

The International Enclosure Movement[†]

PETER K. YU^{*}

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* Associate Professor of Law and Director, Intellectual Property and Communications Law Program, Michigan State University College of Law; Core Faculty, Asian Studies Center, Adjunct Professor of Telecommunication, Information Studies and Media, Michigan State University. An earlier version of this Article was presented at the “Saving Profits, Saving Lives: A Comprehensive Discussion of the Social, Legal, and Economic Implications of Reverse Engineering and Parallel Importing on the Pharmaceutical Industry” Symposium at the University of North Carolina School of Law, the Third Annual Intellectual Property and Communications Law and Policy Scholars Roundtable at Michigan State University College of Law, the 65th Anniversary Conference of the Center for Intellectual Property Law at John Marshall Law School, the Sixth Intellectual Property Scholars Conference at Boalt Hall School of Law, University of California at Berkeley, the “Intellectual Property Rights for Business and Society” Conference at Birkbeck College, University of London, and the 2006 International Law Weekend in New York. This Article also benefits from discussion with the participants of the Fourth Dialogue of the Bellagio Series on Development and Intellectual Property Policy at the Rockefeller Foundation’s Bellagio Study and Conference Center in Bellagio, Italy and the Hong Kong Trade and Development Symposium held during the Sixth World Trade Organization Ministerial Conference in Hong Kong. The Author would like to thank Birgitte Andersen, Doris Long, and Ricardo Meléndez-Ortiz for their kind invitation and hospitality and Obijiofor Aginam, Carlos Correa, Thomas Cotter, Graeme Dinwodie, Aaron Fellmeth, Debora Halbert, Donald Harris, Cynthia Ho, James Love, Ariel Katz, Christopher May, Charles McManis, Liam O’Melinn, Sean Pager, Srividhya Ragavan, John Thomas, Mark Schultz, Jerome Reichman, Norman Siebrasse, Jayashree Watal, and the participants of these events for their valuable comments and suggestions. He is also grateful to Corey Johanningmeier and the staff of the *Indiana Law Journal* for their thoughtful and thorough editing and to Alexander Kanous for excellent research and editorial assistance.

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INTRODUCTION

Most of the recent intellectual property literature concerns the “enclosure of the public domain”¹ or the “one-way ratchet” of intellectual property protection.² While these concerns are significant and rightly placed, a different, and perhaps more important, enclosure movement is currently taking place at the international level. Instead of the *public domain*, this concurrent movement encloses the *policy space* of individual countries and requires them to adopt one-size-fits-all legal standards that ignore their local needs, national interests, technological capabilities, institutional capacities, and public health conditions. Unlike the movement to enclose the public domain, which “fenc[es] off common land and turn[s] it into private property,”³ the international enclosure movement fences off areas that provide attractive policy options for less developed countries.⁴ By virtue of this enclosure, these countries are forced to adopt inappropriate intellectual property systems, and they as a result have also lost their ability to respond to domestic crises within their borders.

The crisis that hitherto has received the widest international attention concerns the lack of ability by less developed countries to combat HIV/AIDS, malaria, and tuberculosis.⁵ Consider HIV/AIDS, for example. Being the leading cause of mortality

1. See, e.g., Yochai Benkler, *Free as the Air to Common Use: First Amendment Constraints on Enclosure of the Public Domain*, 74 N.Y.U. L. REV. 354 (1999); James Boyle, *Fencing off Ideas: Enclosure and the Disappearance of the Public Domain*, DAEDALUS, Spring 2002, at 13; James Boyle, *The Second Enclosure Movement and the Construction of the Public Domain*, LAW & CONTEMP. PROBS., Winter/Spring 2003, at 33 [hereinafter Boyle, *The Second Enclosure Movement*].

2. For discussions of recent expansion of intellectual property protection, see, for example, LAWRENCE LESSIG, *FREE CULTURE: HOW BIG MEDIA USES TECHNOLOGY AND THE LAW TO LOCK DOWN CULTURE AND CONTROL CREATIVITY* (2004); Boyle, *The Second Enclosure Movement*, *supra* note 1; Rochelle Cooper Dreyfuss, *TRIPS—Round II: Should Users Strike Back?*, 71 U. CHI. L. REV. 21, 22 (2004) [hereinafter Dreyfuss, *TRIPS—Round II*].

3. Boyle, *The Second Enclosure Movement*, *supra* note 1, at 33–34.

4. The TRIPs Agreement distinguishes between developing and least developed countries. This Article uses “less developed countries” to denote both developing and least developed countries. When referring to the TRIPs Agreement, however, this Article returns to using the terms “developing countries” and “least developed countries.”

5. The access-to-medicines problem is not new. As Peter Drahos pointed out:

The scale of the access-to-medicines problem has been brought home by the HIV/AIDS crisis. But for poor people and developing countries where the majority of poor people live, the problem has existed for a long time. This problem was there in the case of access to broad-spectrum antibiotics in the 1950s, when the price of tetracycline in many developing countries was held constant for more than ten years, at least in part allegedly due to a price cartel amongst Pfizer, Cyanamid, Bristol, Squibb, and Upjohn. The problem was there in 1979 when Senator

in Africa, the pandemic has claimed the lives of millions of poor, innocent people who died primarily because they had no access to affordable drugs.⁶ As UNAIDS estimated in 2002, “out of a total of 40 million infected people, 36 million who live in developing countries have no access to anti-retroviral drugs, which could prolong their lives. In fact, access to antiretroviral drugs is denied to 96 per cent of HIV carriers, totaling between 5 and 7 million persons, who are in need of immediate treatment.”⁷

To respond to the public health crises in less developed countries and to mitigate the adverse impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights⁸ (“TRIPs Agreement” or “Agreement”), members of the World Trade Organization (WTO) agreed during the WTO Ministerial Conference in Hong Kong (“Hong Kong Ministerial”) to amend the Agreement to allow member states with insufficient or no manufacturing capacity to import generic versions of on-patent pharmaceuticals.⁹ The proposed amendment marked the first time the WTO agreed to

Kennedy made a speech pointing out that “in this International Year of the Child . . . 2.6 million children will die this year from immunizable diseases because they won’t have access to already-developed vaccines.” These days it has become *de rigueur* for senior western political figures to bemoan the spread of the HIV/AIDS crisis in developing countries.

Peter Drahos, *Intellectual Property and Pharmaceutical Markets: A Nodal Governance Approach*, 77 TEMP. L. REV. 401, 402 (2004) [hereinafter Drahos, *Intellectual Property and Pharmaceutical Markets*] (footnotes omitted).

6. For discussions of the global HIV/AIDS crisis, see, for example, Symposium, *The Global AIDS Crisis*, 17 CONN. J. INT’L L. 149 (2002); Symposium, *Global Health and Governance: HIV/AIDS*, 23 THIRD WORLD Q. 191 (2002). Although commentators often use the HIV/AIDS crisis to illustrate the adverse impact of the patent system on less developed countries, the U.K. Commission on Intellectual Property Rights reminded that

[i]t is particularly important not to allow the debate in [the intellectual property] area to be influenced unduly by the HIV/AIDS experience, dramatic though it is. Apart from HIV/AIDS, which is the biggest single cause of mortality in developing countries, TB and malaria claim almost as many lives. Together all three diseases claimed nearly six million lives last year, and led to debilitating illness for millions more. In addition, there are a number of less common diseases which are collectively important. These include, for instance, measles, sleeping sickness, leishmaniasis and Chagas disease.

COMM’N ON INTELLECTUAL PROP. RIGHTS, INTEGRATING INTELLECTUAL PROPERTY RIGHTS AND DEVELOPMENT POLICY: REPORT OF THE COMMISSION ON INTELLECTUAL PROPERTY RIGHTS 30 (2002), http://www.iprcommission.org/papers/pdfs/final_report/CIPRfullfinal.pdf [hereinafter IPR COMMISSION REPORT] (footnote omitted).

7. Rosine Jourdain, *Intellectual Property Rights and Public Health in the Revised Bangui Agreement*, in TRADING IN KNOWLEDGE: DEVELOPMENT PERSPECTIVES ON TRIPS, TRADE AND SUSTAINABILITY 143, 143 (Christophe Bellmann, Graham Dutfield & Ricardo Meléndez-Ortiz eds., 2003) [hereinafter TRADING IN KNOWLEDGE].

8. Agreement on Trade-Related Aspects of Intellectual Property Rights [hereinafter TRIPs Agreement], Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments—Results of the Uruguay Round, 33 I.L.M. 1197 (1994) [hereinafter Marrakesh Agreement].

9. General Council, *Amendment of the TRIPs Agreement*, WT/L/641 (Dec. 8, 2005) [hereinafter December 6 Decision], available at http://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm.

amend one of its core agreements.¹⁰ If adopted, the amendment would make permanent the temporary waivers granted by the decision of the TRIPs Council in August 2003.¹¹

A week before the Hong Kong Ministerial, the WTO member states also extended the deadline for least developed countries to fully implement the Agreement.¹² Along with the Doha Declaration on the TRIPs Agreement and Public Health¹³ (“Doha Declaration”), which delayed the mandatory introduction of patent protection for pharmaceuticals and the protection of undisclosed regulatory data until January 1, 2016,¹⁴ the recent amendments sought to respond to the dissatisfaction among less developed countries of the international intellectual property system.

Although the amendment and the extension focused on the access-to-medicines problem in less developed countries, they will also benefit developed countries, which are experiencing increasing problems concerning access to medicines.¹⁵ Last year, for

10. Press Release, World Trade Org. [WTO], Members OK Amendment to Make Health Flexibility Permanent (Dec. 6, 2005), http://www.wto.org/english/news_e/pres05_e/pr426_e.htm [hereinafter WTO Press Release] (noting that the proposed amendment marked “the first time a core WTO agreement [was] amended”).

11. General Council, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPs Agreement and Public Health*, WT/L/540 (Sept. 1, 2003), 43 I.L.M. 509 (2004) [hereinafter August 30 Decision].

12. Press Release, WTO, Poorest Countries Given More Time to Apply Intellectual Property Rules (Nov. 29, 2005), http://www.wto.org/english/news_e/pres05_e/pr424_e.htm. The deadline was extended until July 1, 2013. The extension was limited to the very few remaining member states that had yet to comply with the TRIPs Agreement or that had offered protection in excess of the TRIPs requirements. See IPR COMMISSION REPORT, *supra* note 6, at 51 (“At least 70% of the population in [least developed countries] are in countries that provide pharmaceutical patent protection, and 27 of the 30 LDCs in Africa also provide it.”); SISULE F. MUSUNGU & CECILIA OH, INNOVATION AND PUBLIC HEALTH, THE USE OF FLEXIBILITIES IN TRIPS BY DEVELOPING COUNTRIES: CAN THEY PROMOTE ACCESS TO MEDICINES? 8 (Commission on Intellectual Property Rights, Innovation and Public Health Studies 4C, August 2005) (“[V]irtually all of the LDC WTO Members have provided intellectual property regimes well ahead of [the 2006] deadline.”), available at <http://www.who.int/intellectualproperty/studies/TRIPSFLEXI.pdf>.

13. WTO, Declaration on the TRIPs Agreement and Public Health, WT/MIN(01)/DEC/2, 41 I.L.M. 755 (2002) [hereinafter Doha Declaration].

14. Because the Doha Declaration only deferred the introduction of patent protection for pharmaceuticals and the protection of confidential test data, some commentators and policymakers have wondered whether exclusive marketing rights were also included as part of the extension. See, e.g., Council for Trade-Related Aspects of Intellectual Property Rights, Proposal on Paragraph 6 of the Doha Declaration on the TRIPs Agreement and Public Health—Joint Communication from the African Group in the WTO, ¶ 6(f), IP/C/W/351 (June 24, 2002) [hereinafter African Group Proposal] (“[T]he transition period for least developed Members, now extended to 1 January 2016, should cover the requirement under paragraphs 8 and 9 of Article 70 to grant exclusive marketing rights, and in order that exclusive marketing rights do otherwise operate as de facto patents they should be clearly delineated or defined to highlight the flexibility.”); Ellen ‘t Hoen, *TRIPs, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way from Seattle to Doha*, 3 CHI. J. INT’L L. 27, 41 (2002) (“Though there seemed to be an understanding among the negotiators in Doha that Paragraph 7 implied that LDCs are not required to provide ‘mail box’ protection or ‘exclusive marketing rights,’ this is not clear from the text of the declaration.”).

15. Frederick M. Abbott, *The Cycle of Action and Reaction: Developments and Trends in*

example, U.S. health officials articulated concerns about the inadequate supply of Tamiflu that might be needed to treat the avian flu pandemic.¹⁶ In addition, the experience of the anthrax attacks in the United States demonstrated the possibility of unforeseen situations of national emergency in developed countries,¹⁷ while the outbreak of the Severe Acute Respiratory Syndrome (SARS) viruses in spring 2003 highlighted the possibility for deadly infectious diseases to spread rapidly from one country to another.¹⁸ Due to aging populations and increasing reliance on prescription drugs, developed countries also face increasingly “strain[ed] government budgets and burden[ed] private health benefits systems.”¹⁹

Focusing on the access-to-medicines problem in less developed countries, this Article examines the international enclosure movement and how it has curtailed the ability of individual countries to respond to national crises within their borders. Part I illustrates the complexity of decisions that countries need to make at the national level.

Intellectual Property and Health [hereinafter Abbott, *Cycle of Action*], in NEGOTIATING HEALTH: INTELLECTUAL PROPERTY AND ACCESS TO MEDICINES 27, 29 (Pedro Roffe, Geoff Tansey & David Vivas-Eugui eds., 2006) [hereinafter NEGOTIATING HEALTH] (stating that it is “increasingly difficult to de-link” the access-to-medicines problem of less developed countries from that of their more developed counterparts).

16. Anita Manning, *Are You a Sitting Duck for Bird Flu?*, USA TODAY, Dec. 7, 2005, at 1D (“U.S. health officials and infectious-disease specialists have discouraged individual stockpiling [of antiviral drugs that are thought to be effective in preventing or lessening the impact of the avian flu], citing shortages and the risk of widespread misuse leading to drug-resistant viruses.”).

17. See Debora Halbert, *Moralized Discourses: South Africa’s Intellectual Property Fight for Access to AIDS Drugs*, 1 SEATTLE J. SOC. JUST. 257, 280 (2002) (discussing the anthrax attacks in the United States).

18. As Obijiofor Aginam acknowledged, “[m]icrobes carry no national passports, neither do they recognize geo-political boundaries or state sovereignty. Propelled by travel, trade, tourism, the phenomenon of globalization, and a host of other factors, public health threats occasioned by an outbreak of a disease in one remote part of the world can easily transcend national boundaries to threaten populations in distant places.” OBIJIOFOR AGINAM, GLOBAL HEALTH GOVERNANCE: INTERNATIONAL LAW AND PUBLIC HEALTH IN A DIVIDED WORLD 6 (2005); see also Robert O. Keohane & Joseph S. Nye, Jr., *Introduction to GOVERNANCE IN A GLOBALIZING WORLD 3* (Joseph S. Nye, Jr. & John D. Donahue eds., 2000) (observing that the first smallpox epidemic, which is recorded in Egypt in 1350 B.C., “reached China in 49 A.D., Europe after 700; the Americas in 1520, and Australia in 1789”); F.M. Scherer & Jayashree Watal, *Post-TRIPS Options for Access to Patented Medicines in Developing Countries*, 5 J. INT’L ECON. L. 913, 938 (2002) (“Reducing the spread of infectious diseases such as AIDS and tuberculosis on other continents has spillover benefits in reducing disease risks at home.”). For a comprehensive discussion of the Severe Acute Respiratory Syndrome, see generally THOMAS ABRAHAM, TWENTY-FIRST CENTURY PLAGUE: THE STORY OF SARS (2005). See also Peter K. Yu, *SARS and the Patent Race: What Can We Learn from the HIV/AIDS Crisis?*, FINDLAW’S WRIT, May 29, 2003, http://writ.news.findlaw.com/commentary/20030529_yu.html.

19. Abbott, *Cycle of Action*, *supra* note 15, at 29; see also MARCIA ANGELL, THE TRUTH ABOUT THE DRUG COMPANIES: HOW THEY DECEIVE US AND WHAT TO DO ABOUT IT xii (rev. ed. 2005) (discussing how the estimated cost of Medicare prescription drug benefit increased from \$400 billion in late 2003 to between \$720 billion and \$1.2 trillion in February 2005); cf. ROBERT BALLANCE, JÁNOS POGÁNY & HELMUT FORSTNER, THE WORLD’S PHARMACEUTICAL INDUSTRIES: AN INTERNATIONAL PERSPECTIVE ON INNOVATION, COMPETITION AND POLICY 202–03 (1992) (suggesting that the aging population problem may be bigger in less developed countries than in their more-developed counterparts).

This Part also explains why policymakers need wide policy space to devise solutions to address these problems. It examines, in particular, the imbalance in the intellectual property system, the lack of an indigenous capacity to manufacture pharmaceuticals, and the defects of the local health care systems. This Part seeks to provide the needed background information to better understand why the TRIPs Agreement needs to be amended to allow policymakers to have wider policy space to develop intellectual property policies to respond to public health crises within their national borders. Although this Part separates for analytical purposes the different types of factors that inhibit access to medicines, it points out that all of these factors are interrelated in a complex, symbiotic relationship regardless of their direct relevancy to intellectual property protection. While correcting the imbalance in the intellectual property system is, by no means, a panacea, a failure to make such correction will perpetuate, or even exacerbate, the existing access-to-medicines problem.

Part II traces the development of the international enclosure movement. It begins by showing how the international intellectual property system was originally designed to preserve the autonomy of countries to devise their own intellectual property policies. This Part then traces how the one-size-fits-all templates enshrined in the TRIPs Agreement and the recent bilateral and regional trade agreements have drastically reduced the policy space available to less developed countries. As this Part shows, despite their limited economic development and technological capabilities, less developed countries are increasingly required to adopt legal standards that are more suitable for their richer and more developed trading partners.

