Regulatory Marketing Approval for Pharmaceuticals as a Non-Tariff Barrier to Trade: Analysis under the WTO's Agreement on Technical Barriers to Trade

Mary Hess Eliason

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Regulatory Marketing Approval for Pharmaceuticals as a Non-Tariff Barrier to Trade: Analysis Under the WTO’s Agreement on Technical Barriers to Trade

MARY HESS ELIASON*

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I. INTRODUCTION

At a fundamental level, pharmaceuticals serve two roles: both as a cure for disease and as a product. As a cure for disease, a drug’s value cannot be quantified because it saves lives. As a product, profit analysis shapes every step of a drug’s progression to market. In least developed nations the barriers to drug access are not solely economic. National regulatory systems for market approval are being used to prevent external pharmaceutical manufacturers from participating in a national market. This article will address how the regulatory framework of pharmaceutical registration may serve as a barrier to trade in drugs, how these regulations affect developing countries who may want and/or need to establish their own pharmaceutical industries, and how the World Trade Organization’s Agreement on Technical Barriers to Trade may permit sanctions against such protectionist policies.

II. THE PHARMACEUTICAL MARKET STRUCTURE

Pharmaceuticals are unique products because all strata of society use them, yet they represent large amounts of technical knowledge, economic investment, and political controversy. For many reasons, drugs are expensive
to make and expensive to obtain. In this section I will describe the general factors which affect the pharmaceutical market, focus on the role that regulatory requirements play in drug pricing, and discuss the challenges drug pricing presents in lesser developed countries.

A. Factors in Drug Pricing

It is difficult to separate the costs regulatory requirements impose on the manufacture and marketing of drugs from other elements which affect the pharmaceutical industry. These other elements include: intellectual property rights, differential pricing structures, compulsory and voluntary licensing, parallel importation, exhaustion, and general expenses in capital equipment and payroll that are inherent in any high tech industry. Economic generalizations about the “pharmaceuticals market” are difficult to assess because competition between drugs is “limited to a group of drugs that

1. Regulatory requirements may be described here as those standards that must be met to sell a drug for human consumption. See discussion infra, Part III, for a more precise definition of regulatory requirements.

2. Intellectual property is the intangible product of human activity. Frederick M. Abbott et al., THE INTERNATIONAL INTELLECTUAL PROPERTY SYSTEM: COMMENTARY AND MATERIALS 21 (1999). An intellectual property right (IPR) is a right to authorize or prevent others from acting in certain ways with respect to intellectual property. Id. at 22. Intellectual property rights, compulsory licensing, parallel importation, IPR exhaustion, human rights and voluntary licensing have been more than adequately discussed elsewhere. See e.g., Frederick M. Abbott, The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health, 99 AM. J. INT’L L. 317 (2005).


4. A compulsory license is “a statutorily created license that allows certain people to pay a royalty and use the [product covered by intellectual property] without the [permission of the IPR holder].” BLACK’S LAW DICTIONARY 938 (8th ed. 2004).

5. See discussion of regulatory arbitrage for definitions, infra, Part III.

6. IPR exhaustion is the principle that once the owner of an intellectual-property right has placed a product covered by that right into the marketplace, the right to control how the product is resold within that internal market is lost. BLACK’S LAW DICTIONARY 614 (8th ed. 2004).

7. But Abbott comments that “competition is perhaps the most powerful policy instrument to bring down drug prices for off-patent drugs. In the United States, when a patent expires the average wholesale price falls to 60% of the branded drug’s price when there is just one competitor.” Frederick M. Abbott, The Doha Declaration on the TRIPS Agreement and Public Health: Lighting A Dark Corner at the WTO, 5 J. INT’L ECON. L. 469, 471 (2002) [hereinafter Abbott, Doha].
are therapeutic substitutes for each other." Therefore the amount of money it takes to develop a particular type of drug may be relatively constant, yet the amount of money a drug will sell for varies widely. Drug pricing and profitability are drastically affected by the nature of the particular drug. Whether the particular drug is a minor improvement over the current treatment, a breakthrough drug in a known disease area, or the first treatment available for a new disease affects that drug's ultimate profitability.

All these elements contribute to high economic, social, and political barriers to market entry and the high price a consumer actually pays. The economic barriers begin with the high costs of research and development [R&D] and are compounded by the high attrition of drugs in the development stages. For instance, one successful drug must pay the research costs of screening 10,000 early stage drugs. Only one out of five drugs which enter clinical trials gets marketing approval in the United States. At every step, potential compounds in the developed

8. Carston Fink, Patent Protection, Transnational Corporations, and Market Structure: A Simulation Study of the Indian Pharmaceutical Industry, INTELLECTUAL PROPERTY AND DEVELOPMENT: LESSONS FROM RECENT ECONOMIC RESEARCH. 231, 251 (Carston Fink & Keith E. Maskus eds., 2005). The market is also segmented into the new drug market and the generic drug market. Though the burden of approving a new drug is larger, and therefore more expensive over all, the regulatory requirements for an already approved drug are similar. In Canada—Patent Protection of Pharmaceutical Products, the WTO rejected stockpiling of patented products for commercial sale before the end of the patent term, but allowed use and sale of patented chemicals if ultimate intention was to be used in testing to be submitted to a regulatory agency for market approval. In its argument, the Canadian government stated that the approval of an already approved drug could take between 3 and 6 years, which includes proof of a viable full production line and tests in humans. Panel Report, Canada—Patent Protection of Pharmaceutical Products, WT/SD114/R (Mar. 17, 2000) [hereinafter Canada—Pharmaceuticals].

9. Fink, supra note 8, at 251. Fink also argues that the pharmaceutical sales market is further segmented: "the market for antibiotics ... can be considered as being independent of the market for, say, cardiovascular drugs. Competition is limited to a group of drugs that are therapeutic substitutes for each other." Id. at 231.

10. "The cost of launching one new drug (including absorbing the R&D costs of drugs that fail to get approval) has increased significantly over recent decades from $138 million in the 1970s to more than $800 million now." PHARM. RESEARCH AND MFRS. OF AM., PHARMACEUTICAL INDUSTRY PROFILE 2005, 9 (Washington, DC: PhRMA, March 2005) [hereinafter PhRMA Profile].

11. Id. at 4, 12 n.9. Though it is debatable whether the United States of America is a good representative of the drug market, what is known is that the global pharmaceutical sales in 2004 were over 500 billion USD. Of this market, 88% is in North America, Europe and Japan. Asia and Latin America combined contribute 11% and Africa less than 1%. But if tablets were counted, middle income countries with large populations would have a larger share based on the large volume/low cost markets for drugs in these countries. Pharmaceuticals: Local Manufacturing, HNP Brief #3, 1 (World Bank, Mar. 2005) [hereinafter World Bank], available at http://www-wds.worldbank.org/servlet/WDS_IBank_Servlet?pcont=details&eid=000090341_20050503161513.

world are evaluated for patentability and potential market share. After such a high investment in any given drug, individual companies jealously guard their patent monopoly in hopes of quickly recovering the costs of research.

Socially, the costs of health care and the burdens of disease induce governments of developed nations and individual consumers to pay high premiums for the newest and latest therapy. The popularity of these new treatments raises the risks and rewards inherent in this industry by creating a race to be the only drug approved for a niche market. Furthermore, nationally imposed requirements to obtain drug regulatory approval can affect the price both indirectly and directly. First, national regulatory requirements affect the price indirectly through intellectual property rights because the period during which a company can sell the drug under the monopoly may be shortened by regulatory delays. Second, national regulatory requirements affect the price directly because, "adherence to [Good Manufacturing Practices] can add significantly to investment and operating conditions of a manufacturing operation." The costs of regulatory compliance are also inflated by compliance with the myriad regulatory schemes in both developed and lesser developed nations. The regulatory barrier to market entry applies for each country in which access is desired, so a drug that is acceptable in most of the developed countries may encounter additional requirements if a

13. The issue of research gaps intersect here. Many argue that these market evaluations indicate that it is un-profitable to spend the effort in finding a cure for many of the diseases affecting developing nations, thereby ignoring serious diseases in favor of more profitable minor ailments or lifestyle therapies. See, e.g., Amy Kapczynski, Addressing Global Health Inequities: An Open Licensing Approach For University Innovations, 20 BERKELEY TECH. L.J. 1031 (2005).

14. A patent right is "the right to exclude others from making, using, marketing, selling, offering for sale, or importing an invention for a specified period (typically 20 years from the date of filing), granted by the federal government to the inventor if the device or process is novel, useful, and nonobvious. 35 U.S.C.A. §§ 101-103." BLACK'S LAW DICTIONARY 1150 (8th ed. 2004). A patent right is also known as a "patent monopoly" and the period of patent protection is often referred to as the "monopoly period."

15. Outterson observes that the patent monopoly in high income countries is rarely unqualified; regulatory systems, health plans and government price setting all limit how much a patented drug will sell for. Outterson, supra note 3, at 213-14.


17. World Bank, supra note 11, at 2.
manufacturer chooses to market it in lesser developed or developing countries and vice versa.

