first patent law in India, enacted in 1856, was assented to by the Governor General on February 28, 1856. *First Indian Patent Law*, INTELLECTUAL PROPERTY RIGHTS (Tech. Info., Forecasting & Assessment Council (TIFAC)), Jan.-Feb. 2002, at 1, available at <http://www.tifac.org.in/do/pfc/pub/jan02.pdf>.

27. The first Law Commission was established in 1834 under the Charter Act of 1833 and under the Chairmanship of Lord Macaulay. This Commission was responsible for the codification of the Penal Code, the Criminal Procedure Code, and other legislation. The second, third, and fourth Law Commissions were instituted in 1853, 1861, and 1879, respectively. During a span of fifty years, the various commissions recommended legislation on a variety of subjects, based mostly on the adaptation of English laws to Indian conditions. The Patents Act was one such piece of legislation. The first Indian patent legislation was modeled along the same lines as the British Patent Act of 1852. See RAJIV JAIN & RAKHEE BISWAS, *LAW OF PATENTS: PROCEDURE & PRACTICE V*, at 1.1-.6 (1999).

28. *Id.*

29. *Id.* at 1.2.

30. *Id.*

31. *Id.*

32. *Id.* The Patents Act of 1911 introduced the concept of the Controller of Industrial Patents and Designs. After the enactment of the Patents Act in 1970, Part I of the earlier

intellectual property statutes lacked a clear policy to pave the way for industrial development through patents. During this period, India was fighting for independence; therefore, the laws accommodated the needs of the colonial British Empire.

After gaining independence in 1947, the Indian government set up law commissions styled after the British system to recommend legal reforms to achieve national objectives. “[T]he Patents Enquiry Committee (1948–1950), also known as the Tek Chand committee, and the committee on the Revision of the Patents Law, also known as the Ayyangar committee (1957–1959), were appointed to review the adequacy of the Indian patent system and to adapt it to conform with national goals.”³³ In reviewing the 1911 patent legislation, the Tek Chand Committee relied on the Report of the Swan Committee, appointed by the Board of Trade in the United Kingdom.³⁴ The Tek Chand Committee concluded that India’s ill-defined patent provisions enabled multinational companies to gain patent rights beyond the scope of their inventions.³⁵ The Tek Chand Committee recommended incorporating compulsory licensing provisions to minimize the potential for abuse of monopolies.³⁶ Although the patent legislation in India was amended in 1950 to incorporate the recommendations regarding compulsory licensing, substantial changes did not result.³⁷

Meanwhile, the first Planning Commission, sought to improve “the standard of living of the people by efficient exploitation of the resources of the country” and to take stock of the state of the nation at that time in its First Five Year Plan.³⁸ Statistics for the period revealed two

legislation was separated into the Designs Act of 1911. This Act protected industrial design until 2000 when it was repealed as a post-TRIPs measure in India.

33. Shondeep Banerji, *The Indian Intellectual Property Regime and the TRIPs Agreement*, in *INTELLECTUAL PROPERTY RIGHTS IN EMERGING MARKETS* 63 (Clarissa Long ed., 2000).

34. N. RAJAGOPALA AYYANGAR, REPORT ON THE REVISION OF THE PATENTS LAW ¶ 8 (1959) [hereinafter AYYANGAR REPORT].

35. Banerji, *supra* note 33, at 63–64. The Tek Chand Committee noted that under the Patents Act of 1911, any invention that related to a “manner of manufacture” was patentable. *Id.* at 63. The Ayyangar Committee recommended a clearer definition of “manner of manufacture,” and the Patents Act of 1970 was written using more specific language. *Id.* at 64–65; AYYANGAR REPORT, *supra* note 34, ¶¶ 46–49.

36. AYYANGAR REPORT, *supra* note 34, ¶¶ 175–189.

37. Banerji, *supra* note 33, at 66. Several amendments were incorporated based on the Tek Chand Committee’s recommendations. One of the results was the addition of a new section that vested in the Controller of Patents the power to grant a patent unless there were good reasons to refuse. *Id.*

38. The Planning Commission was set up in March 1950 by a resolution of the

startling realities. First, India recorded a very high poverty index.³⁹ Income from industries accounted for a mere 6.6% of the gross annual national income.⁴⁰ Only 8% of the total labor force worked in industrial establishments.⁴¹ Consequently, approximately 50% of India's population lived in poverty.⁴² Second, India had the world's highest rate of epidemic diseases.⁴³ Of the total mortality, the rate from epidemic diseases was a high 5.1%.⁴⁴ The poverty and disease conditions resulted in low life expectancy, much like what prevails in the least developed nations today.

India recognized that its woes were exaggerated by the lack of indigenous production of bulk drugs.⁴⁵ The cost of drugs was very high because the Central Government imported drugs.⁴⁶ The heavy reliance on foreign manufacturers resulted in multinationals, which formed more than 90% of the Indian pharmaceutical industry, determining the availability and supply of drugs.⁴⁷ Drug prices were so high that in 1961, Senator Estes Kefauver, Chairman of the U.S. Senate Committee, remarked that Indian drug prices ranked among the highest in the world.⁴⁸ Today, the woes of the least developed countries are comparable to what India faced half a century ago—lack of local

Government of India. PLANNING COMM'N, 1ST FIVE YEAR PLAN intro., *available at* <http://planningcommission.nic.in/plans/planrel/fiveyr/default.html> (last visited Jan. 8, 2006) [hereinafter 1ST FIVE YEAR PLAN].

39. *See id.*

40. *Id.* ch. 29, ¶ 2.

41. *Id.*

42. Press Release, World Bank, India Shows Mixed Progress in the War Against Poverty (Aug. 26, 1997), *available at* <http://worldbank.org> (follow "News" hyperlink; then "Press Releases" hyperlink; then insert date of press release).

43. 1ST FIVE YEAR PLAN, *supra* note 38, ch. 32, ¶ 3. The various epidemic diseases included cholera, smallpox, plague, tuberculosis, and malaria. *Id.*

44. *Id.*

45. *Id.* ch. 32, ¶¶ 84, 91. "'Bulk drug' means any pharmaceutical, chemical, biological or plant product including its salts, esters, stereo-isomers and derivatives . . . used as such or as an ingredient in any formulation." Nat'l Pharm. Pricing Auth., Drug (Prices Control) Order 1995, *available at* http://nppaindia.nic.in/drug_price95/txt1.html (last visited Jan. 8, 2006).

46. *See* Abhijit Dey et al., *Pharmaceutical Marketing in India: A Macroscopic View* (Small Bus. Advancement Nat'l Ctr., Soc'y for Marketing Advances, 1999), *available at* <http://www.sbaer.uca.edu/research/sma/1999/30.pdf>; The Drugs and Cosmetics Act, No. 23 of 1940, *available at* <http://www.indialawinfo.com/bareacts/mainbare.html> (follow "Acts" hyperlink; then follow "Pharma Laws" hyperlink; and then "Drugs and Cosmetics Act, 1940" hyperlink).

47. *See* 1ST FIVE YEAR PLAN, *supra* note 38, chs. 1, 32.

48. Banerji, *supra* note 33, at 79.

manufacturing leading to a high cost of imported drugs for which supply and availability are determined by foreign manufacturers.

The Indian government took two significant steps to promote indigenous manufacturing of medication as a means to control the expenditure on public health. First, the government signed an agreement with UNICEF to locally manufacture penicillin and other antibiotics.⁴⁹ The collaboration resulted in the establishment of the Hindustan Antibiotics Limited in 1954 to manufacture low-cost generic drugs.⁵⁰ Second, conscious of India's poverty issues, the government appointed Justice N. Rajagopala Ayyangar to the Ayyangar Committee in 1957⁵¹ to promote law reforms to improve local industrialization in critical areas like food and drugs.⁵²

B. Towards an Indian Patent Policy

India's patent policy heavily relied on the Ayyangar Committee recommendations until joining the WTO in 1994.⁵³ The Committee's 1959 Ayyangar Report laid the basis for the Indian patent regime.⁵⁴ The Ayyangar Report is significant for its analyses of the adaptability of foreign patent regimes and policy options to address national issues. Notably, when the Ayyangar Committee was established, India was an underdeveloped country with economic conditions comparable to

49. See 1ST FIVE YEAR PLAN, *supra* note 38, ch. 32.

50. See *id.*

51. Justice N. Rajaopala Ayyangar's work on the Committee resulted in the Ayyangar Report. See AYYANGAR REPORT, *supra* note 34.

