THE "PUBLIC HEALTH" OF THE CONVENTIONAL INTERNATIONAL PATENT RÉGIME & THE ETHICS OF "ETHICALS:" ACCESS TO PATENTED MEDICINES

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> "By coming together, the world can turn the tide against HIV/AIDS—once and for all. . . . I call on every member state to maintain its focus, find new ways to join this cause, and bring us closer to the day when malaria deaths are no more."[1]

FOREWORD

Intellectual property law is often classified as a regulatory tool that is intended to secure commercial ends. While this may be true in the majority of cases, there are times when this law becomes a central player in a game with far bigger stakes: specifically, well-being, life, and even death. This research paper considers the present (conventional) international patent régime from the public health perspective, namely that of access to patented medicines.

The Agreement on Trade Related Intellectual Property Rights ("TRIPS") is a central component of the mechanism for the protection of intellectual property rights around the world. While, in principle, TRIPS constitutes a great achievement in the battle against free-riders, it has generated various problems, the most potent of which relates to the Public Health dimension and, more specifically, to Access to Patented Medicines ("APM"). This problem has been further accentuated by bilateral (free trade) agreements that have introduced even more stringent standards of patent protection. In the context of this research paper, patent provisions in the TRIPS agreement and these bilateral (free trade) agreements constitute the Conventional International Patent Régime ("CIPR"). This research paper explores the CIPR in the context of access to patented medicines.

The examination of access to patented medicines brings forth a rich theoretical debate over values, social priorities, allocation of public goods and the purpose of intellectual property. However, the issue itself is far from theoretical. The World Health Organization ("WHO") has reported that, every year, infectious diseases kill fourteen million people around the world. Notably, 90% of these victims reside in developing countries. In light of this, various questions need to be addressed: should the scope of patent rights that are granted to pharmaceutical companies be limited in order to maximize access to patented medicines? Should APM rights trump all other considerations and social benefits that are attained by patent protection? Should the CIPR be obligated to address and ultimately alleviate the suffering of the sick and dying who are in dire need of patented medicines? Should property rights that are granted to patent holders also entail moral obligations towards society at large? Finally, can non-compliance with CIPR be justified on the basis of "survival?"

In the first chapter of this research paper, I shed light on how CIPR regulates and impacts the APM issue. In the second chapter, which constitutes the normative segment of this paper, I contrast and assess the benefits and the pitfalls of a mechanism that ensures access to patented medicines. In chapter three, I propose a model for resolving the APM predicament. Finally, the annex to this research paper encompasses a draft amendment to the TRIPS agreement that embodies my proposed solution.

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[1] President George W. Bush, Address before the United Nations General Assembly (Sept. 25, 2007), *available at* http://www.america.gov/st/texttrans-english/2007/September/20070925120250eaifas0.1523096.html.

CHAPTER ONE

HOW THE CONVENTIONAL INTERNATIONAL PATENT RÉGIME REGULATES ACCESS TO PATENTED MEDICINES

Despite its impact on billions around the world, the Access to Patented Medicines question has yet to be settled. This chapter will show that, while important strides have been made towards resolving this issue, additional steps are still warranted.

1.1 Parameters of the Regulative Framework

The global economy has prompted a "New World Order" with respect to protection of intellectual property ("IP") rights.[2] This has culminated in TRIPS and other ensuing multilateral intellectual property treaties.[3] The TRIPS agreement is annexed to

[2] For more on the international system of IP protection, *see generally* G. GREGORY LETTERMAN, BASICS OF INTERNATIONAL INTELLECTUAL PROPERTY LAW (2001); Marshall A. Leaffer, *The New World of International Trademark Law*, 2 MARQ. INTELL. PROP. L. REV. 1 (1998).

[3] These other treaties include WIPO "Internet Treaties" of 1996, namely the WIPO Copyright Treaty (WCT) and WIPO Performances and Phonograms Treaty (WPPT), as well as bilateral agreements in the form of free trade agreements. *See also* Leaffer, *supra* note 2. For a concise summary of TRIPS, *see* SOUTH CENTRE, THE TRIPS AGREEMENT: A GUIDE FOR THE SOUTH: THE URUGUAY ROUND AGREEMENT ON TRADE-RELATED INTELLECTUAL PROPERTY RIGHTS, 15-24 (1997), *available at* http://www.southcentre.org/publications/trips/tripsagreement.pdf.

the agreement establishing the World Trade Organization ("WTO").[4] The TRIPS agreement covers various types of intellectual property subject mater (including patents) and regulates their protection and enforcement.[5] Among other things, TRIPS allows for inventions relating to "active ingredients" in medicines to be patented.[6] It also prescribes a (minimum) patent term of twenty years for all types of inventions.[7] During that patent term, the patentee enjoys a right of sole use over his patent. Although some exceptions have occurred,[8] the patentee is generally able to set the price of the medicine, thus effectively determining where it is sold and to whom.[9]

TRIPS requires WTO member states to adopt into their respective legal systems a "minimum" level of intellectual property protection. But, in fact, TRIPS has recently raised the standards of IP protection and revamped the enforcement of IP rights.[10] Most countries have now attained membership in the WTO, which is the primary and, by far, the most significant regulative framework for international trade.[11] WTO membership is contingent on its constituents' adoption of its annexed agreements, including the TRIPS agreement.[12] WTO member states are obligated, through a variable timeline, to implement into their national legislation all of the standards of IP protection as prescribed by TRIPS.[13] Thus, the WTO has obligated member states to amend their national IP

[4] The WTO is perceived as a mechanism for facilitating and unifying international trade. PETER GALLAGHER, GUIDE TO THE WTO AND DEVELOPING COUNTRIES (2000). The WTO came into effect on January 1, 1995. The international framework pertaining to trade regulation has been but in place by 1947 with the formulation of the General Agreement on Tariffs and Trade (GATT), and, arguably, had come into existence even earlier. Intellectual property protection, after being included (in 1994) into the WTO framework, rose to the status of other impediments to trade, such as dumping and subsidies, which are also regulated by the GATT/WTO. ROBERT M. SHERWOOD, INTELLECTUAL PROPERTY AND ECONOMIC DEVELOPMENT 67-92 (1990); ASSAFA ENDESHAW, INTELLECTUAL PROPERTY POLICY FOR NON-INDUSTRIAL COUNTRIES 121 (1996); CHRISTOPHER MAY, A GLOBAL POLITICAL ECONOMY OF INTELLECTUAL PROPERTY RIGHTS: THE NEW ENCLOSURES? 78 (2000). The text of the Ministerial Declaration of the Uruguay Round of multilateral trade negotiations stated that

> [i]n order to reduce the distortions and impediments to international trade, and taking into account the need to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade, the negotiations shall aim to clarify GATT provisions and elaborate as appropriate new rules and disciplines.

SHERWOOD at 3. The WTO is a result of the Uruguay Round of trade negotiations, which was concluded in December, 1993. JOHN HOWARD JACKSON ET AL., LEGAL PROBLEMS OF INTERNATIONAL ECONOMIC RELATIONS 289-326 (3d ed. 1995). Notably, the majority of WTO member states (about 68%) are classified as Developing Countries. Thirty other member states are categorized as Least-Developed Countries. World Trade Organization, *Understanding the WTO: The Organization: Members and Observers*, http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm (last visited Mar. 8, 2008).

[5] TRIPS also covers trademarks, copyrights (and other related rights), geographical indications, industrial designs, layout-designs of integrated circuits, and trade secrets. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, 33 I.L.M. 81 (1994) [hereinafter TRIPS].

[6] TRIPS, *supra* note 5, art. 27.

[7] Article 33 of the TRIPS agreement sets a minimum term of protection at 20 years, which begins running from the time of the filing. In some cases relating to pharmaceutical patents, extensions have been granted. These extensions are intended to compensate the "patentee" for time lost during the approval process. *See*, 35 U.S.C. § 156 (2007).

[8] Several leading pharmaceutical firms have responded to such pressures and lowered the prices of some of their medicines. 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 208 (Carsten Fink & Keith E. Maskus eds., 2005).

[9] Patricia M. Danzon & Adrian Towse, *Theory and Implementation of Differential Pricing for Pharmaceuticals, in* INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY RÉGIME 425 (Keith E. Maskus & Jerome H. Reichman eds., 2005).

[10] Suffice it to mention the protection that has been granted to well-known marks; the enforcement authority that has been granted to customs; the recognition for geographical indications and the setting a minimum patent term. DANIEL J. GERVAIS, THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS (1998).

[11] As of July 27, 2007, 151 countries have joined the WTO. *See* WTO Home Page, http://www.wto.org (last visited Mar. 8, 2008).

[12] The 1994 Agreement Establishing the World Trade Organization comprises various multilateral as well as plurilateral agreements. The five main multilateral agreements, binding on all WTO members, address various international trade issues, including intellectual property. These agreements are the General Agreement on Tariffs and Trade (GATT), the General Agreement on Trade in Services (GATS), the Agreement on Trade Related Aspects of Intellectual Property Protection (TRIPS), the Understanding on the Dispute Settlement System (DSU), and the Trade Policy Review Mechanism (TPRM). The WTO performs various functions, including (1) administration and implementation of the multilateral trade agreements that makeup the WTO (including those that deal with IP issues), (2) Provision of a forum for multilateral trade negotiations, (3) Provision of assistance to the resolution of international trade disputes, (4) oversight of international trade policies, and (5) cooperation with other international institutions involved in global economic policy making. Agreement Establishing the World Trade Organization art. III, Apr. 15, 1994, 33 I.L.M. 1144 (1994) [hereinafter WTO Agreement], *available at* http://www.wto.org/english/docs_e/legal_e/04-wto.pdf.

[13] Through TRIPS, members of the WTO are required to comply with the substantive provisions of international agreements and conventions dealing with intellectual property protection (most notably, the Paris and Berne Conventions). The TRIPS Agreement came into effect on January 1, 1995. Developed countries were granted one year to incorporate TRIPS standards into their national laws. Developing countries received five years to comply. Least-developed countries ("LDCs") were given eleven years, but, subsequently, the term was extended by ten more years, though the extension was limited to pharmaceutical patents. Thus, LDCs are not obligated to either provide or enforce patents and data protection with respect to pharmaceutical products until January 1, 2016. *See* Council for Trade Related Aspects of Intellectual Property Rights, *Extension of the Transition Period under Article 66.1 of the TRIPS Agreement for Least-Developed Country Members*, IP/C/25 (July 1, 2002), *available at* http://www.wto.org/english/tratop_e/trips_e/art66_1_e.htm.

legislations so as to bring them into conformity with the dictates of TRIPS and other IP-related treaties and conventions.[14] IP laws of most countries now possess similar, albeit not identical, characteristics and norms relating to the protection and enforcement of IP rights.[15] This "uniformity" is largely owed to the fact that WTO members that do not incorporate TRIPS' standards of protection into their respective legislation (or do not enforce them) may face economic and trade sanctions that are imposed through WTO's Dispute Settlement Mechanism.[16] To date, WTO Dispute Settlement Panel has dealt with a number of disputes. Over ten of these disputes relate to pharmaceuticals.[17] Furthermore, countries that

[14] BUREAU OF NATIONAL AFFAIRS, INTERNATIONAL TREATIES ON INTELLECTUAL PROPERTY 1-14 (Marshall A. Leaffer ed., 2d ed. 1997); *Leading International and National Bodies in Intellectual Property, in* WORLD IP CONTACTS HANDBOOK 43-49 (2002). *See generally* treaties listed on the WIPO web site, http://www.wipo.int/treaties/en/. Many international conventions and treaties regulate intellectual property rights and their protection. The most notable of these are the 1883 Paris Convention for the Protection of Industrial Property, the 1886 Berne Convention for the Protection of Literary and Artistic Works, the 1861 International Convention for the Protection of New Varieties of Plants (UPOV), the 1970 Patent Cooperation Treaty and Regulations (PCT),, the 1891 Madrid Agreement Concerning the International Registration of Marks, the 1989 Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks (Madrid Protocol), the 1996 WIPO Performers and Phonograms Treaty (WPPT), the 1971 Convention for the Protection of Producers of Phonograms Against Unauthorized Duplication of Their Phonograms (Geneva Convention), the 1974 Convention Relating to the Distribution of Program-Carrying Signals Transmitted by Satellite (Brussels Convention), and the Treaty on Intellectual Property in Respect to Integrated Circuits.

[15] However, TRIPS has not provided complete answers to all IP issues. For example, TRIPS excludes Article 21 of the 1886 Berne Convention for the Protection of Literary and Artistic Works relating to moral rights. *See* TRIPS, *supra* note 5.

[16] MAY, *supra* note 4, at 76. DAVID W. PLANT, RESOLVING INTERNATIONAL INTELLECTUAL PROPERTY DISPUTES (1999). For details on the types of disputes that arise, see "Index of Dispute Issues" at World Trade Organization Home Page, http://www.wto.org/english/tratop_e/dispu_e/dispu_subjects_index_e.htm (last visited Mar. 8, 2008). TRIPS allows for settling of disputes between member states over intellectual property issues by applying WTO's Dispute Settlement Mechanism. Jeffrey Waincymer, *Settlement of Disputes within the World Trade Organization: A Guide to the Jurisprudence, in* THE WORLD ECONOMY: GLOBAL TRADE POLICY 2001 24 (Peter Lloyd & Chris Milner eds., 2002). Notwithstanding these unified standards, TRIPS allows its members to exercise some independence, including rules pertaining to parallel imports. Conflicts arising between states over issues that are regulated by the WTO are adjudicated by the Dispute Settlement Body that operates in accordance with the Dispute Settlement Understanding.