B. How Least Developed Nations are Affected by Drug Price

Like the pharmaceutical industry itself, drugs in the developing world are characterized by high prices and complex relationships. The combination of a high product price and high manufacturing price effectively makes purchasing sufficient quantities of drugs from more developed nations impossible for developing nations, and the current solutions to increase access are inadequate. The HIV/AIDS epidemic has brought the cost of drugs to the attention of international bodies, including the WTO. Through the TRIPS agreement and the Doha Declaration, the WTO tried to increase access to drugs by lowering the portion of the price of drugs directly related to the patent monopoly by allowing compulsory licensing. The threat of compulsory licensing has lowered the price of essential drugs to developing nations, but many argue that the price is still "high in relation to available incomes." Furthermore, compulsory licenses are disfavored by the drug's patent

18. For example, a research gap exists where little private research is done on diseases pertinent to least developed nations, since the return of investment on those diseases is limited to income from populations in least developed nations, and not the diseases which dominate developed nations. Conversely, an access gap is one where individual nations have little or no access to drugs, due to pricing or other market mechanisms. See Kapczynski, supra note 13.

19. Id.

20. Agreement on Trade-Related Aspects of Intellectual Property Rights, April 15, 1994, Annex 1C, Article 31, Legal Instruments-Results of the Uruguay Round of Multilateral Trade Negotiations, April, 15, 1994, 33 I.L.M. 1125, 1197 [hereinafter TRIPS]. TRIPS allowed compulsory licensing based on government need. Under TRIPS art 31 governments of developing nations may make, use, or sell a patented product in opposition to the patent holder's wishes by invoking the compulsory license provision. Id. A member country is charged a "reasonable royalty" to exploit the patent, but that value is theoretically much lower than the market value for the drug.


22. To take HIV/AIDS as an example, the cost of patented AntiRetroviral Combination Therapies (ARVs) was more than $10,000/ year, where the generic cost "as little as $168" per year. See Kapczynski, supra note 13. See also World Health Organization, AIDS Epidemic Update (Dec. 2004), available at www.unaids.org/wad2004/EPI_1204_pdf_en/EpiUpdate04_en.pdf (last visited Feb. 24, 2006).

23. Carsten Fink & Keith E. Maskus, Why We Study Intellectual Property Rights and What Have We Learned, in INTELLECTUAL PROPERTY AND DEVELOPMENT: LESSONS FROM RECENT ECONOMIC RESEARCH 1, 10 (Carston Fink & Keith E. Maskus eds., 2005). See also Kapczynski, supra note 13.
holders, because they do not receive their maximum profit from a compulsory license, only a “reasonable royalty.” Compulsory licensing for developing nations is disfavored because it does not create incentives for developing nations to find permanent domestic solutions to their public health crises. Additionally, lesser developed nations have contracted away their compulsory licensing privileges through bilateral agreements to obtain concessions on completely different trade issues.

Drug pricing policy in the developed world affects drug pricing in the developing world. For example, Outterson argues that, though Anti-Retroviral treatments (ARVs), the main therapy for HIV infection, were not patented in most of Sub-Saharan Africa during the past fourteen years, the real barrier to ARV access was the cost of drugs in the developed world. The supply of ARVs to the developing countries had to originate outside their borders, because they did not have the ability to manufacture their own. These external prices, inflated by patent monopolies, limited the scale on which medications were manufactured and the threat of litigation for patent infringement deterred generics manufacturers from exporting the drugs to Sub-Saharan Africa, thereby cutting off an adequate supply of drugs.

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24. TRIPS art 31. The patent holder risks losing a significant market for their drug and the related profits by compulsory licensing.

25. When developing nations have the ability to obtain pharmaceuticals at drastically lowered prices through compulsory licensing, they “reap the full benefits from lower prices . . . yet the costs in terms of diminished research incentives are largely externalized to the developed world.” Alan O. Sykes, TRIPS, Pharmaceuticals, Developing Countries and the Doha “Solution,” 3 CHI. INT’L L. 47, 49 (2002).

26. There are allegations of unfair licenses and bilateral agreements between individual nations where the bilateral trade agreement implements stronger intellectual property protection than what signatories to TRIPS are bound by. There is concern because some believe these “TRIPS Plus” provisions are the product of unequal bargaining power between nations. See Abbott, Doha, supra note 7. See also Access to Medicines At Risk Across the Globe: What to Watch Out For in Free Trade Agreements with the United States, Briefing Note (Médecins Sans Frontières’ Campaign for Access to Essential Medicines) (May 2005).

27. Outterson comments that though Brazil and India were capable of manufacturing and exporting ARVs to Sub-Saharan Africa, any efforts were blocked by dispute resolution in the WTO. Outterson, supra note 3, at 256.

28. Id.

29. Id. See also Mattias Ganslandt et al., Developing and Distributing Essential Medicines to Poor Countries: The DEFEND Proposal, in INTELLECTUAL PROPERTY AND DEVELOPMENT: LESSONS FROM RECENT ECONOMIC RESEARCH 207, 210 (Carston Fink & Keith E. Maskus eds., 2005). “Pharmaceutical firms chronically undersupply the medicinal needs of poor countries, partly because of limited exclusivity in rights, including the need to restrain parallel trade.” Id.
To increase access to pharmaceuticals in the near future, alternatives to manipulation of intellectual property rights (IPRs) should be analyzed. Encouraging lesser developed nations to form local drug industries is an attractive alternative to compulsory licensing. Advantages of a local drug market, especially in AIDS/HIV afflicted countries, include the potential for lower drug prices, strengthened political support for treatment programs, mobilization of resources to overcome health system bottlenecks and unification of political leaders to fight the epidemic.30 Ironically, some lesser developed nations are now providing generic drugs to the least developed nations under compulsory licenses because they were politically and economically able to enter the market.31 However, it is unrealistic to believe that the least developed nations have the infrastructure to create viable drug manufacturing plants overnight. Though each individual nation may not be able to support pharmaceutical manufacturing, Abbott suggests that there is promise for “regional arrangements in which facilities and related infrastructure can be allocated in a way that provides benefits” to all countries in the region.32 In this manner, one country may provide research facilities, another may provide manufacturing ability and packaging, and the staff may come from any of the surrounding countries. In a continent of geographically tied regions, this supply of drugs may be sufficient to treat the entire region.33

Market access to pharmaceuticals has been thoroughly discussed in the framework of WTO Agreements, through the TRIPS Agreement and IPRs, parallel importation, IPR exhaustion, human rights and voluntary licensing.34 This article will focus on the additional burden that regulatory requirements to attaining drug approval present to developing nations and how these laws should be addressed by the WTO.

30. World Bank, supra note 11, at 3. Government action to create a new or improved regulatory system focuses attention on the weaknesses of the current system, and will raise awareness about national health concerns. Increased sensitivity about health related issues common to a region may serve as a ground to foster cooperation between nations which previously have acted at cross-purposes or in direct competition in the past. See generally Frederick M. Abbott, Managing the Hydra: The Herculean Task of Ensuring Access to Essential Medicines, in INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY: UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME 393 (2005) [hereinafter Abbott, Hydra].


32. Frederick Abbott, Hydra, supra note 30, at 419. But Abbott concedes that nations that will need a long-term large supply of medicines, such as ARVs, should create local production to prevent landing in an economically and politically vulnerable position on all trade fronts. Id.

33. Id.

34. See generally Abbott, Doha, supra note 7 (containing background information on the costs of pharmaceuticals and WTO framework).
III. INTRODUCTION TO REGULATORY REQUIREMENTS

A. What are Pharmaceutical Regulatory Requirements?

Pharmaceutical regulatory requirements are the testing procedures required by a national agency to market a drug in that country. Regulatory requirements are imposed on researchers and manufacturers before and after the drug is approved to be sold in a country. Regulatory systems may have at least some of the following components at some level: pre-approval regulatory requirements, such as data from preclinical tests, the components and composition of the drug, animal tests for efficacy and safety, pharmacokinetic and pharmacodynamic data, clinical results, manufacturing, processing and packaging information, and samples of the drugs with its labeling. Post-approval regulatory requirements consist of post-marketing surveillance of the approved drug through spontaneous reports and continuing clinical studies, inspections of the laboratories and manufacturing plants responsible for making the drug, and validation of the manufacturing processes up to commercial production and over time.

Often it is difficult to determine exactly how much testing is needed on a pharmaceutical before that drug is considered "safe" for consumers. Janet Woodcock, former Director of the U.S. Center for Drug Evaluation and Research, describes the need to balance the amount of time it takes to approve a drug, the completeness of the testing requirements, the changing demands of generic acceptance, and international harmonization. She notes that ultimately:

Clinical testing—the premarket testing of drugs—will not detect all the problems. It just can't... because some of the events are rare... and some problems with drugs are caused by the way they're used outside of the parameters for which they're approved... also sometimes we encounter errors in the use of the drug.

Given this uncertainty about whether even the most rigorous regulatory schemes will detect adverse drug events, it is understandable that each

36. Id. at 46.
37. Id. at 10.
38. Id. at 11.
country has developed its own testing requirements based on its own national experience.

National law determines the extent of regulatory requirements, which differ from nation to nation. In Canada-Pharmaceuticals, for example, differences between national regulatory laws were highlighted when, spurred by Canada's more lenient regulatory laws, the United States and the European Union brought a complaint against Canada. The parties alleged that Canada's regulatory law violated TRIPS by allowing generic drugs to obtain regulatory marketing approval during the patent term. The parties also objected to Canada law which allowed the manufacture and stockpiling of a supply of marketable drugs to be sold to consumers the minute the patent term had expired. The WTO Dispute Settlement Body [DSB] concluded that the TRIPS agreement allowed generic manufacturers to make and sell patented drugs before the patent term expired for regulatory submission only but not for stockpiling. This case highlighted the Canadian government's policy of minimizing the cost of drugs to consumers, as embodied through their regulatory scheme.