52. See AYYANGAR REPORT, *supra* note 34; Banerji, *supra* note 33, at 63–69. Under Article 21 of the Indian Constitution, the right to life is a fundamental right: “No person shall be deprived of his life or personal liberty except according to procedure established by law.” INDIA CONST. art. 21, *available at* <http://lawmin.nic.in/coi.htm>. The Supreme Court of India enunciated that the right to life implies the right to a healthy life as part of the “basic structure” of the Constitution. See *Kesavananda Bharati v. State of Kerala*, (1973) 4 SSC 225, (1973) A.I.R. SC 1461.

53. The Ayyangar Report, as modified by the Report of the Joint Committee of Parliament in 1966, forms the backbone of the Indian patent system. See *generally* AYYANGAR REPORT, *supra* note 34, ¶ 8.

54. V.R. Krishna Iyer, Opinion, *GATT, TRIPs and Patent Law—II*, HINDU, Sept. 11, 2000, at 5, *available at* <http://www.hinduonnet.com/thehindu/2000/09/11/stories/05112524.htm>. Justice Krishna Iyer, a renowned Supreme Court Justice in India, expresses his admiration for the Ayyangar Report: “A well-debated, development-oriented and patriotically processed statute of 1970, with a progressive perspective and successful sequel, passed after a thorough study (based on the Justice Rajagopala Ayyangar Commission report) proved a tremendous national triumph for the consumer and the manufacturer alike. This finest and most just parliamentary achievement . . .” *Id.*

today's least developed nations.⁵⁵ The Ayyangar Committee specifically examined issues that continue to be debated in the WTO, including (1) whether patenting food, chemical, and pharmaceutical inventions can affect the underprivileged section's accessibility to these products; and (2) whether compulsory licensing can enable accessibility while at the same time promoting innovation.⁵⁶ Thus, the Ayyangar Report is significant for least developed nations because it highlighted the best practices in foreign patent regimes and examined their suitability to address public health and economic concerns of underdeveloped economies.

1. Patents and Underdeveloped Nations

Like the committees that preceded it, the Ayyangar Committee studied the Swan Committee recommendations.⁵⁷ In the Ayyangar Report, the Committee outlined how the Australians rejected the Swan Committee recommendations that were unsuitable for their local conditions.⁵⁸ Hence, the Ayyangar Committee championed the adoption of a patent regime with a keen sense of achieving national goals. The Committee theorized that local realities in underdeveloped nations cause patent regimes to operate differently than in developed nations.⁵⁹ India, the Committee suggested, should deviate from unsuitable patent policies of industrialized nations.⁶⁰

55. See generally *AYYANGAR REPORT*, *supra* note 34 (repeatedly referring to India as an underdeveloped nation).

56. See *id.*

57. *Id.* ¶ 8.

58. *Id.* ¶ 9; see also *JAIN & BISWAS*, *supra* note 27, at 1.2.

59. *Id.* ¶¶ 24–25.

For developing countries, however, the economic calculus is different for two reasons. First, as net users rather than net exporters of R&D-intensive products, they do not benefit from the monopoly profits that are created by patent protection. On the contrary, their consumers suffer from the higher prices that result. Second, because their markets are small in relation to global demand—at least for pharmaceutical products to treat a number of diseases such as cancer, hypertension, and ulcers—actions taken by developing countries to strengthen patent protection have little impact on the incentive to undertake additional R&D. Thus, a combination of higher costs in the short run and the likely absence of dynamic gains over time means that raising levels of protection would not benefit developing countries.

Arvind Subramanian, *Medicines, Patents and TRIPS: Has the Intellectual Property Pact Opened a Pandora's Box for the Pharmaceuticals Industry?*, *FIN. & DEV. (Int'l Monetary Fund)*, Mar. 2004, at 23, available at <http://www.imf.org/external/pubs/ft/fandd/2004/03/pdf/subraman.pdf>.

60. *AYYANGAR REPORT*, *supra* note 34, ¶¶ 24–25.

While the Ayyangar Committee suggested deviations from the patent regimes of industrialized nations, it also adds that it is unwise to shun a patent system completely. “With all the handicaps which the system involves in its applications to under-developed countries, there are no alternative methods for achieving better results.”⁶¹ The Committee added that a patent system is the “most desirable method of encouraging inventors and rewarding them.”⁶² Without a patent regime, the Ayyangar Committee argued that “[m]anufacturers would not be prepared to develop and produce important machinery if others could get the results of their work with impunity.”⁶³ The security and immunity from competition that patents provide are necessary inducements to work an invention.⁶⁴ The Ayyangar Committee pointed out that even the erstwhile Soviet Union, which followed a socialist economic structure, provided for patents.⁶⁵ A patent regime, the Committee asserted, is an absolute necessity to enable or improve industrialization, provided it is designed “with special reference to the economic conditions of the country, the state of its scientific and technological advance, its future needs[,] and other relevant factors.”⁶⁶ The fine balance between vesting monopoly rights and balancing welfare issues suggested in the Ayyangar Report would greatly benefit least developed nations that must embrace patents to encourage innovation while achieving national objectives.

2. Inventions Relating to Chemicals, Food, and Pharmaceuticals

The Ayyangar Committee treated issues relating to patentability of chemicals, food, and pharmaceuticals as critical for national development. Regarding chemical patents, the Committee traced the history of the law relating to chemical products in Europe. A rule prohibiting product patents for chemicals was first introduced in the German Patent Law of 1877 to stimulate research in alternative methods of producing a product.⁶⁷ Within the next thirty years, Germany’s process patent regime enabled the growth of the chemical

61. *Id.* ¶ 39.

62. *Id.* ¶ 43.

63. *Id.* ¶ 17 (quoting the Swan Committee); see also V.R. Krishna Iyer, *Human Health and Patent Law*, FRONTLINE, Oct. 14, 2000, at 21, available at <http://www.flonnet.com/fl1721/17210790.htm>.

64. AYYANGAR REPORT, *supra* note 34, ¶ 43.

65. *Id.* ¶ 40.

66. *Id.* ¶ 44.

67. *Id.* ¶ 58.

industry.⁶⁸ At the end of World War I, a British Law Amendment Committee chaired by Lord Parker pointed to the German patent system and favored process protection for chemicals, food, and medicine.⁶⁹ Consequently, the U.K. Patent Amendment Act of 1919 passed with the amendments recommended by Lord Parker to bring England on par with Germany.⁷⁰ Taking the German and British experience into consideration, the Ayyangar Committee favored process rather than product protection for chemicals in India.⁷¹

With respect to patenting food, the Ayyangar Committee noted that, except for the United States, most other countries imposed additional restrictions on patents relating to food and medications.⁷² Even countries that allowed product claims for chemicals limited patent protection relating to food and medicines to processes:

The French law of 1844 which permitted the patenting of chemical products . . . confined patents for articles of food and medicine to process claims. Belgium in its Patents law of 1854 adopted the French model. The German law of 1877 denied patents to articles of food, medicinal products, though processes for their preparations were patentable. The Swiss law . . . amended in 1954 [excludes inventions relating to medicines, medicinal mixtures and food products from patentability], but the processes for manufacturing medicine or food are patentable.⁷³

Similarly, Sweden, Spain, and Japan do not allow product claims for articles of food or medicine, and Denmark does not allow any patents on food.⁷⁴ The Italian Patent Act of 1957 prohibits patenting medicinal products.⁷⁵ The Ayyangar Committee also quoted the Sargent Committee's recommendation to make food affordable in England:

During the War it became apparent that Great Britain was

68. *Id.* Prior to 1877, Germany followed the French model. *Id.* Under the French Patent Act of 1844, patents were granted to chemical products per se. *Id.* German scientists and research workers attributed the failure of the French chemical industry to the French product patent system. *Id.* The Ayyangar Committee favorably cited the German belief that the grant of a product patent to chemical products per se precluded alternative processes of production. *Id.*

69. *Id.* §§ 72, 75.

70. *Id.* §§ 72–75.

71. *Id.* § 56.

72. *Id.* § 94.

