March 2016

The Experiences of TRIPS-Compliant Patent Law Reforms in Brazil, India, and South Africa and Lessons for Bangladesh

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THE EXPERIENCES OF TRIPS-COMPLIANT PATENT LAW REFORMS IN BRAZIL, INDIA, AND SOUTH AFRICA AND LESSONS FOR BANGLADESH*

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I. BACKGROUND

The global debate over the consequences of patenting essential products, such as medicines, is not new.[1] Countries have therefore developed divergent approaches; some countries[2] have chosen to exempt

* The Author would like to thank Professor Thomas Cottier (World Trade Institute, University of Bern, Switzerland) and Professor Marianne Levin (Department of Law, Stockholm University, Sweden) for their valuable comments on the first draft of this study.

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1. *See* Jane O. Lanjouw, *The Introduction of Pharmaceutical Product Patents in India: "Heartless Exploitation of the Poor and Suffering"?* 2 (Yale Univ. Econ. Growth Ctr., Discussion Paper No. 775, 1997), *available at* http://www.econ.yale.edu/growth_pdf/cdp775.pdf ("almost 50 developing countries, which were not granted patent protection for pharmaceuticals during the Uruguay Round, fiercely resisted including pharmaceuticals under the patent regime, claiming that vastly higher drug prices would be associated with such patents").

2. Countries such as Italy, Switzerland, Brazil, and India prohibited pharmaceutical patent protection for a considerable period of time to encourage "learning by imitation" and promote the local pharmaceutical industry. *See* Xuan Li, *The Impact of Higher Standards in Patent Protection for Pharmaceutical Industries under the TRIPS Agreement: A Comparative Study of China and India*, 31 WORLD ECON. 1367, 1368 (2008).

medicines from all or parts of patent law,[3] while other countries, such as Canada and Australia, have patent regimes moderated by mechanisms to control prices or to facilitate local production under compulsory licenses.[4] Countries such as India, South Africa, and Brazil have adopted other legal means to allow competitors to circumvent the negative effects of patents by allowing the patenting of processes but not of products.[5]

While implementing a patent law that complies with the agreement on Trade Related aspects of Intellectual Property Rights (TRIPS or TRIPS Agreement),[6] as adopted under the World Trade Organization (WTO), countries such as India, Brazil, and South Africa were confronted with two major concerns: first, the future of the local pharmaceutical industry, and second, access to affordable medicines.[7] These countries' reactions to TRIPS have depended much on the nature of their pharmaceutical industry because that industry is important both economically and socially; however, their intellectual property rights regimes were not TRIPS-compliant. Therefore, these countries were confronted with the issue of how to manage the continued viability of

3. Historically, product patents have been excluded from protection in most developed countries. For example, in France, product patent protection was prohibited under a law effective July 5, 1844, and only limited patent protection has been permitted since January 2, 1966. In Germany, product patents were explicitly excluded under a law effective May 25, 1877, but were then introduced on September 4, 1967. In Switzerland, product patents for pharmaceuticals were explicitly prohibited by the Constitution and were only introduced in 1977. In Italy, pharmaceutical patents were prohibited until 1978. In Spain, product patents were introduced in 1986, just after the country's accession to the European Economic Community (EEC), and the relevant laws came into effect in 1992. The rationale behind not granting product patent protection for pharmaceuticals in each of the example countries was to allow local pharmaceutical companies to imitate and produce patented medicines by using new processes. *See* MICHELE BOLDRIN & DAVID K. LEVINE, AGAINST INTELLECTUAL MONOPOLY 216 (2008).

4. *See* Lydia Mugambe, *The Exception to Patent Rights under the WTO-TRIPS Agreement: Where is the Right to Health Guaranteed?* 21 n.53 (Oct. 2002) (unpublished LL.M. Dissertation, Univ. of Western Cape) (on file with author) ("In an affidavit filed in support of the Treatment Action Campaign, Professor Colleen Flood of the University of Toronto explained how patent law in Canada had evolved since 1923 with the 'expressly stated goal of making food and medicine affordable to the public' . . . . To facilitate this, various legal devices, including compulsory licensing and administrative mechanisms (a Patented Medicines Prices Review Board), were established. However, in common with developing countries, Canada has been pressured to strengthen intellectual property protection. Conversely, in Australia, the government negotiate with industry as a monopolist purchaser and is thus able to provide drugs to the community at greatly reduced prices under a 'Pharmaceutical Benefits Scheme.'").

5. *See* Li, *supra* note 2, at 1368-69.

6. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [hereinafter TRIPS or TRIPS Agreement].

7. *See* Gopakumar K. M., *Product Patents and Access to Medicines in India: A Critical Review of the Implementation of TRIPS Patent Regime*, 3 LAW & DEV. REV. 326, 326 (2010).

the local pharmaceutical industry and provide access to affordable medicines while implementing TRIPS.

India, Brazil, and South Africa have already implemented TRIPS-compliant patent laws[8] and have introduced patent protection for both pharmaceutical products and processes.[9] Those countries' experiences of utilizing TRIPS flexibilities and other possible policy mechanisms provide important lessons for Least Developed Countries (LDCs), such as Bangladesh, as they progress toward TRIPS compliance and adopting pharmaceutical patents.

This study analyzes the policy options used by Brazil, India, and South Africa in their transitions to a TRIPS-compliant patent law and their introduction of pharmaceutical patents. This comparative review can be used to explore possible policy options that can also be utilized by LDCs, including Bangladesh.

Although developing countries such as India, China, and Brazil, played very vital roles as producers and exporters of generic copies of brand-name patented products,[10] they can no longer produce such pharmaceuticals due to the introduction of TRIPS-compliant patent regimes in their respective countries.[11] Only LDCs like Bangladesh can still do so, until January 1, 2016, due to the Doha waiver of 2002for pharmaceutical patents.[12] The TRIPS Council decision of June 11, 2013, approved another eight-year extension permitting non-compliance with

8. *See* Prabhu Ram, *India's New "Trips-Compliant" Patent Regime Between Drug Patents and The Right to Health*, 5 CHI.-KENT J. INTELL. PROP. 195, 195 (2006); LUCIANO MARTINS COSTA PÓVOA, ROBERTO MAZZOLENI & THIAGO CALIARI, *Innovation in the Brazilian Pharmaceutical Industry Post-TRIPS*, *in* TRIPS COMPLIANCE, NATIONAL PATENT REGIMES & INNOVATION: EVIDENCE & INNOVATION 16, 21 (Sunil Mani & Richard R. Nelson eds., 2013), *available at* http://www.ungs.edu.ar/globelics/wp-content/uploads/2011/12/ID-197-Caliari-Mazzoleni-Caliari-Privatization-of-Knowledge-Intellectual-Property-Right.pdf; Bernard Maister & Caspar van Woensel, *Is Compliance Enough: Can the Goals of Intellectual Property Rights Be Achieved in South Africa?* 2 (Leiden Law Sch. Legal Studies Research Paper Series, 2013), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2213263.

9. Ram, *supra* note 8, at 198; Catherine Tomlinson & Lotti Rutter, *The Economic & Social Case for Patent Law Reform in South Africa*, Research Paper (Treatment Action Campaign), Feb. 2014, at 4, *available at* http://www.tac.org.za/sites/default/files/The%20Economic%20and%20Social%20Case%20for%20Patent%20Law%20Reform%20in%20South%20Africa.pdf.

10. *See Developing Countries*, INT'L STAT. INST. (Jan. 1, 2014), http://www.isi-web.org/component/content/article/5-root/root/81-developing.

11. India implemented a TRIPS-compliant patent law on January 1, 2005; Brazil implemented one in May 1997; and South Africa implemented one in 1997. *See* Monirul Azam, *Globalizing Standards of Patent Protection in WTO Law and Policy Options for Bangladesh: An Appraisal* 10 (2011) (on file with author); William W. Fisher III & Cyrill P. Rigamonti, *The South Africa AIDS Controversy: A Case Study in Patent Law and Policy*, HARV. L. SCH.: THE L. & BUS. OF PAT. 11 (last updated Feb. 10, 2005), http://cyber.law.harvard.edu/people/tfisher/South%20Africa.pdf.

12. Azam, *supra* note 11, at 3.

most TRIPS obligations until 2021,[13] which is good news for LDCs like Bangladesh. This extension of transitional periods for LDCs concerns the entire TRIPS Agreement (with the exception of articles 3, 4, and 5 related to national treatment and most-favored nation treatment).[14] Thus, the extension removes LDCs' obligations with regard to pharmaceutical patents and data protection until at least July 1, 2021.[15] The specific pharmaceutical waiver of 2002, which runs until January 1, 2016, could also be subject to a different extension request that could extend well beyond 2021.[16] These extensions create potential export markets for generic producers from LDCs such as Bangladesh because countries that have already implemented TRIPS-compliant patent laws, such as India and Brazil, cannot produce generics of patented medicines.[17] Again, these countries' experiences will be examined herein to understand not only how these countries implemented their TRIPS-compliant patent laws, but also the impact these laws have had.

The TRIPS Agreement itself provides a number of flexibilities for member states to determine their own approach regarding the relationship between intellectual property rights and access to pharmaceuticals.[18] The World Intellectual Property Organization Committee on Development and Intellectual Property defines *flexibilities* as "legal tools that countries can use as they see fit in their national developmental plans and within the framework of the mandatory standards of international obligations."[19] In the context of the TRIPS Agreement, the Committee further stated, "the term flexibilities means that there are different options through which TRIPS obligations can be transposed into national law so that national interests are accommodated and yet TRIPS provisions and principles are complied with."[20] The TRIPS Agreement permits the following flexibilities:

13. Council for Trade-Related Aspects of Intellectual Property Rights, *Extension of the Transition Period under Article 66.1 for Least Developed Country Members*, IP/C/64 (June 11, 2013), http://www.wto.org/english/tratop_e/trips_e/ta_docs_e/7_1_ipc64_e.pdf.

14. *Id*.

15. E-mail from Ellen 't Hoen to E-drug readers (June 12, 2013, 14:36 +0200), *available at* http://www.essentialdrugs.org/edrug/archive/201306/msg00010.php.

16. *Id.*

17. Azam, *supra* note 11.

18. "Members shall give effect to the provisions of this Agreement. Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement. Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice." TRIPS Agreement, *supra* note 6, at art. 1.1.

19. *See* World Intellectual Property Organization [WIPO], *Patent Related Flexibilities in the Multilateral Legal Framework and Their Legislative Implementation at the National and Regional Levels*, at 3, CDIP/5/4 (Mar. 1, 2010).

20. *Id.* at 12.

> Define the nature of the invention and regulate the criteria of patentability within the broad framework of TRIPS Agreement rules;
>
> Establish exceptions to patent rights;
>
> Grant government use and compulsory licenses;
>
> Provide a range of options with respect to the protection of data submitted for regulatory purposes;
>
> Determine country-based policies with respect to exhaustion of rights and allow parallel importation of medicines;
>
> Utilize the "unfair commercial use" option of "protection of undisclosed test data," which can be restricted and limited to promote generic competition and reduce prices.[21]

However, these flexibilities are ambiguous and therefore should be implemented at the national level by considering national developmental goals, the public interest, and the particular country's stage of development.[22] The experiences of Brazil, India, and South Africa will be examined herein against the available TRIPS flexibilities – and other governmental interventions that do not conflict with the TRIPS obligations – so as to determine legislative and policy options that LDCs like Bangladesh might adopt.

II. THE EXPERIENCE OF BRAZIL

Brazil's experience regarding TRIPS-compliant patent law for pharmaceuticals and its societal and national obligation to ensure access to medicines represents a situation in which exploitation by multinational pharmaceutical companies was largely thwarted. This attempted exploitation also gave way to significant reforms in public health policy and reinstated local drug companies as viable contenders in

21. Article 39.3 of the TRIPS Agreement requires member countries to establish protection for submitted test data. However, this requirement is in fact narrowly construed, and countries maintain substantial flexibility in implementation. The public interest in limiting protection for data is to promote competition and to ensure that data protection does not become the means to block the timely entrance of generic competitors to off-patent drugs, because generic competitors drive down price and thereby promote greater access to medicines. *See* CARLOS M. CORREA, PROTECTION OF DATA SUBMITTED FOR THE REGISTRATION OF PHARMACEUTICALS: IMPLEMENTING THE STANDARDS OF THE TRIPS AGREEMENT 47 n.30 (2002).