B. Harmonization of Regulatory Requirements and the International Arena

International organizations may help establish a consensus for pharmaceutical regulatory requirements, but these organizations are predominantly created by developed nations, to meet the needs of developed nations. The current global standard for pharmaceutical

39. Canada—Pharmaceuticals, supra note 8, at IV D (4) (e).

40. Id. Incidentally, Canada also argued that the United States' more restrictive regulatory requirements were a technical barrier to trade. Id. The WTO panel refused to address the issue as to whether a pharmaceutical regulatory requirement was a technical barrier to trade, and decided under the TRIPS Agreement that manufacturing for submission to the regulatory agency was allowed while stockpiling for sale was not. Id.

41. Though, the WTO's Agreement on Technical Barriers to Trade requires that "Members shall take such reasonable measures as may be available to them to ensure that international standardizing bodies and international systems for conformity assessment are organized and operated in a way which facilitates active and representative participation of relevant bodies of all Members, taking into account the special problems of developing country Members," the evidence supporting the proposition that developed countries make allowances for developing countries tends to be related to technology transfer through publication of methods and standards. Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, Apr. 15, 1994, 33 I.L.M. 1125 (1994), Annex IA—Multilateral Agreements on Trade in Goods, Agreement on Technical Barriers to Trade, 12.5 [hereinafter TBT]. Additionally, developed nations view the non-participation in the chemicals markets by developing nations as de facto. The EU's recent REACH proposal, requiring universal high-level testing of all chemicals imported or made in the EU, argues that the proposal will in fact assist developing countries because:
manufacturing is the Standard of Good Manufacturing Practice (GMP),
developed by the U.S. Food and Drug Administration.42

The International Conference on Harmonisation of Technical
Requirements for Registration of Pharmaceuticals for Human Use (ICH)
brings together the regulatory authorities of Europe, Japan and the United
States, and may be the next gold standard for pharmaceutical regulations.43
Registration requirements under the ICH are more stringent than those
for GMP, and most small-scale local manufacturers are not able to meet
GMP standards.44 Furthermore, the ICH system is intimately tied to
industry, the United States FDA is the regulatory lead and United States
industry lead is the Pharmaceutical Research and Manufacturers of
America (PhRMA).45

Another standardizing organization is the International Standardization
Organization (ISO), a non-governmental body which establishes and
disseminates technical regulations for all areas of trade through national
representatives.46 This organization is prominently featured in the WTO
agreements, and acts as a repository for notifications received under the
TBT.47 The ISO suggests that published regulations assist the transfer of

44. World Bank, supra note 11, at 2.
45. David P. Kelly et al., Promoting Public Health and Protecting Consumers in a
Global Economy: An Overview of HHS/FDA’s International Activities, 60 FOOD & DRUG
47. TBT, annex 3C.
technology to less developed nations because they disclose technology and methodologies.  

The ISO states that 146 of its members are developing nations, yet the decisional committees primarily consist of national standardization organizations from developed countries or countries which arguably should not hold lesser developed status.  

Pharmaceutical regulatory requirements are pertinent to the international drug trade because importing countries require that drug imports comply with their national regulatory requirements or an acknowledged equivalent. For instance, Outterson points out that the U.S. Food Drug and Cosmetics Act (FDCA) is a non-tariff barrier to international trade because it does not allow drugs to be imported into the United States without approval from the FDA. However, it is unclear that this barrier to trade is unjustified in light of fears over widespread counterfeiting. It is clear that many countries require approval by their own agency before a drug can be sold in that country.

C. Regulatory Arbitrage: Maximizing Profits Across Regulatory Systems

Like picking a forum to bring suit in, companies and consumers can pick where to market and purchase their drugs based on the most favorable regulatory regime. In regulatory arbitrage, both pharmaceutical manufacturers and consumers evaluate regulatory systems to determine the most profitable environment to make and buy pharmaceuticals. Outterson argues that when one state imposes particularly restrictive
regulatory requirements on an industry, as the United States does, the industry (or its consumers) may relocate to a state with less restrictive regulations, inducing the first state to relax its regulatory system.\(^5\) He argues that the pharmaceutical arbitrage across the U.S.-Canadian border, spurred by government price controls in Canada, encouraged U.S. consumers to "import" the Canadian regulatory system of price fixing into the American pharmaceuticals market.\(^5\) This "importation" induced Congress to re-evaluate its position on foreign drug imports, though it declined to change it.\(^5\)

There is a close connection between intellectual property rights and the chosen regulatory scheme. For instance, clinical data generated from trials required by national regulatory agencies may be protected by some form of national IPRs, placing the regulatory authority in a position to protect IPRs.\(^5\) Industry arbitrage may be based on a country’s IPRs. Maskus notes that strengthening IPR protection indicates to transnational corporations that the country is open to foreign direct investing (FDI), by creating trade liberal, transparent, production and marketing controls.\(^5\) But IPRs are only one of many variables that determine the attractiveness of an FDI location.\(^5\)

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\(^5\) Otterson, supra note 3, at 281.
\(^5\) Id.
\(^5\) Id
\(^5\) Carlos M. Correa, Unfair Competition Under the TRIPS Agreement: Protection of Data Submitted For The Registration of Pharmaceuticals, 3 Chi. J. Int’l L. 69 (2002). Correa subsequently argues that intellectual property protection for clinical data should be carefully scrutinized to support the individual nation’s needs. Id. He discusses one position where IPRs are not given to clinical data because, “the registration of products should not erect barriers to otherwise legitimate competition” and should instead “promote price competition and access to more affordable medicines.” Id.

\(^5\) Keith E. Maskus, The Role of Intellectual Property Rights in Encouraging Foreign Direct Investment and Technology Transfer, in INTELLECTUAL PROPERTY AND DEVELOPMENT: LESSONS FROM RECENT ECONOMIC RESEARCH 41, 62 (Carston Fink & Keith E. Markus eds., 2005). When a transnational company establishes a wholly owned subsidiary in a foreign country, it is considered Foreign Direct Investment. Id. FDI is generally considered to be beneficial to a developing country because it increases the transfer of technology directly, by employing and training local nationals, but the economic benefit a country receives may be limited due to the trans-national corporations engaging in abusive practices such as restrictive licensing conditions and technology grant backs, tied sales or engaging in price discrimination and predation against local firms. Id. at 68.

\(^5\) Fink & Maskus, supra note 23, at 7, commenting on Maskus, supra note 57. Fink comments, “a poor country hoping to attract inward FDI would be better advised to improve its overall investment climate and business infrastructure than to strengthen its
Industry decisions about whether to locate research and manufacturing capability in a host country ultimately affect both regulatory requirements and the strength of intellectual property protection adopted in a given country.\textsuperscript{59} Unfortunately, manufacturing and trade in pharmaceuticals has been associated with nepotism and corruption in some countries with less established governments. National regulatory agencies have been directly implicated; "manufacturers may try to influence regulatory decisions or get preferential market access in exchange for favors."\textsuperscript{60} This sort of relationship exemplifies a different type of regulatory arbitrage, one that does not encourage FDI and technology transfer, and encourages the exploitation of disorganized governments and consumers. Clear and fair marketing regulatory requirements, like the establishment of an intellectual property regime, may indicate a healthy political system and business infrastructure, thereby encouraging investment or business in that country.\textsuperscript{61} But, like inadequate IPRs, inadequate or protectionist regulatory schemes may induce corporations and consumers to look elsewhere to spend their money.

The test case discussed in part V exemplifies the challenges with identifying and combating potentially protectionist regulatory regimes. However the group which lose the most are the consumers, who can not buy their drugs from other countries.

IV. PHARMACEUTICALS AND THE WTO FRAMEWORK

A. Non-Economic Barriers to Trade and the WTO Framework

The WTO was formed in 1995 with the purpose of enabling international trade to the economic benefit of all nations. The WTO creates and administers binding international rules of trade and resolves disputes between countries based on the agreements. The Marrakesh Agreement Establishing the World Trade Organization incorporates all the Multilateral Trade Agreements as a single, integrated instrument.\textsuperscript{62} The General patent regime sharply. . . . However, IPRs are quite important for multinational firms making location decisions among middle-income countries." \textit{Id.}

59. Abbott, \textit{Hydra}, supra note 30, at 410. (Describing how the local and international pharmaceutical industry in South Africa prevented the passage of legislation designed to facilitate lower prices for patented medicines and in doing so distorted the policies of the South African government.).

60. World Bank, \textit{supra} note 11, at 3 (suggesting that regulatory decisions may not always be made solely with the interests of the nation in mind).