73. *Id.* § 95.

74. *Id.*

75. *Id.*

suffering from a lack of medicine and drugs, many of which were the subject of patent rights in this country. On the other hand, it was found that in many European countries (*e.g.*, France, Germany, Switzerland) such substances were not capable of protection under the patent laws of those countries. In this state of things it was considered expedient to modify to some extent the monopoly consequent on the existence of patent rights in regard to such substances.⁷⁶

The Ayyangar Committee noted that “such important articles of daily use as medicine or food which are vital to the health of the community should be made available to every one at reasonable prices.”⁷⁷ The Ayyangar Committee, therefore, suggested that product patents should not be granted in critical areas like food and medicines.⁷⁸ Vesting product patents in food and pharmaceuticals could deny vast sections of the population access to these critical products and violate the constitutional right that Indians have to life and good health.⁷⁹ In the Report, the Committee resonated the words of Justice Krishna Iyer, former Justice of the Supreme Court of India, who stated that the state risks affecting the constitutional right to life if by oblique policy it fails to make medicines (or food) available or accessible to people.⁸⁰ The Ayyangar Committee, however, specified that leaving food and pharmaceuticals completely unpatentable would deny India the benefits from new technology and, thus, would not be in the public interest.⁸¹ Exclusive rights to the process of production would accelerate research in developing alternative processes.⁸² It was expected that process protection could lead to increased diversity of products at competitive prices,⁸³ and that consumers would benefit from the increased competition in a process patent regime. Hence, the Ayyangar Committee recommended limiting protection on food and medication,

76. *Id.* ¶ 98 (citations omitted). The Ayyangar Committee discusses the Sargent Report and § 38A of England’s Patents and Designs Amendment Act of 1919, which marked an introduction to restrictions on patent protection for food and to process patenting. Section 38B(2) introduced compulsory licensing of patents relating to food substances. *See id.* ¶¶ 73–99.

77. *Id.* ¶ 101.

78. *Id.*

79. *See* Banerji, *supra* note 33, at 64; Iyer, *supra* note 63.

80. *See* Iyer, *supra* note 63.

81. AYYANGAR REPORT, *supra* note 34, ¶ 101.

82. *Id.*

83. *Id.*

like chemicals, to the method or the process of making the invention.⁸⁴

3. Industrialization

The Ayyangar Committee noted that one of the woes affecting underdeveloped nations is that foreign patent owners do not work the invention locally, thus depriving the country of competition.⁸⁵ Foreigners own patents in underdeveloped export markets to protect the market from rival competitors.⁸⁶ Such patents do not necessarily benefit the underdeveloped economies.⁸⁷ Thus, in underdeveloped economies, foreign manufacturers become the beneficiaries of the patent system, much to the detriment of national interests.⁸⁸

The solution identified by Ayyangar Committee is meant to encourage national industrialization. The Committee, however, argued that patents should be worked locally to enable national industrialization.⁸⁹ Otherwise, “the social cost involved in the grant of the patent [will not be] offset by any benefit to the community.”⁹⁰ Hence, the Committee suggested that patent regimes in underdeveloped nations should enable the local working of the inventions.⁹¹ The Ayyangar Committee outlined examples from developed nations. When the British wanted to compete with the United States and Germany in large-scale industrial production, the Sir Edward Fry Commission of 1901 recommended the local working requirement to industrialize Britain.⁹² The Committee recommended that India, like Britain, should ensure that inventions are worked locally to facilitate industrialization.⁹³ Locally working the inventions would minimize importation of foreign goods.⁹⁴ The resulting industrialization would offset the disadvantage to local manufacturers who may be unable to capitalize on economies of scale in other jurisdictions.

The Ayyangar Committee outlined compulsory licensing as the remedy to redress the handicap of foreigners not working the invention

84. *Id.*

85. *Id.* ¶ 30.

86. *Id.* ¶ 29.

87. *Id.* ¶ 30.

88. *Id.* ¶¶ 29–30.

89. *Id.* ¶ 38.

90. *Id.*

91. *Id.*

92. *Id.* ¶¶ 126–27.

93. *Id.* ¶ 37.

94. *Id.* ¶¶ 37–38.

locally.⁹⁵ The Committee suggested that the government should retain the right to compulsorily revoke patents when they are not worked locally and compulsorily license patents when the owners refuse to license them.⁹⁶ The Committee canvassed compulsory licensing precedents from developed nations.⁹⁷ After the compulsory licensing mechanism originated in the French Patent Act of 1791, many European countries adopted the provisions to encourage local working of inventions.⁹⁸ The Ayyangar Report is supported by works of Sir Walterscheid, which detailed how patents were granted to lure foreign industries into England.⁹⁹ Sir Walterscheid further asserted that Queen Elizabeth I made an effort “to stimulate domestic production of both raw materials and a wide variety of manufactured goods previously imported from abroad” by granting patents.¹⁰⁰

The Ayyangar Committee further noted that during the period when England benefited from foreign investments, England argued that compulsory licensing was inconsistent with the purpose of the international conventions at the Conference on Industrial Property at Paris in 1878.¹⁰¹ Later, when England suffered the consequences of foreign-owned British patents, the government appointed the Sir Edward Fry Committee in 1901 to analyze the link between compulsory licensing and industrial production.¹⁰² In 1907, Lloyd George, President of the Board of Trade, successfully introduced a bill incorporating compulsory licensing provisions in the House of Commons by highlighting that foreigners owned 6500 out of 14,700 patents issued in 1906 and worked them outside of England.¹⁰³ Consequently, compulsory licensing provisions were introduced in the British patents legislation.¹⁰⁴ The Ayyangar Committee specified that although the threat and competition from German industries deteriorated after World War I,

95. *Id.* pt. V.

96. *Id.* ¶ 125. Impartial arbitrators will decide what royalties are payable for such licenses.

97. *Id.* pt. V.

98. *Id.* ¶ 125.

99. Adam Mossoff, *Rethinking the Development of Patents: An Intellectual History, 1550–1800*, 52 HASTINGS L.J. 1255, 1261–62 (2001).

100. *Id.* at 1261 (quoting Edward C. Walterscheid, *The Early Evolution of the United States Patent Law: Antecedents (Part 2)*, 76 J. PAT. & TRADEMARK OFF. SOC'Y 849, 855 (1994)).

101. AYYANGAR REPORT, *supra* note 34, ¶ 126.

102. *Id.*

103. *Id.* ¶ 129.

104. *Id.*

the United Kingdom continued to enlarge the scope of compulsory licensing provisions.¹⁰⁵ “Though the U.K. has been one of the major industrial countries of the post-war world, she clings with tenacity to the provisions regarding compulsory working”¹⁰⁶ The Committee noted that, compared to the United Kingdom in 1907 to 1919, India remained underdeveloped even in 1947, thus justifying the need to include compulsory licensing provisions.¹⁰⁷

The Ayyangar Committee cited the United States as the only country in the world that did not impose compulsory licensing requirements.¹⁰⁸ The Committee, however, attributed this to the immense wealth and abundance of resources that provided ideal conditions for establishing new industries.¹⁰⁹ Therefore, the proportion of patents that were granted in the United States compared to those that were not worked locally remained very small.¹¹⁰ The Committee rationalized that the United States could afford not to adopt compulsory licensing in a manner that other countries could not.¹¹¹ Hence, the Committee advocated compulsory licensing as the base carrier for the local working requirement.¹¹²

Today’s least developed nations are plagued by the lack of local innovation. In African countries, even the generic drugs are imported from countries like India.¹¹³ As early as the 1950s, the Ayyangar Committee not only identified the importance, but also suggested the means to achieve local industrialization. The Ayyangar Report will be a useful tool for the TRIPs Council, whose sole task under paragraph 6 of the Doha Declaration on TRIPs and Public Health is to enable local

105. *Id.* ¶ 132.

106. *Id.* ¶ 133.

107. *Id.* ¶ 135.

108. *Id.*

109. *Id.*

110. *Id.*

111. *Id.*

112. *Id.* The Ayyangar Committee cites to § 3 of the 1902 British Patent Act, which introduced the principle of “revocation of patent for abuse of the monopoly by non-working” on the ground that the “reasonable requirements of the public with reference to the patented inventions have not been satisfied.” *Id.* ¶ 127. To this date, the expression “reasonable requirements of the public” is found in § 84 of the Indian patent legislation. See Patents Act of 1970, 27 INDIA A.I.R. MANUAL 450, § 84 (1979), available at <http://www.ipindia.nic.in/ipr/patent/patAct1970-3-99.html>.