Part III examines the resistance efforts less developed countries have put up against the international enclosure movement. By focusing on the Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPs Agreement and Public Health²⁰ (“August 30 Decision”) and the recently proposed Article 31*bis* of the TRIPs Agreement,²¹ this Part illustrates the danger of the international enclosure movement. Although the Doha Development Round of Trade Negotiations (“Doha Round”) in the WTO drew attention to the development needs of less developed countries and helped them resist the further adoption of new one-size-fits-all legal standards, it did not enable them to reclaim their lost policy space or roll back the recent expansion of intellectual property rights, for which policymakers in less developed countries and many nongovernmental organizations have hoped. Instead, the Doha Round merely identified the policy space needed by less developed countries and facilitated their negotiation with their developed counterparts about the governing standards within that particular space.

Part IV advances three explanations for the increasing enclosure of policy space of less developed countries by their richer and more developed trading partners. These explanations include the power asymmetry between developed and less developed countries, the incentive-investment divide between national and foreign intellectual property policies, and the globalization of intellectual property rights. Following the discussion of each explanation, this Part offers suggestions on how countries can reform the international intellectual property system to preserve the autonomy needed to tailor policies to local conditions and how less developed countries can reclaim their lost policy space to facilitate greater access to essential medicines.

20. August 30 Decision, *supra* note 11.

21. December 6 Decision, *supra* note 9 (proposing Article 31*bis*).

I. THE NEED FOR POLICY SPACE

In response to pleas from American companies, artists, and inventors for action to address proliferating global piracy, the United States a decade ago forced intellectual property rights onto the Uruguay Round agenda. But for our unremitting pressure, the more than one hundred countries who participated in the Round would not have negotiated stronger rules and disciplines. It was the United States which understood, more than anyone, that uniform protection of intellectual property rights around the world would promote the expansion of international trade, global economic growth, and job creation . . . And until the final stages of the negotiations, many of our trading partners wanted weak or non-existent global intellectual property standards, generous exemptions for developing countries, or the indefinite postponement of multilateral rules so that their local pirates could continue copying American pharmaceuticals, films, sound recordings, software, and books. Fortunately, the outcome was a disappointment for the "purveyors of piracy."

—United States Trade Representative Clayton K. Yeutter²²

You hear that in my country perhaps one out of nine [people] are infected with HIV. Imagine if you [in this auditorium] represented the South African population, and we counted out, one, two, three, four, five, six, seven, eight, nine—you have AIDS. One, two, three, four, five, six, seven, eight, nine—AIDS. We are in fact speaking about the daughter of, the wife of, the sister of, the husband of, the father of, the brother of someone. Perhaps my call to you would be to put the face of one of your loved ones to represent the statistics. Maybe that would help to bring those numbers to life.

—Archbishop Desmond Mpilo Tutu²³

Although many people in the developed world have benefited from better health and longer life, more than two million people in the less developed world continue to lack essential, and often lifesaving, medicines.²⁴ The life expectancy rate in less developed countries is disappointingly low,²⁵ and many of these people suffer from avoidable life-

22. *Pharmaceutical Patent Issues: Interpreting GATT: Hearing Before the S. Comm. on the Judiciary*, 104th Cong. 227 (1996) (statement of Ambassador Clayton K. Yeutter, United States Trade Representative).

23. Desmond Mpilo Tutu, *We Can Be Human Only Together*, 1 SEATTLE J. SOC. JUST. 253, 253 (2002).

24. See Ricardo Meléndez-Ortiz & Khalil Hamdani, *Preface* to NEGOTIATING HEALTH, *supra* note 15, at vii ("Despite evidence of full synergy between good health and economic prosperity, an overwhelming 2 million people die every year from preventable and curable diseases."); Karin Timmermans, *Ensuring Access to Medicines in 2005 and Beyond*, in NEGOTIATING HEALTH, *supra* note 15, at 41 ("From 1977 to 2002, the number of people with regular access to most of the medicines they need has increased from 2.1 billion to nearly 4 billion. While a significant achievement, some 2 billion people still do not have such access.") (citation omitted).

25. GIAN LUCA BURCI & CLAUDE-HENRI VIGNES, WORLD HEALTH ORGANIZATION 165 (2004) ("[T]hose living in absolute poverty are five times more likely to die before reaching the age of five, and two-and-a-half times more likely to die between the ages of fifteen and 59, than

threatening diseases. Commentators generally blame this mishap on the high drug prices caused by the artificial monopolies created by the intellectual property system. While it is undeniable that intellectual property protection is partly responsible for the high prices and resulting inaccessibility of drugs, it is important not to ignore other access barriers that may be only related, or even completely irrelevant to, such protection.

Using the access-to-medicines problem, this Part illustrates the complexity of decisions countries need to make at the national level and the symbiotic relationship of the various factors that could affect the outcome of these decisions. This Part explains why policymakers need wide policy space to devise solutions to address problems in their countries. It examines, in particular, the imbalance in the intellectual property system (the *IP-relevant* factors), the lack of an indigenous capacity to manufacture pharmaceuticals (the *IP-related* factors), and the defects of the local health care systems (the *IP-irrelevant* factors).²⁶ Although these labels highlight the different impact the intellectual property system has on the various factors, the last Section underscores their symbiotic relationship. In doing so, it seeks to dissuade others from citing the IP-irrelevant factors to downplay the problems in the current unbalanced intellectual property system.

A. Intellectual Property Protection

In the public health debate, the pharmaceutical industry²⁷ and the intellectual property system are often demonized,²⁸ and the mass media are filled with “sound bites” describing the patents system as “evil”²⁹ and Big Pharma as “greedy.”³⁰ As

those in higher income groups.”).

26. See Roy Widdus, *Product Development Partnerships on ‘Neglected Diseases’: Intellectual Property and Improving Access to Pharmaceuticals for HIV/AIDS, Tuberculosis and Malaria*, in NEGOTIATING HEALTH, *supra* note 15, at 205, 221 (distinguishing between IP-relevant and IP-irrelevant factors).

27. Throughout this Article, the term “pharmaceutical industry” refers to manufacturers and developers of patented pharmaceuticals. The pharmaceutical industry and some commentators have used research-based pharmaceutical companies to distinguish these companies from their generic competitors. However, the term is a misnomer, because generic manufacturers also undertake research, while some research-based companies also manufacture generic drugs or own generic subsidiaries.

28. As two commentators noted: “[W]hile it appears that northern consumers sometimes benefit, and northern drug firms always benefit from the tightening of intellectual property standards in the pharmaceutical area, the south never benefits. All the south gets are higher prices, fewer manufacturing jobs, and fewer drugs to choose from in the long run.” Eyal Benvenisti & George W. Downs, *Distributive Politics and International Institutions: The Case of Drugs*, 36 CASE W. RES. J. INT’L L. 21, 25 (2004); see also Elhanan Helpman, *Innovation, Imitation, and Intellectual Property Rights*, 61 ECONOMETRICA 1247, 1274 (1993) (“[I]f anyone benefits [from strong intellectual property protection in less developed countries], it is not the South.”).

29. See, e.g., Ranjit Devraj, *Lesser-Than-Evil Patent Law Pleases Drug Firms*, INTER PRESS SERVICE, Mar. 24, 2005 (describing patent law as “lesser-than-evil”); *Patents Jurisprudence*, HINDU, June 10, 2003 (“Patents are monopolies and monopolies are evil unless regulated by law designed to serve social justice, national interests and pragmatic considerations.”); *Uniform Problems*, TIMES INDIA, Aug. 12, 1999 (“The new patents regime is an evil endangering the health of the poor masses.”); Andrew Leonard, *Big Pharma to Africa’s Aid? Really?*,

Graham Dutfield summarized succinctly, major pharmaceutical companies have been widely criticized for taking advantage of their intellectual property rights³¹ in two ways:

[F]irst, by charging high prices for treatments for diseases that heavily affect poor people that are unable to afford them; and second, by putting pressure on developing country governments to prevent the local manufacture or importation of cheaper copied versions of the drugs produced in countries where either they cannot be patented or where the patents are not respected.³²

In response to these critics, the industry claims that “a globally strong patent system is essential for them to remain in the highly expensive business of discovering and developing new drugs.”³³ As it explains, the pharmaceutical business is extremely risky, and the research and development (R&D) costs are always very high.³⁴ Without

SALON.COM, Jan. 20, 2006, at http://www.salon.com/tech/htww/2006/01/20/africa_drugs_2/index.html (referring to one “extreme voice” that holds the perspective, “patents are evil”).

30. See, e.g., Nitya Nanda & Ritu Lodha, *Making Essential Medicines Affordable to the Poor*, 20 WIS. INT’L L.J. 581, 584 (2002) (“The main obstacle to a more constructive direction in the industry is the greed of pharmaceutical companies, which see greater profits in drugs to reduce cholesterol for rich American consumers than in drugs to tackle the killer diseases which affect the world’s poorest people.”); Al Martinez, *Thoughts of Mortality While Scanning the Menu*, L.A. TIMES, Nov. 21, 2005, at E12 (describing “today’s greedy pharmaceutical industry that will shove anything on the market that will make money”); Steven Pearlstein, *Politics Slows Agreement on Lifesaving Drugs*, WASH. POST, July 4, 2003, at E1 (mentioning the “greedy drug companies”).

31. Although patents provide the primary protection for pharmaceuticals, other forms of intellectual property also offer protection. See Keith E. Maskus, *Ensuring Access to Essential Medicines: Some Economic Considerations*, 20 WIS. INT’L L.J. 563, 569 (2002) (discussing the use by Novartis AG of a different trade name for its anti-malarial drug to protect against parallel importation); Pedro Roffe with Christoph Spennemann & Johanna von Braun, *From Paris to Doha: The WTO Doha Declaration on the TRIPS Agreement and Public Health*, in NEGOTIATING HEALTH, *supra* note 15, at 9, 14–15 (“[I]n the case of some drugs, the most efficient manufacturing process is protected as a trade secret or by a separate patent, which may even be owned by a different company.”).

32. Graham Dutfield, *Introduction to TRADING IN KNOWLEDGE*, *supra* note 7, at 6–7.

33. Roffe, *supra* note 31, at 12; see also Richard Adelstein, *Equity and Efficiency in Markets for Ideas*, 17 CONN. J. INT’L L. 249, 260 (2002) (“Dismantling the system of patent monopolies to allow more poor people access to AIDS drugs now might leave us with no way to mobilize resources against the next great global epidemic.”).

34. As Michael Scherer explained:

Most of the R&D outlays incurred by pharmaceutical companies are made to discover therapeutically interesting molecules and prove their efficacy and safety through extensive human trials—i.e., to create knowledge that approximates what economists call a pure public good. Absent legal barriers to copying, once a drug has been found to be safe and effective, another firm might come up with a generic equivalent by spending roughly a million dollars on production process methods and formulation and begin to compete with the pioneering firm. If such generic imitation were widespread and rapid, surplus revenues that repay pioneers’ initial R&D outlays and make them worthwhile would be severely eroded, undermining incentives to invest in research and product testing. Because of the huge disparity between drug finding and imitation costs, multi-industry surveys show,

strong intellectual property protection, the industry would not be interested in making the significant investment needed for developing new medicines, and generic manufacturers would have nothing to copy at all. The lack of intellectual property protection, therefore, would stifle the progress of medical and scientific advances—a result that would be detrimental to both the developed and less developed worlds.

While the industry was correct in identifying the need for protection in the first place, it did not directly respond to the criticisms. After all, most critics challenge neither the importance of intellectual property protection nor the need for incentives to encourage pharmaceutical companies to develop new medicines. Instead, they question whether strong *worldwide* protection is needed to create the requisite incentives or whether such protection is justified in light of the considerable social costs and the existing public health crises. As Sir Richard Sykes, the former chairman of GlaxoSmithKline PLC, acknowledged, “[f]ew would argue with the need for IP protection in the developed world, but some question whether it is appropriate to extend its coverage to the developing world, which the TRIPS agreement is gradually doing.”³⁵

To bolster their case against Big Pharma, critics have pointed out that the industry has overstated its self-reported R&D costs by including in the calculation substantial marketing expenses that are only marginally relevant to therapeutic innovation.³⁶ Some noted further that these marketing expenses, as compared to R&D expenses, are not

pharmaceutical manufacturers attach unusually high importance to the patent system, which in effect grants them 20 years of exclusive rights to their invention from the time a patent application is filed, as a means of recouping their R&D expenditures.

F.M. Scherer, *The Pharmaceutical Industry and World Intellectual Property Standards*, 53 VAND. L. REV. 2245, 2247 (2000) [hereinafter Scherer, *The Pharmaceutical Industry*]. But see F.M. Scherer, *Pricing, Profits, and Technological Progress in the Pharmaceutical Industry*, 7 J. ECON. PERSP. 97, 98 (1993) (noting that “[b]etween 1960 and 1991, pharmaceuticals held first or second rank in 24 years out of 32 on *Fortune* magazine’s annual tabulation of median after-tax profit returns on stockholder’s equity for its 500 largest industrial corporations” and that “[o]n average, over the 32-year period, the return on equity for pharmaceuticals was 18.4 percent, compared to 11.9 percent for all 500 industrials”).

35. IPR COMMISSION REPORT, *supra* note 6, at 30. Some commentators have noted that “new drugs must be sold worldwide, since no company can fully exploit a patented product, recouping its research and development costs solely in its own home market, even in the two largest national markets, the USA and Japan.” Judy Slinn, *Research and Development in the UK Pharmaceutical Industry from the Nineteenth Century to the 1960s*, in DRUGS AND NARCOTICS IN HISTORY 168 (Roy Porter & Mikuláš Teich eds., 1995), *quoted in* GRAHAM DUTFIELD, INTELLECTUAL PROPERTY RIGHTS AND THE LIFE SCIENCE INDUSTRIES: A 20TH CENTURY HISTORY 108 (2003); see also Gerald J. Mossinghoff, *Research-Based Pharmaceutical Companies: The Need for Improved Patent Protection Worldwide*, 2 J.L. & TECH. 307, 307 (1987) (“Whether [the commitment of America’s research-based pharmaceutical companies] can continue depends greatly upon the extent to which foreign governments allow innovators to be rewarded for their inventiveness, monetary investment, and intellectual labor.”).

36. See ANGELL, *supra* note 19, at 119 (stating that marketing and administration expenses “is the largest single item in big pharma’s budget, larger than manufacturing costs and much larger than R&D”); Roffe, *supra* note 31, at 13 (noting that “[d]oubts have been raised about the actual costs of R&D involved in the development of new drugs (especially compared to the marketing costs of pharmaceutical companies)”).

what patents are supposed to pay for in public interest terms.³⁷ They also note that the United States federal government and its national laboratories, such as the National Institutes of Health, have financed a large portion of the R&D costs,³⁸ while major pharmaceutical companies have devoted significant amounts of wasteful resources in developing “me-too drugs” that achieve no or only limited therapeutic advances.³⁹ Thus, the actual need for incentives to invent, critics argue, is much less than the industry has claimed.

In addition, the critics claim that the pharmaceutical industry has been abusing the intellectual property system it obtained. Although patents protect most pharmaceuticals for only twenty years, giving them an estimated effective marketing period of about fourteen years,⁴⁰ the industry has used the intellectual property system to prolong its

37. Thanks to Christopher May for pointing this out.

38. See Roffe, *supra* note 31, at 13 (noting “the important role that publicly funded R&D plays in the discovery of new drugs”); ANGELL, *supra* note 19, at 56 (“[T]he few innovative drugs that *do* come to market nearly always stem from publicly supported research.”).

39. See DUTFIELD, *supra* note 35, at 98 (discussing me-too drugs). In response, however, the industry explained:

[N]o drug company sets out deliberately to develop a follow-on drug. Innovative companies working in the same therapeutic area compete to be the first to market to treat that condition. Normally, just one company can win that race and the medicines produced by runner-up companies become labeled “me too” by default, although they may actually have been developed in parallel with or even earlier than the first drug to market.

INT’L FED’N PHARM. MFRS. & ASS’NS [IFPMA], ADAPTIVE INNOVATION, INTELLECTUAL PROPERTY AND THE PUBLIC INTEREST: HOW PATENT EXTENSION LEADS TO MORE, BETTER AND SAFER MEDICINES 7 (Feb. 3, 2006), <http://www.ifpma.org/documents/NR4234/Adapting%20Innovation%20int.pdf>.

40. As Kevin Outterson explained:

The exclusive marketing period is shorter than the 20-year patent term because several years pass from the patent date until the drug is approved for marketing. By the late 1990s, the U.S. pharmaceutical exclusive marketing period was approximately 14 years. There is some evidence that the period is longer for recent antibiotics. For the last two novel antibiotics approved by the FDA (Zyvox/linezolid and Cubicin/daptomycin), the exclusive marketing period indicated by the FDA Orange Book is 14 to 21 years for Zyvox and 13 to 16 years for Cubicin.

Kevin Outterson, *The Vanishing Public Domain: Antibiotic Resistance, Pharmaceutical Innovation and Global Public Health*, 67 U. PITT. L. REV. 67, 72 n.24 (2005) [hereinafter Outterson, *Vanishing Public Domain*] (citing CONG. BUDGET OFFICE, HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY 45–48 (1998)) (citations omitted). Although the pharmaceutical industry has complained about the long delay caused by the regulatory process, one commentator suggested that the process has served “as an insurance mechanism for the pharmaceutical industry to avoid the high costs associated with product liability for unsafe and ineffective drugs.” James Thuo Gathii, *Construing Intellectual Property Rights and Competition Policy Consistently with Facilitating Access to Affordable AIDS Drugs to Low-End Consumers*, 53 FLA. L. REV. 727, 771 (2001) [hereinafter Gathii, *Construing Intellectual Property Rights*]; see also STUART O. SCHWEITZER, PHARMACEUTICAL ECONOMICS AND POLICY 36 (1997) (noting that “many [pharmaceutical] companies are wary of pursuing drug research relevant to pregnant women because of two recent liability suits”); Alex Berenson, *Jury Calls Merck Liable in Death*

market exclusivity. As Barbara Rosenberg noted, the legal techniques used by the industry include:

- the use of legal provisions and loopholes to apply for a patent extension aiming to extend patent terms;
- suing generic manufacturers for patent infringement in order to increase costs of generics entering the market and to discourage entry (usually referred to as sham litigation);
- applying for excessively broad patents to block research by competitors;
- the modification of drug molecules or the recombination of existent drugs in slightly different ways for which new patents are applied and that may result in an extension of 20 years of exclusionary power;
- the intentional layering of several patents to secure broad and continual exclusionary rights; and
- the use of brand names to increase barriers to entry for a generic drug manufacturer.⁴¹

To make matters worse, the inherent complication and the structural defects of the patent system in many less developed countries have caused generic manufacturers to become uncertain about which patents are relevant to the manufacture or sale of a particular drug. These manufacturers are also confused about the appropriate patent subject matter, the novelty requirement, and the standards for the inventive step.⁴² The many poor-quality patents issued by the local authorities,⁴³ including those that have

of *Man on Vioxx*, N.Y. TIMES, Aug. 20, 2005, at A1 (reporting that a Texas jury found Merck liable and awarded the widow of a man who died in 2001 after taking the drug \$253.5 million in the first Vioxx trial).