61. Fink & Maskus, \textit{supra} note 23.


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Agreement includes an obligation that Members will ensure that their respective governments’ “laws, regulations and administrative procedures” are in conformity with their obligations under the WTO.63

The WTO Agreement promotes free trade by creating and applying rules regarding transparency of trade, harmonization of international trade standards, and non-discriminatory trade practices through its Most Favoured Nation (MFN) treatment.64 MFN requirements provide that a Member State cannot discriminate in how it treats goods coming from different Member States.65 Similarly, national treatment requires Member States to treat products imported from any other Member State the same as it treats like products within its own jurisdiction.66 The WTO also provides an international forum for dispute settlement.67

The WTO has three major documents which cover discriminatory trade practices related to human health: the General Agreement on Tariffs and Trade 1994 (GATT),68 the Agreement on Sanitary and Phytosanitary Measures (SPS) 69 and the Agreement on Technical Barriers to Trade (TBT).70 Through these agreements, the WTO not only presents broad theories of competition law, but allows member nations to regulate their own markets. By requiring each nation’s government to abide by the broad principles of the WTO agreements or face sanctions, the WTO

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63. Id. at art. XVI.4.
66. GATT art. III, as summarized by Fidler, supra note 65.
68. GATT, supra note 64.
70. TBT, supra note 41. Competition is a major issue with TRIPS as well, but it is argued that TRIPS is ill-equipped to regulate competition on a worldwide scale and that any mandatory competitive provisions should be established by the entire WTO rather than by the council on TRIPS alone. Josef DrexI, International Competition Law—A Missing Link between TRIPS and Transfer of Technology, WIPO/WTO Meeting of Intellectual Property and Competition Law, 2003, http://www.wipo.int/documents/en/meetings/2003/wipo_wto/wipo_wto_03_program.html.
ensures that the industries in member nations are regulated by those broad principles as well.\footnote{71}

Disputes involving pharmaceuticals or human health have been brought under all three provisions. Though all three provisions may apply to any given human health fact pattern, the issue of how national regulations regarding drug regulatory approval should be analyzed has not been settled. This article will suggest why protectionist regulatory requirements for pharmaceuticals should be addressed under the TBT, and will analyze the WTO framework for applying these provisions. Finally, there is a request for dispute settlement brought by India pending in the WTO, which argues that Argentina’s pharmaceutical regulatory requirements involved in testing of pharmaceuticals are protectionist in nature and violate the TBT. This article will analyze how the WTO might rule on this dispute in part V.

\section*{B. GATT Most Favoured Nation Treatment}

MFN treatment and national treatment are the heart of nondiscriminatory trade law. MFN status requires that “any advantage, favour, privilege or immunity granted by any contracting party to any product originating in or destined for any other shall be accorded immediately and unconditionally to the like product originating in or destined for the territories of all other contracting parties.”\footnote{72} Article I. 1 prohibits both \textit{de facto} and \textit{de jure} discrimination, implicating laws which on their face are non-discriminatory.\footnote{73} National treatment provides that “products of the territory of any contracting party imported into the territory of any other contracting party shall be accorded treatment no less favourable than that accorded to like products of national origin.”\footnote{74} Like products under this provision are considered to be “products that are in... a competitive relationship.”\footnote{75} This competitive relationship is analyzed

\footnote{71. Agreement Establishing the WTO art. XVI:4. Drexl argues that allowing the WTO members to police competition in their own markets allows richer countries to rely on functioning competition law systems to protect their own markets, while new economies not only have to draft the competition law but face issues such as rejection of the competition idea among local firms, authorities and the general public, problems of corruption, and the inability to establish an independent judiciary to enforce the laws. Additionally, competition authorities in smaller countries may not “dare act against large multinationals if the latter have effectuated considerable investment in a given host country.” Drexl, supra note 70.}

\footnote{72. GATT art. 1.1.}


\footnote{74. GATT art. III. 4.}

with "(i) the properties, nature and quality of the products; (ii) the end-uses of the products; (iii) . . . consumers' perceptions and behaviour in respect to the products; and (iv) the tariff classification of the products" in mind.\textsuperscript{76}

\textbf{C. The Purpose of the TBT}

The purpose of the TBT is to assist all nations, and particularly Developing Nations, in accessing technical markets. The Preamble states that the TBT is meant to "ensure that technical regulations and standards . . . do not create unnecessary obstacles to international trade." To meet that goal, the TBT also supports the promulgation and enforcement of international standards, international conformity assessment systems, and the promotion of technology transfer.\textsuperscript{77} The TBT addresses the complex relationship between national regulatory systems, market access and WTO obligations.\textsuperscript{78} Through the TBT, the WTO tries to balance international trade liberalization with members' right to implement rational regulatory policies.\textsuperscript{79} Access to a particular country's market depends on the level of technical regulation applying in that territory, restrained by the provisions of the TBT non-discrimination clauses.\textsuperscript{80}

The TBT is designed to invalidate technical regulations which were created to serve a protectionist interest. In the public health arena, the WTO has been likened to the U.S. Commerce Clause, in that it restricts a member state from exercising absolute autonomy over trade practices, including those involved with world health.\textsuperscript{81} This analogy is reinforced by the legislative nature of the WTO agreements, which balance free trade against state sovereignty.\textsuperscript{82} If that analogy holds true, the TBT is analogous to a codification of the United States' Dormant Commerce

\textsuperscript{76} Id.
\textsuperscript{77} TBT pmbl.
\textsuperscript{78} Paul Beynon, Community Mutual Recognition Agreements, Technical Barriers to Trade and the WTO's Most Favoured Nation Principle, 28(2) EUR. L. REV. 231, 236 (2003).
\textsuperscript{79} Id. "The adoption per se of technical regulations affects the degree of market access granted by one country to another." \textit{Id.}
\textsuperscript{80} The TBT is in addition to GATT non-discrimination clauses. Any complaint brought under TBT is likely to be brought under GATT's non-discrimination clauses, in particular the public health exemption found in GATT art. 27 (b).
\textsuperscript{82} \textit{Id.}
Like the Dormant Commerce Clause, the TBT seeks to prevent state regulations which place an undue burden on interstate commerce and provides a framework for examining whether the regulation's purpose justifies the burden it places on international trade. At its heart, the TBT prohibits protectionism, but it does not prohibit all protectionist acts. Products imported from another Member's territory "shall be accorded treatment no less favorable than that accorded to like products of national origin and to like products originating in any other country." If regulations are considered to be discriminatory, they must face a least restrictive means test, that "trade regulations shall not be more trade-restrictive than necessary to fulfill a legitimate objective." The ultimate analysis of pharmaceuticals under the TBT begins with two major threshold questions: does the TBT even apply to pharmaceuticals and if so, are regulatory requirements technical regulations subject to the TBT analysis?

D. The Scope of the TBT as Applied to Pharmaceuticals

Drug regulatory requirements are always ostensibly applied to ensure safety, but whether the TBT applies to these requirements is a question

83. The dormant commerce clause grows out of the power to regulate interstate commerce granted to the legislature through U.S. CONST. art. 1 §8. The first inquiry is whether the law affects interstate commerce. If so, the law examined to determine whether it discriminates against out of state competitors. A law may be facially discriminatory or facially neutral but discriminatory in intent or effect. A discriminatory law will likely be struck down as unconstitutional under the dormant commerce clause. If a law is not discriminatory, the court will balance a state's justification for the law against the burden the law imposes on out of state competitors. The court also examines how effective the means used by the state are to achieve their purported purpose. See, e.g., S. Carolina St. Highway Dep't v. Barnwell Bros., 303 U.S. 177, 58 S. Ct. 510 (1938). But see, Alan O. Sykes, Regulatory Protectionism and the Law of International Trade, 66 U. CHI. L. REV. 1, 23 (1999) [hereinafter Sykes, Protectionism] (disagreeing that there is any balancing of interests in the WTO TBT analysis because those who wish to have protectionist policies may do so as long as scientific evidence supports the regulatory policy and the least restrictive trade measures are employed).

84. The difficulties with this type of analysis are highlighted by Klug, who suggests that international agreements which purport in their preambles (the "soft law") to support human rights policies such as access to pharmaceuticals have noble goals, but that the specific treaty provisions (the "hard law") do not necessarily aptly serve these goals because ultimately the treaties are designed to protect the property rights of individuals against "attempts by national governments to address pressing social needs. Heinz Klug, Access to Essential Medicines—Promoting Human Rights Over Free Trade and Intellectual Property Claims, in INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY: UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME 481, 482 (Cambridge Univ. Press 2005).

85. TBT art. 2.1. This standard also applies to government mandated testing.

86. TBT art. 2.2.
of interpretation between the TBT and the SPS Agreement. The TBT explicitly does not apply to sanitary and phytosanitary measures as defined in Annex A of the SPS Agreement. The reference to the SPS Agreement recognizes that the purposes of the TBT and the SPS Agreement are similar, but that regulations under the SPS were designed to "protect domestic agricultural sectors," where the TBT applies to all forms of technical regulations, regardless of their legislative purpose. Since drug regulations do not serve to protect agriculture, they fail to meet the objective of the SPS, but the application of the SPS may nonetheless be broader than its stated purpose.