113. See Anne-christine d’Adesky, *India’s Generics Play a High Stakes Game*, 3 AM. FOUND. FOR AIDS RESEARCH (AMFAR) TREATMENT INSIDER 1 (2002), available at <http://web.amfar.org/treatment/TI/June2002.pdf>. “Cambodia, Indonesia, China and South Korea are importing or plan to import Indian medicines.” *Id.* at 3.

industrialization in least developed nations.

III. ESTABLISHING AN INDIAN PATENT REGIME

The following Part discusses how India prioritized its national obligations and used legal reforms as a means to achieve international trading status. The Indian Patents Act of 1970,¹¹⁴ along with other mechanisms like drug and industrial policies, was used as a tool by India to achieve its national priorities. The establishment of an indigenous pharmaceutical industry caused the Indian government to introduce more trade facilitating measures. Further, the Indian experience demonstrates that tackling national priorities by providing adequate concessions may, in fact, help least developed nations to become trading partners and, thus, benefit from international trade.

A. Indian Patent Legislation

1. Process Patents

Based on the Ayyangar Report, the Indian Patents Act of 1970 allowed differential treatment for food, medicine, and chemical inventions. Rights to inventions relating to food, medicine, and chemicals were limited to process patent protection.¹¹⁵ The process patent regime excluded protection of the end-product, but protected the method or the process of making the product.¹¹⁶ Hence, identical products could be produced by several manufacturers who could each hold a process patent. The process patent regime encouraged innovation in the methods of making known products. The patent legislation enabled India to produce patented products, particularly pharmaceuticals, using different processes.¹¹⁷

114. *See supra* note 112.

115. The Patents Act of 1970 reads as follows:

- (1) In the case of inventions—
- a. claiming substances intended for use, or capable of being used, as food or as medicine or drug, or
 - b. relating to substances prepared or produced by chemical processes (including alloys, optical glass, semi-conductors and inter-metallic compounds),
- no patent shall be granted in respect of claims for the substance them selves, but claims for the methods or processes of manufacture shall be patentable.

Patents Act of 1970 § 5.

116. *Id.*

117. The process patent provisions contravene the product patent regime envisioned under TRIPs, which stipulates that Members shall ensure patent protection “for any

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Further, the term of process patent protection over food, drug, and medical inventions was limited to five years.¹¹⁸ Inventions in food, medicine, drug, and chemical processes were deemed, under § 87 of the Patents Act, to be automatically endorsed with a license of right after three years of the grant of a patent.¹¹⁹ A license of right authorizes any person to manufacture a patented product, notwithstanding the patentee's approval.¹²⁰ Thus, patent exclusivity was effectively enjoyed for only three years in these critical areas. In introducing limited protection to these critical areas, India sought to encourage more competition. The limited rights and protection, India envisaged, would balance innovation with accessibility.

2. Compulsory Licenses and Local Working of Patents

Compulsory licensing provisions provided the vehicle to encourage local working of inventions. The government could, in the public interest, interfere with patent rights and compulsorily license the patent.¹²¹ Patented inventions that were either not reasonably priced or not worked to satisfy the reasonable requirements of the public could be subject to compulsory licensing.¹²² The reasonable requirements of the public were deemed unsatisfied if the invention was not worked in India.¹²³ Similarly, the reasonable requirements of the public were deemed unsatisfied if the existing or proposed trade was prejudiced, the demand for the product was not adequately met, or the local working of the invention was prejudiced due to importation.¹²⁴ The compulsory license provision and the government's ability to issue licenses of right were meant to facilitate local manufacturing of inventions.¹²⁵

The Indian patent legislation served as an important tool to establish and to maintain generic manufacturing capacity. Only in 1994, after the

inventions, whether product or processes, in all fields of technology." TRIPs Agreement, *supra* note 1, art. 27(1). Article 27 of TRIPs requires member countries to establish a product patent regime. Hence, the process patent provisions contravene Article 27.

118. Patents Act of 1970 § 53(1)(a). The term is limited to five years from the date of sealing of the patent, or seven years from the date of the patent, whichever is shorter. *Id.*

119. *Id.* § 87(1).

120. *Id.* § 88.

121. *Id.* § 84. The Controller of Patents compulsorily licenses the patent by considering the nature of the invention and the applicant's ability to work the invention to the public's advantage.

122. *Id.*

123. *Id.* § 90(a).

124. *Id.*

125. This is true even if the government never exercised that power.

indigenous pharmaceutical industry was well-established, the Indian patent legislation underwent significant amendments. The amendments to the Indian patent legislation flowed as a consequence of India's membership in the WTO. The first significant amendment to the 1970 legislation was in 1999 when the Patents (Amendment) Act of 1999¹²⁶ introduced exclusive marketing rights. The Amendment provided for a mechanism to accept product patent applications and grant exclusive marketing rights until India moved to a product patent regime.¹²⁷ The subsequent Patents (Second Amendment) Act of 1999¹²⁸ retained the process patent regime. The beginning of 2005 marked the end of the transitional period for developing nations outlined in Article 70(8) of TRIPs,¹²⁹ signifying that developing nations like India had to fulfill their obligations under Article 70(8).¹³⁰ On April 5, 2005, India's Parliament enacted the third amendment to the Patents Act of 1970, the Patents (Amendment) Act of 2005.¹³¹ This most recent Amendment modified the scope of patentability for pharmaceutical inventions in order to move away from the process patent regime.¹³² Currently, the Indian patent legislation is fully compliant with TRIPs.

The amended legislation certainly creates a milestone for India as far as establishing a TRIPs-compliant patent regime. Notwithstanding the legislation itself, the larger question is the effectiveness of transplanting a TRIPs-compliant patent regime as a mechanism to achieve national or international goals.¹³³ Generally, a sophisticated patent mechanism can indeed serve as an effective tool to achieve targeted objectives of industrialization. The sophistication of a patent regime is reflected by the ability of the system to accommodate both the

126. The Patents (Amendment) Act, 1999, No. 17, Acts of Parliament, 1999, available at http://www.ipindia.nic.in/ipr/patent/patact_99.PDF.

127. *Id.* § 24B. Under the amended legislation, an exclusive marketing right will be granted if the claimed substance is patentable from the date of approval by the Controller of Patents either until the earlier of five years or until patent protection is provided.

128. The Patents (Second Amendment) Act, 1999, No. 49, Acts of Parliament, 1999 (introduced in the Rajya Sabha on Dec. 20, 1999), available at http://www.ficci.com/iprindia/Acts_files/patent.htm.

129. TRIPs Agreement, *supra* note 1, art. 70(8).

130. For detailed views of the Patents (Amendment) Ordinance from India, see Narayan Kulkarni et al., *India Enters Product Patent Regime*, BIOSPECTRUM INDIA, Jan. 6, 2005, available at <http://www.biospectrumindia.com> (follow "Archive" hyperlink; and search by month and year).

131. The Patents (Amendment) Act, 2005, No. 15, Acts of Parliament, 2005.

132. *Id.* § 3(d).

133. See generally J.H. Reichman, *From Free Riders to Fair Followers: Global Competition Under the TRIPs Agreement*, 29 N.Y.U. J. INT'L L. & POL. 11, 27-40 (1997).

original invention as well as the process or follow-on inventions. Adequate and appropriate procedural tools that support the patent system form the hallmark of such sophistication. Developed nations facilitate industrial growth by using procedural tools to provide innovative status to follow-on inventions. Unfortunately, developing nations like India lack exposure to the role procedures, especially patent procedures, play in implementing patent policies. In the past, the lack of proper procedures in India resulted in the denial of patent protection for inventions distinguished through functional structural additions or even process innovations.¹³⁴ I have argued previously that some innovations within India, currently labeled as “copies” of Western patents, may be eligible in the United States for patents using appropriate patent techniques.¹³⁵ The same malady could result in the TRIPs-compliant patent regime of India.¹³⁶ Thus, the amended legislation’s effectiveness in facilitating the Indian government’s ability to generate the maximum potential from India’s generic drug industry, which is required to maintain public health conditions, remains moot.