22. *See* CARLOS M. CORREA, INTELLECTUAL PROPERTY RIGHTS, THE WTO AND DEVELOPING COUNTRIES: THE TRIPS AGREEMENT AND POLICY OPTIONS 6-7 (2000); *see also* CHRISTOPHER MAY & SUSAN K. SELL, INTELLECTUAL PROPERTY RIGHTS: A CRITICAL HISTORY 162 (2006).

the domestic market.[23]

Brazil's public health oriented, TRIPS-compliant approach could be a perfect model for other developing countries and LDCs to utilize. Economic and technological collaboration between the public and private sectors have created a favorable condition for political alliance as well as hospitable ground for balancing local pharmaceutical innovation and access to medicines.[24] Brazil, with a population of over 180 million, is not only an important pharmaceutical market (with sales estimated at $12.7 billion in 2008),[25] it is also an important center for research and development (R&D) with clinical trial facilities, low development costs, and qualified professionals.[26] Although the Brazilian pharmaceutical industry is dominated by multinational corporations, issues surrounding access to medicines have come to the forefront: affordability is one of the main problems in Brazilian health care.[27] About 20% of the 370 established pharmaceutical companies in Brazil are foreign (mainly from Europe or the United States), and it is estimated that they control about 70% percent of the pharmaceutical market in Brazil.[28] Given this tension, Brazil has attempted to create a balance within its intellectual property regime between pharmaceutical innovation and access to medicines.

In 1883, Brazil was one of 16 countries that signed the Paris Convention.[29] This pre-TRIPS convention allowed countries to utilize the patent system as an instrument of economic and technological development.[30] Under the Paris Convention, each country could

23. *See* MATTHEW FLYNN, *Corporate Power and State Resistance: Brazil's Use of TRIPS Flexibilities for its National AIDS Program, in* INTELLECTUAL PROPERTY, PHARMACEUTICALS AND PUBLIC HEALTH - ACCESS TO DRUGS IN DEVELOPING COUNTRIES 149, 149-50 (Kenneth C. Shadlen et al. eds., 2011).

24. *See* Kenneth C. Shadlen, *The Politics of Patents and Drugs in Brazil and Mexico: The Industrial Bases of Health Policies*, 42 COMP. POL. 41, 55 (2009).

25. Press Release, Business Wire, Research and Markets: Pharmaceutical Pricing and Reimbursement in Brazil: Population and Demand for Pharmaceuticals is Forecast to Increase in the Next 12 Years (Jan. 5, 2010) (on file with author).

26. *Id.*

27. *Id.*

28. Kermani Faiz, *Brazil-Not a Market for Faint Hearted*, CONTRACT PHARMA (Oct. 11, 2005), http://www.contractpharma.com/issues/2005-10/view_features/regional-roundup-brazil/.

29. Maria Auxiliadora Oliveira et al., *Brazilian Intellectual Property Legislation, in* INTELLECTUAL PROPERTY IN THE CONTEXT OF THE WTO TRIPS AGREEMENT: CHALLENGES FOR PUBLIC HEALTH 151, 153 (Jorge A. Z. Bermudez & Maria Auxiliadora Oliveira eds., 2004). *See also WIPO-Administered Treaties*, WIPO, http://www.wipo.int/treaties/en/ShowResults.jsp?treaty_id=2 (last visited Nov. 24, 2014).

30. *See* WIPO, *The Impact of the International Patent System on Developing Countries: A Study by Getachew Mengistie*, at 16 (Aug. 15, 2003), www.wipo.int/edocs/mdocs/govbody/en/a_39/a_39_13_add_1.doc.

establish its own intellectual property regime in a way that would favor its own national policies.[31] Brazilian industrial property legislation granted patent protection for pharmaceutical processes and products until 1945.[32] In fact, Brazil was the fourth country in the world and the first county in Latin America to protect the rights of inventors.[33]

The 1945 legislation was modified to exclude the protection of inventions related to foodstuffs, medicines, materials, and substances obtained by chemical means or processes.[34] In 1969, a change in the Brazilian Industrial Property Code completely eliminated patenting in the pharmaceutical sector.[35] However, when Brazil became a member of the WTO,[36] it was required to implement a TRIPS-compliant patent regime that included patent protection for both pharmaceutical products and processes.[37] Brazil institutionalized the TRIPS Agreement by a Presidential Decree in December 1994,[38] and its TRIPS-compliant regime came into effect on May 14, 1996, thereby instituting both pharmaceutical product and process protection.[39]

Brazil began granting patents in the pharmaceutical sector in May 1997.[40] Brazil was criticized by public health groups for implementing a TRIPS-compliant law[41] that failed to fully utilize the flexibilities and safeguards in the TRIPS Agreement and failed to ensure access to medicines.[42] Given this criticism, the Brazilian government took steps to facilitate access to drugs by introducing a number of amendments to its patent law, including a strong compulsory licensing regime.[43] In response to these provisions, multinational pharmaceutical companies and developed countries, particularly the United States, objected,[44] and a WTO dispute was initiated by the United States against Brazil.[45] Daya

31. *Id.*
32. Oliveira et al., *supra* note 29, at 154.
33. *Id.* at 153.
34. *Id.* at 158.
35. *Id.*
36. Brazil has been a member of the WTO since January 1, 1995. *Brazil and the WTO*, WORLD TRADE ORG., http://www.wto.org/english/thewto_e/countries_e/brazil_e.htm (last visited Nov. 18, 2014).
37. *See* John T. Masterson, Jr., *Overview of Intellectual Property Rights and the TRIPS Agreement*, COMMERCE.GOV (Aug. 12, 2002), http://www.osec.doc.gov/ogc/occic/ipr.html.
38. Oliveira et al., *supra* note 29, at 153.
39. *Id.*
40. *Id.*
41. *Id.*
42. *See, e.g.*, Chakravarthi Raghavan, *U.S. to Withdraw TRIPS Dispute against Brazil*, THIRD WORLD NETWORK (June 25, 2001), http://www.twnside.org.sg/title/withdraw.htm.
43. Faiz, *supra* note 28.
44. Oliveira et al., *supra* note 29.
45. On January 31, 2001, the United States requested a WTO Dispute-Settlement Panel to

Shanker noted the main points of contention between the United States and Brazil: local working requirements in the Brazilian Industrial Property Law, parallel importing in the same law, and Brazil's request for consultation for the alleged violation of WTO provisions in United States patent law (regarding patents that were developed with the help of public funding).[46]

In its complaint, the United States asserted that article 68 of Brazil's Industrial Property Law imposed a requirement that a patent be subject to compulsory licensing if not worked in the territory of Brazil, not used to manufacture the product in Brazil, or the patented process was not used in Brazil.[47] The United States viewed these provisions as conflicting with articles 27.1[48] and 28.1[49] of the TRIPS Agreement. The Brazilian law also provided that if a patent owner chose to exploit the patent through importation, others could either import the patented product or obtain the product from the patented process.[50] As Chakravarthi Raghavan stated that "the Brazilian law also provided that if a patent owner chose to exploit the patent through importation, others could either import the patented product or obtain the product from the patented process."[51]

In reply to the complaint, Brazil contended that articles 204[52] and

resolve its differences with Brazil over Brazil's 1996 Industrial Property Law. *See Dispute Settlement: Dispute DS224*, WORLD TRADE ORG., http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds224_e.htm (last visited Nov. 18, 2014).

46. Daya Shanker, Fault Lines in the World Trade Organization: An Analysis of the TRIPS Agreement and Developing Countries 33 (2005) (unpublished Ph.D. dissertation, University of Wollongong), *available at* http://ro.uow.edu.au/theses/497.

47. Article 68(I) of Brazilian Industrial Property Law provides that the following will occasion a compulsory license: "non-exploitation of the object of the patent within the Brazilian territory for failure to manufacture or incomplete manufacture of the product, or also failure to make full use of the patented process, except cases where this is not economically feasible, when importation shall be permitted[.]"

48. Article 27(1) of the TRIPS Agreement, *supra* note 6, provides that "patents shall be available for 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 . . . [P]atents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced."

49. Article 28(1) of the TRIPS Agreement, *supra* note 6, deals with the exclusive rights of the patent owner to "prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product."

50. *See* Raghavan, *supra* note 42.

51. *Id.*

52. 35 U.S.C. § 204 (2012) ("Notwithstanding any other provision of this chapter, no small business firm or nonprofit organization which receives title to any subject invention and no assignee of any such small business firm or non-profit organization shall grant to any person the exclusive right to use or sell any subject invention in the United States unless such person agrees that any products embodying the subject invention or produced through the use of the subject invention will be manufactured substantially in the United States.").

209[53] of the United States patent code[54] had similar provisions; consequently, Brazil raised a dispute against the United States over these provisions.[55] In the end, the complaint was withdrawn due to pressure from public health organizations and human rights groups both from within and outside the United States.[56] Daya Shanker noted that

> the weakness of [Brazil's] position was known to the United States[,] but the main purpose of initiating the dispute appear[s] to be to communicate potential United States displeasure and possible action against weak and poor countries of the Third World so that they would not incorporate such provisions in their patent acts and should such provisions have already been incorporated in their patent acts, that they would not use them.[57]

The success of the United States action was evident from the fact that South Africa, Kenya, and many other African countries refrained from using local working provisions to manufacture anti-AIDS pharmaceuticals even when a substantial part of their population was suffering from AIDS.[58]

However, Brazil managed to obtain price reductions from big pharmaceutical companies by threatening to break patents through the issue of a compulsory license.[59] For example, in 2007, Brazil decided to

53. 35 U.S.C. § 209 (2012) ("[I]n the case of an invention covered by a foreign patent application or patent, the interests of the Federal Government or United States industry in foreign commerce will be enhanced . . . . A Federal agency shall normally grant a license . . . to use or sell any federally owned invention in the United States only to a licensee who agrees that any products embodying the invention or produced through the use of the invention will be manufactured substantially in the United States.").

54. 35 U.S.C. §§ 1 *et seq*. (2006).

55. The United States Patent Law, as consolidated in 2007, among other things, provides that when any patent is obtained, as a result of research funded by the United States and its governmental agencies, the patent should be worked in the United States and cannot be licensed for production elsewhere. *See* 35 U.S.C. § 209 (2012).

56. Médecins Sans Frontières (MSF) and other public health groups, along with 120 Brazilian non-governmental organizations, requested the United States government withdraw its request for a WTO dispute settlement procedure on the Brazilian patent law. The United States brought a complaint before the WTO Dispute Settlement Body (DSB) in Geneva, requesting measures that might handicap the successful Brazilian AIDS program, which is largely based on Brazil's ability to manufacture affordable treatment. *See* GATT Secretariat, *Dispute Settlement: Brazil – Measures Affecting Patent Protection*, WT/DS199/1 (July 5, 2001), *available at* http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds199_e.htm.

57. Shanker, *supra* note 46, at 111.

58. *See* Daya Shanker, *India, the Pharmaceutical Industry and the Validity of TRIPS*, 5 J. WORLD INTELL. PROP. 315, 331 (2002); *see also* Amir Attaran & Lee Gillespie-White, *Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa?*, 286 J. AM. MED. ASS'N 1886, 1886 (2001).

59. *See* Jerome H. Reichman, *Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options*, 37 J. L. MED. & ETHICS 247, 249-50 (2009).

issue a compulsory license for the HIV drug *Storcrin* (the brand name for *Efavirenz*) after failing to secure a considerable discount from the patent owner.[60] The then-President of Brazil signed a compulsory license for *Efavirenz* on the grounds of public interest,[61] which permitted the purchase of the patented pharmaceutical from generic suppliers.[62]

Brazil also established certain rules concerning the granting of compulsory licenses in cases of national emergency and public interest.[63] The definition of *public interest* is broad, "including such matters as public health, nutrition, the protection of the environment, and elements of primordial importance for technological, social or economic development. The possibility to provide compulsory licensing in each of these cases implies that the fulfillment of the [country's] most basic needs would be covered."[64] Thus, Brazil successfully utilized the compulsory license flexibility of TRIPS to protect public health.

In addition to compulsory license provisions, Brazilian law also utilized other TRIPS flexibilities such as parallel importing;[65] experimental use, early working, or *Bolar* exceptions;[66] and a strict novelty requirement.[67] Using parallel-import flexibility, Brazil permitted

60. *See generally* James Packard Love, *Recent Examples of the Use of Compulsory Licenses on Patents*, KNOWLEDGE ECOLOGY INT'L (Research Note 2007:2), *available at* http://www.keionline.org/misc-docs/recent_cls.pdf; Stephen Jenei, *Brazil Signs Compulsory License for Efavirenz*, PATENT BARISTAS (June 6, 2007), http://www.patentbaristas.com/archives/2007/06/06/brazil-signs-compulsory-license-for-efavirenz/.

61. *See* Garima Gupta & Avih Rastogi, *Intellectual Property Rights: Who Needs Them?* 230 (Ctr. for Civ. Soc'y, Working Paper No. 0040, 2002), *available at* http://ccs.in/internship_papers/2002/24.pdf.

62. *See* Sangeeta Shashikant, *Brazil Moves on Compulsory License After Failed Talks with Drug Company*, THIRD WORLD NETWORK (May 3, 2007), http://www.twnside.org.sg/title2/wto.info/twninfo050703.htm ("The Ministerial Ordinance No. 866 dated April 24, 2007 declared that 'there exists the possibility of compulsory licensing of patents in the public interest,' as provided for in national laws, and decided 'to declare public interest in relation to *Efavirenz* for the purposes of the granting of compulsory licensing for public non-commercial use, in order to guarantee the practicability of the National STD and AIDS Programme, ensuring the continuity of universal and free access to all medicines necessary for the treatment of people living with HIV and AIDS.'").