41. Barbara Rosenberg, *Market Concentration of the Transnational Pharmaceutical Industry and the Generic Industries: Trends on Mergers, Acquisitions and Other Transactions*, in NEGOTIATING HEALTH, *supra* note 15, at 74–75.

42. See James Love, *Four Practical Measures to Enhance Access to Medical Technologies*, in NEGOTIATING HEALTH, *supra* note 15, at 241, 252 (describing the inherent complication and structural defects of patent systems in less developed countries).

43. The local authorities in less developed countries are not the only ones that are criticized for the poor quality of the issued patents. Recently, commentators have also widely criticized the U.S. patent system. For discussions of problems within the U.S. patent system, see generally FED. TRADE COMM'N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY (2003), <http://www.ftc.gov/os/2003/10/innovationrpt.pdf>; ADAM B. JAFFE & JOSH LERNER, INNOVATION AND ITS DISCONTENTS: HOW OUR BROKEN PATENT SYSTEM IS ENDANGERING INNOVATION AND PROGRESS, AND WHAT TO DO ABOUT IT (2004); COMM. ON INTELLECTUAL PROP. RIGHTS IN THE KNOWLEDGE-BASED ECON., NAT'L RESEARCH COUNCIL OF THE NAT'L ACADS., A PATENT SYSTEM FOR THE 21ST CENTURY (Stephen A. Merrill, Richard C. Levin & Mark B. Myers eds., 2004). As John Thomas explained, “[b]udgetary limitations, an exploding filing rate, and the increasing range of patentable subject matter are among the reasons that U.S. patent quality appears to be on the decline.” John R. Thomas, *The Responsibility of the Rulemaker: Comparative Approaches to Patent Administration Reform*, 17 BERKELEY TECH. L.J. 727, 728 (2002). Indeed, the problems in the U.S. system are so widespread that Keith Maskus and Jerome Reichman have called for a “moratorium on stronger international intellectual property standards” to prevent the transplant of problems abroad. See Keith E. Maskus & Jerome H. Reichman, *The Globalization of Private Knowledge Goods and the Privatization of Global Public Goods*, in INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME 3, 36–39 (Keith E.

already been struck down elsewhere in the world, have also stifled the development of generic drugs.⁴⁴

In the past decade, major pharmaceutical companies have also used business strategies, such as mergers, acquisitions, co-marketing, co-promotion, and strategic partnerships,⁴⁵ to augment their market power and to reduce, or at least delay, generic competition.⁴⁶ While these mergers and acquisitions allow the companies to decide whether they want the acquired generic manufacturers to continue with production of generic drugs, co-optation and co-marketing strategies force generic manufacturers to divert energies and technological capabilities from generic production.⁴⁷ Because some amount of technological capability is required to manufacture drugs, a change of production will reduce generic competition by taking away the needed resources and technological capabilities.

Even worse, the trend of mergers and acquisitions has been recently heightened by the reduced competitiveness of the pharmaceutical industry. By the mid-1990s, major pharmaceutical companies found it “increasingly difficult to introduce drugs that [were] truly innovative.”⁴⁸ To bolster competitiveness and to generate new revenue

Maskus & Jerome H. Reichman eds., 2005) [hereinafter INTERNATIONAL PUBLIC GOODS] (explaining the need for such a moratorium).

44. See Maskus & Reichman, *supra* note 43, at 36–39 (describing the problem created by poor-quality patents issued in less developed countries); see also Carlos M. Correa, *Can TRIPS Agreement Foster Technology Transfer to Developing Countries?*, in INTERNATIONAL PUBLIC GOODS, *supra* note 43, at 227, 253 (describing the problem created by the listing of “patents of dubious merit and relevance” in the *Orange Book*, which lists patents identified by companies as relevant to medicines sold in the U.S. market, and the United States’s recent effort in promoting a similar system through its free trade agreements). To reduce the confusion over those patents that have already been struck down in developed countries, one commentator proposed to “[s]et up an alert system on patent revocations in developed countries.” Timmermans, *supra* note 24, at 47. This system may be even more effective if it creates a presumption of non-infringement for those generic manufacturers that take advantage of the system.

45. Co-marketing refers to “the sale and marketing of a defined product, which is to be conducted independently and under different trademarks by each party.” Rosenberg, *supra* note 41, at 71. Co-promotion refers to “the sale and marketing of a defined product under a single trademark, where the parties cooperate in managing the overall process of commercialization, from manufacture through sale to the ultimate consumer.” *Id.*

46. Competition has a significant impact on drug prices. For example, “[i]n the USA, the price per dose of penicillin fell from \$20 during the Second World War (when the government purchased all penicillin produced) to \$1 in 1946, and to 10 cents in 1949. Between 1948 and 1955, the price of streptomycin plunged from \$20 per gram to only 15 cents.” DUTFIELD, *supra* note 35, at 118; see also IPR COMMISSION REPORT, *supra* note 6, at 36 (citing a recent study that found that “at least five generic competitors are necessary to push prices down to a minimum”); Alan O. Sykes, *TRIPS, Pharmaceuticals, Developing Countries, and the Doha “Solution,”* 3 CHI. J. INT’L L. 47, 47 (2002) (citing a U.N. study that reports that “150 mg of the HIV drug fluconazole costs \$55 in India, where the drug does not enjoy patent protection, as compared to \$697 in Malaysia, \$703 in Indonesia, and \$817 in the Philippines, where the drug is patented”).

47. See Rosenberg, *supra* note 41, at 72.

48. Meir Perez Pugatch, *Intellectual Property, Data Exclusivity, Innovation and Market Access*, in NEGOTIATING HEALTH, *supra* note 15, at 97, 116. While the manufacturing capabilities, sales growth, R&D expenditures, and ability to generate profits remain high for the industry, the ability to introduce new drugs declined from fifty-three new molecular entities during 1996 to about twenty in 2000. *Id.*; see also DUTFIELD, *supra* note 35, at 96–97 (exploring reasons for the lack of therapeutic breakthroughs by major pharmaceutical companies).

streams, they introduced a new trend of consolidation in the pharmaceutical sector.⁴⁹ While their desperation for new revenues have made it difficult to develop charitable initiatives that respond to public health crises in the less developed world,⁵⁰ the increasing concentration of the pharmaceutical industry has led to greater intellectual property protection. As the market power of these companies grows, they lobby for stronger intellectual property protection, which, in turn, results in further consolidation and restructuring of the pharmaceutical industry.⁵¹ In the end, a vicious cycle of lobbying and consolidation emerges to reduce competition in the local markets,⁵² and the high drug prices and limited therapeutic choices have made consumers worse off.

B. Indigenous Manufacturing Capacity

While the imbalance in the intellectual property system and the consolidation of the pharmaceutical sector have created barriers to accessing essential medicines in many less developed countries, intellectual property protection plays a far less important role in reducing such access in countries that lack an indigenous capacity to develop and manufacture pharmaceuticals. Indeed, when the pharmaceutical industry has to explain why strong intellectual property protection does not impede access to medicines, it usually advances three primary claims to highlight the irrelevancy of intellectual property protection. First, many less developed countries have no or limited intellectual property protection, and major pharmaceutical companies do not hold patents in every

49. See SCHWEITZER, *supra* note 40, at 118 (“Whether in response to rising R&D costs or increased risk associated with developing a successful drug, drug firms throughout the world have consolidated, either through outright mergers or joint marketing agreements.”); Assad Omer, *Access to Medicines: Transfer of Technology and Capacity Building*, 20 WIS. INT’L L.J. 551 (2002) (“Mergers and acquisitions are seen as a means of gaining access to the technology of the firm acquired, of realizing economies of scale and scope, of creating the necessary revenue base for R&D activity, and of speedily penetrating world markets by improving both market access and distribution”); Rosenberg, *supra* note 41, at 70 (“One reason the industry is having consolidation is because the industry’s ability to come up with research flow is not keeping [up] with the attrition for products going off patent.”) (quoting remarks of a senior executive of Pharmacia).

50. See Gathii, *Construing Intellectual Property Rights*, *supra* note 40, at 768–69 (discussing the internal debate within Bristol-Meyers Squibb when it backed out of a commitment of a \$100 million charitable initiative). *But see* Scherer & Watal, *supra* note 18, at 935 (“Under the tax laws of the United States, which is the only nation for which we have detailed information, donations sometimes permit sufficient tax savings to entail little or no out-of-pocket cost to the drug manufacturers.”).

51. See IPR COMMISSION REPORT, *supra* note 6, at 37 (“There is evidence from some countries that the introduction of patents (for example in Italy in 1978) or strengthening the regime, as in Canada in the 1990s, by increasing the market power of foreign multinationals, will result in the consolidation and restructuring of the domestic industry.”); Maskus, *supra* note 31, at 567 (“[A]s patents are granted in the future, it is likely that generic production will be delayed, and the number of generic competitors reduced, in countries where they had been active such as India, China, and Brazil. Pharmaceutical markets in those nations are likely to become more concentrated and less competitive.”).

52. See IPR COMMISSION REPORT, *supra* note 6, at 37 (noting that this cycle “may entail significant costs to the consumer by reducing the degree of competition in the market and increasing imports”).

drug they develop. Second, many diseases in less developed countries are considered neglected, and generic manufacturers are free to develop drugs for those diseases. Third, the health care systems of many less developed countries are inadequate, and the access-to-medicines problem is largely attributed to these inadequacies. This Section discusses the first two claims, and the next Section explores the last.

Consider the first claim. Although the TRIPs Agreement and the existing international intellectual property system have been protective of major pharmaceutical companies, many less developed countries have yet to offer protection, or at least strong protection, for pharmaceuticals.⁵³ Even if protection exists, many drugs will remain unprotected, either because the manufacturers have chosen not to apply for a patent in a particular country or because local or foreign competitors have found ways to develop drugs that offer similar therapeutic benefits without violating the patent.⁵⁴

In fact, because the TRIPs Agreement did not require full protection of pharmaceuticals until January 1, 2005,⁵⁵ generic manufacturers in Argentina, Brazil, China, India, South Africa, and Thailand have been successful in developing cheap, generic versions of on-patent drugs.⁵⁶ In light of this development, the pharmaceutical industry has suggested that the access-to-medicine debate is more properly framed as one between the protection of the pharmaceutical industry and its generic competitors. In March 1998, for example, “PhRMA representative Tom Bombelles suggested that South Africa was a pawn used by India and Argentina to undermine TRIPs.”⁵⁷ As Debora Halbert noted, by suggesting that “in reality, the debate [was] really about whom [sic] will be able to sell South Africa medication,” the industry successfully “shift[ed] the focus away from the enormous health crisis in Africa.”⁵⁸

In the second claim, the industry stated that many less developed countries suffer from neglected diseases, examples of which include measles, malaria, tuberculosis, sleeping sickness, leishmaniasis, and Chagas disease.⁵⁹ Although these diseases affect a

53. See Peter K. Yu, *From Pirates to Partners (Episode II): Protecting Intellectual Property in China in Post-WTO China*, 55 AM. U. L. REV. 901 (2006) [hereinafter Yu, *From Pirates to Partners II*] (noting that China’s rampant counterfeiting problems have greatly reduced Pfizer’s market for Viagra in the country).

54. See Maskus, *supra* note 31, at 567.

55. TRIPs Agreement, *supra* note 8, art. 65(4) (“To the extent that a developing country Member is obliged by this Agreement to extend product patent protection to areas of technology not so protectable in its territory on the general date of application of this Agreement for that Member, as defined in paragraph 2, it may delay the application of the provisions on product patents of Section 5 of Part II to such areas of technology for an additional period of five years.”).

56. Although these countries have been widely recognized for their generic production, Italy had a thriving generic drug industry in the 1950s and the 1960s. See Scherer, *The Pharmaceutical Industry*, *supra* note 34, at 2250 (discussing the generic drug industry in Italy).

57. Halbert, *supra* note 17, at 267.

58. *Id.* at 267–68.

59. For a discussion of neglected diseases, see generally Patrice Trouiller, Piero Olliaro, Els Torreale, James Orbinski, Richard Laing & Nathan Ford, *Drug Development for Neglected Diseases: A Deficient Market and a Public Health Policy Failure*, 359 LANCET 2188 (2002). For the pharmaceutical industry’s response to the neglected-diseases problem, see generally Boris Azaïs & Maciej Gajewski, IFPMA, RESEARCH AND DEVELOPMENT FOR NEGLECTED DISEASES: LESSONS LEARNED AND REMAINING CHALLENGES (2005), http://www.ifpma.org/Documents/NR2536/RD%20for%20Neglected%20Diseases_October04.pdf.

large segment of the population in less developed countries, major pharmaceutical companies, due to the limited profit margins and the lack of reliable profits, have been uninterested in devoting resources to their treatments.⁶⁰ As one commentator noted:

The World Health Organization (WHO) has estimated that only 4.3 per cent of pharmaceutical R&D expenditure is targeted at those health problems, such as malaria and tuberculosis, which primarily concern low- and middle-income countries. According to James Orbinski, former president of the International Council of Médecins Sans Frontières (MSF), while 95 per cent of active tuberculosis cases occur in developing countries, no new drugs for the disease have been developed since 1967. Furthermore, between 1975 and 1999, 1393 new drugs were developed, of which only 13 were for tropical diseases; put differently, 90 per cent of investment into health-related R&D has focused on concerns that only affect 10 per cent of the global population.⁶¹

Moreover, major pharmaceutical companies have chosen to focus their energies and resources on other therapeutic needs. For example, they have invested substantially to develop lifestyle drugs, such as Viagra, Rogaine, and diet drugs. As Henry Gadsden, the former CEO of Merck, once told his researchers, "there are more well people than sick people. We should make products for people who are well."⁶² In addition, the companies have spent a considerable amount of resources on developing and refining drugs that are fairly important in the developed world, such as treatments for cancer, diabetes, and heart and respiratory diseases. Even when they explore treatments for diseases that are dominant in less developed countries, like malaria, they tend to focus more on "prophylaxis for travellers from developed countries rather than [on] vaccines which would be of greater relevance to sufferers in the developing world."⁶³

From the standpoint of profit maximization, the preferences of major pharmaceutical companies make good sense. Although these drugs benefit fewer people and may not be lifesaving, their sale guarantees the companies a predictable, and often handsome, rate of return. Indeed, because many major pharmaceutical companies need a threshold return of close to \$1 billion to justify investment, they have found unattractive the low-end markets in less developed countries.⁶⁴ Many of these companies also face increasing pressure to develop blockbuster drugs to replace old

60. See IPR COMMISSION REPORT, *supra* note 6, at 32–33 (estimating that "less than 5% of the money spent worldwide on pharmaceutical R&D is for diseases that predominantly affect developing countries" and pointing out that the "presence or absence of IP protection in developing countries is of at best secondary importance in generating incentives for research directed to diseases prevalent in developing countries"); SCHWEITZER, *supra* note 40, at 3 (noting that the pharmaceutical industry "is criticized for its marketing and pricing practices—and even for its research and development priorities").

61. Roffe, *supra* note 31, at 13 (citations omitted).

62. DUTFIELD, *supra* note 35, at 97; *see id.* ("[I]t is a fact of economic life that the most profitable medicines are not necessarily the ones that save the most people's lives or even that save any lives at all.").

63. IPR COMMISSION REPORT, *supra* note 6, at 33; *see also id.* ("The majority of HIV vaccines are being developed for genetic profiles of subtype B, prevalent in developed countries, but most AIDS sufferers in developing countries are types A and C.").

64. *See id.* at 32 ("[L]arge pharmaceutical companies are unwilling to pursue a line of research unless the potential outcome is a product with annual sales of the order of \$1 billion.").

ones whose patent protection will soon expire. As Merrill Goozner observed, “[t]here were fifty-two drugs with more than \$1 billion in sales in 2000, but forty-two were slated to lose their patent protection by 2007.”⁶⁵

The industry’s lack of response and its seeming indifference to the public health crises in the less developed world, therefore, necessitates local solutions—in particular the indigenous development and manufacture of pharmaceuticals for treatment of diseases that are unavailable in developed countries and the importation of generic versions of these products from other, usually less developed, countries. Unfortunately, the strong patent rights held by foreign patent holders have significantly curtailed the ability to develop drugs in these countries. To break the patents, commentators and policymakers have suggested the use of compulsory licenses (including the importation of generic drugs under such a license), parallel importation, price control, and other regulatory measures.⁶⁶

Consider, for example, compulsory licensing. Although differential pricing—the practice of charging drugs at different prices in different regions, countries, or market segments—could enable companies to make more profits by including both high-end and low-end customers,⁶⁷ major pharmaceutical companies have been reluctant to make their drugs available at discounted prices, for three reasons. First, they are concerned that the discounted drugs would flow back as parallel imports to their markets in developed countries, such as the United States or members of the European Communities.⁶⁸ As Alan Sykes explained:

65. MERRILL GOOZNER, *THE \$800 MILLION PILL: THE TRUTH BEHIND THE COST OF NEW DRUGS* 229 (2004); see also ANGELL, *supra* note 19, at 15 (“[S]ome of the top-selling drugs—with combined sales of another \$35 billion a year—are scheduled to go off patent within a few years of one another.”).

66. See Abbott, *Cycle of Action*, *supra* note 15, at 29–30 (discussing regulatory responses). But see Robert Weissman, *A Long, Strange TRIPS: The Pharmaceutical Industry Drive to Harmonize Global Intellectual Property Rules, and the Remaining WTO Legal Alternatives Available to Third World Countries*, 17 U. PA. J. INT’L ECON. L. 1069, 1115 (1996) (criticizing the use of price controls as “an unsatisfactory policy instrument”).