B. Drug Policies and Drug Price Control Order

Previous discussions highlighted how the Planning Commission’s First Five Year Plan took stock of the state of the country at the time of India’s independence. By the time India was at the Third Five Year Plan in 1960, the government envisaged “a large increase in the production of drugs in the country and replacement of imported drugs and raw materials by indigenous manufactures.”¹³⁷ In essence, the government noted that although the prices of many essential drugs were reasonable, prices of proprietary brands remained high.¹³⁸ Hence, the emphasis of the third planning period, 1960 to 1965, was on availability of quality, affordable medication. Due to high poverty levels, the government felt that accessibility would be meaningless unless medication was also affordable.¹³⁹

134. See, e.g., *Farbwerke Hoechst & Bruning Corp. v. Unichem Lab.*, 1969 A.I.R. 56 (Bom.) 255. See Srividhya Ragavan, *A “Patent” Restriction on Research & Development: Infringers or Innovators?*, 2004 U. ILL. J.L. TECH. & POL’Y 73, 87–88 (2004), for a discussion of the *Hoechst* case.

135. Ragavan, *supra* note 134, at 74.

136. *Id.*

137. PLANNING COMM’N, 3RD FIVE YEAR PLAN ch. 32, ¶ 45, *available at* <http://planningcommission.nic.in/plans/planrel/fiveyr/default.html> (last visited Jan. 8, 2006).

138. *Id.* ¶ 46.

139. The Indian Constitution emphasizes balancing social and economic rights. See

The government's amendment of the Drugs and Cosmetics Act of 1940 to give the Central Government concurrent powers with states over the manufacture of drugs was the first step to achieving planning objectives. Further, the patent statute was complemented with two mechanisms to help achieve the pharmaceutical objectives over the years. The patent legislation was supplemented with a Drug Policy and Foreign Exchange Regulations Act¹⁴⁰ (FERA) made under the Industrial Policy.¹⁴¹ To make pharmaceuticals more affordable, FERA allowed governmental interference with the market using drug price control orders.¹⁴² To facilitate the indigenous industry, FERA limited the multinational corporations' dominance in the local markets.

Notwithstanding the objectives of the Third Five Year Plan and the carefully crafted Ayyangar Report, the first Drug Policy was actually a direct by-product of the 1962 Chinese aggression toward India.¹⁴³ Fearing the effect of war on public health, the government amended the Defense of India Act of 1915 to allow statutory control over drug prices.¹⁴⁴ Using the statutory authority, the government passed the Drugs (Display of Prices) Order of 1962, which was later revised as the Drugs (Control of Prices) Order of 1963, and the Drugs Prices (Display and Control) Order of 1966.¹⁴⁵ Each of the Orders regulated the drug industry. Meanwhile, faced with the failure of the objectives of the Third Five Year Plan, the government requested that the Tariff

INDIA CONST. pmbl. Article 21 of the Constitution guarantees the right to life, which includes the right to good health. *Id.* art. 21; *see also* Kesavananda Bharati v. State of Kerala, (1973) 4 SSC 225, (1973) A.I.R. SC 1461.

140. Foreign Exchange Regulation Act, No. 46 of 1973, *available at* <http://indiacode.nic.in/fullact1.asp?tfnm=197346>.

141. *See* Ministry of Commerce and Indus., Dep't of Indus. Pol'y & Promotion, http://dipp.nic.in/policy_dipp.htm (last visited Jan. 8, 2006) (listing a sample of all the policies that the Department handles, including industrial development and drug policies).

142. *See* David Scondras, *A Visit to India: Drug Prices, Research & Global Access*, AIDS TREATMENT NEWS #311, Jan. 22, 1999, *available at* <http://www.thebody.com/atn/311.html#india> (arguing that drug prices in India are between 1000% to 4000% cheaper than drug prices in the United States). For example, the price of the antibacterial drug Norfloxacin is \$.06 in India compared to \$12.26 in America. *See* Banerji, *supra* note 33, at 83. The anti-inflammatory drug Piroxicam costs less than \$.05 in India as compared to the American price of \$.115. *Id.* Zidovudine (AZT), a drug retailed for \$5.82 per 300 milligrams in the United States, is sold in India in capsule form for \$1.42 per 300 milligram. *Id.*

143. Piyush Kunnappallil, *Drudgery of Drug Price Controls: Who Benefits?* 1 (2002) (unpublished manuscript, on file with the Ctr. for Civil Soc'y), *available at* http://www.ccsindia.org/Intern2002_11_drug_controls.pdf (last visited Jan. 8, 2006).

144. *Id.*

145. *Id.*

Commission examine prices of certain drugs in 1966.¹⁴⁶ Following the Tariff Commission's Report of 1968, the government introduced the Drug Price Control Order (DPCO) of 1970.¹⁴⁷

1. DPCO 1970 and Foreign Corporations

The DPCO 1970 was passed using the Central Government's power under the Essential Commodities Act of 1955¹⁴⁸ to control the essential commodities for streamlining supply, distribution, and availability at fair prices.¹⁴⁹ The DPCO 1970 allowed for governmental control over drug prices, thus complementing the compulsory license provisions.¹⁵⁰ The DPCO 1970 addressed concerns relating to the high cost of health care.¹⁵¹ "The legislation had a threefold purpose: [1] to enable public access to essential drugs, [2] to provide a reasonable rate of return to companies, and [3] to ensure quality."¹⁵²

The DPCO 1970 restricted pre-tax profit from pharmaceutical business to fifteen percent of sales.¹⁵³ Profits exceeding the fifteen percent margin were appropriated by the government.¹⁵⁴ The price control regime per se did not detrimentally affect the dominance of the multinational companies, which continued their presence in India.¹⁵⁵

146. Aradhna Aggarwal, *Strategic Approach to Strengthening the International Competitiveness in Knowledge Based Industries: The Indian Pharmaceutical Industry 6* (Research & Info. Sys. for Dev. Countries, Discussion Paper No. 80, 2004), available at <http://www.ris.org.in> (follow "Publications" hyperlink; then "Discussion Papers" hyperlink). The Commission examined the prices of eighteen bulk drugs and their single ingredient formulation. *Id.*

The Tariff Commission was established under the Tariff Commission Act of 1951, which functioned under the Ministry of Commerce. Ministry of Commerce & Indus., Tariff Comm'n, <http://tc.nic.in/> (follow "History" hyperlink) (last visited Jan. 8, 2006). The Commission's objectives are to promote industrialization by making recommendations to the Central Government based on tariff studies. *Id.*

147. Aggarwal, *supra* note 146, at 6.

148. The Essential Commodities Act, No. 10 of 1955, available at <http://indiacode.nic.in/fullact1.asp?tfnm=195510>.

149. See Aggarwal, *supra* note 146, at 62.

150. After the DPCO 1970 was passed, the Government of India placed most drugs under price control.

151. See Kunnappallil, *supra* note 143, at 1-2 (discussing the DPCO). The categories were meant to separate drugs most essential for the national health care programs from the other drugs. The degree of price control exercised varied with the category of the drug.

152. Rishi Gupta, *TRIPS Compliance: Dealing with the Consequences of Drug Patents in India*, 26 *HOUS. J. INT'L L.* 599, 608 (2004).

153. Kunnappallil, *supra* note 143, at 2.

154. *Id.*

155. *Id.*

However, multinational companies curtailed launches of new products because they were forced to sell products at lower prices.¹⁵⁶

In 1973, the government introduced FERA to impose restrictions on foreign equity participation.¹⁵⁷ Although the pharmaceutical industry was given priority status, foreign multinationals could only retain a maximum of 74% ownership against a general limit of 40%.¹⁵⁸ The operation of FERA, along with the price control regime, resulted in decreasing participation of multinational companies in the Indian pharmaceutical sector.¹⁵⁹ Several foreign manufacturers chose to consolidate their position and limit their equity holdings in India or assume an Indian identity.¹⁶⁰ For instance, Reckitt & Colman, a multinational, was first established in India in 1934 as Atlantic (East) Ltd.¹⁶¹ In 1951, Reckitt & Colman India Ltd. took over the manufacturing operations of Atlantic (East) Ltd.¹⁶² The Indian company operated as a wholly-owned subsidiary of Reckitt & Coleman U.K. until 1970.¹⁶³ FERA regulations forced it to offer shares to the Indian public in 1970 to reduce its foreign holdings to 70%.¹⁶⁴ The parent company's holdings were further reduced to 40% in 1977 to comply with FERA regulations.¹⁶⁵ Similarly, Dorr-Oliver (India) Ltd., established a presence in India in 1912 as a subsidiary of Dorr-Oliver Inc. U.S.A.¹⁶⁶ Under FERA regulations, in 1977, Dorr-Oliver (India) Ltd. became Hindustan Dorr-Oliver Limited.¹⁶⁷

156. Ajith Sankar, *The Indian Pharma Industry under the Product Patent Regime*, in ICAI CTR. FOR MGMT. RESEARCH, ICMR CASE COLLECTION (BSTR/169) 5 (2005).