[17] Various countries have been involved in these types of proceedings, including Argentina, Brazil, Canada, members of the European Union, India, Pakistan, and the United States. For examples of pharmaceutical disputes, see the complaints by India on Argentina and South Africa. *See* Request for Consultations by India, *Argentina — Measures Affecting the Import of Pharmaceutical Products*, WT/DS233/1 (May 25, 2001); Request for Consultations by India, South Africa — Anti-Dumping Duties on Certain Pharmaceutical Products from India, WT/DS168/1 (Apr. 1, 1999). For some disputes related to patents, *see, e.g.*, Request for Consultations by the United States, *Argentina — Certain Measures on the Protection of Patents and Test Data*, WT/DS196 (May 30, 2000); Request for Consultations by Canada, European Communities — Patent Protection for Pharmaceutical and Agricultural Chemical Products, WT/DS153 (Dec. 2, 1998); Request for Consultations by United States, Pakistan — Patent Protection for Pharmaceutical and Agricultural Chemical Products, WT/DS36 (Apr. 30, 1996).

do not implement TRIPS may be prevented from joining the WTO or may have to endure the burden of retaliatory measures that are sanctioned by that organization.[18] In this regard, TRIPS differs from previous IP agreements in that it provides an effective apparatus that helps ensure its full implementation and enforcement.[19] Indeed, TRIPS has revolutionized intellectual property protection because it has been able to secure the adoption and continued enforcement of its standards.[20] Thus, despite the economic, political and social differences among countries, their respective national IP laws have become exceedingly similar in the rules and norms that they encompass.[21] The standards prescribed by TRIPS have become the "law" within WTO member states.[22] For example, the

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> Settling disputes is the responsibility of the Dispute Settlement Body (the General Council in another guise), which consists of all WTO members. The Dispute Settlement Body has the sole authority to establish "panels" of experts to consider the case, and to accept or reject the panels' findings or the results of an appeal. It monitors the implementation of the rulings and recommendations, and has the power to authorize retaliation when a country does not comply with a ruling.

World Trade Organization, *Understanding the WTO: Settling Disputes: A Unique Contribution*, http://www.wto.org/english/thewto_e/whatis_e/tif_e/disp1_e.htm (last visited Mar. 8, 2008). *See also* Michael Johnson, *The WTO Dispute Settlement System: How it Works*, CTR. FOR TRADE & COM. DIPL. (Apr. 1996), *available at* http://www.commercialdiplomacy.org/simulations/sim_methyl4.htm.

[19] WORLD INTELLECTUAL PROPERTY ORGANIZATION, INTRODUCTION TO INTELLECTUAL PROPERTY: THEORY AND PRACTICE 475 (1997); INTERNATIONAL TRADEMARK ASSOCIATION, DEVELOPING COUNTRIES COMPLIANCE WITH THE TRIPS AGREEMENT: UPDATED VERSION, Oct. 1999, *available at* http://www.inta.org/downloads/tap_trips2000.pdf (last visited Mar. 8, 2008).

[20] Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, Apr. 15, 1994, 33 I.L.M. 1125 (1994); *Policing the World of IP and Solving Rows, in* WORLD IP CONTACT HANDBOOK 18-21 (2002). In addition, WIPO also plays a role in the settlement of some IP-related disputes. *See* WORLD INTELLECTUAL PROPERTY ORGANIZATION, DOMAIN NAME DISPUTE RESOLUTION SERVICE, http://www.wipo.int/amc/en/domains (last visited Mar. 8, 2008); Mimi Mann, *USTR's Special 301 Report Reviews IPR Developments in the Region*, MIDDLE EAST EXECUTIVE REP., Mar. 2000, at 8, 25-29; Howard C. Anawalt, *International Intellectual Property Progress and the Rule of Law*, 19 SANTA CLARA COMPUTER & HIGH TECH. L. J. 383 (2003); Lance Clouse, Note, *Virtual Border Customs: Prevention of International Online Music Piracy Within the Ever-Evolving Technological Landscape*, 38 VAL. U. L. REV. 109, 150 (2003).

[21] Nevertheless, a law in any country should be read in accordance with the background of the entire legal system. In this regard, one needs to consider the constitutional setting, interpretive model and the power of the judiciary vis-à-vis the legislator.

[22] In the context of the bigger picture, TRIPS is regarded as merely one component of Globalization. Just as the latter has become the "pervasive growing universal culture," the former (i.e., TRIPS) has become the "lex" of IP. *See* LAWRENCE M. FRIEDMAN, THE REPUBLIC OF CHOICE: LAW, AUTHORITY AND CULTURE 202-203 (1994). Friedman observes that Globalization manifests itself in the fact that

> each country is linked to every other country, directly or indirectly; there is a single world economy; when one country sneezes the other catch cold; there are

twenty-year patent term is presently prevalent in the patent laws of most countries.[23]

In addition to the multilateral track that is based largely on TRIPS, there exists a bilateral track in the form of Free Trade Agreements ("FTAs"). Among other trade issues, these agreements incorporate elevated standards of IP protection.[24] These standards, collectively referred to as "TRIPS-Plus" standards, include banning the use of originators' product data. This data helps facilitate marketing approval for competing generic versions of a specific medicine. This method of protection is referred to as "data exclusivity". In addition, FTAs typically extend patent terms beyond 20 years via the mechanism of patent term adjustment. They also limit the circumstances in which compulsory licenses on pharmaceutical products may be issued and prohibit the export of drugs produced under compulsory licenses.[25] The United States, as well as Western European states, has been intensely engaged in entering into FTAs with other countries.[26] In the context of this article, patent provisions of the TRIPS agreement and FTAs will constitute the Conventional International Patent Régime ("CIPR"). Both tools (i.e., TRIPS and FTAs) have given pharmaceutical corporations great powers in their endeavors to protect their drug patents around the globe. Such protection has made it much more difficult for poor countries to secure a sustained sup-

not hermit kingdoms any longer, or forbidden cities. . . . The decay of the local, the native, the tribal, is often laid at the door of Western influence.

Id. *See also* Amir H. Khoury, *Trademark Policy: The Case of Arab Countries*, *in* INTELLECTUAL PROPERTY, TRADE, AND DEVELOPMENT: STRATEGIES TO OPTIMIZE DEVELOPMENT IN A TRIPS-PLUS ERA (Daniel J. Gervais ed., 2007); Robert Gutowski, *The Marriage of Intellectual Property and International Trade in the TRIPS Agreement: Strange Bedfellows or a Match Made in Heaven?*, 47 BUFF. L. REV. 713 (1999).

[23] IUPAC COMMISSION ON BIOTECHNOLOGY, EUROPEAN UNION PATENT REGULATIONS, *available at* http://www.itb.uni-stuttgart.de/IUPAC/patent/eu.html (last visited Mar. 8, 2008).

[24] Carlos Correa, *TRIPS and TRIPS-Plus Protection and Impacts in Latin America*, *in* INTELLECTUAL PROPERTY, TRADE AND DEVELOPMENT: STRATEGIES TO OPTIMIZE ECONOMIC DEVELOPMENT IN A TRIPS-PLUS ERA 221 (Daniel Gervais ed., 2007). *See also* Ikechi Mgbeoji, *TRIPS and TRIPS-Plus Impacts in Africa*, *in* INTELLECTUAL PROPERTY, TRADE AND DEVELOPMENT: STRATEGIES TO OPTIMIZE ECONOMIC DEVELOPMENT IN A TRIPS-PLUS ERA 259 (Daniel Gervais ed., 2007).

[25] Nathan Ford, *Patents, Access to Medicines and the Role of Non-Governmental Organisations*, 1 J. GENERIC MED. 137 (2004). *See also* Mary Moran, *Reneging on Doha: An MSF Analysis of Recent Attempts to Restrict Developing Countries' Use of Compulsory Licensing to a Set List of Diseases*, MÉDECINS SANS FRONTIÈRES, May 2003, *available at* http://www.accessmed-msf.org/fileadmin/user_upload/medinnov_accesspatents/renegingondoha.pdf.

[26] The United States has established Free Trade Agreements with Australia, Bahrain, Dominican Republic-Central America-United States TA (CAFTA-DR Costa Rica, Dominican Republic, El Salvador, Guatemala, Honduras and NicaraguaChile, Israel, Jordan, Morocco, North American Free Trade Agreement (NAFTA) (Canada Mexico), Oman Singapore. *See* TradeAgreements.gov, Existing Free Trade Agreements, http://www.tradeagreements.gov/ExistingFTAs/index.htm (last visted Mar. 8, 2008).

ply of medicines at affordable prices for their citizens. These countries' ability to access patented medicines has been diminished.

It is worth noting that, in addition to disciplinary measures prescribed by the multilateral (TRIPS) and bilateral (FTAs) agreements, countries that do not meet IP standards of protection risk unilateral retaliation by other influential countries. This retaliatory tool is frequently utilized by developed countries, namely the United States, as well as countries that are members of the European Union.[27] Thus, the multilateral, bilateral and unilateral tracks have now become effective tools for raising the level of IP protection and enforcement.

1.2 The APM Debate in the TRIPS and TRIPS-Plus Context

From the outset it is important to stress that access to patented medicines constitutes only one component of effective disease treatment. In this regard, one commentator has observed that "effective disease treatment relies on a long chain of factors, including R&D of appropriate medicines; production; quality control; adequate distribution networks; good drug supply management; reliable information for, and adequate training of, healthcare professionals; financial accessibility; and good patient compliance".[28] Furthermore, the Access to Patented Medicines program is not intended to substitute the obligation of states (and individuals) to engage in disease prevention. Preventive measures, such as the use of contraceptives in the case of HIV or the drying of still waters and use of netting in the case of malaria, remain crucial components for resolving those health crises. However, such measures alone cannot provide a solution for the millions of people who have already contracted the diseases or for those who will, regretfully, do so in the future. Another form of prevention that relates to the APM debate is access to immunization. For the purpose of this article, the term "patented medicines" will also in-

[27] Unilateral action is undertaken by the United States based on the Special 301 and Super 301 clauses in the United States Code. These clauses are invoked following relevant findings by the United States Trade Representative. *See* Office of the United States Trade Representative Home Page, http://www.ustr.gov (last visited Mar. 8, 2008).

[28] Ford, *supra* note 25 ("[D]isease prevention is an important intervention that will reduce the need for access to medicines. But, as the HIV pandemic has shown, prevention alone is not enough."); Eric Goemaere et al., *HIV/AIDS Prevention and Treatment*, 360 LANCET 86 (2002). It is resported that forty-two million people are already infected with HIV. Six million of these people live in less developed countries and need antiretroviral therapy today. *See also* B. Pecoul et al., *Access to Essential Drugs in Poor Countries: A Lost Battle?*, 4 JAMA 361-67 (1999).

clude immunization medications.

As discussed in the previous section, the CIPR grants inventors the right of sole use of their registered patents. This system has become the catalyst for the creation of pharmaceutical conglomerates that have been engaged in research and development and have produced thousands of ethical pharmaceutical products. Another consequence of the patent laws has been the right of the patentees to determine the ways in which their respective patents are utilized and sold. The high prices of medicines have, in turn, created a hurdle to accessibility to patented medicines in poor and developing countries. Simply stated, strong patent rights, secured by the conventional IP régime, have empowered pharmaceutical companies to capitalize on their achievements to the highest extent. Pharmaceutical corporations have been able to obtain global patent protection, enabling them to set the prices of their medicines, to grant patent licenses, and to enforce their patent rights in national courts, paving the way for market dominance.[29] In other words, the APM problem appears to be a natural consequence of the existing patent system. That is the case because when innovative pharmaceutical companies exercise their excusive legal rights over their patents, they are able to decide the "when," the "how," and the "how much" that pertain to the sales of their pharmaceutical concoctions. CIPR allows pharmaceutical companies (much like other innovators) to exercise full discretion when it comes to the sale of their products. This patent "aftershock" is not a trivial issue because high prices for medicines effectively exclude many from being able to purchase them. Furthermore, the high prices of medicines may also prevent developing countries from purchasing these products for the benefit of their citizens, or might compel such countries to reduce other health-related expenditures (e.g., decreased investments in hospitals, machines and labs). Indeed, research shows that medicines account for over 80% of health expenditures in developing countries.[30] Costs associated with medicines for the treatment of AIDS and malaria provides sobering proof of the connection between the price of medicines and APM.[31] This problem is most acute in poor countries that have a high number of patients but do not have the financial or research capabilities to independently produce generic drugs that are similar to their patented counterparts. Those countries need to rely on the importation of generic medicines from other states.[32] However, the price issue does not detract from the fact that various other factors affect APM, including physical facilities, number of physicians, and the structure of the health system.

The APM debate is part of a larger debate relating to the value of the entire IP régime. This bigger debate has commenced during the early stages of negotiations leading up to the creation of TRIPS.[33] While one group has approached the creation of TRIPS with anticipation and optimism,[34] another group has treated it – and still does treat it – with concern, suspicion and skepticism.[35] The TRIPS opponents' claim has been that develop-

[29] Pharmaceutical companies' pricing policies have not been effectively challenged.

[30] Ford, *supra* note 25. "Patients in Asia, Africa and Latin America pay on average twice as much as patients in developed countries." *Id.* Ford also contends that the price of medicines can singularly determine whether or not a government is able to treat a particular disease. *Id. See also* JONATHAN D. QUICK & RONNEL B. TOLENTINO, GLOBAL COMPARATIVE PHARMACEUTICAL EXPENDITURES: WITH RELATED REFERENCE INFORMATION, at 56 (Health Economics & Drugs, EDM Series No. 3, 2000).

[31] Today, almost 20 types of drugs are indicated for the treatment of AIDS and AIDS-related illnesses. However, these crucial medications are not available to a number of "high-prevalence countries" due to their high pricing. *See* Lee Jong Wook, Director-General, World Health Organization, Speech to the Fifty-Sixth World Health Assembly (May 21, 2003), *available at* http://www.who.int/dg_elect/wha56_jwlspeech/en/. Analogously,,there is insufficient access to medicines for the treatment of malaria in Africa, a disease that annually claims the life of two million children on that continent. *See* MÉDECINS SANS FRONTIÈRES, ACT NOW TO GET MALARIA TREATMENT THAT WORKS TO AFRICA, (Daniel Berman ed., 2003), *available at* http://www.doctorswithoutborders.org/publications/reports/2003/act_now_report.pdf.

[32] Ford, *supra* note 25, at 142.