63. Decreto No. 3.201, de 6 de Outubro de 1999, DIÁRIO OFICIAL DA UNIÃO [D.O.U.] de 6.10.1999 (Braz.) (translated to English).

64. Gupta & Rastogi, *supra* note 61.

65. Decreto No. 9.279, de 14 de Maio de 1996, D.O.U. de 14.5.1996 (Braz.) (referencing article 43 of TRIPS).

66. This was introduced in Brazil by Law 10.196/2001 as an amendment to Articles 43 & 229 of Law 9.279. *See generally* Anthony Tridico et al., *Facilitating Generic Drug Manufacturing: Bolar Exemptions Worldwide*, WIPO MAG., June 2014, *available at* http://www.wipo.int/wipo_magazine/en/2014/03/article_0004.html (providing a discussion on *Bolar* exceptions, which developed after Roche Products, Inc. v. Bolar Pharm. Co., Inc., 733 F.2d 858 (Fed. Cir. 1984)).

67. Decreto No. 9.279, de 14 de Maio de 1996, D.O.U. de 14.5.1996 (Braz.) (referencing article 229 C).

the import of pharmaceuticals that had previously been commercialized, by the patent holder or by an authorized third party in another country, at a lower price than the price offered in Brazil.[68]

Brazilian Industrial Property Law also included a provision on experimental flexibility, which allowed for the use of an invention without compensating the patent holder.[69] The *Bolar* exception, as it applies in Brazil, allows a company to complete all of the procedures and tests necessary to register a generic product before the original patent expires.[70] *Bolar* flexibility allows for the immediate marketing of a generic pharmaceutical after the patent has expired, thus promoting competition with the patent holder.[71]

Another notable feature of the Brazilian Industrial Property Law is the innovative use of novelty flexibility. The Brazilian National Institute for Industrial Property (INPI) was criticized by health activists, local generic producers, and lawyers for adopting an overly broad definition of *novelty*, resulting in many patent applications that are simply revised versions of already-existing, patented new molecular entities.[72] To avoid this problem, a 1999 Presidential Decree (converted into law in 2001) created and introduced a new provision requiring prior approval from the National Health Surveillance Agency (ANVISA) before granting a patent to ensure that it will not endanger public health or create a barrier for access to medicines.[73] Therefore, from INPI forward, all

68. In September 2003, Decree 4.830 also allowed for the importation of the object from countries where the product is not patented. Therefore, Brazil has the right to import products from any country, including those still using the transition period for pharmaceuticals, such as Bangladesh. Decree 4.830, Sept. 4, 2003, Compulsory Licensing in the Case of National Emergency and Public Interest (translated to English).

69. Decreto No. 9.279, de 14 de Maio de 1996, D.O.U. de 14.5.1996 (Braz.) (referencing article 43).

70. Indus. Prop. Amendment Law 10.196 modified articles 43 and 229 of Law 9.279. Article 43, which describes the limits of rights conferred to the patent holder (Exception to Rights Conferred), was amended to include the *Bolar* exception (early working) to allow local generic producers to complete all of the procedures and tests that are necessary to register a generic product before the original patent expires.

71. This can ultimately lower the price of medicines. The WTO Panel in the *EC–Canada* case validated the *Bolar* exception as compatible with article 30 of the TRIPS Agreement. *See* Report of the Panel, *Canada – Patent Protection of Pharmaceutical Products*, ¶ 4.15, WT/DS114/R (Mar. 17, 2000), *available at* http://www.wto.org/english/tratop_e/dispu_e/7428d.pdf; *see also Exceptions to Patent Rights in Developing Countries*, U.N. CONF. ON TRADE & DEV. [UNCTAD], ICTSD PROJECT ON IPRS AND SUSTAINABLE DEVELOPMENT, Issue Paper No. 17, at 13-14 (2006) (by Christopher Garrison), http://www.unctad.org/en/docs/iteipc200612_en.pdf.

72. *See* Shadlen, *supra* note 24, at 46.

73. *See* Lei No. 10.196, de 14 de Fevereiro de 2001, COL. LEIS REP. FED. BRASIL, 62, Fevereiro 2001 (Braz.); *see also* Dannemann Siemsen & Eduardo da Gama Camara Junior, *Prosecution of Pharmaceutical Patents in Brazil: Tensions Between the Brazilian Patent Office and ANVISA*, LEXOLOGY (July 22, 2013), http://www.lexology.com/library/detail.aspx?g=11c9730b-

pharmaceutical patent applications must go through ANVISA, and these patents can only issue after receiving prior consent from ANVISA.[74] ANVISA denies patents to drugs that lack genuine novelty and where it adjudges that providing exclusive rights would be harmful to public health.[75] ANVISA also uses its authority to prevent patents that would extend the terms of existing patents.[76]

In December 2010, the Brazilian Senate approved the text of a new Competition Act, which had been pending in the Brazilian Parliament since 2005, and finally entered into force on May 29, 2012.[77] It is expected that this law will help Brazil prevent both excessive pricing and abuse of the dominant position by the pharmaceutical industry.[78] However, this law has yet to be tested in the pharmaceutical sector.[79] Brazil also adopted price control regulations, which empowered the Ministry of Health to evaluate the therapeutic advantage of a new patented medicine over an existing treatment and then determine a price ceiling based on the lowest price of the drug in several countries, including the country of origin.[80]

08b9-447e-9d87-f1c82b52d25d ("ANVISA has started to examine pharmaceutical applications after Provisional Presidential Decree N[o.] 2006/1999 was issued, which created the legal procedure of prior consent").

74. ANVISA's intellectual property division was established in 2001 and is housed in INPI's Rio de Janeiro office building.

75. BERMUDEZ OLIVEIRA & EGLEUBIA OLIVEIRA, *Expanding Access to Essential Medicines in Brazil: Recent Regulation and Public Policies in* INTELLECTUAL PROPERTY IN THE CONTEXT OF THE WTO TRIPS AGREEMENT: CHALLENGES FOR PUBLIC HEALTH 129, 136 (Jorge A. Z. Bermudez & Maria Auxiliadora Oliveira eds., 2004).

76. *See* Shadlen, *supra* note 24, at 46.

77. Decreto No. 12.529, de 30 Novembro de 2011, D.O.U. de 30.11.2011 (Braz.). *See also* Marco Botta, *The Brazilian Senate Approves the Text of the New Competition Act*, KLUWER COMPETITION L. BLOG (Feb. 7, 2011), http://kluwercompetitionlawblog.com/2011/02/07/the-brazilian-senate-approves-the-text-of-the-new-competition-act; Ana Paula Martinez & Mariana Tavares de Araujo, *Brazil's New Competition Law One Year After Taking Effect*, LEXOLOGY (June 20, 2013), http://www.lexology.com/library/detail.aspx?g=3155fa30-c311-45b5-8ced-a51f1bec14b0 ("On May 29, 2012, Law No. 12.529/11 took effect, significantly changing the landscape of antitrust enforcement in Brazil. The law (i) consolidates the investigative, prosecutorial, and adjudicative functions of Brazil's three competition authorities into one independent agency; (ii) introduces a mandatory pre-merger notification system; and (iii) introduces changes to the administrative and criminal sanctions applicable to anticompetitive conduct.").

78. *See* Loraine Hawkins, *Review Series on Pharmaceutical Pricing Policies and Interventions* 14 (WHO/HAI Project on Med. Prices & Availability, Working Paper No. 4: Competition Policy, 2011), *available at* http://www.haiweb.org/medicineprices/05062011/Competition%20final%20May%202011.pdf.

79. *Id.*

80. Brazil created a reference price regime for new patented products in 2003. Under this regime, the final price of a new drug in Brazil cannot exceed the lowest price among nine reference countries, which include Australia, Canada, Spain, United States, France, Greece, Italy, New Zealand and Portugal. *See* MGMT. SCI. FOR HEALTH, INC., *Pharmaceutical Pricing Policy*, *in* MANAGING ACCESS TO MEDICINES AND HEALTH TECHNOLOGIES 9.1, 9.9 (2012), *available at*

Apart from public health oriented TRIPS flexibilities, the local pharmaceutical sector in Brazil also benefited from significant government investment in research and production through the Brazilian Ministry of Health.[81] It was stated by Maurice Cassier and Marilena Correa that the Ministry of Health (of Brazil) acting as "health entrepreneur" does not just purchase drugs but also takes an active role in their production.[82]

By using the flexibilities inherent in the TRIPS Agreement and governmental investment in R&D, Brazil was able to balance the need for pharmaceutical innovation with the public health concern of access to medicines.

III. THE EXPERIENCE OF INDIA

India took a similar vision, but a different path towards TRIPS compliance. India entered into the WTO in 1995 and went through a long process of amendments toward a TRIPS-compliant patent regime, which became effective January 1, 2005.[83] The impact of stronger intellectual patent rights created problems for the larger Indian drug firms and greatly damaged the smaller local firms' ability to meet the rising costs of remuneration of experienced and efficient pharmacists and other technical persons.[84]

The Indian pharmaceutical industry, with its 8% share in global pharmaceutical production,[85] holds the third position in terms of volume.[86] India also enjoys a 20% share of the global generic market.[87] Indian pharmaceutical companies play an important role globally in providing life-saving drugs at affordable prices. For instance, 70% of the antiretroviral (ARV) drugs procured to treat HIV/AIDS under the Global

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http://apps.who.int/medicinedocs/documents/s19585en/s19585en.pdf.

81. Brazil invested in 18 public sector labs, which mostly engage in formulation of final dosages and, to a lesser degree, of pharmaceutical inputs. Rahim Rezaie, *Brazilian Health Biotech – Fostering Crosstalk Between Public and Private Sectors*, 26 NATURE BIOTECH. 627, 642 (2008).

82. *See* Maurice Cassier & Marilena Correa, *Intellectual Property and Public Health: Copying of HIV/Aids Drugs by Brazilian Public and Private Pharmaceutical Laboratories*, RECIIS ELEC. J. COMMC'N, INFO. & INNOVATION IN HEALTH, Jan.-Jun. 2007, at 84.

83. Ram, *supra* note 8.

84. *Id.*

85. *See* PRICEWATERHOUSECOOPERS, PHARM. & LIFE SCIENCES, GLOBAL PHARMA LOOKS TO INDIA: PROSPECTS FOR GROWTH 6 (2010), *available at* https://www.pwc.in/assets/pdfs/pharma/Global_Pharma_looks_to_India.pdf.

86. *See The Indian Pharmaceutical Industry Economics*, UKESSAYS, http://www.ukessays.com/essays/economics/the-indian-pharmaceutical-industry-economics-essay.php (last visited Nov. 18, 2014) (highlighting that the Indian pharmaceutical industry has a current turnover of $12 billion).

87. *Id.*

Fund to Fight HIV/AIDS, TB and Malaria (GFATM) come from Indian companies, and 70% of the United Nations Children's Fund (UNICEF), International Development Association (IDA), and Clinton Foundation procurements are also from Indian companies.[88]

Drugs produced in India satisfy 95% of the domestic demand, and two-thirds of the drugs produced in India are exported to the global market.[89] In 2007-2008, the exports of pharmaceuticals by the Indian pharmaceutical industry were around $5.3 billion.[90] Only two multinational corporations (MNCs), GlaxoSmithKline and Pfizer, figure in the top ten pharmaceutical companies in India.[91] Only four multinational corporations find their place among the top twenty pharmaceutical companies in India.[92] Although domestic companies in India now control 80% of the domestic market, this was not the case prior to patent policy reform in 1970; Indian companies only had a 15 % share prior to 1970.[93] Considering this, Indian patent policy reform provides LDCs with important lessons regarding how to utilize the transitional periods to progress toward local pharmaceutical production and innovation and toward TRIPS compliance.

India became an independent nation in 1947, after more than 100 years of British rule, and initially adopted the Patents and Design Act of 1911 (a British piece of legislation).[94] Jawaharlal Nehru, India's first Prime Minister, was concerned about the influence and control of

88. ELLEN F.M. 'T HOEN, THE GLOBAL POLITICS OF PHARMACEUTICAL MONOPOLY POWER 7 (2009).

89. *See* N. Lalitha, *Access to Indian Generic Drugs: Emerging Issues*, *in* INTELLECTUAL PROPERTY, PHARMACEUTICALS AND PUBLIC HEALTH - ACCESS TO DRUGS IN DEVELOPING COUNTRIES 225, 225 (Kenneth C. Shadlen et al. eds., 2011); *and* GEETA GOURI, COMPETITION COMM'N OF INDIA, COMPETITION ISSUES IN THE GENERIC PHARMACEUTICALS INDUSTRY IN INDIA, 1 (2010), http://www.cci.gov.in/images/media/presentations/ComIssGenPharmIndusIndia_20100401142346.pdf.