157. Aggarwal, *supra* note 146, at 6–7. The pharmaceutical industry was included in Appendix I of the Industrial Licensing Policy of 1993. *Id.* These companies' "products were not being produced in India or where the local sector was being dominated by a single (usually foreign) company." *Id.* at 6; *see also* Foreign Exchange Regulation Act, No. 46 of 1973, ¶ 29 (discussing restrictions on establishment of place of business).

158. Aggarwal, *supra* note 146, at 6–7 (discussing Appendix I of the Industrial Licensing Policy).

159. *Id.* at 17; Kunnapallil, *supra* note 143, at 2.

160. Aggarwal, *supra* note 146, at 18–19.

161. Indiainfonline, Global Database, Reckitt & Colman, <http://www.indiainfonline.com/fmcg/glob/reck.html> (last visited Jan. 8, 2006).

162. *Id.*

163. *Id.*

164. *Id.*

165. *Id.*

166. Dorr-Oliver (India) Ltd., About Us, <http://www.hind-dorroliver.com/aboutus.htm> (last visited Jan. 8, 2006).

167. *Id.*

2. Striving for Indigenous Advantage

In 1975, the government appointed a parliamentary committee generally known as the Hathi Committee to analyze the issues relating to the drug industry.¹⁶⁸ The Hathi Committee emphasized “achieving self-sufficiency in medicines and ensuring abundant availability of essential medicines at reasonable prices.”¹⁶⁹ It observed that foreign companies “thwarted attempts by indigenous units to produce bulk drugs by means of import-dumping and filing patent suits.”¹⁷⁰ Hence, the Hathi Committee recommended the development of the indigenous industry by strengthening public sector pharmaceutical companies.¹⁷¹

Consequently, the DPCO 1970 underwent more revisions in 1979.¹⁷² The revised DPCO 1979 compartmentalized drugs into three categories—life-saving, essential, and less-essential—for exercising price control over 370 bulk drugs and over 4000 formulations.¹⁷³ The retail prices of controlled formulations were decided by applying the concept of Maximum Allowable Post-Manufacturing Expenses¹⁷⁴ (MAPE). The most important life-saving drugs were put in Category I and carried the least MAPE.¹⁷⁵ The life-saving drugs in Category I had maximum price control, and the less-essential drugs in Category III had the least price

168. Aggarwal, *supra* note 146, at 7; Bejon Misra, *A Study on Availability and Prices of Medicines in India*, Voluntary Organisation in Interest of Consumer Education (VOICE) ch. 1, § 2 (2002), available at <http://nppaindia.nic.in/report/voicerep.html>.

169. Misra, *supra* note 168, ¶ 1.2.

170. Aggarwal, *supra* note 146, at 7.

171. *Id.*

172. See Kunnapallil, *supra* note 143, at 2–3.

173. Kunnapallil, *supra* note 143, at 2–3; Nat'l Pharm. Pricing Auth., Drug Policy 1986, available at http://www.nppaindia.nic.in/drug_pol86/txt1.html (discussing the 1979 Drug Policy and why it is being revised). A “formulation” is a “medicine processed out of . . . bulk drug or drugs . . . for internal or external use for or in the diagnosis, treatment, mitigation or prevention of disease in human beings.” Drug (Prices Control) Order 1995 § 2; see also Kunnapallil, *supra* note 143, at 1 n.3.

174. “MAPE” . . . means all costs incurred by a manufacturer from the stage of ex-factory cost to retailing and includes trade margin and margin for the manufacturer and it shall not exceed one hundred per cent for indigenously manufactured Scheduled formulations.” Drug (Prices Control) Order 1995 § 7. The DPCO 1995 uses the following formula: $R.P. = (M.C. + C.C. + P.M. + P.C.) \times (1 + MAPE/100) + ED$. *Id.* The pricing formula used in the 1979 Drug Policy was the following: retail price = $(MC+CC+PM+PC) \times (1+MAPE/100) + \text{excise duty}$. In this formula, “MC” represented the material cost including cost of bulk drugs/excipients, “CC” represented the conversion cost as per the dosage form, “PM” represented the cost of packing material suitable to dosage form, and PC represented the packaging charge worked out in accordance with established costing procedures. Sankar, *supra* note 156, at 6 n.14.

175. Kunnapallil, *supra* note 143, at 2.

control.¹⁷⁶ Drugs that did not fall within any of the three categories—the non-essential drugs—had no price control.¹⁷⁷ Government regulations favorable to public sector enterprises were encouraged, while stringent guidelines in the form of approval procedures were introduced to deter foreign companies.¹⁷⁸ Foreign equity participation was limited to 40% and later to a minimal 26%.¹⁷⁹ “[F]oreign companies had to indigenously manufacture bulk drugs and intermediates required for their formulations within a stipulated time frame.”¹⁸⁰ It was also mandatory for foreign companies to set up research and development facilities in the country and spend at least 4% of their turnover annually as recurring expenditure on research and development.¹⁸¹ Commenting on the effect of the DPCO 1979, Piyush Kunnappallil wrote the following:

Through this DPCO, around 80% of the Indian pharma industry (in value terms) was brought under strict price control. The [multinational companies] were the worst hit. With profitability falling steeply, they discontinued many products, especially the life saving products in Category I. In addition, the industrial licensing requirements made it impossible for [multinational companies] to introduce new products. The local players were, nonetheless, in a better position. They could obtain licenses much easily [sic] than [multinational companies] could. They were also able to speedily introduce new drugs. The local players, as a result, were able to keep the coverage of DPCO low and fight the might of established [multinational companies]. However, profitability wise, the Indian pharma sector went through its worst phase from 1979 to 1987.¹⁸²

3. Liberalization of the Pharmaceutical Sector

Further amendments to India’s drug policy were influenced by the Kelkar Committee Report in 1984.¹⁸³ The Drug Policy of 1986¹⁸⁴

176. *See id.* at 2–3; Aggarwal, *supra* note 146, at 7–8.

177. *See* sources cited *supra* note 176.

178. Aggarwal, *supra* note 146, at 7; *see also* Foreign Exchange Regulation Act, No. 46 of 1973.

179. Aggarwal, *supra* note 146, at 7.

180. *Id.*

181. *Id.*

182. Kunnappallil, *supra* note 143, at 3.

183. *See, e.g.*, MINISTRY OF FIN., FINAL REPORT ON INDIRECT TAXES ch. 2 (2002), available at http://finmin.nic.in/kelkar/final_idt.htm.

184. Drug Policy 1986.

established a new price control regime that resulted in another amendment to the DPCO 1979 in 1987.¹⁸⁵ The Drug Policy of 1986 was meant to liberalize the pharmaceutical sector to promote growth.¹⁸⁶ A minimum turnover of \$1,300,000 per annum (Rs. 400 lakhs) was required to enforce price control.¹⁸⁷ Pharmaceuticals having sufficient market competition (at least five active ingredient producers, at least ten formulators, and no more than forty percent of the market share) were exempt from price controls.¹⁸⁸ Consequently, the revised DPCO 1987¹⁸⁹ reduced the number of categories for exercising price control to two: Category I encompassed drugs required for the National Health Program,¹⁹⁰ and Category II encompassed drugs excluded from Category I but considered essential for health needs.¹⁹¹ The MAPE in Category I was 75% (from 40% in the previous DPCO), and the MAPE in Category II was 100% (from 55% in the previous DPCO).¹⁹² The number of drugs under price control was reduced to 142.¹⁹³ The Drug Policy of 1986 encouraged competition for the first time, while ensuring “abundant availability . . . of essential, life saving and prophylactic medicines of good quality” at reasonable prices.¹⁹⁴

By the beginning of 1991, India had begun the process of liberalization. The Industrial Policy of 1991 outlined a reduction of governmental control over industries and private participation in industrial development.¹⁹⁵ In line with the industrial policy, the Drug

nic.in/drug_pol86/txt1.html.