67. For a discussion of differential pricing, see generally Patricia M. Danzon & Adrian Towse, *Theory and Implementation of Differential Pricing for Pharmaceuticals*, in *INTERNATIONAL PUBLIC GOODS*, *supra* note 43, at 425.

68. See Maskus, *supra* note 31, at 566–67 (“There are concerns that if medicines were offered to poorer patients at lower prices the drugs could be resold in the higher-priced segment of the market.”). “While arbitrage is often cited as a factor preventing differential pricing, the real magnitude of the concern must be kept in perspective. Large pharmaceutical companies understand the problems of arbitrage and know how to take appropriate safeguards.” Peter J. Hammer, *Differential Pricing of Essential AIDS Drugs: Markets, Politics and Public Health*, 5 J. INT’L ECON. L. 883, 889 n.10 (2002). The August 30 Decision, for example, requires products produced under a Paragraph 6 license to be “clearly identified as being produced under the system set out in this Decision through specific labelling or marking.” August 30 Decision, *supra* note 11, ¶ 2(b)(ii); see also Carlos Pérez del Castillo, General Council, The General Council Chairperson’s Statement (Aug. 30, 2003), http://www.wto.org/english/news_e/news03_e/trips_stat_28aug03_e.htm [hereinafter Chairperson’s Statement] (including a “[b]est practices’ guidelines” listing the measures major pharmaceutical companies have undertaken “to differentiate products supplied through donor or discounted pricing programmes from products supplied to other markets”); DUTFIELD, *supra* note 35, at 110 (“Companies also use trade mark law to extend their market power beyond the patented drug’s expiry date.”); Shubha Ghosh,

Parallel importation invariably reduces the rents that are earned by pharmaceutical patent holders. To the degree that those rents are important to inducing worthwhile R&D investments, as suggested above, this effect is unfortunate. Parallel imports may also exacerbate the deadweight costs of monopoly by forcing patent holders to abandon price discrimination and revert to policies approaching those of a non-discriminating monopolist, curtailing global output in the process.⁶⁹

Although Professor Sykes was right in terms of the inefficiency created by parallel importation in theory, he overstated the practical impact of such importation. Thus far, many major pharmaceutical companies have refused to take advantage of the low-end markets even though the entry into those markets would potentially generate more profits for them. As a result, the low-end markets remain underserved, and drugs imported from abroad have been sold at a uniform global price. Even when drugs are available at discount prices in less developed countries, “studies of multinational company pricing policies (mainly for ARVs) [have indicated] that until recently there was remarkably little correlation between the price of the same drug and a country’s per capita income.”⁷⁰

Second, major pharmaceutical companies fear that the price concessions would reveal the marginal costs of drug production and would result in public or governmental pressure in developed markets that calls for lower prices, at least for low-income households.⁷¹ Indeed, “the practice of health authorities in some richer countries to engage in ‘reference pricing’” has made the pharmaceutical industry more reluctant to set lower prices in less developed countries.⁷² As Keith Maskus explained, “[i]n a reference pricing system, price controls in one country are based on an index of prices in comparison countries. To the extent that the comparison group includes developing economies, firms may prefer not to offer price discounts there.”⁷³ To solve the reference-pricing problem, two commentators recently proposed the use of confidential rebates in government procurement.⁷⁴

Finally, because wealth is usually distributed very unevenly in many less developed countries—South Africa being the most cited example—some pharmaceutical companies choose to sell their products at high prices that are affordable by the “more affluent minority,”⁷⁵ even if it means that the product will become unaffordable to the

Pills, Patents, and Power: State Creation of Gray Markets as a Limit on Patent Rights, 53 FLA. L. REV. 789, 810 (2001) (discussing how trademarks “serve as barriers to entry for generic manufacturers”). Moreover, “clinical needs in the third world may dictate a range of differences in terms of appropriate drug combinations, composition and dosages. These clinical differences can be consciously exploited to promote product differentiation between first- and third-world treatments.” Hammer, *supra*, at 893.

69. Sykes, *supra* note 46, at 64.

70. IPR COMMISSION REPORT, *supra* note 6, at 36–37.

71. See Abbott, *Cycle of Action*, *supra* note 15, at 29; Hammer, *supra* note 68, at 893–94 (“[E]ven without the threat of physical arbitrage, implicitly revealing information in the very act of setting lower prices in developing countries could lead to an unravelling of high prices in developed countries.”).

72. Maskus, *supra* note 31, at 567.

73. *Id.*

74. Danzon & Towse, *supra* note 67, at 445 (proposing to address “parallel trade and external referencing . . . in low-income countries or market segments using confidential rebates as part of their procurement arrangements”).

75. F.M. Scherer & Jayashree Watal, *Post-TRIPS Options for Access to Patented Medicines*

larger and poorer majority.⁷⁶ As Professor Maskus noted, some “pharmaceutical firms and their distributors in poor countries may find it more profitable to sell drugs in low volumes and high prices to wealthier patients with price-inelastic demand rather than in high volumes at low prices to poorer patients.”⁷⁷

Notwithstanding these concerns, compulsory licensing has been widely used throughout the world, including by such developed countries as Canada, the United Kingdom, and the United States. As the U.K. Commission on Intellectual Property Rights noted, “Canada used compulsory licensing extensively in the pharmaceutical field from 1969 until the late 1980s. This resulted in prices of licensed drugs being 47% lower than in the US in 1982. The UK also used compulsory licensing until the 1970’s, including for important drugs such as Librium and Valium.”⁷⁸ Even the United States has used various compulsory licensing and price control mechanisms to protect low-income households in the country, despite its lack of a national public health emergency.⁷⁹ The United States Code also includes a special provision that allows for the use of patented items by the government and its contractors in return for compensation through a proceeding before the Federal Court of Claims.⁸⁰ It is,

in Developing Countries 45 (Comm’n on Macroeconomics & Health, Working Paper No. WG4:1, 2001), http://www.cmhealth.org/docs/wg4_paper1.pdf.

76. Danzon & Towse, *supra* note 67, at 455 (“[P]ricing in some [less developed countries] is dominated by the demands of small, affluent populations, resulting in prices that are unaffordable to the majority of poorer people.”).

77. Maskus, *supra* note 31, at 566. For a discussion of how the current access-to-medicines debate has been misplaced by ignoring the difference in price elasticities of demand for pharmaceuticals in developed and less developed countries, see generally David W. Opderbeck, *Patents, Essential Medicines, and the Innovation Game*, 58 VAND. L. REV. 501 (2005). As David Opderbeck noted, “The level of patent protection in developing countries and [least developed countries] does not matter when there is an inelastic market for the drug in the North.” *Id.* at 541.

78. IPR COMMISSION REPORT, *supra* note 6, at 42 (footnote omitted).

79. See Srividhya Ragavan, *The Jekyll and Hyde Story of International Trade: The Supreme Court in PhRMA v. Walsh and the TRIPS Agreement*, 38 U. RICH. L. REV. 777, 796–812 (2004) [hereinafter Ragavan, *Jekyll and Hyde Story*] (discussing the use of compulsory licensing and price control mechanisms by the United States under circumstances less threatening than national emergencies).

80. 28 U.S.C. § 1498(a) (2000). As the provision provides:

Whenever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same, the owner’s remedy shall be by action against the United States in the United States Court of Federal Claims for the recovery of his reasonable and entire compensation for such use and manufacture

For the purposes of this section, the use or manufacture of an invention described in and covered by a patent of the United States by a contractor, a subcontractor, or any person, firm, or corporation for the Government and with the authorization or consent of the Government, shall be construed as use or manufacture for the United States.

Id.; see also Frederick M. Abbott, *Managing the Hydra: The Herculean Task of Ensuring Access to Essential Medicines*, in INTERNATIONAL PUBLIC GOODS, *supra* note 43, at 393, 412 [hereinafter Abbott, *Managing the Hydra*] (“No country facilitates government use of patents better than the United States.”).

therefore, no surprise that many less developed countries have become dissatisfied with the international intellectual property system, while others have questioned whether their developed trading partners were trying to “kick away the ladder” that would have allowed them to catch up.⁸¹

Unlike domestic production under a compulsory license (or parallel importation), importation under a compulsory license creates a different problem for major pharmaceutical companies. Instead of forcing these companies to sell at a low price against their wishes, such importation allows generic competitors to provide market substitutes in the companies’ present and future markets. While price control and price discrimination may result in the availability of drugs that can be imported through parallel trade, the drugs needed in less developed countries are often unavailable. As a result, importation under a compulsory license is needed, and careful negotiation has been conducted in the Doha Round to facilitate such importation.

Despite their benefits, compulsory licenses, parallel importation, and regulatory measures provide only limited assistance for countries that lack an indigenous capacity to develop and manufacture pharmaceuticals to mitigate the access-to-medicines problem. A country cannot force a major pharmaceutical company to import a drug against its wishes or to devote resources to develop treatments for a neglected disease.⁸² Likewise, a country that seeks importation—either under a compulsory license or through parallel trade—has to depend on the availability of the discounted or generic version of the drugs elsewhere and the willingness and ability of the source countries to export the products. Importation is simply impossible in situations where the drugs are unavailable in other countries.

Consider, for example, Brazil, which has been viewed by many as the poster child for using compulsory licensing—or, to be more precise, for threatening the use of compulsory licensing—to obtain concessions from major pharmaceutical companies.⁸³

81. HA-JOON CHANG, *KICKING AWAY THE LADDER: DEVELOPMENT STRATEGY IN HISTORICAL PERSPECTIVE* 4 (2002) (tracing the phrase to FREIDRICH LIST, *THE NATIONAL SYSTEM OF POLITICAL ECONOMY* 39 (Sampson Lloyd trans., 1885)).

82. The only possibility seems to be the nationalization of foreign pharmaceutical companies, which provides short-term gains while making long-term sacrifices in the country’s loss of foreign direct investment, its tarnished international reputation, and its becoming the subject of trade sanctions and embargoes.

83. See, e.g., IPR COMMISSION REPORT, *supra* note 6, at 43 (discussing the Brazilian National STD/AIDS Program); ‘t Hoen, *supra* note 14, at 32 (“The Brazil AIDS program serves as a model for some developing countries that are able to produce medicines locally.”). Commentators, nevertheless, noted the importance of not being overly optimistic of the concessions Brazil obtained from major pharmaceutical companies:

What bargaining on price actually does is allow the U.S. and EU to exchange a one time price break for preserving the integrity of the regime as a whole. No rule is renegotiated, no new precedent is established that will operate, however subtly, to redefine the regime or jeopardize the institutionalization of the principles it contains. As a result, it seems more appropriate to view a price break as an isolated victory that is materially important in the short term, but institutionally irrelevant in the long term. Like a political pressure valve installed by the developed states to protect their interests, a price reduction releases pent up pressure for reform while insuring that the underlying system is never placed in jeopardy.

Benvenisti & Downs, *supra* note 28, at 46; Nanda & Lodha, *supra* note 30, at 585 (“The extension of price reductions to developing countries is inferior to a policy of defining and

As Pedro Roffe noted, “[w]hile the [Brazilian] Government never issued a compulsory licence, it managed to use the mere threat of issuing one to reduce the price of individual HIV/AIDS retroviral drugs by up to 75 per cent.”⁸⁴ Notwithstanding the success, it is important to remember that Brazil was successful because it also possessed two unique conditions that made its threat credible. First, the country has an indigenous capacity to develop and manufacture pharmaceuticals, and that capacity has created “a strong negotiating capacity for obtaining low prices from patent holders.”⁸⁵ Second, Brazil contains a lucrative middle class market that U.S. pharmaceutical firms cannot afford to lose or alienate. Compared to other less developed countries, the country “is less dependent on the U.S. for . . . a market for its own exported products.”⁸⁶

As shown by the Brazilian example, the lack of ability of less developed countries to develop and manufacture pharmaceuticals can be attributed to three sets of factors. First, they may lack the needed technical expertise. While the patent system requires applicants to disclose their technology, such disclosure is indecipherable to those unskilled in the art⁸⁷—and sometimes even to those skilled in the art despite the enablement requirement.⁸⁸ To develop the expertise, countries therefore cannot just study patents filed or granted in foreign countries. Instead, they need to send their local scientists abroad to study, bring in foreign experts to train them, or introduce an indigenous patent system.⁸⁹

defending a national IP policy in health-related commodities . . .”).

84. Roffe, *supra* note 31, at 15; see also Joan Rovira, *Creating and Promoting Domestic Drug Manufacturing Capacities: A Solution for Developing Countries*, in NEGOTIATING HEALTH, *supra* note 15, at 227, 236 (noting that the significant productive capacity in the public sector in Brazil “allowed the country to make the threat of compulsory licensing credible and, as a consequence, gave it a strong negotiating capacity for obtaining low prices from patent holders”); Timmermans, *supra* note 24, at 46 (noting that strategies seeking voluntary licenses at reasonable royalty rates “are bound to be the most successful when they are backed up by a realistic ‘threat’ to use TRIPS safeguards or competition laws”).

85. Rovira, *supra* note 84, at 236.

86. Benvenisti & Downs, *supra* note 28, at 44.

87. See Peter Drahos & John Braithwaite, *Economics, Politics, Law and Health: Intellectual Property, Corporate Strategy, Globalisation: TRIPS in Context*, 20 WIS. INT’L L.J. 451, 460 (2002) (noting that “[s]ome of the core knowledge related to the invention was kept back from the patent system as private ‘know-how’” and that “[p]atents were drafted in ways that satisfied the patent office, but were virtually useless to public readers of the documents”); Edmund W. Kitch, *The Patent Policy of Developing Countries*, 13 UCLA PAC. BASIN L.J. 166, 171–76 (1994) (discussing how patents alone might not contain all the necessary information to promote technological advances).

88. See, e.g., 35 U.S.C. § 112 (2000) (“The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art . . . to make and use the same.”); TRIPs Agreement, *supra* note 8, art. 29(1) (“Members shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art . . .”).

89. Kitch, *supra* note 87, at 171–76. Nevertheless, the development of such a system does not necessarily result in a transfer of technology, especially if less developed countries are mainly used as manufacturing sites while key technologies are isolated and protected abroad. See Paul J. Heald, *Mowing the Playing Field: Addressing Information Distortion and Asymmetry in the TRIPS Game*, 88 MINN. L. REV. 249, 258–60 (2003) (discussing the different

Second, less developed countries may lack the financial resources to build up the manufacturing capacity, managerial resources, and business environment that are needed to make the investment worthwhile. For example, studies have shown that the following conditions are crucial for countries to become internally competitive pharmaceutical manufacturers:

- gross domestic product (GDP) greater than about US \$100 billion;
- population greater than about 100 million;
- sufficient numbers of the population enrolled in secondary and tertiary education;
- competitiveness index (UNIDO) greater than about 0.15; and
- a net positive pharmaceutical balance of trade.⁹⁰

Because the markets in less developed countries are very small, it may be virtually unprofitable to develop a local industry that is primarily restricted to the domestic market.⁹¹ Even when several less developed country markets are aggregated, there is no guarantee that the combined market would generate enough purchasing power to make the development of such an industry attractive.⁹²

Moreover, due to a lack of economies of scale, the costs of drug development (including those of clinical studies needed to prove the therapeutic effect of a drug and to secure regulatory approval) may be very high. While large generic manufacturers may be able to afford costly bioequivalence studies, the costs of these studies might be prohibitive for small and mid-sized firms.⁹³ A case in point is Colombia. "A study in Colombia estimated that the requirement of bioequivalence studies for anti-hypertensive and anti-inflammatory drugs would increase the price of domestically

concerns about intellectual property protection between the marketing division and the research and manufacturing division of a foreign company); Yu, *From Pirates to Partners II*, *supra* note 53, at 965–69 (discussing the use of isolation to protect key intellectual assets in countries with rampant counterfeiting and piracy problems).

90. Rovira, *supra* note 84, at 234.

91. *Id.* at 229 (noting that a limited market size "might make unprofitable a local industry restricted to the domestic market"); see also Orphan Drug Act, 21 U.S.C. § 360ee (2004) (providing additional incentives for pharmaceutical companies to undertake research into diseases that affect only a small number of people); Thomas F. Cotter, *Market Fundamentalism and the TRIPS Agreement*, 22 *CARDOZO ARTS & ENT. L.J.* 307, 335 (2004) ("Even in the United States, it took the Orphan Drug Act to make research into some drugs with relatively small demand profitable."). As one commentator explained:

The difference between demand and need is more than semantic. It is important in differentiating between what "is," or what "will be," on the one hand, and what "ought to be," on the other. Need is an important measure of professionally determined objectives but it is often a poor predictor of consumer behavior, either in the health sector or more generally. It is also less useful than one might wish in making forecasts or simulations of policy decisions. Consumption is more determined by demand factors than need

SCHWEITZER, *supra* note 40, at 74; see also Hammer, *supra* note 68, at 888 ("[F]or a market to exist, there must be effective consumer demand manifested in the willingness and ability to pay. Objective need does not automatically translate into effective market demand.").

92. See Maskus, *supra* note 31, at 568 ("[P]urchasing power, even if aggregated across a number of markets, may not be enough to make drug development attractive.").