90. Reji K. Joseph, *India's Trade in Drugs and Pharmaceuticals: Emerging Trends, Opportunities and Challenges*, *in* RIS Discussion Papers, 10 (Discussion Paper No. 159, 2009), *available at* http://www.eaber.org/sites/default/files/documents/RIS_Joseph_2009.pdf.

91. Rasmus Alex Wendt, TRIPS in India 160-78 (Dec. 2007) (unpublished Ph.D. thesis, Roskilde Univ.) (on file with author).

92. *Five Years into the Product Patent Regime: India's Response*, U.N. DEV. PROGRAM: POVERTY REDUCTION AND HIV/AIDS (2010) (by Sudip Chaudhuri et al.), *available at* http://www.scribd.com/doc/57006246/Pharma-Response-to-Product-Patent-Regime.

93. PADMASHREE GEHL SAMPATH, UNITED NATIONS UNIV., ECONOMIC ASPECTS OF ACCESS TO MEDICINE AFTER 2005: PRODUCT PATENT PROTECTION AND EMERGING FIRM STRATEGIES IN THE INDIAN PHARMACEUTICAL INDUSTRY 22 (2005), *available at* http://www.who.int/intellectualproperty/studies/PadmashreeSampathFinal.pdf.

94. Stephen Barnes, Note, *Pharmaceutical Patents and TRIPS: A Comparison of India and South Africa*, 91 KY. L.J. 911, 919-20 (2003).

foreign companies over the Indian economy.[95] This concern was validated in two subsequent committee reports.

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.[96] At the time of both reports, India was dependent on foreign sources for pharmaceuticals, specifically for the import of bulk chemicals and completed medicines.[97] The great majority, some 90%, of the Indian pharmaceutical market was controlled by foreign companies.[98] Indian pharmaceutical prices at that time were among the highest in the world.[99] Initially, India sought to solve this problem by instituting high tariffs and price controls on pharmaceuticals.[100] India then amended its patent laws to encourage imitation and local pharmaceutical production.[101] The change came with the passage of the Patents Act of 1970, which eliminated product patents for pharmaceuticals and only allowed protection under a process patent for a maximum period of seven years.[102]

India thus encouraged the mass production of low-cost pharmaceuticals at the expense of innovation. Prime Minister Indira Ghandi, in her statement to the World Health Organization Assembly in 1982, argued that "[t]he idea of a better-ordered world is one in which medical discoveries will be free of patents and there will be no profiteering from life and death."[103] Given this focus, Indian pharmaceutical companies principally engaged in producing generic versions of name-brand pharmaceuticals by reverse engineering those pharmaceuticals.[104] By applying modified production processes, these companies successfully avoided conflict with the original patent and

95. *Id.*; David K. Tomar, *A Look into the WTO Pharmaceutical Patent Dispute Between the United States and India*, 17 WIS. INT'L L.J. 579, 581 (1999).

96. Barnes, *supra* note 94, at 920.

97. *See* William Greene, *The Emergence of India's Pharmaceutical Industry and Implications for the U.S. Generic Drug Market* 2 (USITC Office of Econ., Working Paper No. 2007-05-A, 2007), *available at* http://www.usitc.gov/publications/332/working_papers/EC200705A.pdf.

98. Tomar, *supra* note 95, at 582.

99. *Id.*

100. *Id.*

101. Pinelopi Koujianou Goldberg, Intellectual Property Rights Protection in Developing Countries: The Case of Pharmaceuticals, Lecture Before the European Economic Association's Congress in Barcelona (Aug. 2009), *in* 8 J. EUR. ECON. ASS'N 31 (2010), *available at* http://www.econ.yale.edu/~pg87/Goldberg_Marshall.pdf.

102. The Patents Act, No. 39 of 1970, INDIA CODE (2012), § 53(1)(a).

103. Goldberg, *supra* note 101.

104. *See* Susan Finston, *India: A Cautionary Tale on the Critical Importance of Intellectual Property Protection*, 12 FORDHAM INTELL. PROP., MEDIA & ENT. L.J. 887, 889 (2002).

infringement lawsuits.[105] By "free riding" on others' inventions, Indian companies avoided R&D costs.[106] By focusing on existing pharmaceuticals, Indian pharmaceutical companies were able to offer generic alternatives at a fraction of the patented name-brand pharmaceutical cost, and thus India quickly entered both the local and global pharmaceutical markets.[107]

The policy to exclude product patents for pharmaceuticals allowed the Indian pharmaceutical industry to grow rapidly. However, by joining the WTO, India agreed to adopt the TRIPS Agreement, which required India to implement patent protection for both pharmaceutical products and processes.[108] After a three-stage amendment process in 1999, 2002, and 2005, India finally entered into a TRIPS-compliant patent regime on January 1, 2005.[109] Thus, India took advantage of the entire transition period.

The impact of stronger intellectual patent rights was felt by larger Indian drug firms and damaged smaller local firms' abilities to meet the rising costs of production and the payment of royalties for patented pharmaceuticals.[110] The Indian TRIPS-compliant patent law was criticized by public health groups as "likely to bring about a legal regime that is less favorable from the point of view of access to drugs for the people of [India]."[111] These groups also argue that the new patent law in India generally provides stronger protection to patent holders, which implies that the balance of interests between inventors and the general public has shifted in favor of the inventor.[112]

However, India tried to preserve public health by incorporating TRIPS flexibilities such as stricter patent standards, pre-grant and post-grant opposition procedures, compulsory licenses and government use, prior-use exceptions, early working or *Bolar* exceptions, research and experimental use exceptions, parallel imports, and limiting data protection.[113]

The Indian patent opposition provision contains 11 grounds for pre-

105. *Id.*

106. *Id.*

107. *Id.* at 889, 894.

108. TRIPS Agreement, *supra* note 6, at art. 27.

109. *See* Janice Mueller, *The Tiger Awakens: The Tumultuous Transformation of India's Patent System and The Rise of Indian Pharmaceutical Innovation*, 68 U. PITT. L. REV. 491, 495 (2007).

110. *Id.* at 533.

111. *See* Rajdeep Goswami, *Compliance of TRIPS in Indian Patent Law*, LEGAL SERVICES INDIA (Apr. 29, 2012), http://www.legalservicesindia.com/article/article/compliance-of-trips-in-indian-patent-law-1103-1.html.

112. *Id.*

113. *See generally* Ram, *supra* note 8.

grant opposition and also permits post-grant opposition.[114] The Indian grounds for post-grant opposition are broad enough to challenge novelty, inventive steps and the process of industrial application, the best method, claims and disclosure of origin, and even the use of indigenous or local knowledge.[115] LDCs could learn from this broad Indian model and adopt more extensive pre-grant grounds for objection as well as a process for post-grant opposition.

India also tried to set high thresholds with respect to the novelty of patent applications so that multinational corporations could not extend the life of a patent by making small changes, a process known as "ever-greening."[116] In 2006, a Swiss-based pharmaceutical company, Novartis AG, challenged the constitutional validity of section 3(d) of the Indian Patent Act, which excluded inventions that were not a "significant enhancement of the known efficacy" of the pharmaceutical.[117] Novartis AG alleged that the provision provided absolute power to the controller of the patent and denied the rights existing under article 27 of the TRIPS Agreement, which obliged WTO member states to provide patent protection to all fields of technology without discrimination.[118] The Indian High Court of Madras held that section 3(d) was not in violation of the Constitution of India and declined to rule on its incompatibility with the TRIPS Agreement.[119]

Government use flexibility is another effective means to curb abuse of patents. A government, or its authorized agent, can use the patents without the patent holder's authorization. The Indian Patent Act of 2005 provides for three types of government use. First, a patent is granted in India with a condition that the government can import the medicines for distribution in public-sector hospitals or any other hospitals.[120] Second, the government or authorized persons can use a patent against a royalty payment.[121] Third, the government can acquire a patent after paying

114. The Patents (Amendment) Act, No. 15 of 2005, INDIA CODE (2012), § 25.

115. *See* Archana Shanker & Neeti Wilson, *The Patent Opposition System in India*, INTELL. ASSET MAG., 14, 16 (July 8, 2010), *available at* http://www.iam-magazine.com/issues/article.ashx?g=4ed76a24-e544-4547-a651-84c0542aecd1.

116. The Patents (Amendment) Act, No. 15 of 2005, INDIA CODE (2012), § 3(a), (d), (e), (p).

117. Novartis A.G. v. Union of India and Others, (2007) 4 M.L.J. 1153 (India), *available at* http://www.scribd.com/doc/456550/High-Court-order-Novartis-Union-of-India.

118. *Id*. Article 27(1) of the TRIPS Agreement, *supra* note 6, states that "patents shall be available for 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 . . . [P]atents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced."

119. *Novartis A.G.*, *supra* note 117.

120. The Patents (Amendment) Act, No. 15 of 2005, INDIA CODE (2012), § 47.

121. *Id.* §§ 99, 100.

compensation.[122] The government may exercise these powers at any time.[123] The patented article, as produced under government use flexibility, can only be sold for non-commercial use.[124] However, the Act provides room for challenging the government decision to use or acquire the invention in the High Courts.[125] This means that the patentee could delay such government use, because the Act provides that the government must prove its need before the Court.[126]

India also incorporated options concerning compulsory licenses for use in cases of public interest.[127] Based on the earlier experiences of Brazil, India uses compulsory licensing options to encourage local production in case of inadequate supply or excessive price of particular medicines.[128] This has effectively and consistently managed to control the costs of several patented drugs by constantly threatening use of the "national emergency" clause provided for under the TRIPS Agreement with regard to compulsory licensing.[129]

Furthermore, the Indian Controller of Patents, while disposing of an application for a compulsory license in *Natco Pharma Ltd. v. Bayer Corporation*, clarified the issue of working the patent in the territory of India.[130] The Controller noted that the phrase, "worked in the territory of India," was not defined in the Indian Patent Act; thus, he had to interpret the phrase with regard to "various International Conventions and Agreements in intellectual property," the 1970 Patent Act, and the legislative history.[131] The Controller, using article 27(1) of TRIPS and article 5(1)(A) of the Paris Convention, adopted the interpretation that failure to manufacture in India supported the grant of a compulsory license to Natco: "[p]atents are not granted merely to enable patentees to enjoy a monopoly for importation of the patented article and . . . the grant of a patent right must contribute to the promotion of technological innovation and to the transfer and dissemination of technology."[132] Nevertheless, "gaps in the [Indian patent] law take away the

122. *Id.* § 102.
123. *Id.* § 100(1).
124. *Id.* § 100(6).
125. *Id.* §§ 100, 103.
126. *Id*. §§ 100, 103.
127. Dipika Jain & Jonathan J. Darrow, *An Exploration of Compulsory Licensing as an Effective Policy Tool for Antiretroviral Drugs in India*, 23 HEALTH MATRIX: J. L.-MED. 425, 431 (2013).
128. *Id*. at 443.
129. *See id.* at 436.
130. *Natco Pharma Ltd. v. Bayer Corp.*, Compulsory Licensing Application No. 1 of 2011 (decided by the Controller of Patents, Indian Patent Office, Mar. 9, 2012).
131. *Id.*
132. *Id*.

effectiveness of a compulsory license regime under the Patents Act. As a result, during the last five years only one application was filed for the issuance of a compulsory license in India."[133] One limitation in the Indian compulsory licensing regime, for example, is that there is no clear guideline with respect to the requirement to pay royalties.[134]

The Indian patent law amendment of 1999 provided for the early working or *Bolar* exception provision to ensure quick entry of generics into the market for competition and hence reduce the price of medicines in India.[135] The 1999 amendment also included a provision on parallel importation by incorporating section 107(A)(b) into the Patent Act.[136] Under this section, parallel importation is permitted when the "importation of patented products by any person [is] from a person who was duly authorized by the patentee to sell or distribute the product."[137] However, this required authorization from the patentee.[138] The result was that a product could not be imported when the product was produced under a compulsory license.[139] This was resolved by a 2005 amendment that enables India to import pharmaceuticals even when the drugs are produced under a compulsory license.[140]

Indian patent law also contains a provision on research and experimental use that allows for the use of patented products for R&D purposes.[141] Another feature of the Indian law is the provision under prior-use exceptions, or the grandfather clause, which allows generic producers to continue the production and marketing of a generic product if they can show they significantly invested in it before January 1, 2005, when the product patent was first introduced in India.[142] However, if any prior use is approved, then the company is required to pay the patent holder a reasonable royalty.[143]

Furthermore, India maintains a price-control mechanism to ensure access to affordable medicines.[144] However, a taskforce popularly known as Dr. Pronab Sen Taskforce, formed by the government of India to evaluate drug control mechanisms, contends that drug control