185. See generally Nat'l Pharm. Pricing Auth., Modifications in Drug Policy 1986 ¶ 8, available at http://www.nppaindia.nic.in/drug_pol86/modif86/mod1.html.

186. See Drug Policy 1986; Aggarwal, *supra* note 146, at 9.

187. Modifications in Drug Policy 1986 ¶ 22.7.2; Suresh Koshy, *The Effect of TRIPS On Indian Patent Law: A Pharmaceutical Industry Perspective*, 1 B.U. J. SCI. & TECH. L. 4, 27 (1995).

188. See sources cited *supra* note 187.

189. Patentmatics, Why India cannot have a clear Drug pricing policy after 57 years of Independence? (Sept. 2004), <http://www.patentmatics.org/pub2004/pub9f.htm> (discussing Drug (Prices Control) Order 1987).

190. Drug Policy 1986 ¶ 5.2.; see also CONFEDERATION OF INDIAN INDUS., REPORT ON THE PHARM. SECTOR IN INDIA 32 (2000), available at <http://www.intracen.org/sstp/Survey/pharma00/India-pharmacafe00-sds.pdf> [hereinafter REPORT ON THE PHARM. SECTOR IN INDIA]; Aggarwal, *supra* note 146, at 9.

191. Drug Policy 1986 ¶ 5.2.; see also REPORT ON THE PHARM. SECTOR IN INDIA, *supra* note 190, at 32; Aggarwal, *supra* note 146, at 9.

192. See Kunnapallil, *supra* note 143, at 3; Aggarwal, *supra* note 146, at 7–9.

193. Kunnapallil, *supra* note 143, at 3.

194. Drug Policy 1986 ¶ 1.5.

195. MINISTRY OF INDUS., STATEMENT ON INDUS. POL'Y (1991), available at <http://siadipp.nic.in/publicat/nip0791.htm>.

Policy of 1986 was revised in 1994 to accommodate this renewed vigor and to encourage competition, liberalization, and innovation.¹⁹⁶ Moreover, in 1994, India became a Member of the WTO. Consequently, a new price control regime was established in the form of the DPCO 1995.¹⁹⁷ Under the DPCO 1995, a uniform MAPE was introduced for formulations under price control.¹⁹⁸ The DPCO 1995 reduced the price-controlled pharmaceuticals to seventy-six.¹⁹⁹ Research and development initiatives were encouraged by exempting active ingredient manufacturers from price control for ten years, provided that inventive processes were developed through research and development.²⁰⁰ Foreign investment was allowed up to fifty-one percent, and industrial licensing was abolished for most bulk drugs and their formulations.²⁰¹ In 1997, the National Pharmaceutical Pricing Authority (NPPA) was created to review and revise existing price controls, monitor the prices of controlled and decontrolled drugs, and enforce the DPCO 1995.²⁰² The NPPA was also given the authority to recover excess amounts when manufacturers charge excessive prices for drugs falling within the price control.²⁰³

4. The Current Regime

Further liberalization ensued when FERA was replaced with the Foreign Exchange Management Act of 2000²⁰⁴ (FEMA), which allowed 100% foreign investment in a new or existing Indian company in the pharmaceutical manufacturing business. Such approval was permitted under the automatic route, which meant that the bureaucracy involving

196. See Govindaraj & Chellaraj, *supra* note 22, at 7; Kunnapallil, *supra* note 143, at 4.

197. Kunnapallil, *supra* note 143, at 4.

198. Drug (Prices Control) Order 1995 § 7. The possibility of allowing a uniform MAPE was first discussed in the Modifications in Drug Policy 1986. See Modifications in Drug Policy 1986 ¶¶ 9–10.

199. See Drug (Prices Control) Order 1995 first sched.; Kunnapallil, *supra* note 143, at 4.

200. Aggarwal, *supra* note 146, at 13.

201. See also OFFICE OF THE MINISTRY OF INDUS. & COMMERCE, HANDBOOK OF INDUS. POL'Y & STATISTICS 2001, MODIFIED POL'Y FOR DRUGS & PHARMS. INDUS. ch. 1, Ex. No. 47, Press Note No. 4 (1994 Series), available at <http://eaindustry.nic.in/handout.htm> (follow "Press Note No. 1 (1993) to 1 (1995 Series)" hyperlink).

202. Misra, *supra* note 168, ¶ 1.4; Gazette of India, O. No. 43 (E) (1970). The Order was issued by the Government of India pursuant to the Modifications in Drug Policy 1996. The NPPA was established as an independent body of experts. REPORT ON THE PHARM. SECTOR IN INDIA, *supra* note 190, at 29, 36; Misra, *supra* note 168, ¶ 1.4.

203. Misra, *supra* note 168, ¶ 1.4.

204. Foreign Exchange Management Act, No. 42 of 1999.

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prior foreign approval was done away with.²⁰⁵ Similarly, the Pharmaceutical Policy of 2002 was made with the dual objectives of reducing price control and improving indigenous research and development.²⁰⁶ Price control now can be exercised in two circumstances: (1) if a particular bulk drug has an annual turnover of Rs. 2500 lakhs (Rs. 25 Crore) and a single firm has 50% or more of the market share; or (2) if a bulk drug had a turnover between Rs. 1000 lakhs (Rs. 10 Crore) and Rs. 2500 lakhs (Rs. 25 Crore) and a single firm has 90% or more of the market share.²⁰⁷ The number of drugs under price control was reduced to twenty-eight.²⁰⁸ Price control was generally abolished in all other cases, although the government retained the right to intervene in the market should prices increase abnormally.²⁰⁹ The Pharmaceutical Policy of 2002 also allowed 100% foreign investments for most categories of drugs, and foreign companies were allowed to import medication into India.²¹⁰ The Policy has increased the MAPE to 100% for all indigenously manufactured drugs and imposed a margin on

205. Ames Gross & Sunil Patel, *Indian Pharmaceutical Industry: Market, Regulatory, Import and Investment Regime*, PACIFIC BRIDGE MED. § 10.4 (2002), available at http://www.pacificbridgemedical.com/publications_India2.html.

Automatic approval is not allowed in cases where industrial licensing is mandatory. Further, [the] “automatic approval” route is not available to foreign companies which either have or have had in the past a joint venture/technical collaboration/trademark agreement for the same or allied product. In such a case the foreign investor will have to apply to the FIPB [Foreign Investment Promotion Board]. A foreign investor may also acquire the whole or part of an existing company by buying out existing shareholders. For this, prior permission will be needed from the FIPB and thereafter the RBI.

Id.

206. Nat'l Pricing Auth., *Pharmaceutical Policy 2002* ¶ 3, available at <http://nppaindia.nic.in/may-2002/policy-02.html>.

207. *Id.* § VI(a); Sankar, *supra* note 156, at 6.

208. Sankar, *supra* note 156, at 6; see Foreign Exchange Regulation Act, No. 46 of 1973; cf. Foreign Exchange Management Act, No. 42 of 1999.

209. *Pharmaceutical Policy 2002* § VI(a). The government will exercise price control based on the Moving Annual Total (MAT) if:

(a) The total MAT value, arrived at as in sub-para (iv) above, in respect of any particular bulk drug is more than Rs.2500 lakhs (Rs.25 Crore) and the percentage share, as defined in sub-para (v) above, of any of the formulators is 50% or more[, or]

(b) The total MAT value, arrived at as in sub-para (iv) above, in respect of any particular bulk drug is less than Rs.2500 lakhs (Rs.25 Crore) but more than Rs.1000 lakhs (Rs.10 Crore) and the percentage share, as defined in sub-para (v) above, of any of the formulators is 90% or more.

Id.