[33] The concept of including IP in the realm of trade regulation appeared during the 1986 Uruguay Round of trade negotiations. For more on the debate pertaining to this inclusion, *see* David Watters, *The Canadian Perspective on GATT-TRIPS Negotiations, in* GLOBAL RIVALRY AND INTELLECTUAL PROPERTY: DEVELOPING CANADIAN STRATEGIES 183-89 (Murray Smith ed., 2003); Carlos Alberto Primo Braga, *The North-South Debate on Intellectual Property Rights,* in *id.* at 173-81; Gutowski, *supra* note 22, at 713.

[34] R. Michael Gadbaw, Symposium, *Trade-Related Aspects of Intellectual Property,* 22 VAND. J. TRANSNAT'L L. 223, 689 (1989); J.H. Reichman, *Compliance with the TRIPS Agreement: Introduction to a Scholarly Debate,* 29 VAND. J. TRANSNAT'L L. 363 (1996); Paul J. Heald, *Mowing the Playing Field: Addressing Information Distortion and Asymmetry in the TRIPS Game,* 88 MINN. L. REV. 249 (2003).

[35] Ruth L. Okediji, *Public Welfare and the Role of the WTO: Reconsidering the TRIPS Agreement,* 17 EMORY INT'L L. REV. 819 (2003); Margaret Chon, *Intellectual Property and the Development Divide,* 27 CARDOZO L. REV. 2821 (2006). Chon provides a sobering outlook on the present situation:

> If the instrumental mandate of intellectual property law is to increase knowledge for positive purposes, then there must be fuller consideration of the provision of basic needs and other global public goods such as food, security, education, and health care. Undernourished, diseased, dying, undereducated, or extremely impoverished populations are viewed by many as negative externalities both qualitatively and quantitatively more serious than the danger of underincentivizing authors and inventors. The latter is the externality to which intellectual property law devotes its exclusive attention. This disjuncture over priorities has highlighted an increasingly untenable intellectual solipsism of the intellectual property policymaking framework, as intellectual property globalization encounters ethical concerns associated with development.

ing countries do not reap equal benefits from the régime and that they are harmed by the stringent system of IP protection that is embodied in TRIPS and the subsequent bilateral agreements comprising TRIPS-Plus.[36] In this endeavor, developing countries are viewed as consumers rather than partners. This is especially evident in the case of the pharmaceutical industry, where the world's leading multibillion-dollar pharmaceutical corporations spring up almost exclusively in the developed countries.[37]

1.3 The Doha Round and the Winds of Change!

The most visible manifestation of the divergence between the *ex ante* promise and *ex post* deficiencies of TRIPS has emerged during the 2001 Doha Round of trade negotiations,, which has brought into the open many points of tension between developed and developing countries.[38] The APM issue has fueled this tension and accentuated the debate between the proponents of TRIPS and its opponents.[39] In November 2001, the WTO Ministerial Conference, convening in Doha, adopted a special Declaration on the TRIPS Agreement and Public Health. This declaration addressed the heated debate between developed and developing countries with respect to access to patented medicines.[40] It came

Id. at 2912.

[36] *See* Lee G. Branstetter, *Do Stronger Patents Induce More Local Innovation?*, *in* INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME, *supra* note 9, at 309; Sandor Vida, TRADEMARKS IN DEVELOPING COUNTRIES 22 (1981); Robert Sherwood, *Intellectual Property Systems and Investment Stimulation: The Rating of Systems in Eighteen Developing Countries*, 37 IDEA 261 (1997); INTELLECTUAL PROPERTY RIGHTS IN EMERGING MARKETS (Clarisa Long ed., 2000); Douglas Greer, *The Economic Benefits and Costs of Trademarks: Lessons for Developing Countries*, 7 WORLD DEV. 638 (1997); Peter O'Brien, *Trademarks in Developing Countries*, 14 J. MOD. AFR. STUD. 297 (1976); Surendra Patel, *Introduction to the Special Issue, Trademarks and the Third World*, 7 WORLD DEV. 649 (1979); Surendra Patel, *Trademarks and the Intellectual Property in Developing Countries*, 7 WORLD DEV. 653 (1979); Robert Rapp & Richard Rozek, *Benefits and Costs of Effects of Trademarks on Arab Countries in the Middle East* (2004) (unpublished Ph.D. dissertation, Haifa University) (on file with author).

[37] The earnings of the leading twenty corporations, in 2006, exceeded one hundred billion USD. *See* List of Largest Fifty Pharmaceutical Companies for the Year 2006, http://en.wikipedia.org/wiki/List_of_pharmaceutical_companies#Top_50_pharmaceutical_companies (last visited Mar. 8, 2008).

[38] Haochen Sun, *The Road to Doha and Beyond: Some Reflections on the TRIPS Agreement and Public Health*, 15 EUR. J. INTERN'L L.123 (2004).

[39] Heinz Klug, *Campaigning for Life: Building a New Transnational Solidarity in the Face of HIV/AIDS and TRIPS*, *in* LAW AND GLOBALIZATION FROM BELOW: TOWARDS A COSMOPOLITAN LEGALITY 118 (Boaventura de Sousa Santos & Cesar A. Rodriguez-Garavito eds., 2005).

[40] The Doha Declaration devoted three sections (seventeen through nineteen) to IP-related issues. *See* Martin Khor, *The WTO, The Post-Doha Agenda and the Future of the Trade System: A Development Perspective*, THIRD WORLD NETWORK, May 2002, http://www.twnside.org.sg/title/mkadb.htm. In fact, countries such as Brazil have been the primary catalysts for the WIPO Development Agenda of 2004. *See* WORLD INTELLECTUAL PROPERTY ORGANIZATION, WIPO DEVELOPMENT AGENDA – 2004, *available at* http://www.wipo.int/ip-development/en/agenda/pcda04.html#background (last visited Mar. 8, 2008). The proposal was submitted by Brazil and Argentina and supported by Bolivia, Cuba, the Dominican Republic, Ecuador, Iran, Kenya, Sierra Leone, South Africa, Republic of Tanzania and Venezuela. *Id.*

[41] *See Pharm. Mfrs. Ass'n of S. Afr. v. Pres. of S. Afr.* 1998 (98) SA at 4183 (S. Afr.), *available at* http://www.fordham.edu/law/faculty/patterson/tech&hr/materials/pharmace.txt. *See also* accompanying text to *infra* note 69.

[42] The anthrax scare came shortly after the September 11, 2001 attacks on the United States.

[43] World Trade Organization, Ministerial Declaration of 20 November 2001, ¶ 4, WT/MIN(01)/DEC/2, 41 I.L.M. 755 (2002), *available at* http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm (refer to paragraph 4) [hereinafter Doha Declaration].

[44] *See* Morán, *supra* note 25 (arguing that the list creates restrictions that are nonsensical from a public health perspective and that these restrictions make essential medicines inaccessible to developing nations).

[45] Moran's report indicates that the list excludes "two of the four top causes of mortality for children under five in Africa" which includes pneumonias and common causes of diarrheal diseases. *Id.* In addition, "[t]he list excludes all non-infectious diseases . . . . All of these diseases . . . have a range of patented drugs available for their management in the West, and all have been omitted from the approved disease list." *Id.*

[46] Ford, *supra* note 25, at 144.

against the backdrop of the South African HIV law suit[41] and the Anthrax scare of 2001.[42] The Doha Declaration promulgated a new strategy and stated that

> [t]he TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all.[43]

Following the Declaration was a list comprised of specific diseases and ailments. The list was intended to make medicines more accessible and less expensive. However, this Declaration has not yet realized its full potential because the patented medicines that are intended to treat some of the most prevalent diseases had been excluded from the list.[44] For example, while the list includes medicines for the treatment of HIV/AIDS, it excludes other diseases that are common causes of mortality in Africa.[45] In this regard, one commentator has cautioned that the "Doha implementation is far from complete, and [that] there is much that countries can still do to provide the strongest possible safeguards against unaffordable prices for much-needed drugs".[46] This "limited list" approach stands counter to the Doha Declaration, which states that "each Member has the right to grant compulsory li-

censes and the freedom to determine the grounds upon which such licenses are granted".[47] Furthermore, the "limited list" model is unsatisfactory because countries cannot be expected to wait until a certain ailment has become "sufficiently" widespread. On the contrary, it would be much more logical and less costly if countries were to respond to health threats in a timely fashion, thus reducing the costs of treatment and loss of human life. In addition to the problems already listed, the "TRIPS-Plus" structure undermines the Doha Declaration. In order to implement the Declaration and to protect public health effectively, one observer noted, "industrialized countries must stop exercising trade pressures to defend the interests of their multinational industries".[48]

Evidently, the Doha Round has proved that points of tension relating to IP, such as data exclusivity, parallel imports and APM, cannot be suppressed indefinitely. In 1994, when TRIPS was drafted, the block of countries that opposed it (e.g., Korea, Brazil, Thailand, and India) appeared to have been silenced. These countries had opposed the linkage between IP protection and international trade.[49] However, the points of tension surrounding the TRIPS agreement, including the issue of APM, did not go quietly into the night. Rather, they had vigorously reemerged within five years after the creation of TRIPS and today remain a focal point of debate and conflict.[50] Indeed, the APM problem is so widely recognized, that in 2003 the United States introduced the five-year President's Emergency Plan for AIDS Relief ("PEPFAR" or "Emergency Plan") in an attempt to fight the global HIV/AIDS pandemic.[51]

[47] Doha Declaration, *supra* note 43, ¶ 5(b).

[48] Ford, *supra* note 25, at 142. *See also* Nicholas Kristof , *Death by Dividend*, N.Y. TIMES, Nov. 22, 2003, at A15; Moran, *supra* note 25; Allyson Pollock & David Price, *New Deal from the World Trade Organisation*, 327 BRIT. MED. J. 571, 571-72 (2003).

[49] GERVAIS, *supra* note 10. *See also* JOHN BRAITHWAITE & PETER DRAHOS, ch. 7 (2000).

[50] In a letter dated September 25, 2007, "[o]ver 100 health, faith-based, consumer, development, labor and fair trade organizations have urged U.S. senators and representatives to co-sponsor S. Res 241 and H. Res 525," which are resolutions that call for revamped United States commitment to promoting medicinal access in developing countries. Robert Weissman, *Coalition Calls on Congress to Support Resolution for Access to Medicines in Developing Countries*, ACCESS TO MEDS. PROJECT, Sept. 25, 2007, http://www.essentialaction.org/access/index.php?/archives/77-Coalition-Calls-on-Congress-to-Support-Resolution-for-Access-to-Medicines-in-Developing-Countries.html. Various organizations, including The American Medical Student Association, Consumer Federation of America, Consumers Union and Oxfam America, have reportedly endorsed the letter. *Id.*

[51] The plan seeks to combat HIV/AIDS by providing funds intended to supply antiretroviral therapies, preventing new infections, and establishing support care in the applicable host nations. *See* OFFICE OF U.S. GLOBAL AIDS COORDINATOR, PRESIDENT'S EMERGENCY PLAN FOR AIDS RELIEF, Feb. 23, 2004, *available at* http://www.state.gov/documents/organization/29831.pdf [hereinafter PEPFAR].

The Doha declaration was not the only multilateral response to the APM problem. In 2003, a decision was reached by the WTO that aimed to strengthen access to patented medicines by authorizing countries that could not produce the medicines themselves to import pharmaceuticals made under compulsory licenses by neighboring states that have manufacturing capabilities.[52] Two years later, WTO members agreed to transform this decision into a permanent amendment of the TRIPS Agreement ("2005 TRIPS Amendment"). However, the amendment will only take effect after two thirds of the WTO members ratify it, which has not happened thus far.[53] The proposed amendment paves the way for exporting patented medicines to states that are in need of such medications ("Eligible Importing Members"). This is achieved by an "authorized" circumvention the compulsory licensing rules, as set out in TRIPS Article 31.[54] Notably, the least developed countries are authorized to utilize this model without prior notification to the WTO of their intent to do so, while most countries are required to notify the WTO about their intent to export or to import pharmaceutical drugs under the compulsory licensing mechanism.[55] This system constitutes an important step towards finding

[52] The 2003 decision is referred to as the "paragraph 6 system" because it facilitates the implementation of paragraph 6 of the 2001 Doha Declaration on the Trade-Related Aspects of Intellectual Property Rights Agreement and Public Health. Notably, this decision has been subject to considerable debate. *See Draft Communication from the European Communities: Proposal for an Amendment of the TRIPS Agreement to Incorporate the Decision Implementing Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, CONSUMER PROJECT ON TECH. (2005), http://www.cptech.org/ip/wto/p6/ec-tripsamendmentproposal.html (last visited Mar. 8, 2008).

[53] On December 6, 2005, WTO members approved changes to TRIPS, rendering the 2003 decision permanent. *See* Amendment of the TRIPS Agreement, WT/L/641 (Dec. 8, 2005), *available at* http://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm [hereinafter 2005 TRIPS Amendment]. However, the amendment would only be formally accepted after two thirds of WTO's members have ratified the change. *See* World Trade Organization, Members Accepting Amendment of the TRIPS Agreement, http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm (last visited Mar. 8, 2008). The present deadline for this acceptance is December 31, 2009. *Id.* As of November 30, 2007, a number of members have formally accepted the 2005 TRIPS Amendment, including the United States, Switzerland, El Salvador, Republic of Korea, Norway, India, Philippines, Israel, Japan, Australia, Singapore, Hong Kong, China, and the European Union. *Id.*

[54] 2005 TRIPS Amendment, *supra* note 53, art. 31bis (proposed).

[55] *See* World Trade Organization, Canada is First to Notify Compulsory Licence [sic] to Export Generic Drug, Oct. 4, 2007, http://www.wto.org/english/news_e/news07_e/trips_health_notif_oct07_e.htm (indicating that Canada and Rwanda have been the first countries to provide notification of the export and import of Canadian-manufactured, TriAvir, a generic triple combination AIDS therapy drug). Due to this notification, the medicine can now be produced and exported to Rwanda, which is unable to manufacture the medicine itself. *Id.*

an amicable solution to the APM predicament. It essentially recognizes that different states have different needs and that the TRIPS structure needs to be amended in order to address these variable needs. The 2005 Proposal achieves this end by amending TRIPS Article 31, and by adding a new Annex to the TRIPS Agreement that includes definitions of the regulatory tools that are used. For example, the proposed Annex to TRIPS creates a new status for certain states, whereby they are entitled, in cases of extreme medical urgency, to utilize the system of compulsory licensing set out in the newly amended TRIPS Article 31bis.[56]

In addition to the proposed amendment to TRIPS Article 31, in April 2006, a World Health Organization ("WHO") commission published a detailed report pertaining to the APM issue. In the report, the WHO highlighted the need for ensuring access to medicines and vaccines across developing countries. According to the WHO, "one of the greatest threats to international health security arises from outbreaks of emerging and epidemic-prone diseases."[57] The WHO also revealed that over 50% of the poorest countries in Africa and Asia do not have access to medicines due to prohibitive pricing.[58]

CHAPTER TWO

THE NORMATIVE SPHERE: SHOULD AN APM MECHANISM BE INCLUDED IN CIPR?