133. Gopakumar, *supra* note 7, at 341.
134. *Id.*
135. The Patents (Amendment) Act, No. 17 of 2005, INDIA CODE (2012), § 107(A).
136. *Id*.
137. *Id.* § 107(A)(b).
138. *Id.* § 48.
139. *Id.*
140. *Id*. § 107(A).
141. The Patents Act, No. 39 of 1970, INDIA CODE (2012), § 47 (retained as it is in the TRIPS-compliant Indian Patent law of 1999).
142. The Patents (Amendment) Act, No. 17 of 2005, INDIA CODE (2012), § 11(A)(7).
143. *Id.*
144. *See* Gopakumar, *supra* note 7, at 352.

mechanisms in India are not effective.[145] The taskforce argued that

> no price regulatory mechanism can be effective unless there is a credible threat of price controls being imposed and enforced. However, it is also felt that the present price control system is inappropriate, inadequate, cumbersome and time consuming.[146]

The taskforce further recommended that price controls should be imposed, not on the basis of turnover, "but on the 'essentiality' of the drug and on strategic considerations regarding the impact of price control on the therapeutic class."[147] It stated that the "ceiling prices of regulated drugs should normally not be based on cost of production, but on readily monitorable market-based benchmarks."[148] The taskforce also recommended implementing a process for active promotion of generic drugs, including mandatory de-branding for selected drugs and requiring all public health facilities to prescribe and dispense only generic drugs, except where no generic alternative exists.[149] It further recommended that in "the case of proprietary drugs, particularly anti-HIV/AIDS and cancer drugs, the government should actively pursue access [programs] in collaboration with drug companies with differential pricing and alternative packaging, if necessary."[150]

India also utilizes traditional medicinal knowledge in the country to ensure access to affordable medicines and has embarked on documenting this traditional knowledge to prevent misappropriation by multinational corporations.[151] Multinational corporations also put pressure on India to introduce test-data protection, which is submitted to get marketing approval; thereby, these corporations have attempted to extend their monopoly pricing beyond the patent term.[152]

> [A]n analysis of article 39 of TRIPS and its legislative history indicates that TRIPS speaks of data protection in a flexible manner, and does not

145. TASK FORCE TO EXPLORE OPTIONS OTHER THAN PRICE CONTROL FOR ACHIEVING THE OBJECTIVE OF MAKING AVAILABLE LIFE-SAVING DRUGS AT REASONABLE PRICES, REPORT SUBMITTED TO THE GOV'T OF INDIA DEPT. OF CHEM. & PETROCHEM 26 (2005), *available at* http://www.pharmaceuticals.gov.in/mshT2810/FTY3.pdf.

146. *Id.* at 53.

147. *Id.* at 29.

148. *Id.*

149. *Id.* at 37, 53.

150. *Id.* at 54.

151. *See* V.K. Gupta, Chairman, Traditional Knowledge Digital Library, TK Documentation and Defensive Protection: An Example from India, Presentation at the WIPO International Symposium 5 (June 26-28, 2011), *available at* http://www.wipo.int/edocs/mdocs/tken/wipo_tk_mct_11/wipo_tk_mct_11_ref_t_5_1.pdf.

152. *See Will Indian Patent Case End Drugs Companies Monopoly*, EHOSPICE (May 2, 2013), http://www.ehospice.com/ArticleView/tabid/10686/ArticleId/4530/language/en-GB/View.aspx.

> mandate data protection to be implemented by bringing in a data exclusivity regime. Thus, the argument that data exclusivity must be provided for in Indian law for India to be in compliance with TRIPS is fallacious. Protection against 'unfair commercial use' under TRIPS must be interpreted to mean protection through non-disclosure and prohibiting others from accessing test data for unfair commercial use. TRIPS gives member states the freedom to choose the nature and extent of protection they want to offer.[153]

That is why most of the Indian pharmaceutical companies claimed that protection need not be in the form of data exclusivity, and therefore, the government of India provided no data exclusivity protection.[154] In 2002, the Indian government also enacted the Competition Act, which may be utilized to prevent abuses of patents, abuses of dominant market positions, and excessive pricing.[155]

India's experience of utilizing TRIPS flexibilities and other governmental intervention options, such as price control, could be utilized by LDCs like Bangladesh when adopting TRIPS-compliant patent law.

IV. THE EXPERIENCE OF SOUTH AFRICA

The South African struggle for access to medicines in the context of TRIPS and pressure from multinational corporations could also be an important consideration for LDCs—especially with regard to competition law. Compared to India and Brazil, South Africa has a larger health crisis to deal with, including a large number of HIV/AIDS patients and problems with access to medicines. That is why "the case of South Africa, economically the strongest African country, is particularly illustrative of this public health crisis and showcases the role domestic

153. Animesh Sharma, *Data Exclusivity with Regard to Clinical Data*, 3 INDIAN J. OF L. & TECH 82, 102 (2007).

154. *See* Shamnad Basheer, *Indian Government Committee Says "No" to Data Exclusivity*, SPICYIP (June 6, 2007), http://spicyip.com/2007/06/indian-government-committee-says-no-to.html ("After multiple deliberations spanning more than 3 years, a government committee has finally submitted its report on regulatory data protection and Article 39.3 of TRIPS. It finds that Article 39.3 does not require 'data exclusivity' and that, at the present moment, it may not be in India's national interest to grant 'data exclusivity' to pharmaceutical drug data. It relies heavily on the Doha Declaration to support this interpretation.").

155. *See generally* Abhilash Chaudhary, Compulsory Licensing of IPRS and Its Effect on Competition (2012) (unpublished research project), *available at* http://cci.gov.in/images/media/ResearchReports/Compulsory%20Licensing%20of%20IPRs%20and%20Its%20Effect%20on%20Competition.pdf. However, until now no successful attempt has been made to use competition law in the pharmaceutical sector. Having a national competition law, India may well embrace the South African experience and apply competition law to the pharmaceutical sector in order to prevent excessive pricing, if that kind of situation were to arise in India.

and international patent law and policies may play in this context."[156]

South Africa has a large and highly developed pharmaceutical system, including considerable local production capacity.[157] The South African Medicines Control Council licensed more than 200 entities as manufacturers, importers, or exporters of medicines by 2008.[158] Africa imports 70% of the medicines it uses, including 80% of its ARV drugs used to treat HIV/AIDS.[159]

On the other hand, South Africa has had patent legislation since at least 1916, and the existing Patents Act was promulgated in 1978.[160] South Africa undertook TRIPS compliance in 1997 with the passage of the Intellectual Property Laws Amendment Act.[161] South Africa also became bound by the Patent Cooperation Treaty in 1999.[162] Further amendments to the Patents Act were made in 2002 and 2005.[163] Although South Africa adopted TRIPS-compliant patent law in principle, it was increasingly contended that medicines already subject to a significant degree of regulation must be construed as public goods because of their critical public health and public interest impacts,[164] and therefore, TRIPS flexibilities should be used to ensure that patent law did not jeopardize public health concerns.[165] Countries such as South Africa and Brazil attracted the wrath of the United States when they adopted TRIPS-compliant laws that used TRIPS flexibilities more

156. Fisher & Rigamonti, *supra* note 11, at 2.

157. *See* Yu-Fang Wen & Thapi Matsaneng, *Patents, Pharmaceuticals and Competition: Benefiting from an Effective Patent Examination System*, Presented at the Competition Commission's Seventh Annual Conference on Competition Law, Economics & Policy 1 n.4 (Sept. 5, 2013), http://www.compcom.co.za/assets/Uploads/events/Seventh-Annual-Conference-on-Competition-Law-Economics-Policy/Parallel-3B/Patents-Pharmaceuticals-and-Competition-Yu-Fang-Wen-and-Thapi-Matsaneng-Annual-Competition-Conference-2013.pdf.

158. REPORT OF THE MINISTERIAL TASK FORCE TEAM ON THE RESTRUCTURING OF MEDICINES REGULATORY AFFAIRS AND MEDICINES CONTROL COUNCIL AND RECOMMENDATIONS FOR THE NEW REGULATORY AUTHORITY FOR HEALTH PRODUCTS OF SOUTH AFRICA 22 (2008), http://pharmaceuticals.gov.in/drpronabreport.pdf.

159. *African Leaders Call for Greater Industrialization of an Emerging Africa*, UNAIDS (Mar. 26, 2013), http://www.unaids.org/en/resources/presscentre/featurestories/2013/march/20130326cotedivoire/.

160. Patents Act 9 of 1916 (S. Afr.); Patents Act 57 of 1978 (S. Afr.).

161. Patents Amendment Act 38 of 1997 (S. Afr.).

162. Patent Cooperation Treaty, June 19, 1970, 28 U.S.T. 7645, 1160 U.N.T.S. 231.

163. Patents Amendment Act 20 of 2005 (S. Afr.); Patents Amendment Act 58 of 2002 (S. Afr.).

164. *See Public Health Ethics*, STAN. ENCYCLOPEDIA OF PHIL. (Apr. 12, 2010), http://plato.stanford.edu/entries/publichealth-ethics/.

165. *See generally* Patrick Bond, *Globalization, Pharmaceutical Pricing, and South African Health Policy: Managing Confrontation with U.S. Firms and Politicians*, 29 INT'L J. OF HEALTH SERVICES 765 (1999); Frederick M. Abbott, *The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO*, 5 J. OF INT'L ECON. L. 469 (2002).

broadly than the United States wanted.[166]

The significance of the South African experience with pharmaceutical patent issues under the TRIPS Agreement goes beyond doctrinal issues. It not only used legislative approaches under the patent law but also used competition law and other governmental intervention for price bargaining to encourage local generic production and R&D based pharmaceutical industries. "[I]t touches upon the more fundamental question of to what extent WTO Member States – in general and particularly, developing countries – should be free to take legislative measures to deal with public health crises and to what extent the patent protection of pharmaceuticals required under TRIPS should limit the range of options available."[167] The South African experience brought the potential tension between patent protection for pharmaceuticals and public health concerns to the forefront of public awareness and triggered "a global debate about what should be allowed and what should be prohibited under TRIPS in order to preserve the incentives for investments in R&D of pharmaceuticals, while still allowing countries the flexibility to respond to public health crises as they deem fit."[168]

The vast majority of South Africans did not have access to health care at all, making health care reform one of the prime concerns for the post-apartheid government.[169] This paralleled the mandate within South Africa's newly-adopted Constitution to take substantial policy measures to ensure access to affordable health care for its citizens.[170] Accordingly, the post-apartheid government appointed a National Drug Policy Committee to revamp South Africa's health care system.[171] After a series of investigations and consultations with relevant stakeholders, the Committee found that some of the most notable deficiencies were the lack of equity in access to essential drugs, the comparatively high prices for pharmaceuticals in the private sector, and the loss of drugs through poor security in the public sector.[172]

The pharmaceutical companies in South Africa disapproved the findings and argued that even lowering drug prices would not solve the

166. *See* Bond, *supra* note 165, at 769; Abbott, *supra* note 165, at 471.

167. Fisher & Rigamonti, *supra* note 11, at 13.

168. *Id.* at 14.

169. *See* Bronwyn Harris et al., *Inequities in Access to Health Care in South Africa*, 32 J. PUB. HEALTH POL'Y 102, 103 (2011), *available at* http://www.palgrave-journals.com/jphp/journal/v32/n1s/full/jphp201135a.html.

170. Fisher & Rigamonti, *supra* note 11, at 2-3 (citing S. AFR. CONST., 1996).

171. *Id*.

172. *Id.* (citing S. AFR. DEPT. OF HEALTH, NAT'L DRUG POLICY FOR SOUTH AFRICA 9-10 (1996) (referencing drug pricing)).

access problem, as South Africa did not have an adequate infrastructure for the distribution of drugs.[173] The South African companies referred to India as an example of a country where access was and is an issue, despite the availability of generic versions of AIDS drugs.[174]

However, considering excessive pricing of medicines by the multinational corporations in South Africa, the government inserted a new section 15C into the South African Medicines and Related Substances Control Act (MRSCA).[175] The primary purpose of this amendment was to enable South Africa to benefit from lower prices abroad for the same drugs.[176] The enactment of MRSCA, with its provisions for parallel importation, raised serious criticism by the supporters of patent protection for the pharmaceutical industries (as they considered it among the options for issuing compulsory licensing) and received strong support from the public health groups.[177] Nevertheless, the planned modifications, including section 15C, were signed into law by President Nelson Mandela on December 12, 1997.[178]

In an attempt to delay or halt implementation of the amendments, the pharmaceutical companies challenged the constitutionality of the amended MRSCA before the High Court of South Africa in February 1998.[179] While challenging section 15C, the plaintiffs argued: (i) the amended provision entailed an inappropriate delegation of powers to the executive branch of government, as the Minister of Health was authorized to determine the application of patent rights irrespective of the South African Patents Act and to determine the conditions for the supply of more affordable medicines without any limiting guidelines; (ii) that it would empower the Minister of Health to deprive intellectual property owners of their property without compensation in violation of article 25 of the South African Constitution (which provides for the protection of property rights); and (iii) that it would violate the obligation under Article 27 of TRIPS, and as South Africa committed to meet TRIPS obligations, it would also violate articles 44(4), 231(2), and

173. *See* Sabin Russell, *New Crusade to Lower AIDS Drug Costs/Africa's Needs at Odds with Firms' Profit Motive*, SFGATE, (May 24, 1999, 4:00 AM), http://www.sfgate.com/health/article/New-Crusade-To-Lower-AIDS-Drug-Costs-Africa-s-2929307.php.