210. *Pharmaceutical Policy 2002* ¶ 2.

importers' profitability at 50%.²¹¹ Finally, the Policy outlines that it will encourage the "generation of intellectual property" by indigenous companies.²¹²

The various drug price control orders present an interesting trend. When India became independent, the pharmaceutical sector was dominated by multinational companies. In the mid-1970s, foreign equity participation was limited to 74%, further reduced to 40%, and then reduced to 26% by 1986.²¹³ With the development of the pharmaceutical industry, foreign participation was again encouraged up to a maximum of 51% in 1994.²¹⁴ By 2002, a country confident of its pharmaceutical abilities was willing to allow 100% foreign participation and importation of pharmaceuticals.²¹⁵ Similarly, a country that was struggling in the 1970s to properly copy drugs for local requirements filed 33% of the global filings of drug master files and abbreviated new drug applications with the United States Food and Drug Administration in 2004.²¹⁶ That same year, Ranbaxy, an Indian drug company, was featured among the top ten generic drug companies in the world.²¹⁷ Wockhart, another Indian company, does business in over ninety countries.²¹⁸ Also, in 2004, Nicholas Piramal India Limited acquired the global inhalation anesthetics business of Rhodia Organique Fine Limited (Rhodia), U.K.²¹⁹ The same company, in 2005, invested 17% equity in BioSyntech Inc., a Canadian biotech research company.²²⁰ The Indian pharmaceutical industry itself is ranked fourth in the world in terms of volume and thirteenth in terms of value.²²¹ In creating the generic drug industry, the Indian policy has emphasized the availability of reasonably priced high quality drugs since 1947.²²² The emphasis on

211. *Id.* §§ VI(b), VI(c).

212. *Id.* § V(b).

213. Aggarwal, *supra* note 146, at 6–7.

214. *Id.* at 8.

215. *Id.* at 24.

216. Sankar, *supra* note 156, at 8.

217. *Id.* at 9.

218. *Id.* at 10.

219. Press Release, Nicholas Piramal India Ltd., Nicholas Piramal Acquires Rhodia's global Inhalation Anaesthetics Business (Dec. 17, 2004), <http://www.nicholaspiramal.com/docs/NPIL-RhodiaIA.pdf>.

220. Press Release, Nicholas Pirmal India Ltd., Nicholas Piramal India Limited Invests 17% equity in Canadian Biotech Research Company—Biosyntech, Inc. (July 7, 2005), http://www.nicholaspiramal.com/media_pr20.htm.

221. Sankar, *supra* note 156, at 12.

222. *See generally* 1ST FIVE YEAR PLAN, *supra* note 38.

reasonable price of pharmaceuticals has helped the development of the generic drug industry. The development of a generic drug industry has helped India tackle its public health woes. The low cost of medicines resulted in public health becoming accessible. The Indian government gained the ability to deal with several public health conditions or a threat to public health independently without having to account for foreign imports. This scenario should be contrasted with South Africa, which was forced to repeatedly ask the United States to reduce the cost of drugs in 1996 to handle a public health crisis.²²³ Similarly, increased private production of generic drugs allowed the government to ensure that infrastructural constraints impeding accessibility to medication were simultaneously tackled.²²⁴

IV. FIRST AMONG THE INEQUALS

The important question is whether the Indian experience can be replicated in other nations to deal with the current health pandemics, given the various constraints imposed by the WTO. The attempt to resolve this issue necessitates that we re-examine the objectives of becoming a TRIPs signatory. The TRIPs Agreement meant to harmonize intellectual property while achieving the specific objectives of social and economic welfare outlined in Articles 7 and 8. From this perspective, solutions to the paragraph 6 issue should be based on the notion that public health is an important component for achieving national and global objectives. Unstable public health conditions can potentially upset national productivity, cause international disruption to trade, and destabilize more economies.²²⁵ The Indian experience is

223. See Helene Cooper et al., *AIDS Epidemic Traps Drug Firms in a Vice: Treatment vs. Profits*, WALL ST. J., Mar. 2, 2001, at A1 (discussing the 1996 meeting between Jones Popovich, the American trade representative, and AIDS activists on the South Africa issue).

224. The various plans show that the development of the indigenous pharmaceutical industry forced the government to increasingly look at infrastructural issues that were required to facilitate the industry. See *supra* note 38. This included improving the infrastructure to access the drugs, hospitals, health care education, and dissemination of information. All of which are vital for improving the national public health systems.

225. See generally Rebecca Buckman, *Outbreak Crimps Toy Industry's Buying Season*, WALL ST. J., Apr. 30, 2003, at B1 (discussing how the outbreak of Severe Acute Respiratory Syndrome (SARS) in China has affected sales in even smaller industries, like the toy industry, and impacted sales of several American retailers); Lori Bollinger & John Stover, *Country Report, The Economic Impact of AIDS in South Africa*, POL'Y (Futures Group Int'l Bath, Eng.), Sept. 1999, available at <http://www.policyproject.com/pubs/SEImpact/southafr.pdf> (discussing how the epidemic outbreaks potentially affect several sectors of the international economy and stunt international markets); Peter Yu, SARS and the Patent Race: An Introduction to the "Patent Law, Social Policy, and Public Interest" Symposium (unpublished

useful for demonstrating that the TRIPs Council must appreciate that governments need to devise solutions by prioritizing *national* needs before catering to *international* trade. Such understanding requires that countries are allowed (1) to use patent policies to achieve national ambitions but pursue their own levels of development and (2) to emphasize indigenous industrialization without disrupting the markets of other WTO Members.

Both of the above are supported by the historical experiences of developed nations. Historically, every developed nation used patent mechanisms to protect indigenous industries.²²⁶ Even now, the developed countries have been unable to open the agriculture sector to promote fair trade by reducing subsidies, which harms the local farming sector but benefits international trade. Similarly, the patent development curve in developed nations, particularly the United States and the United Kingdom, moved steadily upwards from the early 1800s until the mid-1900s before a sustainable patent system was crystallized. Thus, developed nations took about one hundred and fifty years to establish a sophisticated patent regime. Forcing developing countries to “catch up” and ease into the current patent regime within a matter of only ten years may be unwise, because it pressures developing nations to make inappropriate choices from an incomplete understanding of patent mechanisms.

Future solutions should prioritize local rather than global needs by increasing the term of exemption for pharmaceutical patents or discriminatorily pricing pharmaceuticals in a manner consistent with economic conditions in developing and least developed nations. Likewise, exceptions can be created by further extending the transitional periods for pharmaceutical patents.²²⁷ Alternatively, under the Doha Declaration, governments may be allowed to compulsorily license or duplicate drugs, provided that they impose adequate restrictions on parallel importation of generic drugs into the developed nations.²²⁸ Similarly, exceptions should allow the manufacturers of

manuscript), available at <http://ssrn.com/abstract=451640>.

226. See generally Ragavan, *supra* note 10 (providing a comparative study on historical development).

227. E-mail from Professor Peter K. Yu, Assistant Professor of Law, Michigan State University College of Law, to Srividhya Ragavan, Associate Professor of Law, University of Oklahoma Law Center (Sept. 25, 2005, 15:36 CST) (on file with author).

228. See Srividhya Ragavan, *The Jekyll and Hyde Story of International Trade: The Supreme Court in PhRMA v. Walsh and the TRIPS Agreement*, 38 U. RICH. L. REV. 777, 796 (2004).

generic drugs, like India, to export drugs to African countries without the impediments of Article 31(f).²²⁹ The dispute settlement body of the WTO should take account of national responsibilities when deciding on derogation from international obligations. Thus, several solution alternatives are available to prioritize local rather than global needs and must be fully explored. Solutions prioritizing global trade ahead of domestic needs may potentially harm the globe itself by destabilizing the economies of the world.

CONCLUSION

Something had to be right for the industry to be where it is today. While the Indian patent system lacked a western sense of sophistication, it certainly achieved its national objectives. At the tenth anniversary of TRIPs, we should go back to the drawing board to determine the cost and benefits of having placed international obligations above national needs. With bird-flu threatening to become an epidemic, it is important to appreciate that some national issues may actually become a barrier to international trade if left unsolved. At the very minimum, such a cost-benefit analysis would sensitize Members to the unique national impediments of other Members to embracing the international trade regime.

229. See TRIPs Agreement, *supra* note 1, art. 31(f).