One commentator has summed up the APM issue as a "battle between public health and company wealth."[59] However, this view

[56] Article 31bis defines an eligible importing Member as follows:

> [A]ny least-developed country Member, and any other Member that has made a notification to the Council for TRIPS of its intention to use the system set out in Article 31bis and this Annex ('system') as an importer, it being understood that a Member may notify at any time that it will use the system in whole or in a limited way, for example only in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use.

2005 TRIPS Amendment, *supra* note 53.

[57] World Health Organization, The WHO Agenda, http://www.who.int/about/agenda/en/index.html (last visited Mar. 8, 2008).

[58] *WHO Panel Says Poor Countries Should Have Access to Patented Medicine*, UNITED NATIONS RADIO, Apr. 3, 2006, http://www.un.org/radio/story.asp?NewsID=4211. The Chairperson of the WHO Commission called on the pharmaceutical industry not to "enforce patents in poor countries." Furthermore, the Chairperson urged the industry to collaborate with the newly-industrialized countries in order to facilitate the transfer of technology and to be "generous" in granting voluntary licensing in cases where medicines are greatly needed. *Id.*

[59] Ford, *supra* note 25, at 138.

> One-third of the world's population lacks access to the most basic essential drugs. For the destitute sick in the developing world, the price of medicines can determine whether they will be treated. Patents drive drug prices up, the resultant monopoly status allowing the producer to charge whatever price the market will bear.

Id.

of the problem is an oversimplification, because it overlooks the crucial need to safeguard the incentive to create and ignores the fact that most of pharmaceutical research projects do not culminate in patented medicines. In other words, if pharmaceutical companies do not secure earnings that cover their research and development ("R&D") costs, running costs, and the costs of unsuccessful research as well, they are likely to limit their research operations. This decrease in research will, in turn, considerably reduce the rate of medicinal innovation worldwide.

2.1 Theoretical Backdrop of the Debate

The issue of access to patented medicines brings forth a rich theoretical debate regarding values, social priorities, allocation of public and private goods, and the purpose of intellectual property law.[60] However, the issue itself is far from being merely theoretical. The WHO has reported that, every year, infectious diseases kill fourteen million people around the world.[61] Notably, ninety percent of those victims reside in developing countries.[62] In light of this situation, various questions need to be addressed: should the scope of patent rights that are granted to pharmaceutical companies be limited in order to maximize access to patented medicines? Should APM rights trump all other considerations and social benefits that are attained by patent protection laws? Should the CIPR be obligated to address and alleviate the suffering of the sick and dying who are in dire need of patented medicines?[63] Should property rights that are granted to patent holders also en-

[60] *See* Hanoch Dagan, *The Social Responsibility of Ownership*, 92 CORNELL L. REV. 1255 (2007) (providing a more in-depth analysis of incorporating social responsibility into the concept of property).

[61] In 2007, 33.2 million (30.6 – 36.1 million) people were estimated to be living with HIV, 2.5 million (1.8 – 4.1 million) people became newly infected, and 2.1 million (1.9 – 2.4 million) people died of AIDS. *See Global HIV Prevalence Has Leveled Off*, WORLD HEALTH ORGANIZATION, Nov. 20, 2007, http://www.who.int/mediacentre/news/releases/2007/pr61/en/index.html. Ford, *supra* note 25, at 137.

[62] Ford, *supra* note 25, at 137. *See also* WORLD HEALTH ORGANIZATION, THE WORLD HEALTH REPORT 2001: MENTAL HEALTH: NEW UNDERSTANDING, NEW HOPE 144 (Angela Haden & Barbara Campanini eds., Shelagh Probst trans., 2001), *available at* http://www.who.int/whr/2001/en/whr01_en.pdf.

[63] *See* Peter Yu, *Ten Common Questions About Intellectual Property and Human Rights*, 23 GA. ST. U. L. REV. (2007) (analyzing similar questions), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=979193#PaperDownload.

tail moral obligations towards society at large?[64] Finally, could non-compliance with the CIPR be justified on the basis of "survival"?[65]

At the outset, it would be very tempting to opt for one of two opposing approaches. The first approach states that patent protection should end where saving lives or alleviating suffering begins; that is, patent law should be subordinate to certain social interests. The second approach indicates that, medicines should be treated in the same manner as any other commodities or inventions, and that their prices should be determined by the patentee, in accordance with the rules of supply and demand. While the first approach is driven by pure socio-humanitarian motives, the second is based on the incentive to innovate. This chapter critically examines both arguments.

2.2 The Argument for Enhancing Access to Patented Medicines

Skeptics of the existing patent régime cite various reasons for their concern over the APM issue. In their view, enforcement of stringent patent rights leads to higher prices for medicines, which will also be detrimental to local manufacturing of generic drugs. Thus, while patent protection may "generate enhanced returns to innovation," it will come "at the cost of reduced rates of diffusion."[66] One study has estimated that TRIPS patent rules will dramatically raise prices of patented medicines for developing nations and curb access to the newest drugs.[67] The reason for the price increase is that TRIPS rules disallow the use of generic (i.e., affordable) versions of patented medicines. The inability to use generic drugs creates a serious setback for developing countries be-

[64] *See* Tamara Straus, *The Moral Calculus of AIDS*, ALTERNET, Apr. 10, 2001, http://www.alternet.org/story/10706/ (stating that profit motives make drug manufacturers and policy makers indifferent towards solving the AIDS crisis). *See generally* Doha Declaration, *supra* note 43.

[65] Rosielyn Alviar Pulmano, Note, *In Search of Compliance with TRIPS Against Counterfeiting in the Philippines: When is Enough Enough?*, 12 TRANSNAT'L LAW 241, 255 (1999) (indicating that developing nations view counterfeiting as "an effective medium in accelerating their economic and technological advancement"). In the case of developing countries, it might also be logical to subscribe to Pulmano's assertion that poor nations utilize counterfeiting as a tool for "expediting the transfer of technology, but on terms and conditions compatible [with the country's needs]." *Id.*

[66] Timothy Swanson & Timo Goeschl, *Diffusion and Distribution: The Impacts on Poor Countries of Technological Enforcement Within the Biotechnology Sector*, *in* INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME, *supra* note 9, at 669, 670.

[67] F.M. Scherer & Jayashree Watal, *Post-TRIPS Options for Access to Patented Medicines in Developing Countries*, 5 J. INT'L ECON. L. 913 (2002).

cause the low-cost generic drugs have proved to be life-savers (literally speaking) in many developing countries, including Brazil, Cameroon, South Africa, Thailand, and Kenya.[68]

In 1998, a legal standoff occurred between pharmaceutical corporations and the South African government over the latter's authorization to use generic substitutes of patented HIV. This standoff constitutes a classic example of how much is at stake for both parties in the debate.[69] While pharmaceutical corporations were asserting their patent rights, the South African government was citing its obligation towards its citizens—to provide them with affordable medicines. A similar standoff over generic drugs for treating AIDS patients took place in Thailand. That impasse involved the use of generic versions of Didanosine and Fluconazole, both brand-name drugs sold at high prices.[70] Thailand's actions have prompted trade retaliation by the United States, and that, in turn, caused Thailand to challenge the patentability of Didanosine.[71]

Furthermore, a vibrant APM mechanism might create a crucial safety valve for venting many of the North-South tensions pertaining to TRIPS. By allowing access to life-saving patented medicines, the WTO might quell a potential rebellion by its poorer member states. Such a rebellion is highly probable given the high percentage of populations of developing countries that are in dire need of patented medicines. Any member state might thus at-

[68] *See* Ford, *supra* note 25, at 139-42 (discussing the positive effects of the availability of generic drugs to developing nations, including the reduction of Brazilian AIDS mortalities by over 50%through the distribution of antiretroviral drugs since 1997). Similarly, Cameroon has been able to establish the lowest prices for antiviral therapy (277 USD per person) by allowing the importation of generic medicines. *Id. See also* Jane Galvano, *Access to Antiretroviral Drugs in Brazil*, 360 LANCET 1862, 1863 (2002) (discussing the substantial decline in Brazilian AIDS mortality). The Kenyan struggle for affordable and accessible medicines has also been widely covered. *See* Samuel Siringi, *Generic Drugs Battle Moves from South Africa to Kenya*, 357 LANCET 1600 (2001); *Kenya Readies AIDS Drugs Law*, BBC NEWS, Apr. 22, 2001, http://news.bbc.co.uk/1/hi/world/africa/1291200.stm; *Kenya to Make AIDS Drugs*, BBC NEWS, Sept. 19, 2003, http://news.bbc.co.uk/2/hi/africa/3123008.stm; Ellen Hoen, *TRIPS, Pharmaceutical Patents and Access to Essential Medicines: A Long Way From Seattle to Doha*, 3 CHI. J. INT'L L. 27 (2002) (providing additional discussion regarding the inaccessibility of affordable medicines in developing countries).

[69] *Pharm. Mfrs. Ass'n of S. Afr. v. Pres. of S. Afr.* 1998 (98) SA at 4183 (S. Afr.), *available at* http://www.fordham.edu/law/faculty/patterson/tech&hr/materials/pharmace.txt. This case was finally abandoned by the pharmaceutical companies, primarily due to the public outcry that it generated. *See* Tido von Schoen Angerer et al., *Access and Activism: the Ethics of Providing Antiretroviral Therapy in Developing Countries*, 15 AIDS S81, S83 (Supp. 5 2001).

[70] *See generally* David Wilson et al., *Global Trade and Access to Medicines: AIDS Treatments in Thailand*, 354 LANCET 1893 (1999) (providing analysis of the APM issue in Thailand).

[71] JIRAPORN LIMPANANONT, THAILAND: THE IMPACT OF PRESSURE FROM THE U.S. 41-43 (2002); Khabir Ahmad, *Thailand Court Forces Reversal of Drug Firm Antiretroviral Patent*, 360 LANCET 1231 (2002).

tempt to opt out of its TRIPS obligations by citing the more pressing obligation of ensuring the physical survival of its citizens;[72] nations might cite their innate right to "self preservation."[73] In reality, signs of such unrest are already evident and were one of the likely catalysts of the Doha Declaration.[74]

Another benefit of a strong APM mechanism is an enhanced moral standing of CIPR, which would then be viewed as a system that takes heed of the needs of the poor. By providing a vibrant and effective APM mechanism, CIPR is likely to gain a strong moral footing. This would allow the CIPR to advance other IP subject matter, such as copyrights, trademarks, design patents, and trade secrets more effectively. In other words, a patent régime with a strong APM mechanism would generate more support because it would be deemed to contribute to the creation of a more balanced and moral régime. This is especially important given the degree of skepticism surrounding IP protection, whereby TRIPS and TRIPS-Plus are perceived to be tools in the hands of the rich IP-owning "North."[75] Skeptics would contend that TRIPS comprises non-universal norms that are not "applicable to non-industrialized societies."[76] Notably, this skepticism is part of a broader academic discourse that relates to globalization generally. According to one view, globalization serves Western financial and

[72] JOHN STUART MILL, ON LIBERTY 13 (1859), *availale at* http://books.google.com/ (in the search box, enter "Mill On Liberty,"press the "Search Books" button, and select the first result). The concept of self-preservation is evident in the works of Mill. According to Mill, "the sole end for which mankind are warranted, individually or collectively, in interfering with the liberty of action of any of their number is self-protection." *Id.* at 6.

[73] This type of claim stems from Hobbes's contention that legal norms are based on the underlying premise that it is not reasonable to act in a manner that is detrimental to one's own life or well-being. HOBBES, LEVIATHAN 143 (1962). *See also* MARK TEBBIT, PHILOSOPHY OF LAW 82 (2004). Hobbes perceived legal norms to be a tools for one's own preservation.

[74] *See* Doha Declaration, *supra* note 43. *See also* Peter K. Yu, Symposioum, *Intellectual Property at a Crossroads: The Use of the Past in Intellectual Property Jurisprudence: Currents and Crosscurrents in the International Intellectual Property Regime*, 38 LOY. L.A. L. REV. 323, 325 (2004) (discussing developing nation's dissatisfaction with TRIPS since its establishment in the 1990's).

[75] *See Re-thinking TRIPS in the WTO: NGOs Demand Review and Reform of TRIPS at Doha Ministerial Conference*, URFIG, Sept. 2001, www.urfig.org/sup-trips-doha-wto-ngo-pt.htm. *See also* Joint NGO Statement and Letter of Petition, THIRD WORLD NETWORK, www.twnside.org.sg/title/joint5.htm (last visited Mar. 8, 2008).