93. Rovira, *supra* note 84, at 234.

manufactured products by a percentage of between 46 and 61 per cent.”⁹⁴ It is, therefore, no surprise that a recent study presented at a World Bank forum noted the lack of evidence to suggest that domestic production will necessarily reduce prices and improve quality and access to medicines.⁹⁵

Finally, less developed countries are often vulnerable to development-related problems that affect the “availability of special technologies, reliable supplies of high-quality raw materials, dependable provision of top-quality water, electricity, gas and other utilities . . . [and] sufficient human resources, such as experts in pharmaceutical development, quality assurance and regulatory processes.”⁹⁶ Insufficient regulatory capacity has also resulted in a high percentage of drugs failing quality control tests as well as the wide availability of counterfeit drugs.⁹⁷

In sum, many different factors determine whether a country has manufacturing capacity, and the capacity level varies from one country to another. To underscore these varying levels of manufacturing capacity, a study by the United Nations Industrial Development Organization (UNIDO) grouped countries into the following categories:

1. no manufacturing facilities and dependency upon imported, finished medicines;
2. packaging of already formulated medicines and small-scale local production of sterile or non-sterile formulations, such as intravenous (IV) fluids;
3. formulation of drugs in final dosage form and some production from imported intermediates;
4. production from imported intermediates and manufacture of some intermediates from local materials; and
5. production of active substances and processing to produce the required pharmaceutical dosage forms.⁹⁸

Although the study was published in 1980, its main conclusion remains valid today. “[T]he high technological capacity required for research and development . . . and [active pharmaceutical ingredients] production is concentrated in the industrialized

94. *Id.*

95. W.A. KAPLAN & R. LAING, LOCAL PRODUCTION OF PHARMACEUTICALS: INDUSTRIAL POLICY AND ACCESS TO MEDICINES: AN OVERVIEW OF KEY CONCEPTS, ISSUES AND OPPORTUNITIES FOR FUTURE RESEARCH (HNP Discussion Papers, World Bank, 2005), <http://siteresources.worldbank.org/HEALTHNUTRITIONANDPOPULATION/Resources/281627-1095698140167/KaplanLocalProductionFinal.pdf>, cited in Rovira, *supra* note 84, at 232.

96. Rovira, *supra* note 84, at 233 (quoting World Health Org. [WHO], MANUFACTURE OF ANTIRETROVIRALS IN DEVELOPING COUNTRIES AND CHALLENGES FOR THE FUTURE 1 (2004), http://www.who.int/gb/ebwha/pdf_files/EB114/B114_15-en.pdf).

97. See BURCI & VIGNES, *supra* note 25, at 188 (“[E]ven if drugs are available, weak drug regulation may mean that they are substandard or counterfeit.”); Nanda & Lodha, *supra* note 30, at 586 (“Surveys from a number of developing countries show that between 10 and 20 percent of sampled drugs fail quality control tests.”).

98. Rovira, *supra* note 84, at 230; see also Nanda & Lodha, *supra* note 30, at 589 (tabulating the results of a 1992 study concerning the structure of the global pharmaceutical industry).

world and in a few emerging countries.”⁹⁹ The rest of the world either consists of formulators or has insufficient or no manufacturing capacity.

C. Health Care System

The last claim the pharmaceutical industry and their supporters usually advance concerns impediments within the local health care system. As one commentator asked rhetorically, “‘What is the point of developing drugs when they cannot be distributed?’”¹⁰⁰ Some commentators and pundits even went so far to claim that the local impediments are so serious that the intellectual property system has only limited impact on the access to medicines in these countries. In their studies, Amir Attaran and Lee Gillespie-White found that “the extreme dearth of international aid finance, rather than patents, is most to blame for the lack of antiretroviral treatment in Africa.”¹⁰¹ As these commentators imply, patent reforms would not be effective unless reforms were first taken to address the local impediments.

Among the oft-cited IP-irrelevant factors are “poor management, high inflation, pervasive corruption, crumbling infrastructure, ethnic/civil conflicts, population displacement, excessive military spending, inequitable distribution of resources and chronic youth unemployment.”¹⁰² The industry also underscore the fact that the poor in these countries often have to struggle to meet basic needs; they “lack clean drinking water, food, shelter, electricity, schools, and basic health care.”¹⁰³ Even with the promise of low-cost or donated drugs, it is unclear how much more effectively these countries can provide cures and treatments for diseases.¹⁰⁴

While the development-related problems in these countries are serious and the local health care systems are inadequate, it is a mistake to use these problems to dismiss the impact of the unbalanced intellectual property system on access to medicines. Poor

99. Rovira, *supra* note 84, at 231. Countries that have the capacity to produce these ingredients “include India, China, Thailand, Egypt, Brazil, Mexico, Argentina and, to some extent, Yugoslavia and Turkey.” *Id.*

100. Tove Iren S. Gerhardsen, *US Declares Opposition to WHO R&D Resolution as Proponents Raise Questions*, INTELL. PROP. WATCH, <http://www.ip-watch.org/weblog/index.php?p=311> (May 22, 2006) (quoting Julian Morris, Executive Director, International Policy Network).

101. Amir Attaran & Lee Gillespie-White, *Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa?*, 286 J. AM. MED. ASS’N 1886, 1891 (2001).

102. J.M. Spectar, *The Hybrid Horseman of the Apocalypse: The Global AIDS Pandemic & the North-South Fracas*, 29 GA. J. INT’L & COMP. L. 253, 267 (2001); Pharm. Research & Mfgs. Am. [PhRMA], *Health Care in the Developing World*, <http://world.phrma.org/exec.summary.html.html> (last visited Apr. 2, 2007) (“Some developing countries also are hampered by political leadership that lacks the will to confront or even acknowledge their nation’s health care needs.”).

103. Peter K. Yu, *Bridging the Digital Divide: Equality in the Information Age*, 20 CARDOZO ARTS & ENT. L.J. 1, 10 (2002).

104. See IPR COMMISSION REPORT, *supra* note 6, at 31 (“[W]ithout extra funding for medicines and health delivery services, treatment for all those requiring [antiretroviral therapies for HIV/AIDS] will remain unaffordable even at the cheapest generic prices.”); Scherer & Watal, *supra* note 18, at 939 (“[I]t must be recognized that the poorer residents of the world’s least affluent nations cannot pay even the marginal cost of drugs that might save their lives or permit them to become productive workers.”).

countries, by definition, are poor; they lack resources, technical expertise, and economic development. As Sisule Musungu of the South Centre reminded the U.K. Commission on Intellectual Property Rights:

I would like to discourage the Commission from arriving at the conclusion in this debate {that it is all} about infrastructure and resources. If that is the conclusion, I think you will have what the title says: "People are Poor". So don't make recommendations that people are poor because we know that. We are trying to solve their problems, not to tell them that they are poor.¹⁰⁵

Today, the health care systems of many less-developed countries suffer from underdevelopment, and the lack of health care personnel, medical knowledge, and the needed infrastructure to administer medicines and to deliver cures and treatments has compounded the public health crises.¹⁰⁶ Consider Nigeria, for example:

In 2001, Nigeria on the advice of activists purchased generic anti-AIDS drugs. The World Bank, the U.S. Agency for International Development and the Gates Foundation, among others, donated more than \$150 million to help with distribution.

Two years later, only about 800 people have been treated, and the tons of drugs in the government stockpile will expire in less than six months. The Nigerian Directorate of the National Programme to Fight AIDS concluded that Nigeria's woeful health infrastructure was the real reason for the failure.¹⁰⁷

105. IPR COMMISSION REPORT, *supra* note 6, at 39 (quoting Sisule Musungu, Presentation at Session on Medicines, Commission on Intellectual Property Rights Conference (Feb. 21–22, 2002)).

106. See IPR COMMISSION REPORT, *supra* note 6, at 38 ("[I]mproper administration [of medicines] may [also] contribute to the development of drug resistance, apart from being ineffective."); see also Colin Robert Crossman, *Arming Our Enemies: How Parallel Imports Could Increase Antimicrobial Resistance*, 31 N.C. J. INT'L L. & COM. REG. 823, 824–33 (2006) (discussing resistance to antimicrobials); Nanda & Lodha, *supra* note 30, at 587 ("Irrational use of drugs also remains widespread, despite progress in drug selection, therapeutic information and training . . . [and] is contributing to growing anti-microbial resistance, particularly in relation to major infectious diseases, including bacterial diarrhoea, gonorrhoea, malaria, pneumonia and tuberculosis."). For example, some drugs may be "exhausted through antibiotic resistance by the time it reaches the public domain." Outterson, *Vanishing Public Domain*, *supra* note 40, at 73. If these drugs are introduced or administered improperly during the patent term, they may lose their effectiveness by the time the patents expire and will never become available to the less developed world in the same way they do to their more developed counterparts. As Kevin Outterson lamented, the poor in those situations will be "left with nothing except a cruel memory of a fading hope." *Id.*

107. Robert Goldberg, *Disease Control*, WASH. TIMES, May 15, 2003, at A19. As Keith Maskus explained:

Many poor countries have a shortage of clinics, hospitals, medical personnel and means for transporting patients. The inability to fund health programs adequately is partially the result of chronically limited budgets. It also stems from governments placing relatively little emphasis on social programs including health. The resource constraint may be compounded by an inability to levy user charges to cover even the operational costs of providing public health care services. Poor

Combined with factors discussed in the previous Sections, this example shows that less developed countries are often confronted with different types of factors.

Thus, the problems confronting less developed countries in the public health area are not limited to intellectual property protection. IP-irrelevant factors are also important causes of the problem. When researchers account for the causes of the access-to-medicines problem, they usually include three different types of factors. Some of them are IP-relevant, some of them are only IP-related (in the sense that intellectual property protection is not *directly* relevant to the outcome of the factors), and the remainder are IP-irrelevant.

Consider, for example, the list compiled by the WHO Department of Essential Drugs of the various factors contributing to the proper access to medicines. The first group of factors, which concern the availability of the needed therapeutic products, includes such factors as basic research, discovery, and development—all factors in which intellectual property protection arguably plays an important role. However, the list also includes a second group of factors that affect the accessibility of the product:

- ensuring quality, rational selection, and appropriate prescribing and use;
- a distribution system of effectiveness and efficiency;
- economic factors—for example, cost, pricing, procurement, and financing;
and
- knowledge and ‘health-seeking’ behaviour of ‘consumers.’¹⁰⁸

Although the intellectual property system may influence the effects of some of the economic factors, in particular availability of the products at affordable prices and the choice of sources of those products, many of the factors remain largely IP-irrelevant (or at best IP-related).¹⁰⁹

Similarly, Keith Maskus, a former World Bank economist, grouped the three types of factors together in his list concerning the demand and supply of essential medicines. As Professor Maskus explained:

Access refers to both supply and demand factors. The supply of essential medicines has both a static dimension, referring to difficulties in distributing existing drugs, and a dynamic dimension, referring to the effectiveness of incentives to develop new drugs. Demand factors, which are also both static and dynamic, include incomes, financing, and prices. Thus, several elements contribute to the shortage of medicines relative to needs in poor countries.¹¹⁰

communities may be isolated from health care systems by geography, language, and differences in beliefs about disease and appropriate modes of healing. Maskus, *supra* note 31, at 565; *see also* IPR COMMISSION REPORT, *supra* note 6, at 30 (“Where appropriate treatments already exist, access to them depends on affordability, and the availability of the health service infrastructure to support delivery.”).

108. Widdus, *supra* note 26, at 217.

109. Even the economic factors include such IP-irrelevant factors as “import tariffs, procurement efficiency, and distributor mark-ups.” *Id.*; *see also* IPR COMMISSION REPORT, *supra* note 6, at 37 (“The actual price [of the drug] to the patient is complicated by import duties, local tariffs, taxes and wholesaler profits.”).

110. Maskus, *supra* note 31, at 565.

Interestingly, regardless of whether he focuses on the supply or demand side or static or dynamic factors, the list includes all three types of factors—factors that are IP-relevant, IP-related, and IP-irrelevant.

In sum, although inappropriate intellectual property protection contributes to high drug prices and the resulting access-to-medicines problem in less developed countries, it is important not to overlook many of the other factors that are only related or completely irrelevant to intellectual property protection. Because defects in the current intellectual property system can be *indirectly responsible* for a lack of access to medicines in these countries by affecting the impact of the IP-irrelevant factors, even though they may not be *directly responsible* for such a lack, it is very important to distinguish among the IP-relevant, IP-related, and IP-irrelevant factors and develop solutions that are tailored to each type of factor. While a correction of the imbalance in the intellectual property system may not alleviate the adverse effects of the IP-irrelevant factors, confusion over the different types of factors will not only delay efforts to address the problems, but may also exacerbate them by misdirecting resources and energies while creating illusions of success.

D. A Complex, Symbiotic Relationship

Although the foregoing discussion intentionally separates for analytical convenience the IP-relevant, IP-related, and IP-irrelevant factors, this Section points out that the complex and symbiotic relationship between intellectual property and public health has rendered none of these factors determinative.¹¹¹ This is, indeed, why commentators and policymakers sometimes confuse the impact of these factors in policy debates concerning access to medicines. For example, intellectual property protection may affect a country's technological base as well as its ability to transfer technology (or its need to acquire technology for promoting economic development). Such transfer, in turn, would affect a country's indigenous capacity to develop and manufacture pharmaceuticals. Meanwhile, an appropriate intellectual property system could help facilitate the transfer of technology from the technology-rich countries to the technology-poor ones.¹¹² Article 66 of the TRIPs Agreement, for example, requires

111. See Abbott, *Managing the Hydra*, *supra* note 80, at 424 (noting that the public health problem in less developed countries "is multi-faceted, and addressing one aspect often reveals new challenges").

112. As Edith Penrose explained:

The strongest argument supporting the proposition that foreign patenting helps to transfer technology, thus assisting economic development, is essentially as follows: much of the technology required for industrial development is patented, and the patents are owned by business corporations in the industrial countries. The disclosure of the technology which is contained in the patent grant and is public knowledge is rarely sufficient to permit its full application without the know-how and the technical help of the patentee. Business firms will not give this know-how and this help in conditions which might rob them of the protection their patents provide and in circumstances where it would be difficult to prove ownership and where consequently anyone could use the technology made available; moreover, "embodied technology," that is, patented machinery, is often obtainable only from firms holding the patents, who may refuse to sell in the absence of patent

developed countries to provide incentives for their businesses and institutions to help create “a sound and viable technological base” in least developed countries by promoting and encouraging transfer of technology.¹¹³ Intellectual property protection may also be essential to the development of generic manufacturers. For example, commentators have attributed the success of the generic drug industry in India to the country’s patent law.¹¹⁴ Although the law did not offer protection to pharmaceutical products until recently, it offered strong protection to processes used in manufacturing pharmaceuticals.¹¹⁵

Moreover, health problems go hand in hand with poverty, which to some extent can be furthered by high drug prices, especially if a significant portion of the population is in need of medical assistance.¹¹⁶ As Geoff Tansey noted:

Three of the Millennium Development Goals directly focus on health—reducing child mortality, improving maternal health, and combating HIV/AIDS, malaria and other diseases. Another goal—to eradicate extreme poverty and hunger—is increasingly affected by the health of the population in many developing countries, especially in rural Africa where HIV/AIDS is devastating farming families and undermining their ability to farm.¹¹⁷

Indeed, “if a sick person has to pay more for a pharmaceutical product as a result of a patent, it means that he or she will have less to spend on other essentials of life such as food or shelter.”¹¹⁸

protection. Thus, the patent becomes a necessary, though naturally not a sufficient, condition for the transfer of technology.

Edith Penrose, *International Patenting and the Less Developed Countries*, 83 *ECON. J.* 768, 771 (1973).

113. TRIPs Agreement, *supra* note 8, art. 66(2).

114. As Peter Drahos noted: “India’s success in building a strong pharmaceutical industry was based in large measure upon its recognition of patents for pharmaceutical processes, but not for pharmaceutical products.” Peter Drahos, *Securing the Future of Intellectual Property: Intellectual Property Owners and Their Nodally Coordinated Enforcement Pyramid*, 36 *CASE W. RES. J. INT’L L.* 53, 76 (2004).

115. Patents Act, No. 39 of 1970; § 5, 27 *INDIA A.I.R. MANUAL* 450 (2d ed. 1979) v.27 (stipulating that “[i]n the case of inventions . . . claiming substances intended for use, or capable of being used, as food or as medicine or drug . . . no patent shall be granted in respect of claims for the substances them selves, but claims for the methods shall be patentable”).

116. See WHO, *THE WORLD HEALTH REPORT 1995: BRIDGING THE GAPS 1* (1995) (“Poverty wields its destructive influence at every stage of human life from the moment of conception to the grave. It conspires with the most deadly and painful diseases to bring a wretched existence to all who suffer from it.”); Spectar, *supra* note 102, at 258 (“It is becoming increasingly apparent that underdevelopment causes AIDS and that AIDS causes underdevelopment.”); Tutu, *supra* note 23, at 254 (“I do not have to tell you that disease causes poverty, and poverty causes disease; it is a horrendous, deadly, unholy symbiosis.”). See generally Spectar, *supra* note 102, for a discussion of the nexus between the global AIDS pandemic and development problems in Africa and showing how AIDS fuels poverty and how, in turn, poverty fuels the spread of AIDS.

117. Geoff Tansey, *Introduction: Legal Fictions and Public Health*, in *NEGOTIATING HEALTH*, *supra* note 15, at 2.

118. IPR COMMISSION REPORT, *supra* note 6, at 36; see also Maskus, *supra* note 31, at 565 (“Poor households may sacrifice medical treatment in favor of other urgent needs.”).

At the macro level, health problems could also lower the productivity of a country—to the point that it will fall behind its trading partners in terms of economic development, technological innovation, industrial progress, and national competitiveness. As Srividhya Ragavan noted in the HIV/AIDS context, “[a]n epidemic increase of AIDS reduced life expectancy and affected labor and economic output, as the younger casualties increase. Consequently, national productivity declined in several developing nations since the loss of labor from the loss of each life affected a proportionate value of output.”¹¹⁹

Thus, although this Article separates the different types of factors that affect the access-to-medicines problem, the factors are, in reality, interrelated and therefore can be both the causes *and* effects of each other. Accordingly, if we are to effectively address the public health crises in less developed countries, it is very important to take a holistic perspective and target each aspect of the problem, because efforts that succeed in addressing one aspect may alleviate the impact of the others. To do so, countries need to have considerable policy space to tailor their intellectual property systems not only to IP-relevant conditions, but also to IP-related and IP-irrelevant ones. Although correcting the imbalance in the intellectual property system is, by no means, a panacea, a failure to make such correction will certainly perpetuate, or even exacerbate, the existing access-to-medicines problem in light of the complex relationship.

II. THE ENCLOSURE OF POLICY SPACE

When intellectual property protection is criticized for its ill effects on public health, critics have always described the intellectual property system as if it were a single, uniform system. However, such a description cannot be more inaccurate. There are, indeed, many different types of intellectual property systems. A system that is effective in a rich country may not work well for a poor country. Likewise, a system that works well for a predominantly agricultural economy may be unsuitable for a high-technology economy.