A sanitary or phytosanitary measure is defined by the WTO to be one that was taken to protect human life from "additives, contaminants, toxins, or disease-causing organisms in their food beverages [or] feedstuffs" or from "plant- or animal-carried diseases." This "test" for applicability of the TBT or the SPS is only a legal distinction, in that "regulations being developed by governments do not always treat safety and quality issues separately." Where a regulation addresses both safety and quality, the safety element would be handled under the SPS and the quality element would be handled under the TBT. The troubling issue is that, with pharmaceuticals, the quality requirements frequently are issues of safety. To confuse matters further, notification of regulations under the TBT and the SPS may be sent to the Secretariat, which then disseminates them to the participating nations, so realistically a notification could be copied verbatim and sent to the Secretariat twice. Though


88. TBT art. 1.5.

89. WTO/WHO, supra note 87, at 34.

90. Id. at 36, Box 1.

91. Id. at n.7.

92. Id.

93. FDA, supra note 35.

94. The TBT requires that if the nation has opted into the ISO, then regulations are sent there. Otherwise they are sent to the Secretariat. The ISO is a repository and policy making body which promulgates international technological standards, but also accepts notification of an individual nation's adopted technological standard. TBT annex 3C. A standard, as opposed to a technical regulation, is defined in the TBT as "a document approved by a recognized body that provides for common and repeated use, rules
there is confusion regarding which agreement a pharmaceutical might fall under, the language of and the references to the SPS state that it applies to human health issues related to food additives.95 Because pharmaceuticals are not food and do not serve the SPS's policies of harmonizing agricultural standards to facilitate commerce, they should not be analyzed under the SPS.

Even if drug regulatory requirements do not fall under the SPS, these requirements may not fall under the TBT if they are neither a technical regulation nor a conformity assessment procedure. A technical regulation is defined in the TBT as a “document which lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory.”96 Technical regulations may have both prohibitive and permissive elements,97 and the product or group of products to which it applies must be identifiable from the technical regulation.98 Compliance is measured through “conformity assessment procedures” or quality control testing. A conformity assessment procedure is defined as “any procedure used, directly or indirectly, to determine that relevant requirements in technical regulations or standards are fulfilled.”99 Under the TBT, either technical regulations or conformity assessment procedures can be found to be an unnecessary barrier to trade.

National regulatory requirements may be divided into technical regulations and conformity assessment procedures. Based on the definitions in the TBT for technical regulations and conformity assessment procedures recited above, the standards for toxicity, efficacy, other clinically related data, weights, labeling and packaging are likely technical regulations

guidelines or characteristics for products or related processes... with which compliance is not mandatory.” TBT annex I. Definition 2. Under the TBT notifications go to the ISO, but the ISO has technical groups for food products, chemistry, laboratory equipment, clinical laboratory testing, and in vitro diagnostic test systems, evaluation of medical devices, and health informatic systems (which covers standardization of data reporting), http://www.iso.org/iso/en/standardsdevelopment/tc/tclist/. It is notable that the United States requested dispute resolution against the European Communities regarding growth hormones in beef under both the TBT and the SPS. Panel Report, European Communities—Measures Concerning Meat and Meat Products (Hormones), WT/DS26/R (Aug. 18, 1997). The European Communities agreed that the disputed measure fell within the SPS, and so the issue was explicitly excluded from analysis under the TBT. Id. at 4.2.4.4. 95. SPS annex A.1. 96. TBT art. 15.5 annex I definition 1. 97. Appellate Body Report, European Communities—Measures Affecting Asbestos and Asbestos-Containing Products WT/DS135/AB/R (Mar. 12, 2001) [hereinafter EC—Asbestos]. 98. Appellate Body Report, European Communities—Trade Description of Sardines, WT/DS231/AB/R, at paras. 176, 180 (Sept. 26, 2002). 99. TBT annex I definition 3.
while the manufacturing and testing evaluations are probably conformity assessment procedures. GMP standards apply solely to pharmaceutical production. 100 Though the general field of pharmaceuticals is large, it is sufficient to differentiate them from other products, like electronics. 101 GMP regulations are a procedure that attempts to ensure that manufacturing processes are capable of consistent manufacture of pharmaceuticals, that all steps in the manufacturing process are clearly defined, reviewed and validated, including the calibration of all machinery involved and the adequate training of employees. 102 Additionally, GMP requires retrievable records guaranteeing the quality of every step of the process and product up to the time of sale. It also requires that complaints are examined to find the cause and that the appropriate measures are taken to address them. 103 In international trade, conformity assessment procedures are of primary importance because nations require compliance with their own technical regulations to access their markets, and compliance is established through these procedures. 104

Assessing pharmaceutical regulatory requirements, it is clear that they represent either technical regulations or conformity assessment procedures.

101. Id.
102. Id.
103. Id.
104. Discussion of a new regime for chemicals testing before importation under the EU’s REACH proposal at the Committee on Technical Barriers to Trade supports this conclusion. Committee on Technical Barriers to Trade—Minutes of the Meeting of 1 July 2004, G/TBT/M/33 (July 1, 2004). REACH would require that enterprises that manufacture or import more than one ton of a chemical per year register it in a central database. Any substances which have a production volume of more than 100 tons would need to get those chemicals evaluated by the European authority. Lastly, specific permission would need to be sought and granted to use chemicals with known hazardous properties. Unlike earlier regulations, this would be required for both new and previously existing substances, rather than only new substances. This system was created by the European Community in 2001 and presented to the WTO Committee on Technical Barriers to Trade in 2003 for comment. See REACH, supra note 41. Since the presentation of this proposal, multiple nations have expressed concern that though the regulation is non-discriminatory in appearance, it could be discriminatory in practice. Committee on Technical Barriers to Trade—Minutes of the Meeting of 1 July 2004, G/TBT/M/33 (July 1, 2004). They also suggest that non-EU producers and suppliers would bear an added burden with compliance. Id. Finally, the requirements were seen as so onerous that compliance was considered a significant trade barrier for developing countries, “who might not have sufficient resources and expertise to meet the proposed requirements.” Id.
It is also clear that they fall under the TBT because they affect one or more given products, specify technical characteristics of the products which allow them to be marketed in the Member country, and compliance with these requirements is mandatory.

E. General Analysis Under the TBT

1. Notice: Does the Regulation Deviate from International Standards?

Overall, the TBT encourages nations to adopt internationally-recognized technical regulations and conformity assessment procedures. Members shall give positive consideration to accepting as equivalent technical regulations of other Members, even if these regulations differ from their own, provided they are satisfied that these regulations adequately fulfil the objectives of their own regulations. Individual nations are allowed to create their own regulations when there are no internationally recognized ones or they choose to deviate from the international standard to satisfy a legitimate objective. When they do, they are required to notify the Secretariat and the ISO.

Similarly, analysis of conformity assessment procedures begins with a determination of whether or not the procedure complies with the “relevant guides or recommendations issued by international standardizing bodies.” If the procedure deviates, then the member is supposed to use the parts of the regulation which are relevant and appropriate, unless they deviate for reasons such as the “protection of human health or safety.” Like technical regulations, notification is also required if the deviation has a significant effect on trade.

2. Notice: Does the Regulation Have a Significant Effect on Trade?

When an international standard does not exist or a Member chooses not to adopt the international standard, unless the alternative regulation or procedure has a “significant effect on trade,” there is no requirement to specially notify the ISO or Secretariat of the deviation. A significant

105. TBT art. 2.5
106. Id.
107. Id.
108. TBT art. 2.9.2
109. TBT art. 5.4.
110. Id.
111. TBT art. 5.6.2.
112. TBT arts. 2.9, 5.6.
effect on trade may be “in a specific product or group of products or products in general.” To determine the regulation’s significance, consideration is given to the value of the trade to other Members, the potential growth of such imports, and the difficulties in complying with the measure. The legitimacy of the deviation may be questioned by other Members, but the nation does not need to change its regulation to comply with the comments. Until a complaint is made to the Dispute Resolution Panel, the nation is not required to justify the regulation if it claims it is necessary to protect human health or safety. Since dispute resolution carries with it both costs of money and time and implications for goodwill with third party nations, there is a disincentive to bring a complaint against any but the most blatant protective practices.

113. Decisions and Recommendations Adopted by the Committee since January 1, 1995, Committee on Technical Barriers to Trade, g/tbt/1/rev.7, 16 (November 28, 2005).
114. Id.
115. TBT art. 2.9.4.
116. In summary, dispute settlement litigation in the WTO starts when one country brings a complaint to the WTO Secretariat. Consultations and/or mediations are established between the two countries and, if necessary, a mediator from the WTO. This process has a time limit of 60 days. Third party countries who demonstrate an interest in the litigation are permitted to intervene. Once the countries involved have decided that they cannot reach an agreement, a panel of experts is appointed to rule on the matter. The countries then submit arguments, in written form, rebut those arguments. The panel makes one interim ruling and submits it to the countries for argument. A final ruling is then made within an approximately six month time limit. Once the panel has ruled, the decision goes to the entire WTO body, and can be overturned if every nation, including the “defendant,” agrees it should. Panel rulings are automatically implemented, and if the losing country does not comply, trade sanctions may be applied. Both parties have the ability to appeal the panel decision to the WTO Appellate Body that reviews the decision below. Since every step has statutory time limits, the whole process should take less than one year and three months. DSU, supra note 67.
117. Id.
118. However, developed nations have demonstrated that they are willing to fight for their IPRs in pharmaceuticals in the WTO by joining the Canada—Pharmaceuticals decision. An unfavorable dispute resolution could have devastating effects for a developing nation if it either brings a suit or responds to a suit. In particular, the costs of defending and possibly losing a suit based on charges of pharmaceutical patent infringement would not be limited to sanctions based on the patent infringement. In the WTO, sanctions can extend to any part of trade, and not just the trade issue in dispute. See Abbott, Doha, supra note 7. See also Carlos M. Correa, Internationalization of the Patent System and New Technologies, 20 Wis. Int’l L.J. 523, 543 (2002) (for information on the costs of patent litigation to developing countries and small entities).
3. Dispute Resolution: Is There A Legitimate Objective?