[76] Ruth Gana, *The Myth of Development, The Progress of Rights: Human Rights to Intellectual Property and Development*, 18 J.L. & POL'Y 315, 317-318 (1996); M. Khor, *How the South is Getting a Raw Deal at the WTO, in* VIEWS FROM THE SOUTH: THE EFFECTS OF GLOBALIZATION AND THE WTO ON THIRD WORLD COUNTRIES 19, 22-23, 26-27 (Sarah Anderson, ed.., 2000). *See also* W. Bello, *Building an Iron Cage: The Bretton Woods Institutions, The WTO and the South, in* VIEWS FROM THE SOUTH: THE EFFECTS OF GLOBALIZATION AND THE WTO ON THIRD WORLD COUNTRIES, *supra*, at 74-77.

commercial interests, stripping developing countries of economic and cultural independence.[77] Those who hold this view contend that developing countries are coerced into adopting concepts of "free trade" and "competition" and into abandoning concepts of "self-sufficiency" and "independence."[78]

Another argument against TRIPS (and against CIPR generally) is that TRIPS was formulated by state actors that were not acting in their "original position" behind "a veil of ignorance."[79] In other words, the standards and rules prescribed by TRIPS were reached at a time when the interests of the parties involved were clear: the developed countries that created TRIPS had formulated rules that best served their own interests. For example, patent protection is expansive under TRIPS and benefits the pharmaceutical companies, which are primarily located in developed countries. Indeed, TRIPS legislative history shows that developing countries have adopted TRIPS standards, including those relating to patents, not by choice but out of a necessity that is driven by a dual "threat."[80] The first threat is the risk of not attaining WTO membership and losing foreign investments. The second threat relates to economic sanctions that other WTO member states can impose on the non-compliant developing country.[81]

But, the main justification for allowing access to patented medicines is that patent rights benefiting the innovator also carry with them "a bundle of social responsibilities."[82] This is particularly true with respect to patented medicines because unlike other inventions, medicines possess the unique properties of alleviating pain and suffering, curing ailments, and prolonging life. Because of these attributes, drug patent owners should be subjected to the

[77] *See* Angela R. Riley, *Indigenous Peoples and the Promise of Globalization: An Essay on Rights and Responsibilities*, 14 KAN. J.L. & PUB. POL'Y 155 (2004). *See also* Peter Drahos, *When the Weak Bargain with the Strong: Negotiations in the World Trade Organization*, 8 INT'L NEGOTIATIONS 70-109 (2003).

[78] *See* Ruth L. Okediji, *Back to Bilateralism? Pendulum Swings in International Intellectual Property Protection*, 1 U. OTTAWA L. TECH. J. 125, 129-30 (2004); Scott Burris et al., *Nodal Governance*, 30 AUSTL. J. L. PHILO. 30, 40-41 (2005); Peter Drahos, *An Alternative Framework for the Global Regulation of Intellectual Property Rights*, 1 AUSTRIAN J. OF DEV. STUDS. (2005).

[79] Rawls' concept of the "Veil of Ignorance."

[80] GERVAIS, *supra* note 10; Khoury, *supra* note 22, at 299.

[81] Conflicts arising between countries over issues that are regulated by the WTO are adjudicated by the Dispute Settlement Body that operates in accordance with the Dispute Settlement Understanding. Furthermore, countries wishing to join the WTO have had to amend their respective national laws or to enact new laws in accordance with their TRIPS obligations in order to improve their chances of being admitted into the WTO.

[82] For a more in-depth analysis of the social responsibility concept, *see* Dagan, *supra* note 60. *See also* Ronen Shamir, *Corporate Social Responsibility: A Case of Hegemony and Counter-Hegemony, in* LAW AND GLOBALIZATION FROM BELOW: TOWARDS A COSMOPOLITAN LEGALITY 92 (Boaventura de Sousa Santos & Cesar A. Rodriguez-Garavito eds., 2005).

dictations of "global ethics."[83] I therefore support the observation that "[i]n an increasingly rights-oriented world, little attention is placed on responsibility."[84] Consequently, my view is synonymous with the position whereby "[a]ll actors in the global village must acknowledge and address the responsibilities that are necessarily correlative to the existence of rights."[85] Property rights cannot exist in a vacuum, "but must be balanced against claims of humanity."[86] Furthermore, because of their "public goods" nature, pharmaceutical preparations should be classified as sui-generis legal creatures. This is so due to the fact that while medicines are undisputedly commercial commodities, they also constitute a "common heritage of mankind."[87]

2.3 The Case Against the APM Initiative

The first claim against allowing APM, notwithstanding the inherent "public goods" nature of medicines, is that the system will reduce the rewards (and incentives) for the holders of pharmaceutical patents. In this regard, an APM mechanism appears to contravene both of the major theories that justify IP protection: namely, the *labor* theory and the *utilitarian* theory. The argument is that if pharmaceutical companies could no longer exercise control over their products, then they would, in effect, be robbed of the fruits of their labor.[88] In addition, the APM mechanism might offset the incentive to innovate: the *utilitarian* theory holds that protection of intellectual property rights constitutes a precondition for innovation and creativity. Accordingly, absent a financial incentive, pharmaceutical companies would be very reluctant to maintain their R&D activities.[89] In the long run, all nations would suffer a detriment as future generations would be less and less inclined to invest their time and effort in creativity and innovation.[90]

Those who oppose the APM initiative might also argue that the high prices of patented medicines stem from high R&D expenses and low success rates of the process used to develop new medicines. Indeed, for every ethical medicine that reaches the market, there are tens of research projects that have failed. Moreover, each medicine must undergo a rigorous, time consuming, and expensive research process in order to qualify for commercial use.[91] Another possible reason that pharmaceutical corporations set high prices for patented drugs is that they do so in an attempt to counterbalance the effects of cheap brand medications that are shipped to developing and poor countries ending up on the shelves of developed countries' pharmacies. In this case, the purpose of securing brand medicines at highly discounted prices for poor countries would be frustrated. The logic is that the higher the price of an imported medicine, the less likely it is that it will be re-exported to the markets of developed countries. Indeed, some commentators altogether reject the notion that the APM problem is a consequence of market domination by pharmaceutical corporations; they deem the problem to be symptomatic of the lack of infrastructure and organization in poor and developing countries.[92]

2.4 Assessing the Arguments

The impasse between the need for APM and the conventional international patent régime is part of the general debate relating to the effect of intellectual property protection on poor and developing countries. According to some, the protection of intellectual property rights is deemed to constitute a precondition for conducting international trade and for the success of developing countries because it is said to strike a fair balance between the interests of all countries.[93] Some advocates go even further and pro-

[83] *See* Riley, *supra* note 77, at 155, 163.
[84] *Id.*
[85] *Id.*
[86] *Id.*
[87] Carol B. Thompson, *International Law of the SEA/SEED: Public Domain Versus Private Commodity*, 44 NAT. RESOURCES J. 841, 841 (2004).
[88] For a discussion of the "Labor" theory, *see* Justin Hughes, *The Philosophy of Intellectual Property*, 77 GEO. L.J. 287, 302 (1988) (Locke "refers to labor as 'pains'"); *see also* Lawrence Becker, *The Labor Theory of Property Acquisition*, 73 J. PHIL. 653, 655 (1976) (contending that Locke viewed labor as "something unpleasant enough so that people do it only in the expectation of benefits").
[89] MICKEY KANTOR, U.S. FREE TRADE AGREEMENTS AND THE PUBLIC HEALTH, (2005), http://www.who.int/intellectualproperty/submissions/US%20FTAs%20and%20the%20Public%20Health.pdf (last visited Mar. 8, 2008).
[90] *See* Robert M. Sherwood, *Human Creativity for Economic Development: Patents Propel Technology*, 333 AKRON L. REV. 351 (2000); *see also* Gutowski, *supra* note 22, at 715.
[91] The medication goes through five stages of examination, namely in silica (the formulation stage), in vitro (the lab testing stage), in vivo (testing on live beings, usually animals), human testing (through clinical studies), and another testing stage on the wider population, once the medicine is approved.
[92] Eric Noehrenberg, *The Realities of TRIPS, Patents and Access to Medicines in Developing Countries, in* LAW, ECONOMICS AND POLITICAL ECONOMY 170 (Meir Pugatch ed., 2006).
[93] PETER GALLAGHER, GUIDE TO THE WTO AND DEVELOPING COUNTRIES 16 (2000). *See also* KEITH E. MASKUS, INTELLECTUAL PROPERTY RIGHTS IN THE GLOBAL ECONOMY (2000) (contending that the "balance of evidence strongly suggests" that intellectual property rights provide an important foundation for promoting technology transfer, local innova-

claim IP protection to be a high priority for human civilization; as such, infringement on intellectual property is not only regarded as merely an act against private ownership, but also as an act against civilization generally because it creates a disincentive for innovation.[94] This approach seems to suggest that the standards that are prescribed by TRIPS (or even bilateral agreements) constitute the "grand norm" of IP protection.[95] On the other hand, given the impasse with respect to patented medicines, it is not at all clear that TRIPS constitutes a true "grand norm" for all countries.[96]

Others contend that IP protection is an economic tool in the hands of the West, and that it has created an "unfair" régime.[97] Additionally, TRIPS is deemed to have created (and cemented) an unfair balance of costs and benefits that necessitates a reformulation of its structure.[98] In accordance with this view, TRIPS constitutes a "limited domain" because its primary focus is on the interests of innovators and developed countries, as opposed to the interests of consumers and developing countries.[99] The APM debate accentuates this point; CIPR could thus be classified as an "unjust" system because it appears to maximize the wealth of de-

tion and economic growth in the long run); Sherwood, *supra* note 90; Gutowski, *supra* note 22; Jean Raymond Homere, *Intellectual Property Rights Can Help Stimulate the Economic Development of Least Developed Countries*, 27 COLUM. J.L. & ARTS 277, 283-98 (2004). For a discussion of the benefits to developing countries, including a cost-benefit analysis of IP rights, *see id.* at 283-290. For a discussion of the benefits to Least Developed Countries, *see id.* at 291-298.

[94] A. AL-KSIWANI, INTELLECTUAL PROPERTY 12 (Al-Warrak Publishing, 1998) (crediting intellectual property with the development of politics, economics, law, society, technology, science, industry, trade, and literature).

[95] IAN MCLEOD, LEGAL THEORY 71 (1999) (reflecting on Kelsen's concept of "Grundnorm"); James Boyle, *The Politics of Reason: Critical Legal Theory and Local Social Thought*, 133 U. PA. L. REV. 685 (1985). For more on the concept of the "Grand Norm," *see* HANS KELSEN, PURE THEORY OF LAW (1934).

[96] Gana, *supra* note 76, at 326 (stating that TRIPS comprises non-universal norms that are not "applicable to non-industrialized societies").

[97] Khor, *supra* note 76; *see also* Bello, *supra* note 76.

[98] Yu, *supra* note 74. *See also* Daniel J. Gervais, *Intellectual Property, Trade & Development: The State of Play*, 74 FORDHAM L. REV., 505 (2005); Sun, *supra* note 38; Margo A. Bagley, *Legal Movements in IP: TRIPS, Unilateral Action, Bilateral Agreements, and HIV/AIDS*, 17 EMORY INT'L L. REV. 101 (2003); James T. Gathii, *The Structural Power of Strong Pharmaceutical Patent Protection in U.S. Foreign Policy*, 7 J. GENDER RACE & JUST. 267 (2003). It is worth mentioning that the idea of reallocating costs and benefits in order to achieve a more just equilibrium between market players is not new. It has been used in various contexts that have been dealt with by the fields of law and economics, including the spheres pertaining to the environment and global justice. *See, e.g.*, Lawrence Goulder, *Philosophy Talk: The Environment and Global Justice* (KALW radio broadcast Sept. 28, 2004), *available at* http://www.philosophytalk.org/TheEnvironmentandGlobalJustice.htm.

[99] Frederick Schauer, *The Limited Domain of Law*, 90 VA. L. REV. 1909, 1916 (2004) (using the term "limited domain" to describe "[a] legal system in which only a tiny fraction of society's moral, political, and practical norms are cognizable as law or usable in the legal system").

veloped countries at the expense of developing ones. It also overlooks the needs of the masses for cheap and accessible patented medicines. In this regard, CIPR reflects John Locke's interpretation of human nature, which suggests that humans (and in my view also countries) have a tendency to create laws that satisfy their egoistic natures.[100] Thus, while developed countries reap the gains from the sale of medicines, poor and developing countries appear to be acting contrary to their inherent economic tendency to maximize their wellbeing.[101] These developing countries are, in effect, playing a "zero sum game,"[102] which leads to consistently detrimental results. Furthermore, research indicates that TRIPS was not a product of developed countries' unbiased efforts, but rather TRIPS resulted from a compromise between international IP laws and developed countries' national interests. The drafting history of the TRIPS Agreement attests to this theory.[103] National IP laws have been amended (or enacted) in order to meet TRIPS-WTO obligations. Thus, these laws are not a product of pure national sovereignty, but rather a by-product of the "bigger picture," in which developing countries view TRIPS as a trade-off package comprised of WTO obligations and gains that they hope to derive from membership in the WTO. This is especially evident in the case of the pharmaceutical industry, where developed countries have an uncontested advantage in the area of research and development, as well as in their production capabilities. Consequently, the legal norms pertaining to IP rights have not been shaped in accordance with direct national interests (and needs), but have become intertwined in the wider context of globalization and international trade regulation.[104] One view contends that the globalization of trade (in which the WTO and TRIPS play a substantial role) only serves Western financial and commercial interests. This has rendered developing countries "victims" of globaliza-

[100] SHIRLEY ROBIN LETWIN, ON THE HISTORY OF THE IDEA OF LAW 112 (Cambridge Univ. Press 2005) (contending that "left to himself, man is incomplete, for he is a dependent being. If he did not subordinate his will to another superior will, satisfaction of his own desires would be the only measure of his actions." *See also* JAMES TULLY, A DISCOURSE ON PROPERTY: JOHN LOCKE AND HIS ADVERSARIES 6 (1980).

[101] RICHARD A. POSNER, ECONOMIC ANALYSIS OF LAW 23 (6th ed. 2003) ("[M]any areas of law, especially the great common law fields of property, torts, crimes, and contracts, bear the stamp of economic reasoning.").

[102] A term that reflects a state of affairs, whereby the gains of party A are balanced by party B's losses.

[103] *See* GERVAIS, *supra* note 10; Khoury, *supra* note 22; Amir H. Khoury, *The Development of Modern Trademark Legislation and Protection in Arab Countries of the Middle East*, 16 TRANSNAT'L LAW. 249 (2003); Gutowski, *supra* note 22.

[104] JOHN HOWARD JACKSON, LEGAL PROBLEMS OF INTERNATIONAL ECONOMIC RELATIONS 291, 885-92 (3d ed. 1995).

tion because they have effectively delegated their powers of economic decision-making to the (rich) North and its corporations, while, in the process, threatening their own economic viability and, as in the case of patented medicines, the physical well-being (and in some cases survival) of their citizens.[105] It is, therefore, possible to conclude that CIPR standards cannot constitute the "grand norm" for all countries. A solution to the conflicting interests is therefore required. Ideally, the solution would take stock of the social responsibility that is placed on the shoulders of the privileged innovators, the captains of human progress and science.