For rhetorical effects, this Article uses the labels “rich-country” and “poor-country” to denote the different types of intellectual property systems needed by developed and less developed countries, as well as to underscore the interrelatedness of the IP-relevant, IP-related, and IP-irrelevant factors. Despite the labels, it is important to bear in mind that there is a wide spectrum of intellectual property systems, which range from no protection in any sector on the one end to very strong protection in all technological fields on the other, with varying protection in varying fields in between.¹²⁰

119. Ragavan, *Jekyll and Hyde Story*, *supra* note 79, at 821 (footnotes omitted); see also WHO, THE WORLD HEALTH REPORT 1999: MAKING A DIFFERENCE 49 (1999) (“[Malaria] causes widespread premature death and suffering, imposes financial hardship on poor households, and holds back economic growth and improvements in living standards.”).

120. See sources cited in Peter K. Yu, *From Pirates to Partners: Protecting Intellectual Property in China in the Twenty-First Century*, 50 AM. U. L. REV. 131, 233 n.502 (2000) [hereinafter Yu, *From Pirates to Partners I*].

It is also important to remember that, like the self-selected designations in the TRIPs Agreement of “developing country” and “least developed country,”¹²¹ there are many levels of economic development and gradations of poverty. Although both Burkina Faso and India are described as “less developed countries” in this Article, they face very different problems and have different amounts of resources for addressing their problems. In fact, two commentators recently proposed an index to illustrate how the U.N. classification of developed, developing, and least developed countries “is an inappropriate basis for achieving an equitable balance between the rights of patent owners and users.”¹²² As they explained, “The U.N. classification, based solely on per capita income, was developed for giving economic aid. It was not meant for handling a complex issue such as HIV/AIDS, which encompasses epidemiological issues (such as incidence of infection in the population).”¹²³

Although in theory countries need different systems due to their varying economic, social, cultural, and technological conditions, in practice they may not be able to adopt a particular system even if that system would best suit their interests and local conditions. Whether they can do so will depend on whether they have sufficient policy space. With the establishment of the TRIPs Agreement and the proliferation of bilateral and regional trade agreements, the policy space for countries to maneuver their intellectual property policy has been very limited. As a result, less developed countries sometimes have to implement a rich-country intellectual property system despite their limited economic development and technological capabilities.

A. Pre-Enclosure

When the Paris Convention for the Protection of Industrial Property (“Paris Convention”) was established,¹²⁴ countries disagreed significantly over such issues as compulsory licenses, parallel importation, working requirements, and filing systems.¹²⁵ Some countries, like the Netherlands and Switzerland, did not even have a patent system,¹²⁶ while others, like Germany, remained heavily influenced by the anti-patent

121. For discussions of these designations, see generally Guglielmo Verdirame, *The Definition of Developing Countries Under GATT and Other International Law*, 39 GERMAN Y.B. INT’L L. 164 (1996); WTO, Who Are the Developing Countries in the WTO?, http://www.wto.org/english/tratop_e/devel_e/d1who_e.htm (last visited Mar. 8, 2006).

122. Bradly Condon & Tapen Sinha, *Global Diseases, Global Patents and Differential Treatment in WTO Law: Criteria for Suspending Patent Obligations in Developing Countries*, 26 NW. J. INT’L L. & BUS. 1, 41 (2005).

123. *Id.*

124. Paris Convention for the Protection of Industrial Property, Mar. 20, 1883, revised at *Stockholm* July 14, 1967, 21 U.S.T. 1583, 828 U.N.T.S. 306 [hereinafter Paris Convention]. The Paris Convention is the first international industrial property regime covering patents, trademarks, industrial designs, and other forms of unfair competition.

125. For a discussion of the different permissible standards under the Paris Convention, see generally G.H.C. BODENHAUSEN, *GUIDE TO THE APPLICATION OF THE PARIS CONVENTION FOR THE PROTECTION OF INDUSTRIAL PROPERTY* (1968).

126. Although the Netherlands enacted patent law in 1817, it repealed the law in 1869. Fritz Machlup & Edith Penrose, *The Patent Controversy in the Nineteenth Century*, 10 J. ECON. HIST. 1, 3, 5 (1950). For a discussion of the Netherlands and Switzerland during the time when they did not have a patent system while nearly all other industrialized countries had such a system in

movement.¹²⁷ To enable countries to coordinate patent protection at the international level, the Paris Convention struck a compromise by allowing each country to decide how it protects patents within its borders.¹²⁸ Instead of creating a uniform system, the Convention embraced the anti-discrimination principle of national treatment and left considerable room for countries to experiment with different patent systems.¹²⁹

For example, countries could decide whether they wanted to include a local working requirement or a compulsory licensing provision.¹³⁰ They could explore whether the protection of patents in processes provided sufficient incentives or whether they also needed to extend protection to products. They could even determine whether they wanted to protect patents in the first place. In the case of the Netherlands and Switzerland, for example, the contracting members of the Paris Convention allowed them to join the Convention without even implementing patent protection.¹³¹ Eventually, Switzerland introduced patent protection in 1888,¹³² and the Netherlands followed suit in 1910.¹³³

Although the Paris Convention worked well for developed country members for decades, the decolonization effort and the subsequent emergence of less developed countries have called into question the extent of protection in the international intellectual property regime. While there was initial disagreement among member states over the extent of harmonization,¹³⁴ such disagreements gave way to those

place, see generally ERIC SCHIFF, *INDUSTRIALIZATION WITHOUT NATIONAL PATENTS* (1971).

127. Peter K. Yu, *Currents and Crosscurrents in the International Intellectual Property Regime*, 38 *LOY. L.A. L. REV.* 323, 349 (2004) [hereinafter Yu, *Currents and Crosscurrents*]. For discussions of the anti-patent movement, see generally Heinrich Kronstein & Irene Till, *A Reevaluation of the International Patent Convention*, 12 *LAW & CONTEMP. PROBS.* 765 (1947); Machlup & Penrose, *supra* note 126.

128. Roffe, *supra* note 31, at 9 (“The local exploitation of patents—and subsequently the granting of compulsory licenses—was conceived, at the time of the Paris Convention, as the balancing element and the compromise to appease the European anti-patent sentiments of the 19th century.”). The original Paris Convention is excerpted in EDITH TILTON PENROSE, *THE ECONOMICS OF THE INTERNATIONAL PATENT SYSTEM* 56–57 (1951).

129. See Paris Convention, *supra* note 124, art. 2 (providing for the national treatment of foreign rights holders).

130. See STEPHEN P. LADAS, *PATENTS, TRADEMARKS, AND RELATED RIGHTS: NATIONAL AND INTERNATIONAL PROTECTION* 9–16 (1975) (discussing the “laboratory effects” of legal innovation); Sungjoon Cho, *A Bridge Too Far: The Fall of the Fifth WTO Ministerial Conference in Cancun and the Future of Trade Constitution*, 7 *J. INT’L ECON. L.* 219, 238 (2004) (discussing the “laboratory effect” of regionalism, which allows countries to experience trial and error and learning-by-doing at the regional level); John F. Duffy, *Harmony and Diversity in Global Patent Law*, 17 *BERKELEY TECH. L.J.* 685, 707–08 (2002) (discussing how countries can develop legal systems by experimenting with new regulatory and economic policies through interjurisdictional competition).

131. See Yu, *Currents and Crosscurrents*, *supra* note 127, at 351–52. Nevertheless, it is important to note that both countries had trademark laws in place, and such protection might have justified their membership in the Paris Convention. See SCHIFF, *supra* note 126, at 22.

132. PENROSE, *supra* note 128, at 123–24. Commentators have disagreed as to whether 1888 or 1907 should be regarded as the year in which the Swiss patent system began. See SCHIFF, *supra* note 126, at 85–86.

133. Machlup & Penrose, *supra* note 126, at 6.

134. The members of the original Paris Convention included Belgium, Brazil, Ecuador, France, Great Britain and Ireland, Guatemala, Italy, the Netherlands, Portugal, Salvador, Serbia,

between the existing and new members of the Paris Convention. In the mid-1970s, less developed countries began to demand a revision of the Paris Convention to lower the minimum standards of intellectual property protection as applied to them and to expand compulsory licenses available under the Convention.¹³⁵ Meanwhile, the United States objected vehemently to those demands, thus precipitating the famous stalemate between developed and less developed countries in the 1981 Diplomatic Conference in Nairobi.¹³⁶

B. TRIPs Enclosure

In response to this stalemate, developed countries, led by the United States and influenced by multinational corporations,¹³⁷ abandoned the intellectual property-based forum in the mid-1980s in favor of the General Agreement on Tariffs and Trade (GATT),¹³⁸ a trade-based forum which eventually became the WTO. After negotiations for close to a decade, countries finally agreed to the Marrakesh Agreement Establishing the World Trade Organization,¹³⁹ which included in its annex an intellectual property-related multilateral agreement known as the TRIPs Agreement.¹⁴⁰ To the benefit of the pharmaceutical industry, which lobbied heavily for stronger international intellectual property protection,¹⁴¹ the TRIPs Agreement remade the

Spain, Switzerland, and Tunis. Yu, *Currents and Crosscurrents*, *supra* note 127, at 351. Ecuador denounced the Convention a year after the Convention went into effect in 1884, and the United States ratified the Convention in 1887. *Id.* Interestingly, these members were at very different stages of industrial development. As Friedrich-Karl Beier pointed out:

It is interesting to note that of the 14 signatory states, the large majority were only at the beginning of their industrial development, including such countries as Brazil, Ecuador, Guatemala, Salvador, Serbia, and Tunisia. Thus, the Paris Convention was not conceived and agreed upon as a protective instrument for industrialized countries. It included from the beginning countries in various stages of technological, economic and legal development. Of the original signers of the Paris Convention, only England, France and—to some extent—Switzerland were industrially developed. The majority of the other more developed nations, the United States, Japan, Germany and Austria were initially skeptical as to the benefits of the Paris Convention and only joined it later; the United States in 1887, Japan in 1899, Germany in 1903 and the Austro-Hungarian Empire in 1909.

Friedrich-Karl Beier, *One Hundred Years of International Cooperation—The Role of the Paris Convention in the Past, Present and Future*, 15 INT'L REV. INDUS. PROP. & COPYRIGHT L. 1, 3–4 (1984).

135. Yu, *Currents and Crosscurrents*, *supra* note 127, at 357.

136. *See id.*

137. *See generally* SUSAN K. SELL, PRIVATE POWER, PUBLIC LAW: THE GLOBALIZATION OF INTELLECTUAL PROPERTY RIGHTS (2003) (discussing how multinational corporations have lobbied in both the United States and the European Communities for the creation of the TRIPs Agreement).

138. *See* Yu, *Currents and Crosscurrents*, *supra* note 127, at 357–58 (discussing the shifting of negotiations in the intellectual property area by developed countries from the World Intellectual Property Organization forum to the WTO forum).

139. Marrakesh Agreement, *supra* note 8.

140. TRIPs Agreement, *supra* note 8.

141. *See* SELL, *supra* note 137, at 47–48. An important indicator of the success of these lobbying efforts was the Advisory Committee for Trade Negotiations (ACTN), which was

international intellectual property rules based on the rich-country model and modified the system in four significant ways.

First, “[i]t introduced the concept of non-discrimination in all fields of technology for patent applications.”¹⁴² Article 27 states explicitly that patents need to “be available for any inventions, *whether products or processes, in all fields of technology*, provided that they are new, involve an inventive step and are capable of industrial application.”¹⁴³ It further stipulates that “patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.”¹⁴⁴ This provision is important because many less developed countries had, until the establishment of the TRIPs Agreement, offered protection only to the processes of manufacturing pharmaceuticals, but not to pharmaceutical products. As one commentator recalled:

A study published by the United Nations in 1975 found that many developing and developed countries excluded pharmaceutical products as patentable inventions. At that time, the list covered most of the developing world as well as the Soviet Union and the former socialist countries of Eastern Europe. Austria, Canada, Italy, Japan, Spain and Switzerland were also in the same category and Italy and Japan even excluded pharmaceutical processes from patent protection.¹⁴⁵

To allow member states time and resources to develop their patent system, the Agreement provided a transitional period of four years for developing countries and initially a period of ten years for least developed countries.¹⁴⁶ (The transitional period for least developed countries has recently been extended to seventeen and a half years for most products.)¹⁴⁷ In addition, the Agreement allowed those countries that had yet to offer patent protection for pharmaceutical products to introduce such protection no later than January 1, 2005.¹⁴⁸ To make up for the lack of protection, the Agreement required these countries to set up a mailbox system to collect applications that were filed before the introduction of patent protection¹⁴⁹ and to offer exclusive marketing rights for five years from the date of marketing approval or until the time when the patent was either granted or denied.¹⁵⁰

Although the Doha Round extended the deadline for least developed countries to offer protection for pharmaceuticals to 2016,¹⁵¹ the compliance deadline for developing countries, like Argentina, Brazil, India, South Africa, and Thailand,

constituted by the Executive Branch to solicit private sector views on trade policy. The committee was chaired by none other than Edmund Pratt of Pfizer. *Id.* at 48.

142. Roffe, *supra* note 31, at 9.

143. TRIPs Agreement, *supra* note 8, art. 27(1) (emphasis added).

144. *Id.*

145. Roffe, *supra* note 31, at 13 (citing UNITED NATIONS, THE ROLE OF THE PATENT SYSTEM IN THE TRANSFER OF TECHNOLOGY TO DEVELOPING COUNTRIES (1975)); *see also* Scherer, *The Pharmaceutical Industry*, *supra* note 34, at 2247–48 (“Even Switzerland, home to three of the world’s leading pharmaceutical companies, abstained until 1977 from granting drug product patents.”).

146. TRIPs Agreement, *supra* note 8, arts. 65–66.

147. *See supra* note 12 and accompanying text.

148. *See* TRIPs Agreement, *supra* note 8, art. 65(4).

149. *Id.* art. 70(8)(a).

150. *Id.* art. 70(9).

151. Doha Declaration, *supra* note 13, ¶ 7.

remains the same. Because these countries, along with China, are the main providers to other less developed countries of generic drugs and related ingredients, the expiry of the transitional period for developing countries is likely to result in an increase in the prices of new medicines and a corresponding decrease in access.¹⁵² By taking away the domestic market needed to make it profitable to develop a generic drug industry, the end of this transitional period could also dry up the sources of generic medicines, even though the recently proposed amendment to the TRIPs Agreement allows member states to export generic medicines to other countries lacking sufficient manufacturing capacity.

Second, the TRIPs Agreement includes a set of complex procedural rules delineating the conditions under which a country can issue a compulsory license¹⁵³ — or, in TRIPs terms, “[the] use [of the patent] without authorization of the right holder.”¹⁵⁴ Article 31(b), for example, states that a compulsory license may not be issued unless “the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time.”¹⁵⁵ Member states are allowed to waive the “reasonable commercial efforts” requirement “in the case of a national emergency or other circumstances of extreme urgency or in cases of public noncommercial use.”¹⁵⁶ Article 31(c) states that “the scope and duration of [the license] shall be limited to the purpose for which it was authorized.”¹⁵⁷ Articles 31(d), (e), and (f) require that such uses be “non-exclusive,”¹⁵⁸ “non-assignable,”¹⁵⁹ and “authorized predominantly for the supply of the domestic market of the Member authorizing such use.”¹⁶⁰ Articles 31(g) and (h) further provide that such uses “be

152. See Timmermans, *supra* note 24, at 41–42; see also IPR COMMISSION REPORT, *supra* note 6, at 35 (“The existence of patents in potential supplier countries may allow the patentee to prevent supplies being exported to another country, particularly through controls on distribution channels.”).

153. See Roffe, *supra* note 31, at 9.

154. TRIPs Agreement, *supra* note 8, art. 31.

155. *Id.* art. 31(b).

156. *Id.*

157. *Id.* art. 31(c).

158. *Id.* art. 31(d).

159. *Id.* art. 31(e).

160. *Id.* art. 31(f). Although the word “predominantly” is undefined in the TRIPs Agreement, commentators have noted that Article 31(f) also allows countries to authorize “export of a ‘non-predominant’ part of the production.” Frederick M. Abbott, *The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health*, 99 AM. J. INT’L L. 317, 319 (2005) [hereinafter Abbott, *WTO Medicines Decision*]; accord Scherer & Watal, *supra* note 75, at 29 (“The ‘predominantly’ term in Article 31(f) clearly implies that some exportation under compulsory license in the exporting nation will be allowed.”). Even the European Communities conceded, in their proposal for a permanent Paragraph 6 solution, that Article 31(f) “does . . . allow a non-prcdominant part of the products concerned to be destined to supply foreign markets (except under the circumstances addressed by Article 31(k)).” Communication from the European Communities and Their Member States, *Paragraph 6 of the Doha Declaration of the TRIPS Agreement and Public Health*, ¶ 3, IP/C/W/352 (June 20, 2002) [hereinafter EC Proposal]. Meanwhile, the African Group has proposed to interpret Article 31(f) “to mean that up to 49.9 percent of the production can be exported.” African Group Proposal, *supra* note 14, ¶ 6(d).

terminated if and when the circumstances which led to it cease to exist and are unlikely to recur"¹⁶¹ and that "the right holder . . . be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization."¹⁶² Finally, "any decision relating to the remuneration provided in respect of [the license] shall be subject to judicial review or other independent review."¹⁶³

Third, the TRIPs Agreement planted the seed for the protection of undisclosed information, which has not been covered by any previous multilateral agreement.¹⁶⁴ Article 39(3) specifically provides:

Members, 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.¹⁶⁵

Although the pharmaceutical industry has been pushing for a much broader interpretation,¹⁶⁶ commentators have suggested that the meaning of "unfair commercial use" under this provision should be interpreted in a similar fashion as in trade secret law.¹⁶⁷ As Jerome Reichman pointed out, such an interpretation "follows from the fact that the drafters of Article 39.3 expressly linked it to Article 10*bis* of the Paris Convention and thus to the duty it imposes to avoid any 'act of competition contrary to honest practices in industrial or commercial matters.'"¹⁶⁸ Commentators have also

161. TRIPs Agreement, *supra* note 8, art. 31(g).

162. *Id.* art. 31(h).

163. *Id.* art. 31(j).