174. *Id.*

175. *Medicines and Related Substances Control Amendment Act No. 90 of 1997*, REPUBLIC OF S. AFR. GOV'T GAZETTE (Dec. 12, 1997) (amending the Medicines and Related Substances Control Act No. 101 of 1965, as amended by Act Nos. 65/1974, 17/1979, 20/1981 and 94/1991).

176. *Id.*

177. The planned modifications, including section 15C, were signed into law by President Nelson Mandela on December 12, 1997. *See id.*

178. *Id.*

179. *See* Notice of Motion in the High Court of South Africa (Transvaal Provincial Division), Case No. 4183 (1998).

231(3) of the South African Constitution.[180]

However, the South African government defended its amended legislation stating that section 15C was constitutional as it granted the Minister of Health only limited powers to abrogate patent rights, and "under the South African Constitution it had an obligation to protect its citizens' right to health."[181] Further, it claimed that section 15C was consistent with TRIPS, arguing that TRIPS allows parallel imports and that section 15C did not address the issue of compulsory licensing.[182] The South African Government alleged that it was being held to a "TRIPS-plus" standard, and therefore a higher level of patent protection beyond the requirements of TRIPS, both by the U.S. government and by the private plaintiffs in the lawsuit.[183] The constitutional challenge over the amended MRSCA had the effect of temporarily staying its implementation.[184]

The contentious position by the public health activists and pharmaceutical companies in South Africa regarding MRSCA was explained in a study:

> [W]hile AIDS activists such as the South African Treatment Access Campaign (TAC) called for international protests against 'drug profiteering' and claimed that delaying the implementation of the amended MRSCA would only cost additional lives, the pharmaceutical companies defended the court action on the grounds that 'parallel importation of drugs would undermine the ability of pharmaceutical companies to charge different prices in different parts of the world' and that a 'tiered pricing strategy allows wealthier countries to subsidize poorer ones, and the drug companies still get profits they need for research.'[185]

Supporting the position of the South African Government, the then-Health Minister of South Africa stated, "[w]e are not intending to bust any patents. [We are] not intending to break any treaties. All we want to do is to give health services to the people who are poor in this country,

180. *Id.* ¶¶ 2.1, 2.3, and 2.4; *see also* Tshimanga Kongolo, *Public Interest versus the Pharmaceutical Industry's Monopoly in South Africa*, 4 J. WORLD INTELL. PROP. 609, 616-19 (2001).

181. *See* Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines*, OXFORD SCHOLARSHIP ONLINE, 2008, at 12, *available at* http://isus-stiftung.de/attachments/article/60/Background_of_the_Debate.pdf.

182. *See* Joint Study by the WHO and the WTO Secretariat, *WTO Agreements & Public Health* 106 (2002), https://www.wto.org/english/res_e/booksp_e/who_wto_e.pdf.

183. Fisher & Rigamonti, *supra* note 11, at 6 (citing Statement by the South African Delegation, Minutes of the Council for TRIPS Special Discussions on Intellectual Property and Access to Medicines, IP/C/M/31 (July 10, 2001)).

184. *Id*.

185. *Id*.

and to the people who have been denied those health services for centuries."[186]

But the pharmaceutical companies viewed section 15C as a threat to their business, and they feared that the explicit authorization of parallel imports could turn into an example for other countries.[187] The multinational corporations, mostly led by the United States pharmaceutical industry, strongly opposed the enactment of section 15C and asserted that it was tantamount to a complete abrogation of patent rights and was leading to a violation of South Africa's obligations under the TRIPS Agreement.[188] A representative of Bristol-Myers Squibb stated: "Patents are the lifeblood of our industry. Compulsory licensing and parallel imports expropriate our patent rights"; the only beneficiary of the erosion of patents would be the generic drug industry.[189]

The Pharmaceutical Research and Manufacturers of America (PhRMA), a trade group representing the United States pharmaceutical industry, managed to convince the United States government that the issue was sufficiently important to warrant putting pressure on South Africa to repeal the contested legislative measures.[190] James Joseph, United States Ambassador to South Africa at that time, wrote a letter to representatives of the South African government, strongly urging South Africa to alter section 15C and stating that "my Government opposes the notion of parallel imports of patented products anywhere in the world."[191] As a result, "South Africa was put on the Special 301 'watch list' both in 1998[192] and 1999[193] upon a determination by the U.S. Trade Representative (USTR) that South Africa lacked adequate intellectual property protection to an extent that merited bilateral attention."[194] By placing South Africa on the watch list, there was a possibility the United States could impose unilateral trade sanctions on South Africa.[195]

186. *Id*. at 7.

187. *Id.*

188. American subsidiaries accounted for 27% of the pharmaceutical market in South Africa, which was a higher share of the market than South Africa's local pharmaceutical industry. *See* Lynne Duke, *Nkosazana Zuma – Activist Health Minister Draws Foes in South Africa*, WASH. POST, Dec. 11, 1998, at A41.

189. Fisher & Rigamonti, *supra* note 11, at 5.

190. *Id*. at 7; *South Africa's Health Committee Rejects MRSCA Bill Change*, PHARMA LETTER, Oct. 21, 1997.

191. Fisher & Rigamonti, *supra* note 11, at 5.

192. *Id*. at 7.

193. 1999 USTR Special 301 Report (also stating that "South Africa's Medicines Act appears to grant the Health Minister ill-defined authority to issue compulsory licenses, authorize parallel imports, and potentially otherwise abrogate patent rights"). Fisher & Rigamonti, *supra* note 11, at 7 n.34.

194. Fisher & Rigamonti, *supra* note 11, at 7.

195. *See* 19 U.S.C. § 2411 (2012).

However, the United States did not bring a WTO case against South Africa due to a huge public health campaign both inside and outside the United States and the possible negative publicity.[196] The role of the then presidential candidate Al Gore was also important, as he was co-chairman of the United States/South Africa Binational Commission.[197] He had been actively involved in pressuring South Africa to give in to the demands of the pharmaceutical industry, as he had become one of the main targets of AIDS activists who had long urged the United States government to change its policy towards South Africa.[198] In April 2001, the pharmaceutical companies dropped their court challenge to section 15C and agreed to cover the South African government's legal expenses in the face of what has been described as a public relations nightmare.[199]

Behind the scenes discussions leading to withdrawal of the lawsuit involved Kofi Annan, the Secretary General of the United Nations, who was contacted by Jean-Pierre Garnier, the CEO of GlaxoSmithKline, on behalf of the largest pharmaceutical companies, to broker a deal with Thabo Mbeki, the President of South Africa.[200] The European Union and the World Health Organization supported South Africa's position.[201] As part of the deal, South Africa reiterated its pledge to comply with TRIPS when implementing the amendments to the MRSCA and invited the pharmaceutical industry to help draft future regulations.[202]

South Africa's position reflected a struggle between excessive pricing of patented medicines by the pharmaceutical companies and societal and constitutional obligations to ensure access to medicines and the right to health care. It also fairly represented the broader international struggle over the scope of and exceptions to internationally-recognized intellectual property rights under the TRIPS

196. Fisher & Rigamonti, *supra* note 11, at 8.

197. *Id*.

198. *Id*.

199. As some journalists put it, "Can the pharmaceuticals industry inflict any more damage upon its ailing public image? Well, how about suing Nelson Mandela?" Helene Cooper & Scott Hensley, *AIDS Epidemic Puts Drug Firms In a Vise: Treatment vs. Profits*, WALL ST. J. (Mar. 2, 2001, 10:47 PM), http://online.wsj.com/news/articles/SB983487988418159849.

200. Fisher & Rigamonti, *supra* note 11, at 9.

201. *See* Rachel L. Swarns, *Drug Makers Drop South Africa Suit Over AIDS Medicine*, N.Y. TIMES (Apr. 20, 2001), http://www.nytimes.com/2001/04/20/world/drug-makers-drop-south-africa-suit-over-aids-medicine.html?pagewanted=all.

202. Fisher & Rigamonti, *supra* note 11, at 10. But due to numerous legal and political challenges, such as settlement of court cases, delays in the formation of a pricing committee and effective implementation of MRSCA only began in 2007. *See* Ann M. Simmons, *Firms Clear Way for Cheaper AIDS Drugs*, CHI. TRIB. (Apr. 20, 2001), http://articles.chicagotribune.com/2001-04-20/news/0104200289_1_cheaper-aids-drugs-health-minister-manto-tshabalala-msimang-standard-triple-therapy. *See also* Cooper & Hensley, *supra* note 197; Swarns, *supra* note 201.

Agreement.[203]

This South African case reflects that the issue of parallel imports is a matter left to the individual WTO member state to decide. Although MRSCA provided an option for parallel imports, the South African patent law did not make explicit provisions for it.[204] In general, section 45(1) of the Patents Act stated that the patent owner had the right to exclude others from importing the invention to which the patent relates during the duration of the patent.[205]

However, an amendment in 2002 added section 45(2), which provides for the exhaustion of rights.[206] But it also does not contain any wording that indicates international exhaustion, or parallel importation, is permitted.[207] That is why South Africa issued a draft national policy on September 4, 2013, which proposes changing South Africa's intellectual property laws to adopt a number of health safeguards, including an easy to use parallel importation mechanism.[208] The nonexistence of international exhaustion for parallel imports was also confirmed by an announcement on November 5, 2013, by the Department of Trade and Industry of South Africa, which noted that the Patents Act, as it stands, does not address pricing of medicines, despite the fact that the National Policy on Intellectual Property seeks to address such matters.[209] It further noted that South Africa will amend its legislation to address issues of parallel importation and compulsory licensing in line with the Doha Decision of the WTO on Intellectual Property and public health.[210]

Most countries and commentators agree with South Africa that

203. *See generally* HEINZ KLUG, *Pharmaceutical Production and Access to Essential Medicines in South Africa*, *in* INTELLECTUAL PROPERTY, PHARMACEUTICALS AND PUBLIC HEALTH - ACCESS TO DRUGS IN DEVELOPING COUNTRIES 29-55 (Kenneth C. Shalen et al. eds., 2011).

204. This aspect was considered by the High Court in Stauffer Chem. Co. v. Agricura Ltd. (1979) BP CP 168. The Judge confirmed that only national exhaustion was intended, and he found nothing which would induce him to depart from this principle. *See* Esmé du Plessis & Danie Dohmen, *Exhaustion of Rights: A South African Perspective*, Presentation at the WIPO Regional Seminar for Certain African Countries on the Implementation and Use of Several Patent-Related Flexibilities 15 (Jan. 29-31, 2013), *available at* http://www.wipo.int/edocs/mdocs/patent_policy/en/wipo_ip_dur_13/wipo_ip_dur_13_ref_tz14b.pdf.

205. Patents Act 57 of 1978 (S. Afr.) § 45(1).

206. *Id*. § 45(2).

207. *See Draft National Policy on Intellectual Property 2013*, at 6 (S. Afr.), http://ipasa.co.za/wp-content/uploads/2013/07/IPASA-Extracts-from-Submission-made-on-the-DRAFT-NATIONAL-POLICY-ON-IPFalsepdf.

208. *Id*. at 6-8.

209. Tamar Kahn, *South Africa 'Seeks Balance' Between Intellectual Property, Public Health*, BUSINESSDAY (Nov. 6, 2013, 1:54 PM), http://www.bdlive.co.za/national/health/2013/11/06/south-africa-seeks-balance-between-intellectual-property-public-health.

210. *Id*.

article 6 of TRIPS is based on a country-by-country approach to the exhaustion of intellectual property rights and parallel imports.[211] "This view is based on a plain reading of the TRIPS Agreement as well as on its drafting history."[212] Although the issue of parallel imports was discussed by the TRIPS negotiators, they failed to reach a consensus on the subject: developing countries favored international exhaustion, the United States advocated national exhaustion, and the European Union tried to preserve the principle of European Union-wide exhaustion.[213]

The South African controversy also centered on the question of whether it was compatible with articles "30 and 31 in TRIPS for a WTO member state to grant compulsory licenses to lower drug prices to combat AIDS."[214] Articles 30 and 31 in TRIPS set forth the conditions for the validity of a domestic compulsory licensing scheme.[215] To the extent that such a scheme does not "unreasonably conflict with the normal exploitation of the patent" and does not "unreasonably prejudice the legitimate interests of the patent owner," it is legal under Article 30.[216] "If these general requirements are not met, however, the compulsory licensing mechanism is only permissible if it complies with the detailed prerequisites listed in Article 31."[217] "In the context of South Africa, pharmaceutical companies feared that the Minister of Health could use the amended MRSCA to bypass these provisions to their detriment and to the benefit of South African manufacturers of generic drugs."[218]

But in reality, this has rarely happened – despite the fact that, in addition to MRSCA, the South African Patents Act of 1978 provides an avenue for the government and the courts to enforce compulsory licenses.[219] Thus, despite having a huge health crisis and access problems, South Africa has never used compulsory licenses.[220]

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211. *See* UNCTAD-ICTSD, RESOURCE BOOK ON TRIPS AND DEVELOPMENT 439 (2005) (regarding the drafting history of TRIPS, including parallel imports).