In my view, the solution begins with committing to a new outlook on the nature of patent rights in the pharmaceutical field and with considering the issue from a wider perspective that takes human rights into account.[106] Indeed, there is a pressing need to counterbalance "private goods" with "public goods," as they relate to the needs of the sick and dying masses in poor and developing countries.[107]

[105] Other research warns against the current technological transfers in the form of "turn key" projects because those projects create a trap of "technological and colonial" dependency that entails intellectual dependency. M. Waridi, *The Role of Technology in the Backwardness of Countries*, 145 MINISTRY OF ED. & ARTS OF THE IRAQI REPUBLIC 9 (1978). Some go as far as to equate the current situation with "market dictatorship" and "modern imperialism." These call for the need to focus on opportunities for growth and stability that can be achieved through equality, raising domestic production, and self-sufficiency. J. Asfour, *Globalization and Issues of Cultural Identity* 50 AL-NAHJ MAG. 6 (1998). Asfour predicts that Arab countries will ultimately clash with certain aspects of Globalization due to the system's inherent contradictions, including "development and poverty," "tolerance and fanaticism," "freedom of trade and new forms of domination." *Id.* *See also* HOWARD HANDELMAN, THE CHALLENGES OF THIRD WORLD DEVELOPMENT 2, 14, 15, 29-32, 213-227 (1996) (where athe author considers a possible solution in the form of "Industrialization Strategies"). *See also* N. RAGHED, THE SEVEN MASKS OF GLOBALIZATION (2001) (proclaiming "seven masks of Globalization," namely politics, economics, culture, media, security, technology, and civilization). According to Raghed, the consequent unraveling of those masks will reveal the real face of Globalization; Globalization is portrayed as a phenomenon that knows no compassion or leniency and that does not tolerate competition.

[106] Heinz Klug, *Comment: 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, *supra* note 9, at 481; 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, *supra* note 9, at 393; David Goren, *Pharmaceutical Innovation and Intellectual Property Rights: A Global Public Good?*, *in* LAW, ECONOMICS AND POLITICAL ECONOMY, *supra* note 92, at 159.

[107] *See generally* Geoff Tansey, *Comment: Whose Rules, Whose Needs? Balancing Public and Private Interests*, *in* INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME, *supra* note 9, at 662; Gregory Shaffer, *Recognizing Public Goods in WTO Dispute Settlement: Who Participates? Who Decides? The Case of TRIPS and Pharmaceutical Patents Protection*, *in* INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME, *supra* note 9, at 884.

CHAPTER THREE

A MORE JUST CIPR BY INVOKING A VIABLE APM MECHANISM

3.1 "Carpet" Adoption v. "De-linking"

A broad spectrum of models could be applied to international intellectual property protection. At one end, is the submissive option of fully adopting the TRIPS agreement and committing to TRIPS-Plus standards without any reservation. This position is one that calls for the adoption of TRIPS standards of protection as well as all the "TRIPS-Plus" provisions that have been inserted into bilateral trade agreements, where the bulk of IP "activism" is currently taking place. On the opposite end of the spectrum is a position that opts for a complete deviation from CIPR. The latter model feeds on the disillusionment with CIPR, especially in the public health domain and specifically in the APM context.

These two polarized solutions have strong footings in one of two theories, the Development theory and the Dependency theory that generate the Development-Dependency debate.[108] Although these theories emanate from discourse within the politico-economic sphere,[109] they have a bearing on IP-related discourse.[110] Dependency theorists contend that the "world capitalist economy has resulted from a relation of domination by a few metropolitan countries ('*The Center*') and the 'subjugation' and subordination of most of Africa, Asia and Latin America ('*The Periphery*')."[111] Dependency theorists argue that the "Center" has dominated the "Periphery" by employing various tactics and strategies including

[108] THE POLITICS OF DEVELOPING AREAS, (Gabriel A. Almond & James S. Coleman eds., 1960); *see also* LUCIAN W. PYE & SIDNEY VERBA, POLITICAL CULTURE AND POLITICAL DEVELOPMENT (1965); COMPARATIVE MODERNIZATION: A READER (Cyril E. Black ed., 1976); HANDELMAN, *supra* note 105, at 12; SAMUEL P. HUNTINGTON, POLITICAL ORDER IN CHANGING SOCIETIES (1968); BJORN HETTNE, DEVELOPMENT THEORY AND THE THREE WORLDS (1990).

[109] The "Dependency" theory is said to emanate from earlier economic theories by Karl Marx and Friedrich List. *See* FRIEDRICH LIST, THE NATIONAL SYSTEM OF POLITICAL ECONOMY (S. S. Lloyd trans., 1885); KARL MARX, CAPITAL: A CRITIQUE OF POLITICAL ECONOMY (1961); WILLIAM HENDERSON, FRIEDRICH LIST: ECONOMIST AND VISIONARY (1983).

[110] Amir H. Khoury, *supra* note 80.

[111] ASSAFA ENDESHAW, INTELLECTUAL PROPERTY POLICY FOR NON-INDUSTRIAL COUNTRIES, LAW SOCIAL CHANGE AND DEVELOPMENT SERIES (1996).

the formulation of an international division of labor[112] and, more recently, the creation of stringent standards for the protection of IP rights (including patented medicines) that are effectively owned and controlled by the rich and industrialized countries (i.e.. the "Center").[113] According to this line of reasoning, the "Periphery" has been prevented from attaining industrialization and has remained in the capacity of supplier of raw materials. This domination of the "Periphery" by the "Center" has cemented the relationship between the two into "passivity" and "dynamism," respectively.[114]

Development theorists continue to press developing countries to increase their enforcement of IP rights as a means for development.[115] Dependency theorists, on the other hand, would suggest that increased compliance with IP laws merely serves to widen the economic rift between the rich "North" and the poor "South." Accordingly, Dependency theorists conclude that developing countries cannot progress by merely copying "Western" standards of IP protection because they will always be dependent on "Western" intellectual property instead of developing their own IP régime, comprising a "fluid international system."[116] Dependency theorists are pessimistic about the possibility of bridging the gap between the "Center" and the "Periphery" generally and, especially, with respect to IP and technology transfers.[117] Develop-

[112] *Id.* Starting in the sixteenth century, condemning the periphery to agriculture contributed to its domination by the Center. Poor countries were not wholly dependent on developed countries. ENDESHAW, *supra* note 111.

[113] Erin Kathleen Bender, *North and South: The WTO, TRIPS, and the Scourge of Biopiracy*, 11 TULSA J. COMP. & INT'L L. 281, 282 (2003) ("The World Trade Organization (WTO) dominates all international trade, and has been tailored by the industrialized countries of the North to embed Northern dominance over the South.").

[114] ENDESHAW, *supra* note 111, explains that this relationship has reflected negatively on countries of the "Periphery" in various ways, including limitations being placed on the exchange process, the freedom of independent economic decision-making, and the proliferation of technology. Supporters of the Dependency theory further contend that this unbalanced exchange (between the "Center" and the "Periphery") is manifested by the permanent transfer of value-added products from the "Center" to the "Periphery." That, in turn, is said to have caused a lack of foreign currency reserves and lack of capital accumulation in countries of the "Periphery." Thus, a vicious circle has been created, whereby countries of the "Periphery" were largely relegated to the production and export of food and raw materials and forced to trade for industrial imports on unfavorable terms. *See* HANDELMAN, *supra* note 105, at 15, 21 n.34.

[115] The proponents of the TRIPS régime have remained steadfast in their stance, which is that the TRIPS régime is beneficial to the economic development of Developing countries and even "Least Developed Countries." *See* Homere, *supra* note 93, at 283-90.

[116] Bello, *supra* note 76, at 90.

[117] *Id.* at 89. *See also* Khor, *supra* note 40.

> Whilst the WTO is supposed to be based on the principle of reciprocal benefits, TRIPS has proven to be inherently and in practice very imbalanced, as developed countries (with greater technological capacity and with greater ability to use the IPR system) have reaped the overwhelming share of benefits amounting to large values, whilst developing countries are carrying the heavy burden of costs.

Id. MAURICE DOBB, SOME ASPECTS OF ECONOMIC DEVELOPMENT: THREE LECTURES (1955) (noting that the problem of industrialization is not one of finance, but of economic organization and predicting that as long as developing countries do not do away with economic dependency, they will remain prone to colonial theft). "The idea that knowledge — information, science, art, music, literature — can be property is a recent and pernicious fraud perpetrated by certain industries." Steven J. Owens, Intellectual Property Is Fraud, DARKSLEEP.COM, http://darksleep.com/notablog/format.cgi?article=Intellectual_Property_Is_Fraud.foo (last visited Mar. 8, 2008).

ment theorists attempt to tackle economic and technological underdevelopment by advocating for the adoption (or transplantation) of norms that exist in industrialized countries together with the mechanisms and systems that are intended to enforce those norms.[118] They urge developing countries to adopt methods that are undertaken by developed countries, so that the developing countries, too, could achieve economic and political modernization.[119] In this context, one commentator asserts that "economic development is a dynamic process" and that intellectual property may help convert "free riders" into "fair followers."[120] Moreover, proponents of TRIPS reason that today's industrialized countries were once themselves developing countries and that their progress was positively affected by intellectual property protection.[121] Conversely, Dependency theorists caution that such an approach is

[118] ENDESHAW, *supra* note 111, at 5. In this context, development theorists would appear to argue that "ICs (industrialized countries) have developed because of the existence of specific forms of laws and institutions, while non-ICs failed to do so because they had no such laws and institutions or were 'traditional.'" *Id.*

[119] "[W]hile there are reasons to be concerned about potential exercise of market power by firms endowed with greater intellectual property protection, the balance of evidence strongly suggests that intellectual property rights provide an important foundation for promoting technology transfer, local innovation, and economic growth in the long run." C.F. Bergsten, *Preface*, *supra* note 8; ENDESHAW, *supra* note 111, at 2, 11-52; ZVI YEHUDA HERSHLAG, THE PHILOSOPHY OF DEVELOPMENT REVISITED (1984); Francis G. Snyder, *Law and Development in Light of the Dependency Theory*, 14 LAW & SOC'Y REV. 723 (1980); Leonard J. Theberge, *Law and Economic Development*, 9 DENV. J. INT'L L. & POL'Y 231 (1980); Dudley Seers, *The Birth, Life and Death of Development Economics*, 10 DEV. & CHANGE 707 (1979); Paulo R. de Almeida, *The Political Economy of Intellectual Property Protection: Technological Protectionism and Transfer of Revenue Among Nations*, 10 INT'L J. TECH. MGMT. 214, 214-29 (1995).

[120] J.H. Reichman, *From Free Riders to Fair Followers: Global Competition Under the TRIPS Agreement*, 29 N.Y.U.J. INT'L L. & POL. 11 (1997).

[121] KAMIL IDRIS, WORLD INTELLECTUAL PROPERTY ORGANIZATION, INTELLECTUAL PROPERTY, A POWER TOOL FOR ECONOMIC GROWTH 1-3 (2022), *available at* http://www.wipo.int/about-wipo/en/dgo/wipo_pub_888/index_wipo_pub_888.html (last visited Mar. 8, 2008); World Intellectual Property Organization, World Intellectual Property Organization, Intellectual Property and Small and Medium-Sized Enterprises, http://www.wipo.int/about-ip/en/studies/publications/ip_smes.htm (last visited Mar. 8, 2008).

likely to lead to greater dependency of developing countries on the developed ones. What is more, Dependency theorists have argued that, throughout history, people, nations, and countries have charted different paths of development. Accordingly, they contend that it is a misconception, indeed a mistake, to single out one developmental path and to rule out the rest.[122] My proposed model comes against the backdrop of these two opposing theories.

3.2 Characteristics of the Proposed Model

Given all of the above, it is quite evident that CIPR, in its current form, fails to provide a satisfactory response to concerns about APM. A full adoption of TRIPS, without regard for its humanitarian deficiencies, would also fail to recognize the social responsibilities of pharmaceutical patent holders. Similarly, I also reject the model that calls for a complete de-linking from the CIPR because such a solution overlooks the benefits of that régime, namely, of securing incentives for further innovation and foreign direct investment ("FDI").[123] The above-described situation regarding the lack of sufficient access to medicines has prompted individual initiatives for providing medicines to those in need.[124] Governments have undertaken two types of actions in attempts to offset the APM imbalance. The first method relates to compulsory licensing, which allows the production of patented medicines.[125] The second method is referred to as "parallel imports," or gray market goods, where governments allow for the importation of cheaper generic versions of patented medicines.[126]

[122] Lakshmi Sarma, *Biopiracy: Twentieth Century Imperialism in the Form of International Agreements*, 13 TEMP. INT'L & COMP. L.J. 107, 108, 116-19 (1999); ENDESHAW, *supra* note 111, at 2. Theotonio Dos Santos, *The Structure of* Dependence, 60 AM. ECON. REV. 231 (1970); WARNER BAER, THE ECONOMICS OF PREBISCH AND ECLA IN LATIN AMERICA: PROBLEMS IN ECONOMIC DEVELOPMENT (1962). It is also argued that re-enacting the actions of today's industrialized countries is not a viable option because it is not possible to reconstruct the circumstances under which those countries had developed.

[123] Keith Maskus et al., *Patent Rights and International Technology Transfer Through Direct Investment and Licensing, in* INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME, *supra* note 9, at 265.

[124] One of many non-governmental organizations (NGOs) is Medecins Sans Frontieres ("MSF"). MSF is a medical emergency relief organization that provides assistance through over 500 medical programs in eighty countries worldwide. *See* http://www.msf.org for more on the activities of MSF; *see also* James Orbinski, President, Médecins Sans Frontières, Nobel Peace Prize Acceptance Speech (Dec. 10, 1999), *available at* http://nobelpeaceprize.org/eng_lect_99m.html Other NGOs include the Treatment Action Campaign in South Africa and the AIDS Access Coalition in Thailand.