Through dispute resolution, the reason for the technical regulation is assessed to determine whether or not it fulfills a legitimate objective. A legitimate objective under the TBT is not explicitly defined, but the preamble lists acceptable reasons for discriminatory trade laws, such as "for the protection of human, animal or plant life or health." The TBT allows regulations or conformity assessment procedures to restrict trade for "legitimate objectives" with little or no burden of proof to determine that the objective is legitimate until litigation is initiated through the dispute resolution process. In the dispute resolution process the reason for the conformity assessment procedure will be evaluated in light of the reason given to justify its deviation from the accepted international procedure.

4. Dispute Resolution: Is this the Least Trade Restrictive Means, Taking Account of the Risks?

A legitimate objective should be "no more trade-restrictive than necessary to fulfil a legitimate objective, taking into account the risks non-fulfilment would create." In this assessment, the Dispute Settlement Panel analyzes the reason for the objective as proven by the risks the nation will bear if the regulation is not followed, balanced against how discriminatory the regulation is. The TBT suggests that the nation's argument should be backed up at this point by some sort of evidence, such as "available scientific and technical information, related processing technology or intended end-users of products." There is no

119. TBT pmbl.
120. Id.
121. Conformity assessment procedures have not made it to the dispute resolution panel, but the language is similar to that for technical regulations and so it is likely to be analyzed the same way.
122. TBT art. 2.2.
123. Id. But see TRIPS art. 39.3 (where clinical data submitted to a regulatory agency for a new drug submission is considered proprietary, and cannot be relied on for the abbreviated new drug submission by a generic manufacturer to obtain approval). This leads to an international standard, the TRIPS agreement, being restrictive on countries that wish to allow reliance on clinical data, and choose to import into a country who does not allow reliance on clinical data, arguably for reasons of human health. But the rationale behind not relying on others' clinical data may be complicated by pressures by the importing country's national pharmaceutical sector as well as government regulatory safety policy. WHO Drug Information Vol. 19 No. 3 2005, Intellectual Property Protection: Impact on Public Health 236, 238. It gets more complicated if the industry member that the generic is hoping to compete with was the one who conducted the clinical trials in a foreign country, perhaps for foreign marketing approval. See also INTERNATIONAL FEDERATION OF PHARMACEUTICAL MANUFACTURERS AND ASSOCIATIONS,
specific burden of proof to establish that there is a legitimate objective, only a line drawing situation.\textsuperscript{124}

Analysis of conformity assessment procedures differs from technical regulations at this point. According to the TBT, conformity assessment procedures should not prepare, adopt or apply a procedure to deny access for suppliers of like products under conditions less favourable than those granted the suppliers of that Member state or any other state.\textsuperscript{125} The TBT also endeavors to ensure that the regulatory process embodied in a conformity assessment procedure is not applied to purposely delay or prevent any particular nation's products from entering the national market.\textsuperscript{126} Lastly, the TBT specifies that "the siting of facilities used in conformity assessment procedures and the selection of samples are not such as to cause unnecessary inconvenience to applicants or their agents."\textsuperscript{127} These restrictions attempt to prevent any national favoritism through easily foreseeable bureaucratic mechanisms. The question is whether they are applicable to national pharmaceutical registrations to prevent protectionist practices.

Since pharmaceutical regulatory requirements almost always fall under human health and safety, such regulations will likely have a decent argument that they fulfill a "legitimate objective" or adequate reason. As the safety of a drug is never completely known, even when approved,\textsuperscript{128} it may be easy to claim that acceptance of anything but the "branded" sources makes the drug unsafe.\textsuperscript{129} Unfortunately, the established manufacturing companies with reputations for safety tend to be solely in developed countries. If the regulation "significantly affects trade," the Member is then required to notify the ISO and the Secretariat.\textsuperscript{130} Only truly discriminatory regulations in a normative sense are likely to be brought under the TBT because each nation is permitted to maintain its own standards. Yet the challenge is to determine how the regulation


\textsuperscript{125} TBT arts. 5.1, 5.1.1.

\textsuperscript{126} TBT art. 5.2.1.

\textsuperscript{127} TBT art. 5.2.6.

\textsuperscript{128} FDA, supra note 35.

\textsuperscript{129} For instance, the REACH proposal establishes a branded source for all chemicals in the EU, not only pharmaceuticals. REACH, supra note 41.

\textsuperscript{130} TBT art. 2.9.
affects trade in a protectionist manner, especially since there are minimal proof requirements before litigation in the WTO. In effect, substantive justification for the regulation’s purpose to promote human health is only mentioned when it noticeably will affect trade and another nation institutes dispute resolution. Only then must the defending party must prove that its regulation fulfils a legitimate objective in light of the risks involved and that it is the least restrictive means available.

V. ANALYSIS OF ARGENTINA—PHARMACEUTICALS

In May of 2001, India filed a request for consultations in the WTO Dispute Settlement Body against Argentina for discriminatory trade practices related to Argentinean pharmaceutical regulatory law. The laws in question required that importing countries fall into one of two Annexes of quality compliance. Annex 1 stipulated that (1) “all drugs and other pharmaceuticals must be registered with the National Administration of Drugs, Foodstuffs and Medical Technology under the Ministry/Department of Health of Argentina;” and (2) the exporting manufacturer’s drugs must either “(a) be manufactured in facilities approved by the relevant governmental bodies of these countries” or (b) in facilities approved. In the Argentinean legislation, this Annex was followed by a list of countries, which omitted India.


132. TBT art. 2.2

133. Request for Consultations by India, Argentina—Measures Affecting the Import of Pharmaceutical Products, WT/DS233/1 (May 30, 2001) [hereinafter Argentina—Pharmaceuticals]. Since May of 2001 there has been no further information about this suit. The analysis contained in this article is all hypothetically based on the limited facts from the request for dispute resolution and application of previous WTO decisions and the TBT structure. Because medicines have not been addressed in a manner outside IPRs, all arguments are hypothetical.

134. The specific Argentinean laws cited in the complaint were, Law/Act No. 24.766 and Decrees No. 150/92 which was modified to No. 177/93 and can be found, in Spanish, at: http://www.anmat.gov.ar/principal.htm [hereinafter ANMAT]. Other problems with the Argentinean regulatory laws and procedures have already been disputed. The United States previously brought a challenge against Argentina under TRIPS to enforce the right to keep clinical data confidential, the right to process patents, the right to preliminary injunctions and other concerns. See Request for Consultations by the United States, Argentina—Patent Protection for Pharmaceuticals and Test Data Protection for Agricultural Chemicals, WT/DS171/1 (May 10, 1999) and Request for Consultations by the United States, Argentina—Certain Measures on the Protection of Patents, WT/DS196/1 (June 6, 2000). PhRMA’s commentary on Argentinean pharmaceutical practice suggests that the patent implications of 24.766 and its regulatory laws are not acting together.

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India brought the complaint under the TBT for its substantive provisions, the GATT to support Most Favoured Nation treatment, and the Agreement Establishing the WTO to reinforce the conformity obligations of Member countries. To succeed in its complaint under the TBT, India will have to prove, that: (1) This regulation is a technical regulation or conformity assessment procedure; (2) that this regulation/conformity assessment procedure has no equivalent in international standardizing agencies or that it deviates from that provided by international standardizing agencies,^{136} (3) that the deviation significantly affects trade, (4) that the deviation of these regulations does not fulfill a legitimate objective; (5) that the measure is not justified in light of the risks of not having the measure; and (6) the Argentinean law was more trade restrictive than necessary to fulfill the legitimate interest of protecting human health. The following is a hypothetical analysis of Argentina’s regulations in light of the TBT.\(^{137}\)

\textbf{A. Are the Argentinean Regulations Either Technical Regulations or Conformity Assessment Procedures?}

Annex 1 of the Argentinean regulation requires that “all drugs and other pharmaceuticals” be registered with Argentinean regulatory authority and must meet that authority’s “manufacturing and quality control

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^{135} Available at http://www.anmat.gov.ar/principal.htm. A simple solution to India’s complaint would be to add them to the list of accepted nations. But the legislation listed on ANMAT still omits India.

^{136} TBT arts. 2, 2.2.

^{137} This article will not address analysis under the MFN provisions of GATT or the Agreement Establishing the WTO, nor will it analyze the suit under the SPS.
requirements” regardless of where they are manufactured.138 It is clear that the regulation identifies pharmaceutical products as a group, deals with product characteristics and production methods, and mandates compliance.139 Under that standard it would be a technical regulation. However, it is also a conformity assessment procedure, because the law describes a registration process which determines whether “relevant requirements in technical regulations or standards” are met.140 This regulation, therefore, should be analyzed as both a technical regulation and a conformity assessment procedure.

B. Is There an Applicable International Standard or Procedure for the Manufacturing and Testing of Drugs, and Does the Local Standard Deviate from International Standards?