212. Fisher & Rigamonti, *supra* note 11, at 11.

213. *Id.*

214. Fisher & Rigamonti, *supra* note 11, at 13.

215. *See* TRIPS Agreement, *supra* note 6, at art. 30, 31.

216. For example, in a case brought by the European Union against Canada, a WTO Panel decided that Canada's "pre-expiration testing" exemption was consistent with article 30 of TRIPS, while its "stockpiling" exemption was not. *See* Report of the Panel, *supra* note 71, ¶ 8.1.

217. Fisher & Rigamonti, *supra* note 11, at 13.

218. *Id.*

219. Patents Act 57 of 1978 § 4 (S. Afr.) ("State bound by patent - A patent shall in all respects have the like effect against the State as it has against a person: Provided that a Minister of State may use an invention for public purposes on such conditions as may be agreed upon with the patentee, or in default of agreement on such conditions as are determined by the commissioner on application by or on behalf of such Minister and after hearing the patentee.").

220. *See Bayer's Attempt to Block Generic Production of Sorafenib Rejected; Case on India's*

The South African government has yet to make use of a statutory power that entitles it to "use an invention for public purposes."[221] If the terms and conditions of such government use – which includes the licensing of generic companies as a mechanism for reducing drug prices – cannot be agreed upon, the state must approach the courts for assistance.[222] There are no reported judgments on terms and conditions associated with such compulsory licenses, which almost certainly indicates that none have ever been granted.[223] It is true that the risk that a licensee may itself become the target of litigation is an inhibition: non-issuance of a compulsory license is the primary source of reluctance to antagonizing large competitors.[224] But if the regulatory framework was easier (or less risky) to use, there seems little doubt that such licenses would more readily be sought.[225]

Due to the lack of a substantial patent examination and opposition system, the South African patent office may grant patents that could restrict entry of generic medicines.[226] The South African patent office does not conduct a substantial patent examination like Brazil and India. Therefore, it does not check novelty and non-obviousness of the invention; it merely registers patents that fulfill the formalities set out for

First Compulsory License Still to be Heard in Court, FIX THE PATENT LAWS (Sept. 19, 2012), http://www.fixthepatentlaws.org/?p=420.

221. "State bound by patent - A patent shall in all respects have the like effect against the State as it has against a person: Provided that a Minister of State may use an invention for public purposes on such conditions as may be agreed upon with the patentee, or in default of agreement on such conditions as are determined by the commissioner on application by or on behalf of such Minister and after hearing the patentee." Patents Act 57 of 1978 § 4.

222. "Compulsory licence in case of abuse of patent rights - (1) Any interested person who can show that the rights in a patent are being abused may apply to the commissioner [a High Court judge] in the prescribed manner for a compulsory licence under the patent." In terms of § 56(2), the rights in a patent are deemed to be abused if within a stated period of years there is without satisfactory reason inadequate or no commercial exploitation; if demand is not being met adequately and on reasonable terms; and if "by reason of the refusal of the patentee to grant a licence or licences upon reasonable terms, the trade or industry or agriculture of the Republic or the trade of any person or class of persons trading in the Republic, or the establishment of any new trade or industry in the Republic, is being prejudiced, and it is in the public interest that a licence or licences should be granted." *Id.* § 56(2).

223. However, there are few reported decisions on court-granted compulsory licenses under section 56 of the South African Patent Act. Three cited cases in this regard include: Syntheta (Pty) Ltd (formerly Delta G Scientific (Pty) Ltd v. Janssen Pharmaceutica NV and Another 1999 (1) SA 85 (SCA) at 88I (S. Afr.); Sanachem (Pty) Ltd v. British Tech. Grp. plc 1992 BP 276, and Afitra (Pty) Ltd and Another v. Carlton Paper of SA (Pty) Ltd 1992 BP 331. This provision was successfully used in at least one matter to induce a major pharmaceutical company to grant a voluntary licence. *See* Fisher & Rigamonti, *supra* note 11, at 54.

224. Fisher & Rigamonti, *supra* note 11, at 38.

225. *See generally* David Vaver, *Intellectual Property Today: Of Myths and Paradoxes*, 69 CAN. BAR REV. 98 (1990).

226. *See* Wen & Matsaneng, *supra* note 157, at 9.

registration.[227]

The absence of a local patent examination system means patents are granted without substantive review and without verifying whether they meet the patentability requirements provided for in the South African Patents Act.[228] The patent office has no filter to ensure that patents are granted only when they are deserved.[229] This undermines the country's ambition to provide free access to medicines and to boost local production by its own generic industry.[230] This is a major drawback to the patent application system in South Africa, because setting high thresholds and strict examination of novelty character could give some policy room for local generic producers to oppose patent applications for pharmaceuticals.[231] It is considered that the multinational pharmaceutical industry is fully exploiting this weakness in South Africa's legal and patent systems to extend market exclusivity on key medicines that are nearing patent expiry.[232] According to one study, 2442 pharmaceutical patents were registered in South Africa in a single year (2008).[233]

Another loophole in the South African patent system is that South African legislation makes no provision for pre-opposition procedures; it limits the examination of applications and specifications to the Registrar of Patents, who is empowered to grant the application if it complies with the requirements of section 34 of the Patents Act.[234] However, inspection by the public is permitted after the patent has been sealed and granted.[235]

Furthermore, there appears to be a complete lack of transparency in the patent prosecution process, as the relevant statute merely requires the registrar to engage in a formal tick-box approach to an application.[236] Given that patent grants, particularly in the case of essential medicines, have such far-reaching impacts on the broader public, the process ought to accommodate public scrutiny and comment. Due to the lack of pre-grant opposition procedures and effective post-grant procedures, the South African opposition procedure may not be helpful to local generic

227. *Id.*

228. *Id.* at 3.

229. *Id.*

230. *Why South Africa should Examine Pharmaceutical Patents*, MEDICINS SANS FRONTIERES ACCESS CAMPAIGN 11-12 (2013), *available at* http://www.msfaccess.org/content/why-south-africa-should-examine-pharmaceutical-patents [hereinafter *Examine Pharmaceutical*].

231. ETHEL TELJEUR, INTELLECTUAL PROPERTY RIGHTS IN SOUTH AFRICA: AN ECONOMIC REVIEW OF POLICY AND IMPACT 50 (2003).

232. *Examine Pharmaceutical*, *supra* note 230, at 12.

233. *Id.* at 2.

234. *See* David Cochrane, *Patents and Public Health – The New Frontier*, CIP (Mar. 4, 2014), http://blogs.sun.ac.za/iplaw/2014/03/04/patents-and-public-health-the-new-frontier/.

235. Patents Act 57 of 1978 § 12 (S. Afr.).

236. *Id.* § 34.

producers.

Act 57 of the South African Patents Act of 1978 (as last amended in 2002)[237] covers most of the exclusions envisaged by article 27 of TRIPS, namely: exclusions of patents on inventions that encourage offensive or immoral behavior, as listed in section 25(4)(a); exclusions of patents for any variety of animal or plant, or any essential biological process for the production of animals or plants, not including a micro-biological process or the product of such a process, as listed in section 25(4)(b); and exclusion of patents on any surgical, therapeutic, or diagnostic method of treatment of humans or animals, as listed in section 25(11).[238] Furthermore, section 36 of the Patents Act empowers the Registrar of Patents to refuse any application that is frivolous or that encourages illegal, immoral, and offensive behavior, including publication or exploitation.[239] As the concepts of morality and offensive behavior are relative concepts, particularly in a diverse and evolving society such as South Africa, it is unclear how this provision is to be applied.

There are no general exemption provisions in South African patent law such as the early use exception or the *Bolar* exception. South African patent law also does not contain an explicit provision for educational, experimental, or research exceptions, nor for the export of an invention manufactured on a non-commercial scale in pursuance of the early working exception.[240]

Nevertheless, section 69A of the Patents Act was introduced by a legislative amendment in 2002 and provides for a *Bolar*-type exception.[241] As experimental use exception and *Bolar*-type exception is not clear enough therefore may lead to varied interpretations and could not be used by generic producers effectively and could lead to court cases for delaying generic entry in the market. It is also noted that stock-piling of products made or imported under section 69A (1) is prohibited by section 69A (2).[242]

237. *Id.* § 57.

238. *Id.* § 25(11).

239. *Id.* § 36.

240. TELJEUR, *supra* note 231, at 51. Esmé Du Plessis, *The Impact of Public Health Issues on Exclusive Patent Rights*, Report Q.202 (S. Afr.) (2008), AIPPI, https://www.aippi.org/download/commitees/202/GR202south_africa.pdf.

241. Section 69A provides as follows: "It shall not be an act of infringement of a patent to make, use, exercise, offer to dispose of, dispose of or import the patented invention on a non-commercial scale and solely for the purposes reasonably related to the obtaining, development and submission of information required under any law that regulates the manufacture, production, distribution, use or sale of any product. (2) It shall not be permitted to possess the patented invention made, used, imported or acquired in terms of subsection (1) for any purpose other than for the obtaining, development or submission of information as contemplated in that subsection."

242. Plessis, *supra* note 240, at 2.

On the other hand, there is no reference of test data protection within the Patent Act's protection of clinical trial data in South Africa, which predates the Patent Act's inclusion in the TRIPS Agreement.[243] In line with the practice of regulatory authorities worldwide, the Medicines Control Council (MCC) does not publicly disclose or share data submitted for registration purposes.[244] But when considering an application for the registration of a generic equivalent, the MCC does not require the applicant to furnish any new data on the safety and efficacy of the drug, but merely on the quality of the generic equivalent.[245]

Upon review of existing South African law, it is revealed that its competition law provides a more effective sanction than its patent law against patent abuse in the form of an anti-competitive compulsory license, which is consistent with article 31(k) of TRIPS.[246] The South African Competition Commission has already applied competition law successfully in the pharmaceutical sector to deal with restrictive practices and abuse of a dominant position.[247]

In *Hazel Tau and Others vs. GlaxoSmithKline and Boehringer Ingelheim*,[248] the prices set by the two litigating companies were considered an obstacle to accessing ARV medicines.[249] The Competition

243. *See* Cecilia Oh, *Domestic Legislation and Court Decisions on Intellectual Property Rights and Public Health in South Africa* 7 (2011), LOCAL-PHARMA-PRODUCTION.NET, http://www.local-pharma-production.net/fileadmin/dateien/Country_studies/Country_analysis_-_South_Africa.pdf (noting that the Medicines and Related Substances Control Act, No 101 of 1965, controls the regulation of medicines in South Africa and does contain general confidentiality provisions related to medicines. Sections 22B and 34, read together, suggest that there is general protection of information submitted in respect of the regulation of medicines against unfair commercial use. Again, section 22B permits the Director General of Health to disclose information relating to medicines where it is deemed "expedient and in the public interest.").

244. *Id*. at 4. *See* MEDICINES CONTROL COUNCIL, GENERAL INFORMATION 4 (2008), *available at* http://www.kznhealth.gov.za/research/mccinfo.pdf.

245. *See An Analysis of Patent, Competition and Medicines Law*, U.N. DEV. PROGRAMME: USING LAW TO ACCELERATE TREATMENT ACCESS IN SOUTH AFRICA 108 (Oct. 2013) (by Chan Park, Achal Prabhala, & Jonathan Berger), *available at* http://www.undp.org/content/dam/undp/library/hivaids/English/using_law_to_accelerate_treatment_access_in_south_africa_undp_2013.pdf.

246. *See* Robert D. Anderson, Competition Policy and the TRIPS Agreement: More Guidance Needed? Where Might We Look? What Insights from Policy Evolution at the National Level?, Presentation at the WIPO Symposium on Intellectual Property and Competition Policy 8, 12 (May 11, 2010), *available at* http://www.wipo.int/export/sites/www/meetings/en/2010/wipo_ipcp_ge_10/presentations/anderson.pdf.

247. *See* Catherine Saez, *UNDP Report Promotes Competition Law to Boost Access to Medicines*, INTELL. PROP. WATCH (May 19, 2014), http://www.ip-watch.org/2014/05/19/undp-report-promotes-competition-law-to-boost-access-to-medicines/.