[125] Maskus et al., *supra* note 123, at 265.

[126] Doha Declaration, *supra* note 43.

My proposed model draws on these solutions and develops them further. In a nutshell, the model aims to preserve the CIPR framework, while creating viable checks and balances in the form of a flexible model of compulsory licensing. Despite the apparent rift between CIPR and APM, it is still possible to join the two systems conceptually. Indeed, the proposed model seeks to refine the 2005 WTO amendment to the TRIPS Agreement. An enhanced APM system would not stand counter to TRIPS but would rather reflect the "sprit" of that Agreement, as it appears in Article 7:

> The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

Concerns with the CIPR have prompted calls to incorporate a "substantive equality principle within the intellectual property decision making framework," this serving as a precondition for a true union of IP and the concept of development.[127] My proposed model advocates for incorporating a workable APM mechanism into the CIPR. It seeks to create clear safeguards for the needs of developing countries from within the CIPR.[128] This would ultimately attain Aristotelian "distributive justice" among nations in the context of patented medicines.[129] Consequently, my proposed model is not about revolution, but rather about reform. Indeed, as discussed earlier, there have already been attempts to resolve the APM issue. The proposed model complements these efforts.

3.2.1 Reformulating the Cost-Benefit Approach

A popular rationale for IP protection is that it helps maximize the aggregate wealth of society at large. This, in turn, is used to justify the burden that is placed on some member states and

[127] Margaret Chon, *Intellectual Property and the Development Divide*, 27 CARDOZO L. REV. 2821, 2912 (2006); *see also* L. Danielle Tully, *Prospects for Progress: The TRIPS Agreement and Developing Countries After the Doha Conference*, 26 B.C. INT'L & COMP. L. REV. 129 (2003).

[128] Some are rather skeptical about remedying the deficiencies of TRIPS from within. *See, e.g.*, Carlos M. Correa, *Can the TRIPS Agreement Foster Technology Transfer to Developing Countries?, in* INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME, *supra* note 9, at 227, 256 (arguing that "the issues affecting the transfer of technology to developing countries are unlikely to be resolved from within the limited contours of the TRIPS Agreement and other WTO disciplines").

[129] MAY, *supra* note 4, at 155; Glynn S. Lunney, Jr., *Trademark Monopolies*, 48 EMORY L.J. 367 (1999).

societies.[130] But, in light of the CIPR deficiencies in the APM context, such a theory of efficiency does not seem to hold water. Indeed, as evidenced by the Doha Round, the current régime overlooks the allocation of entitlements and obligations among member states. It is worth noting that the TRIPS Agreement recognizes the rights of member states to take measures that are necessary to protect their interests, especially with respect to "public health and nutrition." It suffices to note that Article 8 of the TRIPS Agreement declares that

> [m]embers may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.
>
> Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

Clearly, this article, much like Article 7 of TRIPS, has remained within the periphery of TRIPS and the entire CIPR; in other words, neither of these articles has really shaped international IP policy. Rather, they have both remained largely dormant.[131] Nevertheless, the normative weight of these articles remains relevant, and they can still be used to justify any future reformulation of the CIPR in the context of APM.

3.2.2 Counterbalancing the WTO: The WIPO Development Agenda

In light of the fact that developing countries have largely been sidelined by WTO's structure, some voices advocate "forum shifting" in the form of a merger, or extensive cooperation, between WTO and World Intellectual Property Organization

[130] "[T]he common law is best [not perfectly] explained as a system for maximizing the wealth of society." RICHARD POSNER, ECONOMIC ANALYSIS OF LAW, 23 (6th ed., 2003). This cost-benefit analysis pertaining to TRIPS symbolizes the clear trade-off that IP protection involves between the aggregate maximization of wealth through innovation and trade benefits facilitated by WTO membership vis-à-vis the losses inflicted on countries that need to provide patent protection to foreign patents without receiving a share of the income that is generated by patents or the economic power that they harness.

[131] The 2005 proposal to amend Article 31 of TRIPS is one instance where the rationale of Article 8 has come into action.

("WIPO").[132] These efforts to restructure the CIPR have manifested themselves in the form of a "Development Agenda" that has been advanced by WIPO.[133] WIPO's Development Agenda aims to create a more sustainable TRIPS régime by addressing many of the existing questions regarding public health, biodiversity; human rights, and plant genetic resources used in food and agriculture. These questions have a strong bearing on the APM debate. WIPO's Development Agenda can contribute directly to the success of the Doha Declaration relating to public health. Furthermore, given the variety of state interests involved, it appears that long term success of the CIPR is contingent on sustained and open dialogue, which can be best achieved with the help of WIPO. The main reason for this is that CIPR and WIPO complement each other in terms of IP administration, protection, and enforcement. WIPO has been entrusted with the administration of most of the leading IP conventions relating to standard-setting agreements and international registration of IP rights. Furthermore, WIPO's structure allows for more effective representation of developing countries because WIPO's general assembly is based on the concept of one vote per state.[134] Such a voting system would allow the "silent majority," comprised mainly of developing countries, to have its voice heard. Notably, cooperation between WTO and WIPO already exists in the form of an agreement, the

[132] Laurence F. Helfer, *Régime Shifting: The TRIPS Agreement and New Dynamics of International Intellectual Property Lawmaking*, 29 YALE J. INT'L L. 1, 25-28, 75-82 (2004).

[133] *Development Agenda*, ELECTRONIC FRONTIER FOUNDATION, http://www.eff.org/IP/WIPO/dev_agenda/ (last visited Mar. 8, 2008). "The Development Agenda gives WIPO the opportunity to move beyond the narrow view that any and all IP protection is beneficial, and choose instead to act strategically to spur economic growth, foster innovation, and help humanity." *Id.*

[134]

> Article 6, General Assembly
> (1)
> *(a)* There shall be a General Assembly consisting of the States party to this Convention which are members of any of the Unions.
> *(b)* The Government of each State shall be represented by one delegate, who may be assisted by alternate delegates, advisors, and experts.
> . . . .
> (2) The General Assembly shall:
> . . . .
> (v) approve the measures proposed by the Director General concerning the administration of the international agreements referred to in Article 4(iii);
> . . . .
> (3)
> *(a)* Each State, whether member of one or more Unions, shall have one vote in the General Assembly.

Convention Establishing the World Intellectual Property Organization art. 6, July 14, 19617, *amended* Sept. 28, 1979, 21 U.S.T. 1749, 828 U.N.T.S. 3, *available at* http://www.wipo.int/export/sites/www/treaties/en/convention/pdf/trtdocs_wo029.pdf.

aim of which is to "establish a mutually supportive relationship" and "appropriate arrangements for cooperation" between both organizations.[135] Although the current agreement between the two institutions is a technical one, lacking any operative function, it can—and should—be amended to include a special reference to the APM issue.

3.2.3 Empowering Local Industry through the Accessibility of Research Data

The proposed model seeks to advance APM, so that all member states could develop their national pharmaceutical industries and gear them towards research and development. In order to achieve this, national governments should apply TRIPS in a manner that is conducive to national public health. The local pharmaceutical industry should be encouraged to expand its research activities, which may be achieved by relaxing the prohibitions pertaining to research data that has been submitted by individual pharmaceutical companies. Such sharing of data would prevent local industries from making the same mistakes (such as reaching dead ends) already made by their counterparts.[136] The *Data Exclusivity* defense that has been advanced by TRIPS-Plus should be relaxed in order to accommodate the needs of new pharmaceutical corporations situated in developing countries in their R&D efforts. This approach can be justified by the suffix of TRIPS Article 39(3).[137] Thus, the proposed model would include a "making available" clause that ensures access to relevant research data from around the world, to be utilized by local industry in special cases.

[135] Agreement between the World Intellectual Property Organization and the World Trade Organization, Preamble, Dec. 22, 1995, 35 I.L.M. 754, *available at* http://www.wipo.int/export/sites/www/treaties/en/agreement/pdf/trtdocs_wo030.pdf.

[136] This would prompt local pharmaceutical industries to manufacture low-cost generic medicines, thus having a lowering effect of the price of similar branded medications due to competitive pricing pressures. In addition, this would lead brand-name pharmaceutical companies to focus their attention on the development of new medicines in order to maintain their lead in the market.

[137] TRIPS, *supra* note 5, art. 39(3) provides that

> [m]embers, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.

3.2.4 Granting of Compulsory Licenses

The core of my proposal revolves around a revised compulsory licensing model. It should be noted that Article 31 of TRIPS provides for compulsory licensing. Compulsory licensing constitutes an important tool that is intended, among other things, to remedy practices that have been deemed to be anticompetitive. However, such licenses are subject to certain restrictions that render the entire scheme slow and cumbersome. For example, compulsory licenses are limited to cases where member states have failed to acquire a voluntary license based on "reasonable terms and conditions within a reasonable period of time."[138] Furthermore, the license is contingent on the "requirement to pay adequate remuneration in the circumstances of each case, taking into account the economic value of the license."[139] In addition, there is a requirement that decisions relating to these licenses "shall be subject to judicial or other independent review by a distinct higher authority."[140]

Although these conditions may be warranted in most cases involving patents, they are rather problematic with respect to pharmaceutical preparations and especially so in the case of life threatening illness, where speed and accessibility are of the essence. Here, a specific compulsory licensing model is required. The best evidence of this need appears in the 2005 TRIPS Amendment, which includes a new Article 31bis that focuses on pharmaceuticals. My proposed model builds on this concept of compulsory licensing and suggests a more workable and structured mechanism, with clear checks and balances. For example, if a medical emergency is declared in a certain state, that state would be allowed to produce, or to seek assistance in producing, the patented medicines, without first having to acquire a formal license (compulsory or otherwise) from the patent owner or having to notify the WTO. The proposed model is based on a retroactive, rather than a prospective, licensing mechanism. In this manner, the licensing process would not slow down production of the relevant medication. The patent owner would be entitled to retroactive compensation that would counterbalance his potential losses. Such compensation would be contingent on a showing by the patent holder that the compulsory license was utilized without justifi-

[138] *Id.* at art. 31.

[139] *Id.*

[140] *Id.* at art. 31(i).

cation.[141] Furthermore, in order not to frustrate the entire purpose of the proposed APM system, the state that invoked the compulsory licensing mechanism would be held accountable for royalties in the amount equivalent to the actual profits collected from the sale or use of the medication within its jurisdiction. Thus, if the beneficiary state made no profit from dispensing the medication, then it would not be liable for any royalty payments. In cases where the state is unable to pay royalties that it owes, it may seek the assistance of specific global funds, such as the PEPFAR Emergency Fund.[142]

3.2.5 Sanctioning "Collective" Compulsory Licenses

During the Doha Round, WTO's TRIPS Council was asked to provide solutions for the inability of some countries to utilize compulsory licensing provisions. Such inability has been most prevalent in the case of pharmaceuticals because many countries do not have national industries that are capable of producing sophisticated medicines.[143] The 2005 TRIPS Amendment responds to this issue. I propose an even more sophisticated model in the form of a Collective Compulsory Licensing scheme that would enable a developing country to produce a patented medicine in collaboration with a third, "assisting," country that has the technical and scientific capabilities. The assisting country would effectively act as a proxy in utilizing the compulsory license on behalf of the state that lacks a competent pharmaceutical industry or machinery necessary for the drug's production. The assisting state, however, would be prevented from using the license as a pretext for circumventing patent protection within its own jurisdiction. Thus, the proposed mechanism would maintain a balance between the legitimate interests of all parties.

3.2.6 Determining Cases that Justify the Granting of Compulsory Licensing

The main challenge for my proposal is that of determining the cases where the need to access a certain patented medicine

[141] In addition to the patent related measures detailed above, there might also be a need to encourage comparative advertising among brands in order to enable the less well known brands to get a competitive advantage. This is especially justified when pharmaceutical products that are similar with respect to active ingredients are offered at cheaper prices.

[142] PEPFAR, *supra* note 51.

[143] Khor, *supra* note 40.

should supersede the economic rights of the patent holder. If the need to access a medicine is established, then the proposed rules would tolerate importation and sale of cheaper generic versions of that medicine or allow for the granting of a compulsory license needed to produce that medicine. Ideally, the need to access medicines would be established by an impartial party that is capable of determining the existence of a national medical emergency ("NME") that would justify taking such a drastic step. In my view, the most suitable entity to be entrusted with such a sensitive task is the WHO. This organization possesses both the professional and the technical tools needed to make the necessary determination. In fact, the WHO is already engaged in tracking and mapping the spread of infectious diseases, as well as other illnesses, worldwide.[144] The role of the WHO would not be limited to issuing NME rulings, but it would also extend to assisting the WTO in deciding and settling any disputes that might arise in such cases. It is worth noting that the WHO has already attempted to compile a list of "essential medicines."[145] Until 2001, this list was ineffective because it was only allowed to contain low-cost medications. In 2001 the "low-cost" limitation was removed, rendering the list a more effective tool for supporting access to patented "essential" medicines.[146] I also propose that WIPO be called upon to assist the WHO in cases involving an NME. Notably, over the years, WIPO has accumulated substantial experience in international IP-related dispute resolution. This experience could be helpful in the APM context as well.[147]

In addition to the WHO's power to make NME determinations, WTO member states should be granted the right to independently declare a medical emergency. This power would only be invoked in cases of extreme urgency. In those cases, the slower process of assessment by the WHO would not be sufficient. The best example of this relates to the Anthrax threat in the post-9/11 days, or the bird flu fears of the not too distant past.[148]

[144] *See* Public Health Mapping and GIS Map Library, World Health Organization, http://gamapserver.who.int/mapLibrary/ (last visited Mar. 8, 2008).

[145] Essential Medicines List, World Health Organization, http://www.who.int/mediacentre/factsheets/fs325/en/ (last visited Mar. 8, 2008). Following the same rationale, the WHO has also advocated the need to create a list for Essential Medical Devices. *Access to Essential Medical Devices*, WORLD HEALTH ORGANIZATION, http://www.who.int/medical_devices/access/en/ (last accessed Mar. 8, 2008).

[146] Ford, *supra* note 25, at 138 (citing Richard Laing et al., *25 Years of the WHO Essential Medicines List: Progress and Challenges*, 361 LANCET, May 17, 2003, at 1723-29).