Whether there is an applicable international standard could be argued in favor of either India or Argentina. India could argue that international standards such as GMP are recognized as the gold standard for manufacturing of pharmaceuticals and their quality control acceptable in the developed world.141 India should also claim that it intends to comply with GMP provisions.142 Argentina could reply that, despite the GMP provisions, each nation has its own regulatory requirements, and that GMP provisions are limited to the drug itself, not the registration process. The requirement that the pharmaceuticals “meet the National Health Authority’s manufacturing and quality control requirements” does deviate from the GMP standard for the production of drugs if this requirement imposes more than GMP standard, but it is unclear how this law is applied.143

India could argue the law is facially neutral, but applied with a protectionist intent and effect. There is evidence that Argentina does not recognize the results of quality control testing performed by either the United States or Europe,144 but Argentina could reiterate that even the

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138. Argentina—Pharmaceuticals, supra note 133.
139. See discussion of GMP supra part III A and IV D.
140. TBT annex I definition 3.
141. World Bank, supra note 11.
142. Since “the leading India drug companies derive most of their profits from sales within the United States and other high income markets” it is plausible that India has both the capacity and intention to import GMP compliant pharmaceuticals into Argentina. Outterson, supra note 3, at 243.
143. The complaint is unclear how nations ended up in Annex I or Annex II.
United States and European Communities require duplicative testing. If this is so, the deviation from international standards may be a question of how the law is applied rather than what the law says. The TBT does require that nations not apply their laws in an anticompetitive manner.\textsuperscript{145} India could argue that Argentina has no valid reason for requiring repeated testing from any of the Nations listed on the Annexes due to reliable international standards, because if drugs from either the United States or Europe are acceptable without retesting in other states, the results should also be acceptable to Argentina.\textsuperscript{146} Additionally, India could repeat the PhRMA allegations that Argentina creates unnecessary barriers and delays to marketing approval for imported pharmaceuticals.\textsuperscript{147}

\textbf{C. Does the Deviation Create a Significant Effect on Trade?}

Whether a deviation creates a significant effect on trade is balanced by the value of the trade to the members, the potential growth of the import market, and how difficult it is for the applicant to comply with the measure.\textsuperscript{148} India could claim that its pharmaceutical industry is

\begin{quote}

\textit{must be performed locally resulting in product launch delays and additional expenditures}” (emphasis added).
\end{quote}

\textsuperscript{145} TBT art. 5.1.1. Members shall ensure that “conformity assessment procedures are prepared, adopted and applied so as to grant access . . . under conditions no less favorable than those accorded to suppliers of like products of national origin or originating in any other country” (emphasis added).

\textsuperscript{146} India is in the unique position of being both a very sympathetic plaintiff and the world’s best known patent infringer, depending on who is asked. Because India supplies generic (and patented) drugs to developing nations under compulsory licenses it has gained acclaim as being a pharmaceutical “Robin Hood” who steals from rich PhRMA to give to poor developing nations in need. But legal writers blame India’s limited research capacity on their lax intellectual property regime and argue that the lack of IPRs has resulted in an “inability to meet even the most rudimentary health requirements,” for its own population. Barbosa, \textit{supra} note 52, at 243. See also Fink, \textit{supra} note 8, at 231.

\textsuperscript{147} PhRMA Estimate, \textit{supra} note 144.

PhRMA Members continue to suffer from barriers due to restrictive import policies, anticompetitive practices and the implementation of unnecessary standards, testing, labeling and certification requirements . . . . The government of Argentina imposes high import duties on pharmaceutical products. Overall customs procedure requires supporting documentation and additional payment of fees. In addition to prescription drugs, free samples and products for clinical trials are also subject to import duties in Argentina. There are significant delays due to bureaucratic proceedings.

\textit{Id.} Whether PhRMA is a reliable or logical source for India to find support is a different question.

\textsuperscript{148} See discussion, \textit{supra} note 114 and accompanying text.
important to its national economy. India might then argue that its main export to Argentina is chemicals, yet it has almost no market share.\textsuperscript{149} Argentina would likely reply that the market is not growing sufficiently to outstrip its domestic pharmaceutical manufacturers which provide pharmaceuticals at competitive prices.\textsuperscript{150} India might reply it cannot participate at all, since they are not on the Annexes, and so any pharmaceutical imports are a growth in the value of the market.\textsuperscript{151}

\textbf{D. Does the Deviation Fulfill a Legitimate Objective or Purpose?}

If it were determined that the regulation deviates from the international standard, the question would become whether the deviation fulfills a “legitimate objective” or an acceptable reason. Argentina would most likely claim that Argentinean government agency supervision of manufacturing facilities is necessary to maintain strict safety levels. India could argue that GMP procedures serve all the needs of a national registration agency: that each step of the pharmaceutical’s manufacture is recorded and validated, that the quality of any given batch of pharmaceutical may be easily ascertained through records, and that drugs which pose a hazard may be easily tracked and recalled.\textsuperscript{152} This would be a difficult point to establish, since even the United States’ FDA does not evaluate drugs solely based on compliance with GMP standards. If India could establish that all of its pharmaceutical exports are acceptable under the most restrictive regulatory requirements on the planet that address safety,\textsuperscript{153} then it could argue that for purposes of harmonization, its drugs should be acceptable to Argentina.

\begin{itemize}
\item \textsuperscript{149} In 2003 Argentina imported 25 percent of its nucleic acids and heterocyclic acids from India, but significantly less than one percent of its pharmaceutical imports came from India. \textsc{National Center for Trade Information, Report: “India & Latin American Countries—Sector wise Trade Analysis,” available at http://www.ncti-india.com/} (last visited Feb. 27, 2006)(also available from author). This it notable, because the purpose of nucleic acids is often for pharmaceutical research or production. These statistics do not decisively indicate whether India is capable of competing at that level in the market for consumer pharmaceuticals rather than precursors or research reagents.
\item \textsuperscript{150} It is interesting to note that as of 1988, locally owned companies held 58 percent of the pharmaceutical market share, up from 45 percent in 1977. \textsc{Fink, supra note 8, at 254 n.4.}
\item \textsuperscript{151} \textit{Supra} note 149. India’s pharmaceutical profit likely comes almost exclusively from exports, as its population may not be able to pay the prices manufacturers can find abroad. From India’s general export data, it exports roughly six times the value of the pharmaceuticals it imports. \textsc{Directorate General of Commercial Intelligence and Statistics of India, India’s Foreign Trade by Chapters and Sections, Table 1, Apr. to Sept. 2005, available at http://dgciskol.nic.in.}
\item \textsuperscript{152} See the discussion of the European goals of GMP, \textsc{supra, Part IV.D.}
\item \textsuperscript{153} Such as those in the United States of America or Europe.
\end{itemize}
To positively refute India’s claims of equivalency, Argentina’s best option would be to offer physical proof of non-equivalence. This could be proof of counterfeit products being introduced under an Indian company’s labels, or lack of bioequivalence in a sampled population from those drugs provided to the United States and those provided to Argentina. ¹⁵⁴

E. Is the Measure Justified in Light of the Risks of Not Having the Measure?

The TBT requires that, “in assessing such risks relevant elements of consideration are, inter alia: available scientific and technical information, related processing technology or intended end-uses of products.”¹⁵⁵ EC-Hormones divided risk assessment into a two step process that “should (i.) identify the adverse affects on human health (if any) arising from the presence of [the law] . . . and (ii.) if any adverse affects exist, evaluate the potential of occurrence of such effects.”¹⁵⁶ This is not solely a quantitative analysis, as the TBT envisions “not only risk ascertainable in a science laboratory operating under strictly controlled conditions, but also risk in human societies as they actually exist, in other words, the actual potential for adverse effects on human health in the real world.”¹⁵⁷

If Argentina were to rely on risk to human health to provide a legitimate purpose for its regulations, the best support for that purpose would be actual reports of injuries resulting from drugs which were inadequately screened by the Argentinean regulatory agency. If Argentina had a history of counterfeit drugs damaging individuals, like Brazil or Haiti have, then additional safety measures may be considered.

¹⁵⁴. The Argentinean regulatory agency may already have the evidence to establish the inadequate quality of India’s pharmaceutical exports. “Even the Indian government has recognized that Indian pharmaceutical manufacturers continue to produce ‘spurious, substandard, and irrational products.’” Susan Finson, India: A Cautionary Tale on the Critical Importance of Intellectual Property Protection, 12 FORDHAM INT’L PROP. MEDIA & ENT. L.J. 891, 895 (2002), quoting The 4th Annual Report 1999-2000 of the Organization of Pharmaceutical Producers of India (OPPI) at 6 (2000). This in contrast to the assertion that much of the major Indian corporations’ income comes from the United States or other developed countries—which presumably require strict compliance with GMP. Outterson, supra note 3, at 243.

¹⁵⁵. TBT art. 2.2.


¹⁵⁷. Fidler, supra note 65, at 242.
necessary. Notably, Argentina would have to present significant, relevant, scientifically backed and validated proof. These measures are only preventative and there had not been any instances of counterfeiting involving India in the past.

If the measures are precautionary, India could argue that other countries do not require localized manufacturing despite the potential for human harm. India would need to emphasize that internationally organized and overseen inspections are sufficient in countries with the most rigorous regulatory regimes. There is no reason for Indian manufacturing to bear the burden of additional inspections by Argentineans. Argentina could reply that it may still require additional inspections because the United States and Europe do reserve the right to inspect any imported drugs. If the dispute resolution panel has already agreed that the measures deviate from international norms, Argentina may not be able to argue this point.

F. Is the Argentinean Law More Trade Restrictive Than Necessary to Fulfill the Legitimate Interest of Protecting Human Health?