164. JAYASHREE WATAL, INTELLECTUAL PROPERTY RIGHTS IN THE WTO AND DEVELOPING COUNTRIES 4 (2001) (noting that undisclosed information "has never been the subject of any multilateral agreement before").

165. TRIPs Agreement, *supra* note 8, art. 39(3).

166. IFPMA, A REVIEW OF EXISTING DATA EXCLUSIVITY LEGISLATION IN SELECTED COUNTRIES (4th rev. ed. 2005), http://www.ifpma.org/documents/NR2306/DataExclusivity_JAN05_revised.doc [hereinafter IFPMA REVIEW].

167. See Jerome H. Reichman, *The International Legal Status of Undisclosed Clinical Trial Data: From Private to Public Goods*, in NEGOTIATING HEALTH, *supra* note 15, at 133, 141–42 [hereinafter Reichman, *International Legal Status*] ("[T]he meaning of 'unfair commercial use' will depend upon the kind of practices that domestic and foreign trade secret laws have traditionally regarded as unfair."); see also IPR COMMISSION REPORT, *supra* note 6, at 50 ("TRIPs does not require the imposition of data exclusivity, as such, on these test data, only protection against unfair commercial use."); Carlos María Correa, *Unfair Competition Under the TRIPs Agreement: Protection of Data Submitted for the Registration of Pharmaceuticals*, 3 CHI. J. INT'L L. 69, 71 (2002) [hereinafter Correa, *Unfair Competition Under the TRIPs Agreement*] ("At the time the TRIPs Agreement was concluded, few countries had adopted the exclusivity approach developed in the United States and Europe.").

168. Reichman, *International Legal Status*, *supra* note 167, at 142 (quoting Paris Convention, *supra* note 124, art. 10*bis*(2)); see also Correa, *Unfair Competition Under the TRIPs Agreement*, *supra* note 167, at 75–76 ("Even if it may be argued that free riding or unfair

highlighted the additional requirement that the affected pharmaceutical or agricultural chemical products “utilize new chemical entities.”¹⁶⁹

Fourth, the TRIPs Agreement requires that the mandatory dispute settlement process of the WTO be used to settle all disputes arising under the Agreement.¹⁷⁰ Although the dispute resolution provision does not focus specifically on pharmaceuticals or patent protection, it improves the enforceability of international intellectual property laws and provides countries with substantial exports of pharmaceutical products a means to induce other trading partners to protect their products. It is, therefore, no surprise that the first intellectual property dispute to reach the WTO Dispute Settlement Body concerned the United States’ challenge to the noncompliance of India’s patent system with respect to its lack of a mailbox system as required by Article 70(8) of the TRIPs Agreement.¹⁷¹

Indeed, many commentators have considered the dispute settlement process a crowning achievement of the Uruguay Round.¹⁷² Ironically, although the process was primarily used by developed countries in the first few years of its establishment, less developed countries have recently begun to use the process more frequently.¹⁷³ Despite their growing use of the process, the latter have had only very limited success in getting developed countries to amend their laws.¹⁷⁴ Some commentators, as a result, have begun to question the effectiveness of the WTO dispute settlement process.¹⁷⁵

use of such data by third parties may create unfair advantages or unjust enrichment, it is not the role of an intellectual property system to solve competition problems that do not relate to the creation or use of ideas.”).

169. Correa, *Unfair Competition Under the TRIPS Agreement*, *supra* note 167, at 74–75 (discussing “new chemical entity” as an important condition for the application of Article 39(3) of the TRIPs Agreement).

170. See TRIPs Agreement, *supra* note 8, art. 64.

171. Panel Report, *India—Patent Protection for Pharmaceutical and Agricultural Chemical Products*, WT/DS50/R (Sept. 5, 1997) [hereinafter *India Mailbox Panel Report*].

172. See William J. Davey, *The WTO Dispute Settlement System: The First Ten Years*, 8 J. INT’L ECON. L. 17, 32 (2005) (“Dispute settlement is one of the great successes of the WTO.”); Rochelle Cooper Dreyfuss & Andreas F. Lowenfeld, *Two Achievements of the Uruguay Round: Putting TRIPS and Dispute Settlement Together*, 37 VA. J. INT’L L. 275 (1997) (noting that the two achievements of the Uruguay Round are, as the title suggests, “Putting TRIPS and Dispute Settlement Together”); Ruth Okediji, *Toward an International Fair Use Doctrine*, 39 COLUM. J. TRANSNAT’L L. 75, 149–50 (2000) (“One of the most celebrated accomplishments of the WTO system is the dispute resolution mechanism which adds legitimacy to the overall design of the new trading system.” (footnote omitted)).

173. See Davey, *supra* note 172, at 17 (“The first half of [the first ten years of operation of the WTO dispute settlement process]—from 1995 through 1999—was characterized by extensive use of the system by the United States initially, and later by the EU.”); *id.* at 24 (noting that “the US and the EC no longer were as dominant as complainants in the system” and that “developing country use of the system increased dramatically” in the second half of the first decade of operation of the WTO dispute settlement process).

174. See Yu, *From Pirates to Partners II*, *supra* note 53, at 939–40 (discussing the United States’ failure to amend laws despite adverse decisions before the WTO Dispute Settlement Body).

175. See, e.g., Benvenisti & Downs, *supra* note 28, at 21 (“[T]ribunals are institutionally inclined to level the playing field among states, but because their power and prestige depends on the extent to which their decisions are followed by powerful states, this entrepreneurial bent is inevitably held in check to some degree.”).

C. TRIPs Flexibilities

While the TRIPs Agreement required stronger protection of pharmaceuticals, many countries remained reluctant to introduce such protection until the implementation deadline. Consider India, for example. Following its loss in the WTO dispute settlement process, India introduced a “mailbox” system collecting patent applications that had been filed since the inception of the TRIPs Agreement and exclusive marketing rights pursuant to Article 70(9) of the Agreement.¹⁷⁶ However, the country did not strengthen the patent protection of pharmaceutical products (as compared to pharmaceutical processes) until it introduced a new patent law shortly before the January 1, 2005, deadline.¹⁷⁷ While this law, no doubt, will have a major impact on the development and availability of cheap, generic drugs and related ingredients, it includes specific provisions to allow generic manufacturers to continue selling drugs that are already developed by paying reasonable royalties to the patent holders.¹⁷⁸ The law also “limit[s] the granting of patents on minor improvements to existing products in a provision addressing new forms of the same substance and new uses of known substances.”¹⁷⁹

Moreover, the TRIPs Agreement did not foreclose all the policy space available to less developed countries under the Paris Convention. To balance the heightened protection the Agreement requires, Articles 7 and 8, along with the preamble, include various public interest safeguards. For example, Article 7 states explicitly that “[t]he 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.”¹⁸⁰ Article 8 recognizes the needs of member states to “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.”¹⁸¹ As Jerome Reichman suggested, these safeguards, taken together, may provide “a basis for seeking waivers to meet unforeseen conditions of hardship.”¹⁸²

Indeed, the WTO dispute settlement panel considered Articles 7 and 8 very favorably in *Canada—Patent Protection of Pharmaceutical Products*, in which the

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

177. The Patents (Amendment) Act, 2005, No. 15, Acts of Parliament, 2005, available at http://www.ipindia.nic.in/ipr/patent/patent_2005.PDF; see Abbott, *Cycle of Action*, *supra* note 15, at 27 (noting that India did not introduce pharmaceutical product patent protection until the beginning of 2005); see also Srividhya Ragavan, *Of the Inequals of the Uruguay Round*, 10 MARQ. INTELL. PROP. L. REV. 273, 281 (2006) (discussing recent changes in the Indian patent regime).

178. Abbott, *Cycle of Action*, *supra* note 15, at 27.

179. *Id.* at 27–28.

180. TRIPs Agreement, *supra* note 8, art. 7.

181. *Id.* art. 8(1).

182. J.H. Reichman, *The TRIPs Agreement Comes of Age: Conflict or Cooperation with the Developing Countries*, 32 CASE W. RES. J. INT’L L. 441, 461 (2000) (footnote omitted).

European Communities challenged the regulatory review and stockpiling exceptions in the Canadian patent law for violation of the TRIPs Agreement.¹⁸³ Although the panel agreed with the European Communities that “the three limiting conditions attached to Article 30 testify strongly that the negotiators of the Agreement did not intend Article 30 to bring about what would be equivalent to a renegotiation of the basic balance of the Agreement,” it maintained that “the specific meaning given to [those] limiting conditions . . . must be examined with particular care [in light of] . . . the goals and the limitations stated in Articles 7 and 8.1.”¹⁸⁴

In addition, the TRIPs Agreement includes many “flexibilities” that countries built into its intentionally ambiguous provisions during the negotiation process. As Jayashree Watal noted, the “constructive ambiguities”¹⁸⁵ inherent in these provisions might further provide less developed countries with a bulwark against the continuous expansion of intellectual property rights and might even enable them to “‘claw[]’ back much of what was lost in the negotiating battles in TRIPS.”¹⁸⁶ These flexibilities are important, because less developed countries, through careful interpretation of the ambiguous provisions, may be able to push for language that meets their needs while preserving the policy space appropriately reserved to them during the negotiation process.

Article I of the TRIPs Agreement states specifically that member states are “free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.”¹⁸⁷ As Frederick Abbott highlighted, this freedom includes at least the following flexibilities:

The TRIPS Agreement . . . does not . . . restrict the authority of governments to regulate prices. It . . . permits [compulsory or government use licenses] to be granted. It permits governments to authorize parallel importation. The TRIPS Agreement does not specify that new-use patents must be granted. It allows patents to be used for regulatory approval purposes, and it does not require the extension of patent terms to offset regulatory approval periods. The TRIPS Agreement provides a limited form of protection for submissions of regulatory data; but this protection does not prevent a generic producer from making use of publicly

183. Panel Report, *Canada—Patent Protection of Pharmaceutical Products*, § 7.26, at 154, WT/DS114/R (Mar. 17, 2000).

184. As the Panel stated in full:

In the Panel’s view, Article 30’s very existence amounts to a recognition that the definition of patent rights contained in Article 28 would need certain adjustments. On the other hand, the three limiting conditions attached to Article 30 testify strongly that the negotiators of the Agreement did not intend Article 30 to bring about what would be equivalent to a renegotiation of the basic balance of the Agreement. Obviously, the exact scope of Article 30’s authority will depend on the specific meaning given to its limiting conditions. The words of those conditions must be examined with particular care on this point. Both the goals and the limitations stated in Articles 7 and 8.1 must obviously be borne in mind when doing so as well as those of other provisions of the TRIPS Agreement which indicate its object and purposes.

Id.

185. WATAL, *supra* note 164, at 7.

186. *Id.*

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

available information to generate bioequivalence test data. The TRIPS Agreement provides substantial discretion for the application of competition laws.¹⁸⁸

Finally, policymakers, commentators, and nongovernmental organizations have also begun to explore the potentially conflicting obligations of less developed countries under the human rights treaties,¹⁸⁹ such as the Universal Declaration of Human Rights,¹⁹⁰ the International Covenant on Civil and Political Rights,¹⁹¹ and the International Covenant on Economic, Social and Cultural Rights (ICESCR).¹⁹² They argue that human rights obligations will provide the “maximum limits” of intellectual property protection.¹⁹³

In recent years, human rights organizations have been particularly sympathetic to the inability of less developed countries to afford protection for patented pharmaceuticals in light of the massive HIV/AIDS crises within their borders. In August 2000, for example, the United Nations Sub-Commission on the Protection and Promotion of Human Rights adopted Resolution 2000/7 on “Intellectual Property Rights and Human Rights,” which stated that “actual or potential conflicts exist between the implementation of the TRIPS Agreement and the realization of economic, social and cultural rights.”¹⁹⁴ In June 2001, the United Nations Commission on Human Rights further explored the relationship between human rights and intellectual property rights, noting, in particular, that access to medicines is a human right and that the

188. Abbott, *Cycle of Action*, *supra* note 15, at 30 (citations omitted).

189. See, e.g., Paul L.C. Torremans, *Copyright as a Human Right*, in COPYRIGHT AND HUMAN RIGHTS 1 (Paul L.C. Torremans ed., 2004); Laurence R. Helfer, *Toward a Human Rights Framework for Intellectual Property*, 40 U.C. DAVIS L. REV. 971 (2007) [hereinafter Helfer, *Toward a Human Rights Framework*]; Peter K. Yu, *Reconceptualizing Intellectual Property Interests in a Human Rights Framework*, 40 U.C. DAVIS L. REV. 1039 (2007) [hereinafter Yu, *Reconceptualizing Intellectual Property Interests*].

190. Universal Declaration of Human Rights, G.A. Res. 217A (III), U.N. Doc. A/810 (Dec. 10, 1948).

191. International Covenant on Civil and Political Rights, *opened for signature* Dec. 16, 1966, 999 U.N.T.S. 171 (1976) (entered into force Mar. 23, 1976).

192. International Covenant on Economic, Social and Cultural Rights, *opened for signature* Dec. 16, 1966, 993 U.N.T.S. 3 (entered into force Jan. 3, 1976).

193. See, e.g., Dreyfuss, *TRIPS—Round II*, *supra* note 2, at 27 (“[T]he WTO system must begin to recognize substantive maxima on the scope of available protection”); Laurence R. Helfer, *Human Rights and Intellectual Property: Conflict or Coexistence?*, 5 MINN. INTELL. PROP. REV. 47, 58 (2003) (noting the need to articulate “maximum standards of intellectual property protection” because “[t]reaties from Beme to Paris to TRIPS are all concerned with articulating ‘minimum standards’”); Laurence R. Helfer, *Regime Shifting: The TRIPS Agreement and New Dynamics of International Intellectual Property Lawmaking*, 29 YALE J. INT’L L. 1, 58–59 (2004) [hereinafter Helfer, *Regime Shifting*] (discussing how less developed countries can use a strategy of “regime shifting” to develop counterregime norms that set up maximum standards of intellectual property protection); Okediji, *Toward an International Fair Use Doctrine*, *supra* note 172, at 168 (proposing to develop an international fair use doctrine as a “ceiling”); Peter K. Yu, *TRIPS and Its Discontents*, 10 MARQ. INTELL. PROP. L. REV. 369, 402 (2006) (“[T]he international intellectual property regime, to some extent, is handicapped by its lack of maximum standards.”) (emphasis in original).

194. ESCOR Res. 2000/7, U.N. Doc. E/CN.4/Sub.2/RES/2000/7 (Aug. 17, 2000).

TRIPs Agreement should be interpreted with flexibilities to promote such access.¹⁹⁵ Most recently, the Committee on Economic, Social and Cultural Rights (CESCR) stated in its interpretive comment of the ICESCR:

The right of authors to benefit from the protection of the moral and material interests resulting from their scientific, literary and artistic productions cannot be isolated from the other rights recognized in the Covenant. States parties are therefore obliged to strike an adequate balance between their obligations under article 15, paragraph 1 (c), on one hand, and under the other provisions of the Covenant, on the other hand, with a view to promoting and protecting the full range of rights guaranteed in the Covenant. In striking this balance, the private interests of authors should not be unduly favoured and the public interest in enjoying broad access to their productions should be given due consideration. States parties should therefore ensure that their legal or other regimes for the protection of the moral and material interests resulting from one's scientific, literary or artistic productions constitute no impediment to their ability to comply with their core obligations in relation to the rights to food, health and education, as well as to take part in cultural life and to enjoy the benefits of scientific progress and its applications, or any other right enshrined in the Covenant. Ultimately, intellectual property is a social product and has a social function. States parties thus have a duty to prevent unreasonably high costs for access to essential medicines, plant seeds or other means of food production, or for schoolbooks and learning materials, from undermining the rights of large segments of the population to health, food and education.¹⁹⁶

In sum, although the TRIPs Agreement has strengthened intellectual property protection while reducing the policy space of WTO member states, it still has left some space for less developed countries to develop their own intellectual property system. Unfortunately, this limited space is now beginning to disappear as the United States and the European Communities push aggressively for bilateral and regional TRIP-plus trade agreements. Apart from these agreements, the lack of legal expertise and the desperate need for financial assistance also have made it difficult for less developed countries to take advantage of the flexibilities built into the TRIPs Agreement.

D. TRIPs-Plus Enclosure

While less developed countries were examining the flexibilities available under the TRIPs Agreement and promoting their development agenda at the World Intellectual

195. The High Commissioner, *Report of the High Commissioner on Economic, Social and Cultural Rights: The Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights*, ¶ 32, delivered to the Sub-Commission on the Promotion and Protection of Human Rights, U.N. Doc. E/CN.4/Sub.2/2001/13 (June 27, 2001).

196. Comm. on Econ., Soc. & Cultural Rights, *General Comment No. 17: The Right of Everyone to Benefit from the Protection of the Moral and Material Interests Resulting from Any Scientific, Literary or Artistic Production of Which He Is the Author (Art. 15(1)(c))*, ¶ 35, U.N. Doc. E/C.12/GC/17 (Jan. 12, 2006) [hereinafter *General Comment No. 17*], available at [http://www.unhcr.ch/tbs/doc.nsf/898586b1dc7b4043c1256a450044f331/03902145edbbe797c125711500584ea8/\\$FILE/G0640060.pdf](http://www.unhcr.ch/tbs/doc.nsf/898586b1dc7b4043c1256a450044f331/03902145edbbe797c125711500584ea8/$FILE/G0640060.pdf).