248. Dani Cohen & Jennifer Cohen, *Competition Commission Finds Pharmaceutical Firms in Contravention of the Competition Act*, COMPETITION COMMISSION (Oct. 16, 2003), www.cptech.org/ip/health/sa/cc10162003.html.

249. In brief, the fact is that the pharmaceutical companies, GlaxoSmithKline and Boehringer,

Commission ruled that the companies had violated the Competition Act of 1998 by denying "a competitor access to an essential facility, [setting] excessive pric[es] and engag[ing] in an exclusionary act."[250] Yet the Commission stated that

> [o]ur investigation revealed that each of the firms has refused to license their patents to generic manufacturers in return for a reasonable royalty. We believe that this is feasible and that consumers will benefit from cheaper generic versions of the drugs concerned. We further believe that granting licenses would provide for competition between firms and their generic competitors. We will request the Tribunal to make an order authorizing any person to exploit the patents to market generic versions of the respondent's patented medicines or fixed dose combinations that require these patents, in return for the payment of a reasonable royalty.[251]

Even though the two companies denounced the complaint as unfounded, they compromised with the Commission and granted voluntary licenses to produce a generic version of their patented pharmaceuticals.[252] Since this case, there has been substantial progress in South Africa toward providing access to pharmaceuticals for patients with HIV/ AIDS.[253]

The South African model of competition law could be utilized by developing countries and LDCs, including Bangladesh, to prevent excessive pricing of medicines.

V. COMPARATIVE REVIEW AND LESSONS FOR LDCS INCLUDING BANGLADESH

This analysis highlights that India, Brazil, and South Africa used different options in their transition to a pharmaceutical patent regime and TRIPS-compliant patent law. India and Brazil substantially revised

patent owners of ARV (HIV/AIDS) drugs, set unjustifiably high prices for these drugs in South African markets. AZT (300 mg) is sold at $0.92 as compared to the WHO generic price of $0.25. Compulsory licensing negotiation under the South African Patent Act proved futile as the companies demanded a 25% royalty on sales as compared to the international rate of 4-5%. The Competition Commission took action under section 8 of the South African Competition Act, which prohibits "a dominant firm to charge an excessive price to the detriment of the consumers," ordering the issuance of licenses to market generic versions of the patented ARV drugs in return for the payment of a reasonable royalty to be decided by the Competition Tribunal. *See* Fisher & Rigamonti, *supra* note 11, at 52.

250. Fisher & Rigamonti, *supra* note 11, at 52.

251. Rachel Roumet, *Access to Patented Anti-HIV/AIDS Medicine: The South African Experience*, 32 EUR. INTELL. PROP. REV. 137, 140 (2010).

252. Fisher & Rigamonti, *supra* note 11, at 54.

253. Roumet, *supra* note 251.

national patent law using the flexibilities present in the TRIPS Agreement. These flexibilities are also available to LDCs, such as Bangladesh, as they move towards TRIPS compliance. The issues for LDCs like Bangladesh are which flexibilities to adopt and when during the transition process the chosen flexibilities should be utilized. The different policy options taken by these countries can be represented diagrammatically, as in Table 1.1 below.

Table 1.1: Policy Options Used by Brazil, India, and South Africa

TRIPS Stages	**Legislative Position**	**India**	**Brazil**	**South Africa**	**Remarks**
Pre-TRIPS	1. No patent protection for pharma-ceuticals 2. Process patent only 3. Limited duration for pharma-ceutical patent protection	To encourage the generic production of drugs and to develop imitating capacity, India prohibited product patents and allowed only process patents for pharma-ceuticals Process patent for pharma-ceuticals granted only for seven years	Brazil eliminated both process and product patents for pharma-ceuticals	South Africa provided both product and process patents for pharma-ceuticals without any substantive examination	India allowed process patents only during the pre-TRIPS regime, whereas Brazil eliminated patent protection for pharma-ceuticals altogether; South Africa provided both product and process patents even during the pre-TRIPS period

Transitional periods (until January 1, 2005, for developing countries and until January 1, 2016, for LDCs, which has been further extended until July 1, 2021)	Utilization of full transition period	India utilized the full transition period and implement-ed TRIPS-compliant patent law in 2005	Brazil approved a TRIPS-compliant patent law in 1996 (Industrial Property Law 9.279) and implemented it in May 1997	South Africa undertook to become TRIPS-compliant in 1997	Brazil and South Africa introduced TRIPS-compliant law several years before the 2005 deadline, whereas India waited until the expiration of the transition period
Flexibilities under TRIPS-Compliant Patent Law and other available policy options	Strict patentability requirements: absolute novelty and high level of disclosure Early working or *Bolar* exception and research & experimental use. Pre-grant and post-grant opposition Compulsory license and government use Parallel imports Prior-use exception Limit test data protection 8.Price control	India has included all these legislative options in its national patent law	Brazil has included all these provisions in its national patent law, especially compulsory licensing; but use of traditional medicine is not significant and test data protection is not limited as in India	South Africa included some of the TRIPS flexibilities, such as compulsory licensing and parallel imports, and also has competition law and price control mechanism; but it has no substantive patent examination system, pre-grant opposition, or clear rules on experimental use and prior use; on the	A combination of the Brazilian and Indian approach may be useful to balance innovation and public health In addition, the South African experience of price control and competition law could be useful for LDCs

	9.Utilization of traditional medicinal knowledge 10. Competi-tion law			other hand, it provides test data protection	

The requirement to move toward TRIPS-compliant patent law has created apprehension within Bangladesh.[254] The fear is that the price of pharmaceuticals in the local market will increase and that local pharmaceutical companies may not survive the high cost of royalties for patented medicines and the need to compete with multinational corporations.[255] In this regard, the experiences of Brazil, India, and South Africa in utilizing the TRIPS flexibilities and other alternative measures to balance innovation and access to pharmaceuticals should be considered by Bangladesh and other LDCs.

The present patent regime in Bangladesh has no provisions to effectively utilize the TRIPS flexibilities as India, Brazil, and South Africa have done. Importantly, to utilize the flexibilities, consideration will be necessary to amend Bangladesh's Patents and Designs Act of 1911.[256] In addition to utilizing TRIPS flexibilities, the government of

254. Mohammad M. Azam & Kristy Richardson, *Pharmaceutical Patent Protection and TRIPS Challenges for Bangladesh: An Appraisal of Bangladesh's Patent Office and Department of Drug Administration*, 22 BOND L. REV. 1, 4 (2010).

255. *Id.*; *see generally* M. Monirul Azam, *Globalizing Standards of Patent Protection in WTO Law and Policy Options for the LDCs: The Context of Bangladesh*, 13 CHI.-KENT J. INTELL. PROP. 402 (2014).

256. Patent law in the Indian sub-continent, including Bangladesh, has its origin in the 19th century, when it was under the rule of the British East India Company. The first legislation relating to patents was enacted as Act VI of 1856 and was based on the British Patent Law of 1852. Subsequently the power to rule the Indian subcontinent transferred from the East India Company to the British Crown via the Government of India Act 1858. New legislation for granting "exclusive privileges" for invention was introduced as Act XV of 1859. This legislation contained certain modifications of the earlier legislation, namely the grant of exclusive privileges solely to useful inventions and extension of the priority period from six months to 12 months. But this Act excluded importers from the definition of inventor, and it was also substantially based on the British Patent Act of 1852 with certain departures, which included allowing assignees to make applications in India and also taking prior public use or publication in India or the United Kingdom for the purpose of ascertaining novelty. Later, the British Government enacted the Patents & Designs Protection Act of 1872 and also the Protection of Inventions Act of 1883. These two Acts were later consolidated into The Inventions & Designs Act of 1888. Finally abolishing the earlier patent laws, the Indian Patents & Designs Act of 1911 was enacted, consolidating all the patents and designs issues, including establishment of the office of controller of patents and designs. Bangladesh adopted the same law as established by the Patents and Designs Act of 1911, and Bangladesh's law remains unchanged today. *See History of Indian Patent System*, GOV'T OF INDIA, http://ipindia.nic.in/ipr/patent/patents.htm (last visited July 27, 2013); *see also* MOHAMMAD MONIRUL AZAM, INTELLECTUAL PROPERTY, WTO AND BANGLADESH (2008); *see generally* Azam,

Bangladesh could adopt a competition law based on the experience of South Africa and could also revise price control mechanisms based on the experiences of India and Brazil. The Government of Bangladesh enacted Competition Act, 2012 in June of 2012.[257] According to one study, "[a] draft bill for such a law was first proposed in 1996; however, it took sixteen years to finally come to fruition."[258]

The progress of the Competition Bill has been delayed: "the political will to implement a competition law is limited, and there is some opposition from business groups."[259] "Indeed, competition problems are potentially more serious in a country [such as Bangladesh] with a weaker private sector, where one or a few dominant firms can take control" and abuse their dominant position.[260] "The media coverage . . . suggests [that] Bangladesh may suffer from significant competition problems, with substantial costs to consumers" and to the public health sector of Bangladesh, more particularly.[261]

However, considering some weaknesses within South African competition law, it is suggested that in any future Bangladeshi competition law, the Competition Commission should have authority to issue compulsory licenses, to recommend fixed royalty rates, and to "expressly allow for the export of products produced under compulsory licenses in order to maintain sustainable investment."[262] In addition, LDCs may also stipulate in national competition law that compulsory licensing could be granted in cases of anticompetitive behavior, such as in the case of a patent holder's unilateral refusal to grant a license (i.e., refusal to deal).[263] Competition law could also be applied in the case of obtaining pharmaceutical patents in an unjustified and fraudulent manner.[264] The issues of "poor quality" and "frivolous" patents and

supra note 255.

257. RAFIA AFRIN & DANIEL SABET, WILL BANGLADESH'S NEW COMPETITION LAW PROVE EFFECTIVE? 1 (2012), *available at* http://www.ulab.edu.bd/CES/documents/Competition_law_07-12.pdf.

258. *Id.*

259. *Id.*

260. *Id.* at 2.

261. *Id.*

262. *See* Azam, *supra* note 255, at 462; TENU AVAFIA ET AL., TRADE LAW CENTRE FOR SOUTHERN AFRICA, THE ABILITY OF SELECT SUB-SAHARAN AFRICAN COUNTRIES TO UTILISE TRIPS FLEXIBILITIES AND COMPETITION LAW TO ENSURE A SUSTAINABLE SUPPLY OF ESSENTIAL MEDICINES: A STUDY OF PRODUCING AND IMPORTING COUNTRIES 4-5 (2006).

263. *See Intellectual Property and Competition Law: Exploration of Some Issues of Relevance to Developing Countries*, ICTSD PROJECT ON IPRS AND SUSTAINABLE DEVELOPMENT, Issue Paper No. 21, at 20 (2007) (by Carlos M. Correa), *available at* http://www.iprsonline.org/resources/docs/corea_Oct07.pdf.

264. In fact, these patents should never be granted in the first place. But lack of proper resources, expertise, and proper examination in LDCs may allow for such fraudulent registrations.

regulatory practices, such as marketing approval and data exclusivity, can also be controlled under competition law.[265]

Furthermore, some existing research indicates that despite having impressive sales and export growth, the local pharmaceutical industry in Bangladesh – particularly after the introduction of the 1982 Drug Control Ordinance – helped Bangladesh ensure the supply of generic medicines at a lower price but limited the local industrial development of innovative capacity for basic research and patenting of new medicines.[266] On the other hand, lack of proper monitoring by the Directorate General of Drug Administration in Bangladesh raises the issue of quality medicines.[267] Also, a lack of expertise and required resources in the Bangladeshi patent office raises the issue of capability to deal with the pharmaceutical patent and TRIPS-compliant patent law.[268]

VI. CONCLUDING REMARKS

This study identified options used by Brazil, India, and South Africa during the transition to a TRIPS-compliant patent regime. These options enabled them not only to promote the local pharmaceutical industry, but also to maintain access to medicines. The experiences of India, Brazil, and South Africa in utilizing TRIPS flexibilities provide important lessons for LDCs as they transition to TRIPS-compliant patent law.

This study also explored how these countries utilized these options to generate the right balance between the interests of the pharmaceutical industry and the increased demand by the public for affordable medicines. On this basis, the current position is that LDCs need to utilize the benefit of the TRIPS transition period and must consider technological and infrastructural limitations to lobby for the further extension of transition periods.[269] The future of the pharmaceutical industry in LDCs lies at the center of which legislative and policy intervention options are taken by the Bangladeshi government to implement a TRIPS-compliant patent law and to what extent local industry could utilize TRIPS waiver periods to develop technological and innovative skills for transition from a copycat nation to an

In these situations, competition law could play an important role.

265. *See* Correa, *supra* note 263.

266. Azam & Richardson, *supra* note 254, at 6.

267. *Id.* at 11-14.

268. *Id.* at 10.

269. *Id.* at 1-2.

innovative nation.[270]

270. *Id.*