To prevail, India would have to show discriminatory/protectionist intent or effect. At first glance, the Argentinean regulations treat nations differently, as shown by the lists of countries following the Annexes. That India is not on either list indicates that it cannot participate in the market at all, where other countries, such as the United States or many of the European countries can. But the burden of proof is high for India: it would have to show either that there was discriminatory intent in creating the legislation—through legislative history or other commentary—or that the effect is discriminatory.

India has a plausible argument for discriminatory effect, because under the legislation, it cannot participate in Argentina's pharmaceutical market at all. However, the lists of countries on the two Annexes are

158. Barbosa, supra note 52 (discussing Brazil and Haiti's troubles with counterfeit pharmaceuticals).
159. The fact that India brought this case is particularly interesting because it is a developing country which, by all accounts, is beginning to compete for a share of the pharmaceutical market on an international stage. While its participation is presently relatively limited to the generic drug market, it is beginning to have the capacity to research and develop new drugs. Fink, supra note 8, at 231. Since it is a more recent participant in international pharmaceutical markets, it may be reasonable to distrust Indian standards of quality.
160. Outterson, supra note 3. See also REACH, supra note 41.
161. ANMAT, supra note 134.
limited,162 so Argentina could argue that India needs to prove to its regulatory agency that India markets safe and effective drugs before Indian pharmaceutical manufacturers are allowed access to Argentinian consumers. This legislation is more burdensome than the REACH proposal,163 which permits any country to produce chemicals and participate in the market, yet requires registration and evaluation of those chemicals for safety purposes.164

India could request that it be given favorable treatment as a developing country. Under Article 12 of the TBT, deference should be given to a developing nation’s abilities and resources.165 But it is clear that the agreement only contemplates that one party to the transaction is a developing nation. Article 12.3 says that Members shall take into account the development, financial and trade needs of developing nation when creating technical regulations and conformity assessment procedures so as not to create an obstacle to trade to products from a developing country.166 Likewise, developing countries “should not be expected to use international standards as a basis for their technical regulations or standards . . . which are not appropriate for their financial or trade needs.”167 Under these guidelines, Argentina merits leniency for creating a standard that differs from the international norm, and India merits leniency for not meeting that standard. Since both countries are economically viable developing countries, it is arguable that these provisions do not apply at all.168

162. A total of less than 30 countries are listed in the legislation. ANMAT, supra note 134.
163. REACH, supra note 41.
164. Id.
165. TBT art 12.1. “Members shall provide differential and more favourable treatment to developing country members.” Id.
166. TBT art. 12.3.
167. TBT art. 12.6.
168. It could be argued that India should not be considered a developing nation anymore at least for pharmaceutical exports, because it provides drugs to other nations through compulsory licenses. It could also be argued that Argentina is in the same position. The WTO provides: “There are no WTO definitions of “developed” and “developing” countries. Members announce for themselves whether they are “developed” or “developing” countries. However, other members can challenge the decision of a member to make use of provisions available to developing countries.” Who Are Developing Countries in the WTO?, http://www.wto.org/english/tratop_e/develop_e/dldwho_e.htm. The WTO cite refers readers to the United Nations to determine whether “developing country” status applies. Id. There, both countries are given preferential trade status by the United States and other countries. United Nations Conference on Trade and Development, New York & Geneva, Jan. 11, 2005, Generalized
G. Will India Succeed With its Claim?

India arguably has a very strong case for finding protectionist practices, but any decision has many ramifications over a very large industry whose policies are already spotlighted by concerns over human rights and intellectual property. If India could successfully prove discriminatory intent behind the statute, it should win. If India could establish that it cannot access the market at all where other nations participate, and that its manufacturers would be able to compete with safe effective drugs, it should be able to establish there was a breach of the TBT.

India is not in the best position to bring this suit. If the United States or the European Union were omitted from the law and brought this suit, there would be a greater presumption that the drugs are safe and effective, but Argentina would be able to gain deference through its developing country status. Arguably, there is not a single WTO Member who is in a strong position to bring this suit.

VI. POSSIBLE SOLUTIONS FOR PROTECTIONIST REGULATORY REGIMES

One solution to protectionist regulatory practices is international harmonization for all regulatory requirements. Outterson argues that all "national regimes for testing the safety and efficacy of patented drugs are inefficient, duplicating scientific work and wasting resources unnecessarily" because each new chemical entity requires clearance by each national regulatory authority where the drug will be sold. He suggests a "reference" approval process, where safety and efficacy of a particular drug would be referenced against approval in certain benchmark countries that WHO prequalification would satisfy bioequivalence for generic drugs or good manufacturing practices, that IPRs would be separated from drug marketing approvals, and where clinical trials would not be repeated for generic drugs without a clear benefit to human health. With the advent of ICH and the WHO prequalification project there is movement towards a truly global standard of both drug production and regulation. Unfortunately, the bar may be set at a level that developing nations cannot reach with emerging pharmaceutical manufacturers. It may also be difficult to achieve consensus as to the

169. Outterson, supra note 3, at 237.
170. A project where dossiers on providers of certain essential drugs are tested and approved for use around the world. Id.
particulars of the registration process, because each nation has its own experience and needs.\textsuperscript{171} The expense to establish a truly international drug regulatory agency suggests that its policies will be dominated by those who paid for it, to the detriment of poorer nations. Pharmaceutical regulations are not ‘one size fits all’ and it may be impossible to find a workable middle ground that allows all nations to participate in the international market. Though the TBT tries to recognize and support an individual nation’s needs, its general policy-based provisions may be too permissive, leaving room for opportunistic governments to develop protectionist regulations.\textsuperscript{172}

\textbf{VII. CONCLUSION}

Pharmaceuticals are particularly difficult to address under discriminatory trade practices. Addressing non-competitive regulatory practices alone will not be effective in assisting entry by lesser developed nations into the international (or national as the case may be) pharmaceutical market without assistance on other levels. At this time, while there has been no indication whether the WTO would analyze pharmaceutical regulatory requirements under the TBT,\textsuperscript{173} it is unclear that discriminatory regulatory regimes would be addressed adequately by any other agreement, including the SPS.\textsuperscript{174} However, under the SPS the proof requirement for the justification of the regulatory requirement would need to be backed up by scientific evidence,\textsuperscript{175} and might prevent some of the more discriminatory regulatory regimes.

\textsuperscript{171} Some nations may have experiences with particular drugs which have drastically affected their regulatory requirements. For instance, extended pre-clinical studies might be required for a disease model where the earliest drugs were shown to have late-emerging heart complications. The current type of chemicals used to treat that disease have been shown not to have this complication, yet the agency still requires an extended pre-clinical study, delaying the approval of any new drugs for that disease. Another nation may never have discovered that complication, or had determined that they could shorten the study period and still avoid the complication and adjusted their regulation accordingly.

\textsuperscript{172} See TBT art. 12 and discussion of how to analyze a dispute when both nations are developing, \textit{supra} note 165 and accompanying text.

\textsuperscript{173} \textsuperscript{www.wto.org} (the website indicates that though it has been updated pursuant to this request for dispute resolution as of January 5, 2007, there are no additional documents). The lack of commentary on this decision may be notable, especially if this topic is an issue of negotiations, under the Doha Round of negotiations, started in 2001.

\textsuperscript{174} Drexl, \textit{supra} note 70.

\textsuperscript{175} WTO/WHO, \textit{supra} note 87, at 37 §39 (comparing the SPS and TBT and concluding that the SPS can only apply to health measures which are based on a
Even if the TBT is the proper place to bring suits against discriminatory regulatory processes in pharmaceuticals, this agreement may not alleviate the burden of disease on least developed nations. It is unrealistic to expect a least developed nation to successfully create its own pharmaceutical industry in a short period of time.\textsuperscript{176} Lesser developed nations may have little government infrastructure and the technology is complicated. The World Bank suggests that, "pharmaceutical manufacturing should only be encouraged in countries that have an effective control agency to enforce GMP. If this capacity is lacking, the costs of building and upgrading a drug regulatory agency that can oversee the industry effectively need to be considered in the overall calculation."\textsuperscript{177}

Additionally, the barriers to entry into the international pharmaceutical market are being raised. For instance, the REACH Proposition adds new registration requirements for all chemicals entering into the EU, regardless of whether they have already been evaluated by an internationally recognized standard previously accepted by the EU.\textsuperscript{178} Likewise, ICH is progressing, and threatens to replace GMP guidelines with even higher standards.\textsuperscript{179} Abbott suggests that as more lesser-developed nations become able to compete with large pharma on an international scale for both generic and new drug markets there will be "efforts to impose regulatory restrictions designed to protect PhRMA."\textsuperscript{180} If this comes to pass, then analysis of pharmaceuticals and protectionist regulatory practices will be at the forefront of the debate on how to supply pharmaceuticals to developing nations. Until then, it is sufficient to recognize that there is a need to highlight and discourage protectionist regulatory practices, and try to determine the proper forum to address the most obvious offenses.

\textsuperscript{176} See discussion, supra, Part II.A.
\textsuperscript{177} World Bank, supra note 11, at 2.
\textsuperscript{178} REACH, supra note 41.
\textsuperscript{179} EMEA guidelines on GMP has a new annex which was adopted to enact the ICH guidelines, http://pharmacos.eudra.org. See discussion of ICH, supra, Part II.B.
\textsuperscript{180} Abbott, Hydra, supra note 30, at 423.