[147] For example, dispute settlement involving domain names.

[148] According to the WHO, outbreaks of highly pathogenic H5N1 avian influenza that began in south-east Asia in mid-2003 and later spread to parts of Europe were the largest

Another related question pertains to the scope of coverage: should the APM mechanism be limited to ailments of potentially epidemic proportions, or should it include any medical case, even if it is not life-threatening? On its face, it seems that there is no moral basis for distinguishing between a medicine that prolongs one patient's life and a medicine that alleviates the pain and suffering of another patient, especially one who suffers from a chronic disease. However, the proposed model would face much less resistance if it is limited (at least in its initial phase) to life-saving medicines. Ultimately, I propose to apply the model in a more expansive manner to cover medications that are intended to treat chronic diseases as well as life-threatening conditions.

3.2.7 Setting the Term of a Compulsory License

Another safeguard to ensure that the APM scheme and its compulsory licensing mechanism are not used illegitimately, would be by limiting the term of such licenses. The time frame would be set by the WHO after it considers various factors, including the severity of the illness, the extent and scope of public exposure, and the time that is required to curb or alleviate the medical condition. The reason for setting a compulsory license term is that an opened-ended license is likely to significantly frustrate the patentee's rights. The license term could be extended in order to accommodate cases in which the declared medical emergency persists despite the fact that the license has expired. However, these extensions would not be granted automatically, but would instead be subject to review and contingent on certain conditions, namely effective use of the license during the initial term and continued existence of the declared medical emergency.

I propose the incorporation of this model, comprised of the above-mentioned elements into the TRIPS Agreement. Ideally, the model would be incorporated as a new chapter within the

and most severe to date. At first, nine Asian countries had reported outbreaks, but in late July 2005, the virus spread geographically beyond its original focus in Asia to affect poultry and wild birds in the Russian Federation and adjacent parts of Kazakhstan. Almost simultaneously, Mongolia reported detection of the highly pathogenic virus in wild birds. In October 2005, the virus was reported in Turkey, Romania, and Croatia. In early December 2005, Ukraine reported its first outbreak in domestic birds. Most of these newer outbreaks were detected and reported quickly. *See Avian Influenza ("Bird-Flu") – Fact Sheet*, WORLD HEALTH ORGANIZATION, http://www.who.int/mediacentre/factsheets/avian_influenza/en/#countries (last visited Mar. 8, 2008).

TRIPS agreement.[149] The proposed chapter is annexed to this research paper. Furthermore, in order to ensure the viability of this model, WTO member states must not circumvent or forfeit rights and obligations arising from the model in future trade agreements. Member states would also commit to revise any existing trade agreement, the terms and conditions of which are counter to the proposed model.

ASSESSMENT AND CONCLUSIONS

During the past two decades, protection for intellectual property rights has increasingly become a focal point in the arenas of international trade and diplomacy. In 1994, it became an integral component of the World Trade Organization (WTO) through the adoption of the Agreement on Trade-Related Intellectual Property Rights (TRIPS).[150] The TRIPS Agreement has become the "lex" in the field of international intellectual property protection. The TRIPS-Plus standards that have been introduced through free trade agreements have raised the level of IP protection even further. Consequently, most countries have been actively engaged in enacting new national laws and amending the existing ones in order to render them TRIPS-compliant or to meet commitments undertaken in bilateral agreements.[151] Evidently, the right of sole use that is enjoyed by patentees has created a barrier for those who seek, but cannot afford, certain patented medicines. In my view, patentees of pharmaceuticals are bound by a duty to those suffering from ailments that might be alleviated or cured by their patented medicines. This position stems from a defined view regarding the nature of property and is supported by Articles 7 and 8 of the TRIPS Agreement.

This research paper sheds light on the CIPR from the public health and APM perspectives. The topic is inherently tied to a larger debate, relating to the nature of IP protection; in fact, it is symptomatic of a deeper ideological standoff between the "haves" and "have-nots," that is also referred to as the North-South divide. I submit that the CIPR constitutes a "limited domain" in that it

[149] In this case, there would not be any need to amend the TRIPS agreement by adding article 31bis (as proposed by the 2005 TRIPS Amendment).
[150] TRIPS, *supra* note 5. For a survey of the WTO system, *see* Amir H. Khoury, *Well-Known and Famous Trademarks in Israel: TRIPS from Manhattan to the Dawn of a New Millennium!*, 12 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 991, 991-1002. For a legal history of the events leading up to the WTO structure, *see* Erin Kathleen Bender, *North & South: The WTO, Trips, and the Scourge of Bio Piracy*, 11 TULSA J. COMP. L. 281, 289-310 (2003).
[151] Sarma, *supra* note 122, at 125-26.

fails to address particular interests of developing countries with respect to the access to patented medicines.[152] Moreover, the CIPR, as it stands, has not delivered on its promise to promote IP protection for the benefit of all.[153] My research and proposal delve into past and current attempts to resolve the APM problem. To date, the CIPR remains devoid of any structured workable model for resolving the APM predicament. Notably, the 2005 TRIPS Amendment, which would grant certain countries compulsory licensing rights, has not yet come into force.

Indeed, the arguments presented by Dependency theorists, coupled with the unbalanced structure of TRIPS, undermine its perceived moral basis and require a reevaluation of its structure.[154] This is not surprising, given that TRIPS was formulated by developed countries and tailored, first and foremost, to suit their own needs and interests. The Dependency theory provides additional rationales of the CIPR deficiencies in the APM context. Those deficiencies have been brought to public awareness by the Doha Round of trade negotiations. Furthermore, the WTO 2003 Decision and 2005 TRIPS Amendment, amending TRIPS Article 31, provide the best examples of the monumental change that is needed in order to remedy the APM predicament.

After having ruled out extreme solutions (i.e., full adoption or complete de-linking from CIPR), I submit that the solution to the APM debate should take the form of a model that is more attuned to the needs of developing countries. My proposed model aims to transform the Doha Declaration from a declaration of principles into a workable model within the existing TRIPS framework. Such an approach can reinvigorate and revitalize

[152] Schauer, *supra* note 99, at 1910, observing that

> at the heart of understanding the phenomenon of law and the character of legal argument, may be an appreciation of the fundamental narrowness of the law and a grasp of the way in which the characteristic modalities of law serve to screen out, often successfully, what would in other decisional settings be good arguments, important facts, and desirable values.

[153] TRIPS, *supra* note 5, art. 7 (warning against the risk that IP protections will themselves constitute barriers to trade).

[154] Gerald B. Wetlaufer, *Systems of Belief in Modern American Law: A View from Century's End*, 49 AM. U. L. REV. 1, 78 (1999), echoing a similar notion, that

> one step in the right direction is to acknowledge the deep differences within the larger legal community; to give up the illusion that we are a single community, which illusion is the source of so much disappointment; to acknowledge the multiplicity of perspectives and to admit that even our own perspective is both contingent, and what is harder, contestable; and to seek out the origins and the intelligibility of those perspectives which are most alien to us.

K. AL-AHMAR, THE ROLE OF IP AND INDUSTRIAL PROPERTY & E-COMMERCE IN GROWTH 20 (Dar Arrida Publ. 2000); K.E. MASKUS & M. LAHOUEL, COMPETITION POLICY AND INTELLECTUAL PROPERTY RIGHTS IN DEVELOPING COUNTRIES: INTERESTS IN UNILATERAL INITIATIVES AND A WTO AGREEMENT, 13 (1999).

TRIPS and render it a more pragmatic, just, and viable régime. In my view, a viable APM mechanism that is interjected into the existing TRIPS Agreement, without undermining its basic structure of patent protection, constitutes the correct approach. On the one hand, this approach would ensure the rewards and incentives for innovators, while, on the other hand, it would be responsive to the needs of poor and developing countries. A balanced system that supports APM would advance the CIPR because it will address the interests of all concerned parties. There has been nothing to suggest that the WTO has been allowed to take over the role of the national governments, which are typically more attuned to the pressing health needs of their respective nationals. Thus, each sovereign state should be free to utilize the APM mechanism in a manner that best serves its citizens. My proposed draft amendment to the TRIPS Agreement is annexed below.

ANNEX

PROPOSED

PART VIII

TO

THE AGREEMENT ON TRADE RELATED INTELLECTUAL PROPERTY RIGHTS

PUBLIC HEALTH:

ACCESSIBILITY TO PATENTED MEDICINES (APM)

Art. 74:

Public Health in TRIPS

Recognizing the gravity of the public health problems that afflict many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria, and other epidemics.

Stressing the need for the Agreement on Trade-Related Aspects of Intellectual Property Rights to be part of the wider national and international action addressing these problems.

Recognizing the 2003 Decision and the 2005 TRIPS Amendment relating to the proposed amendment of Article 31 of the TRIPS Agreement.

Recognizing the concerns about the effects of intellectual property protection on prices of medicines.

Affirming the importance of promoting access to medicines for all.

Members of the WTO have resolved and agreed to enter the norms of this Part VIII into their national legislations, and to conduct their domestic affairs and international relations accordingly.

Art. 75:

Members with a Declared "National Medical Emergency"

Not withstanding the obligations of members in this agreement, members included in the annexed list of countries, when

having a declared National Medical Emergency shall be entitled to:

Require patent owners to provide medicines at a quantity and price that are required by the local market.

Issue compulsory licensing for the production of patented medicines that treat or remedy or reduce or curb the spread of Epidemic Ailments or suffering resulting therefrom.

Art. 76:

Setting and Updating the List of "Epidemic Ailments"

(a) The Epidemic Ailments that patented medicines are intended to treat will be updated from time to time, as the need arises, by the World Health Organization ("WHO"). The WHO shall undertake to establish a specialized committee that is delegated the task of carrying out all WHO-related functions in accordance with this Agreement.

(b) Notwithstanding (a) of this Article, absent a determination by the WHO, each member shall be entitled to determine whether a case at hand constitutes a National Medical Emergency or other circumstances of such extreme urgency that a National Medical Emergency is deemed imminent. HIV/AIDS, tuberculosis, and malaria, among other epidemics, constitute a National Medical Emergency.

Art. 77:

Revoking Declaration of "National Medical Emergency"

The declaration of National Medical Emergency can be cancelled or retracted following a determination that said emergency has ceased to exist or did not exist in the first place. Such a determination may by rendered by:

(a) A WTO dispute resolution panel in consultation with the WHO and/or any national health organization and/or authority within the relevant jurisdiction.

(b) Notwithstanding (a) of this Article, a Member may unilaterally, and at any time, cancel or retract its declaration of National Medical Emergency.

Art. 78:

Issuing a Compulsory License

(a) Following a valid determination of National Medical

Emergency, a compulsory license may be issued by the affected member state's national government to an entity, located within the jurisdiction of that member state. Such an entity would need to possess the capacity to manufacture the pharmaceutical product under the patent.

(b) A compulsory license shall not be contingent on the approval of the patent holder of the relevant patented active ingredient.

(c) Notwithstanding (b) of this Article, the patent holder may petition the WTO Dispute Settlement Body or national courts and seek compensation for its substantiated losses. Such compensation shall be contingent on a showing that the compulsory license was utilized without justification (i.e., that a National Medical Emergency had not occurred) or that actual losses have been sustained by the patent owner. Absent repayment by local industry, the state issuing the compulsory license shall be liable for the payment of damages in the amount equal to the actual profits collected from the sale of the pharmaceutical product within its jurisdiction.

Art. 79:

Subject Matter of a Compulsory License

(a) In addition to sanctioning the production of a patented medicine by a national industry, and in order to expedite the production of a medication, the compulsory license may also allow national pharmaceutical research and development entities to utilize all research data and results that were compiled or reached by the original patent holder.

(b) All member states in which the original patent is registered will divulge such relevant information.

(c) All disputes in this regard will be refereed by the WTO Dispute Settlement Body, which would consult with WHO and WIPO.

Art. 80:

Member with Insufficient or no Manufacturing Capacities in the Pharmaceutical Sector

After obtaining a compulsory license, if a member state does not possess a mechanism capable of producing the needed pharmaceutical product, the state would be entitled to seek assistance of industries operating within another member state (Assisting

Member). The government of the Assisting Member must give prior consent to such assistance, which consent would be contingent on the following:

(1) License is intended to produce medicines for the consumption of the citizens and residents of the member state with a declared National Medical Emergency only.

(2) License will be used by Assisting Member for the sole purpose of exporting the relevant medicine to the member with a declared National Medical Emergency.

Art. 81:

Initial Term of Compulsory License

For each compulsory license, a specific initial term will be determined and prescribed by WHO. In determining each specific term, WHO would take into consideration the following factors, as well as other factors that it deems relevant:

Severity of the illness.

Extent and scope of public exposure.

Estimated time that is required in order to curb or alleviate the National Medical Emergency.

Art. 82:

Term Extension

Notwithstanding Article 81, the term of the compulsory license may be extended, given a prior authorization by the WTO dispute settlement panel. The authorization to extend the license will be granted if the following conditions are established by the state issuing the license:

License was effectively applied during the initial term.

License contributed substantially to the reduction in the price of the medicine.

License contributed substantially to facilitating access to the relevant medicine.

License was not used in order to export or transfer the relevant medicine beyond the borders of the member with a declared National Medical Emergency.

License contributed to reducing or curbing the spread of the relevant epidemic or can potentially contribute to this effect in the immediate or foreseeable future.

Member state remains on the list of countries with a declared National Medical Emergency.

The ailment that the medicine is intended to treat remains classified as an Epidemic Ailment.

Art. 83:

Non-Circumvention and Active Implementation Declaration

(a) WTO member states undertake not to circumvent or forfeit rights arising from this Part VIII in any future trade agreement. Furthermore, each member state undertakes to revise any existing free trade agreement, to which it is a member, and to amend any provision that negates, undermines, or nullifies this chapter.

(b) Member states also undertake to revise duly any existing trade agreement the terms and conditions of which are counter to the provisions of this Part VIII.

[NETWORKED] MEMORY INSTITUTIONS: SOCIAL REMEMBERING, PRIVATIZATION AND ITS DISCONTENTS

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