Property Organization (WIPO),¹⁹⁷ their developed counterparts were actively exploring ways to increase intellectual property protection without reopening the TRIPs negotiations. Lobbied heavily by the pharmaceutical industry,¹⁹⁸ the United States and the European Communities began to explore the use of bilateral and regional trade agreements to increase protection of pharmaceuticals outside of the TRIPs Agreement.¹⁹⁹ Through these agreements, developed countries sought to reduce the negotiating position and policy space of their less developed counterparts while further aligning intellectual property laws of their trading partners with those of their own.²⁰⁰ Although the United States is not the only country that has aggressively pushed for TRIPs-plus trade agreements, this Article focuses primarily on the United States' actions because of their representativeness for the recent bilateral and regional efforts, their considerable implications for public health, and their differences from similar agreements initiated by the European Communities, which are often filled with more compromises among its members.²⁰¹

Commentators generally describe the bilateral or regional trade agreements as "TRIPs-plus," suggesting that the new agreements require a higher degree of protection than is required under the TRIPs Agreement. However, to properly understand the impact of the different provisions and the needed policy responses, it is important to distinguish among three different types of provisions: "TRIPs-plus," "TRIPs-extra," and "TRIPs-restrictive."²⁰² "TRIPs-plus" provisions increase the commitments of less developed countries by increasing the protection stated in the TRIPs Agreement, which allows member states to "implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the

197. See World Intellectual Prop. Org. [WIPO], Press Release, Member States Agree to Further Examine Proposal on Development (Oct. 4, 2004), http://www.wipo.int/edocs/prdocs/en/2004/wipo_pr_2004_396.html (reporting about the proposal by Argentina and Brazil to "fully incorporate" and "to take immediate action in providing for the incorporation of a "Development Agenda" in the Organization's work program.").

198. See Abbott, *WTO Medicines Decision*, *supra* note 160, at 349–50 ("U.S. PhRMA stands strongly behind [the recent bilateral and regional] efforts.") (citing PhRMA, "SPECIAL 301" SUBMISSION TO THE USTR, app. B (2004)).

199. Yu, *Currents and Crosscurrents*, *supra* note 127, at 392–400.

200. As the Trade Act of 2002 stated:

The principal negotiating objectives of the United States regarding trade-related intellectual property are . . . to further promote adequate and effective protection of intellectual property rights, including through . . . ensuring that the provisions of any multilateral or bilateral trade agreement governing intellectual property rights that is entered into by the United States reflect a standard of protection similar to that found in United States law

19 U.S.C. § 3802(b)(4)(A)(i)(II) (2000).

201. MUSUNGU & OH, *supra* note 12, at ix ("The EU trade policy with respect to intellectual property protection in third countries especially developing countries is more nuanced and a little more favourable to public health in developing countries.").

202. See, e.g., MARISTELA BASSO & EDSON BEAS, EXPLORING OPTIONS AND MODALITIES TO MOVE THE IP DEVELOPMENT AGENDA FORWARD 7 (2005), http://www.iprsonline.org/unctadictsd/bellagio/Bellagio2005/Mbasso_Paper.pdf (discussing "the TRIPs-plus and TRIPs-extra trend"); Carlos M. Correa, Remarks at the Hong Kong Trade and Development Symposium (Dec. 15, 2005) (noting the need to distinguish between "TRIPs-plus" and "TRIPs-extra" provisions).

provisions of this Agreement.”²⁰³ For example, although the TRIPs Agreement requires the protection of patents for only twenty years, recent free trade agreements have required a limited extension of the patent term based on the period during which a product undergoes regulatory review,²⁰⁴ similar to the Hatch-Waxman Act of 1984 in the United States.²⁰⁵

By contrast, “TRIPs-extra” provisions add commitments that are not covered by the TRIPs Agreement. Examples of these provisions are those that call for the establishment of a data-exclusivity regime to protect clinical trial data submitted during the regulatory approval process,²⁰⁶ the linkage of the registration of pharmaceutical products to their patent status,²⁰⁷ and the requirement that patents be granted for “new uses,” or second indications, of known compounds.²⁰⁸ Because Article 6 of the TRIPs Agreement notes that the Agreement does not resolve the exhaustion issue, one can also classify as TRIPs-extra a provision banning parallel importation of cheap, generic

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

204. *See, e.g.*, Central America-Dominican Republic Free Trade Agreement art. 15.9.6, May 28, 2004 [hereinafter CAFTA], *available at* http://www.ustr.gov/assets/Trade_Agreements/Bilateral/CAFTA/CAFTA-DR_Final_Texts/asset_upload_file934_3935.pdf; United States-Australia Free Trade Agreement, U.S.-Austl., art. 17.9.8, May 18, 2004 [hereinafter U.S.-Australia FTA], *available at* http://www.ustr.gov/assets/Trade_Agreements/Bilateral/Australia_FTA/Final_Text/asset_upload_file469_5141.pdf; United States-Singapore Free Trade Agreement, U.S.-Sing., art. 17.9.8, May 6, 2003 [hereinafter U.S.-Singapore FTA], *available at* http://www.ustr.gov/assets/Trade_Agreements/Bilateral/Singapore_FTA/Final_Texts/asset_upload_file708_4036.pdf.

205. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, § 156, 98 Stat. 1585, 1598 (codified as amended at 15 U.S.C. 355 (2000)); *see also* DUTFIELD, *supra* note 35, at 128 (discussing supplementary protection certifications that were used to make up for the time taken to secure marketing authorization in Europe).

206. *See, e.g.*, CAFTA, *supra* note 204, art. 15.10.1; U.S.-Australia FTA, *supra* note 204, art. 17.10.1; U.S.-Singapore FTA, *supra* note 204, art. 16.8.1.

207. *See, e.g.*, CAFTA, *supra* note 204, art. 15.10.2; U.S.-Australia FTA, *supra* note 204, art. 17.10.4; U.S.-Singapore FTA, *supra* note 204, art. 16.8.4; *see generally* Carlos M. Correa, *Bilateralism in Intellectual Property: Defeating the WTO System for Access to Medicines*, 36 CASE W. RES. J. INT’L L. 79, 88–91 (2004) [hereinafter Correa, *Bilateralism in Intellectual Property*]. As Professor Correa noted:

The patent-registration linkage ignores that patents are private rights, as stated in the Preamble of the TRIPs Agreement, and that, whether a given product infringes or not, a patent is a legal matter entirely separate from the technical issues concerning safety and efficacy of drugs. Health authorities have no knowledge or experience whatsoever to assess the claims of a patent.

Id. at 89. Professor Correa also criticizes the patent registration linkage for “creat[ing] a presumption of validity of pharmaceutical product patents which health authorities are neither empowered nor have the capacity to challenge.” *Id.* at 91.

208. *See, e.g.*, U.S.-Australia FTA, *supra* note 204, art. 17.9.1; U.S.-Bahrain Free Trade Agreement, U.S.-Bahr., art. 14.8.2, Sept. 14, 2004, *available at* http://www.ustr.gov/assets/Trade_Agreements/Bilateral/Bahrain_FTA/final_texts/asset_upload_file211_6293.pdf. *Cf.* Abbott, *Cycle of Action*, *supra* note 15, at 30 (“The TRIPs Agreement does not specify that new-use patents must be granted.”); Correa, *Bilateralism in Intellectual Property*, *supra* note 207, at 82 (“[WTO m]embers have considerable discretion in defining this concept, which excludes second indications, new formulations, or dosage forms.”).

drugs.²⁰⁹ Similarly, one can consider as TRIPs-extra a provision allowing the contracting parties to resolve their dispute in a forum other than the mandatory WTO dispute settlement process.²¹⁰ As the coverage of intellectual property laws continues to expand,²¹¹ TRIPs-extra provisions are likely to be found in many free trade agreements.

From the standpoint of dispute resolution, these TRIPs-extra provisions are also likely to be very important, as the WTO rules do not require disputes arising under these provisions to be settled by the mandatory WTO dispute settlement process. In fact, the existence of these provisions has helped rejuvenate the United States Trade Representative's section 301 process.²¹² In *United States—Sections 301–310 of the Trade Act of 1974*, the WTO Dispute Settlement Panel stated that WTO member states are prohibited from taking retaliatory measures before they have exhausted all of the actions permissible under the rules.²¹³ That panel decision, however, does not affect provisions that lie outside of the WTO agreement, including the TRIPs-extra provisions.

Finally, "TRIPs-restrictive" provisions are those that neither increase the protection under the TRIPs Agreement nor cover a new area outside of the Agreement. They are important to the current analysis, because they limit the policy choices of less developed countries by restricting how they interpret the Agreement. Usually, such TRIPs-restrictive provisions take away the flexibilities less developed countries had obtained during the TRIPs negotiations, although a bilateral or regional agreement arguably could help foster a common position concerning the interpretation of the Agreement.²¹⁴ A textbook example of a TRIPs-restrictive provision initiated by developed countries is one that requires less developed countries to introduce the 1991 Act of the International Union for the Protection of New Varieties of Plants²¹⁵ (UPOV) to protect plant varieties.²¹⁶ The TRIPs Agreement, by contrast, provides flexibility for member states to decide whether they want to do so "by patents or by an effective *sui*

209. See, e.g., U.S.-Australia FTA, *supra* note 204, art. 17.9.4; U.S.-Morocco Free Trade Agreement, U.S.-Morocco, art. 15.9, June 15, 2004, available at http://www.ustr.gov/assets/Trade_Agreements/Bilateral/Morocco_FTA/Final_Text/asset_upload_file797_3849.pdf.

210. For a discussion of the choice-of-forum provisions in the bilateral and regional free trade agreements initiated by the United States, see generally PETER DRAHOS, *THE BILATERAL WEB OF TRADE DISPUTE SETTLEMENT* (2005), [http://www.twinside.org.sg/title2/FTAs/Dispute Resolution/TheBilateralWebOfTradeDisputeSettlementPeterDrahos.doc](http://www.twinside.org.sg/title2/FTAs/Dispute%20Resolution/TheBilateralWebOfTradeDisputeSettlementPeterDrahos.doc).

211. See Peter K. Yu, *Intellectual Property and the Information Ecosystem*, 2005 MICH. ST. L. REV. 1, 5 [hereinafter Yu, *Intellectual Property and the Information Ecosystem*] (discussing the expansion of categories of intellectual property rights).

212. For discussion of the section 301 process, see Yu, *From Pirates to Partners I*, *supra* note 120, at 138–40.

213. Panel Report, *United States—Sections 301–310 of the Trade Act of 1974*, WT/DS152/R (Dec. 22, 1999).

214. See SISULE F. MUSUNGU, SUSAN VILLANUEVA & ROXANA BLASETTI, *UTILIZING TRIPS FLEXIBILITIES FOR PUBLIC HEALTH PROTECTION THROUGH SOUTH-SOUTH REGIONAL FRAMEWORKS* 13, 20 (2004), <http://mednet2.who.int/tbs/global/s4968e.pdf>.

215. International Convention for the Protection of New Varieties of Plants, Dec. 2, 1961, 33 U.S.T. 2703, 815 U.N.T.S. 89 (amended Mar. 19, 1991).

216. See, e.g., CAFTA, *supra* note 204, art. 15.1.5(a); U.S.-Australia FTA, *supra* note 204, art. 17.1.2(e); U.S.-Singapore FTA, *supra* note 204, art. 16.1.2(a)(ii).

generis system or by any combination thereof.”²¹⁷ An example in the public health context is a limitation of the scope of diseases for which a compulsory license under the proposed TRIPs Article 31 *bis* will be used.²¹⁸ The Doha Declaration “recognize[s] the gravity of the public health problems afflicting many developing and least-developed countries, *especially* those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.”²¹⁹

E. Summary

More than a century ago, when the Paris Convention was established, countries were able to preserve the autonomy they needed to devise their own intellectual property policies. Unfortunately, because of their colonial status, many less developed countries were not members of the Paris Convention and never had this autonomy until after their declaration of independence. Instead, intellectual property laws were transplanted onto their soil from the colonial powers.²²⁰ Although most colonies became independent after the Second World War, the intellectual property laws from the former controlling powers remain on the books, survive state succession, or have been retroactively adopted as part of the post-independence national law.²²¹ As Ruth Okediji observed:

It is well-known . . . that most developing countries retained the structure and form of laws and institutions established during the colonial period, including intellectual property laws. Until 1989, Lesotho operated under the Patents, Trade Marks and Designs Protection Proclamation of 1919, a United Kingdom

217. TRIPs Agreement, *supra* note 8, art. 27(3)(b).

218. See Abbott, *WTO Medicines Decision*, *supra* note 160, at 352–53 (discussing the use of the phrase “in particular” in CAFTA to limit the scope of necessary measures to protect public health).

219. Doha Declaration, *supra* note 13, ¶ 1 (emphasis added).

220. As Ruth Okediji explained:

Intellectual property law was not merely an incidental part of the colonial legal apparatus, but a central technique in the commercial superiority sought by European powers in their interactions with each other in regions beyond Europe. Granted, intellectual property systems in Europe prior to the seventeenth century were neither fully developed nor had intellectual property protection become a systematic policy designed primarily for encouraging domestic innovation. Whatever protections existed, however, would be exerted against other Europeans in colonial territories in the process of empire building. The first multilateralism [which occurred during the early period of European contact through trade with non European peoples] thus was characterized predominantly by the extension of intellectual property laws to the colonies for purposes associated generally with the overarching colonial strategies of assimilation, incorporation and control. It was also characterized by efforts to secure national economic interests against other European countries in colonial territories.

Ruth L. Okediji, *The International Relations of Intellectual Property: Narratives of Developing Country Participation in the Global Intellectual Property System*, 7 SING. J. INT’L & COMP. L. 315, 324–25 (2003) (citations omitted).

221. For an excellent discussion of how the former colonies conducted their international intellectual property relations following their declaration of independence, see *id.* at 325–334.

instrument. Mauritius, a former French colony, continued to operate under its Trade Marks Act (1868) and Patents Act (1975) for over twenty years after obtaining independence in 1968. Swaziland also inherited its IP regime “as a colonial legacy.” The same is true with respect to other laws and institutions. Indeed, prior to the compelled compliance with intellectual property rights imposed by the TRIPS Agreement, many developing and least developed countries still had as their own domestic laws the old Acts and Ordinances of the colonial era. While some developing countries had laws in place that attracted the ire of the developed countries by explicit refusals to grant patents to pharmaceutical products, or through compulsory licensing provisions, or by the failure to enforce recognized rights, many others simply had obsolete laws.²²²

By the time the TRIPs Agreement was established, the autonomy preserved in the Paris Convention was no longer available to less developed countries. In lieu of choices that are sensitive to local conditions, the Agreement includes many minimum standards that require poor countries to develop a rich-country intellectual property system.

With the proliferation of recent bilateral and regional trade agreements ratcheting up protection for pharmaceuticals, this slight room for maneuvering has been further reduced to the point that countries are now required to introduce an intellectual property system that achieves uniformity at the expense of local needs, national interests, technological capabilities, institutional capacities, and public health conditions. As less developed countries continue to struggle with their economic development and public health crises, the need for this autonomy and the corresponding ability to select an appropriate intellectual property system has never been more important.

Although this Article focuses on WTO developments, it is important not to ignore similar developments at WIPO, whose initiatives are sometimes hindered by the heavy reliance on filing fees from the Patent Cooperation Treaty,²²³ the narrow definition of its mandate, and the development of training programs that serve this narrow mandate.²²⁴ Indeed, the recent negotiation of the proposed Substantive Patent Law Treaty²²⁵ has raised a lot of important questions about not only the balance of the international intellectual property system, but also WIPO’s role in the international enclosure movement. In WIPO’s defense, there have also been many interesting developments concerning the WIPO Development Agenda that help to resist the

222. *Id.* at 335–36 & n.73 (footnotes and citations omitted).

223. *See, e.g.*, CHRISTOPHER MAY, *THE WORLD INTELLECTUAL PROPERTY ORGANIZATION: RESURGENCE AND THE DEVELOPMENT AGENDA* 37 (2007) (noting the processing of applications under the Patent Cooperation Treaty and other treaties “provide[s] the majority of the funds for the rest of WIPO’s undertakings”); Margaret Chon, *Intellectual Property and the Development Divide*, 27 *CARDOZO L. REV.* 2821, 2844 n.109 (2006) (“WIPO’s operating budget is derived substantially from fees generated from Patent Cooperation Treaty filing fees, most of which come from applications filed by developed country members.”).

224. Christopher May, *Capacity Building and the (Re)production of Intellectual Property Rights*, 25 *THIRD WORLD Q.* 821, 822 (2004) (“[C]apacity building for [intellectual property rights] . . . may also lead to effective ‘epistemic lock-in’: capacity building programmes socialise policy makers, practitioners and others into a specific way of dealing with, and regulating, IPRs. It encourages the development of a TRIPs mind-set.”).

225. *See* WIPO, *Open Forum on the Draft Substantive Patent Law Treaty (SPLT)* (Mar. 2006), http://www.wipo.int/meetings/en/2006/scp_of_ge_06/.

continuous enclosure—or, at least, push for the type of enclosure that would better promote economic development in less developed countries.²²⁶ Because many of these developments remain in flux, and because this Article focuses primarily on Article 31 *bis* of the TRIPs Agreement, this Part does not discuss developments at WIPO. It is, nevertheless, important to acknowledge and beware of the role of those developments in the international enclosure movement.

III. THE NEGOTIATION OF POLICY SPACE

Although there has been a “one-way ratchet” of intellectual property protection and the public domain is increasingly enclosed,²²⁷ the international enclosure movement has not been a unidirectional movement. Instead, there have been repeated contestations between developed and less developed countries over the appropriateness and ultimate adoption of legal standards.²²⁸ The repeat resistance and challenges by less developed countries following the negotiation of the TRIPs Agreement eventually led to the launch of the Doha Round, which underscored their need to have wide policy space to develop intellectual property policies that take into consideration the public health crises within their national borders. This Part focuses on these challenges and resistance efforts, using as illustrations the August 30 Decision of the General Council and the recently proposed Article 31 *bis* of the TRIPs Agreement. This Part points out that, although the Doha Round drew attention to the development needs of less developed countries and “ma[d]e a start in some rebalancing of the asymmetry of the Uruguay Round,”²²⁹ it did not enable them to reclaim their lost policy space or to roll back the recent expansion of intellectual property rights.²³⁰ Instead, it merely identified the policy space needed by less developed countries and facilitated their negotiation with their developed counterparts about the governing standards within that particular space.

A. Doha Declaration

The Doha Declaration came at a time when developed countries were eager to move on to other issues in the international trade agenda,²³¹ while the international

226. For a concise discussion of the WIPO Development Agenda, see MAY, *supra* note 223, at 76–82.

227. See sources cited *supra* notes 1–2.

228. See Susan Sell, *Intellectual Property and Public Policy in Historical Perspective: Contestation and Settlement*, 38 LOY. L.A. L. REV. 267 (2004) (discussing the repeated process of contestation and settlement in the intellectual property arena); Yu, *Currents and Crosscurrents*, *supra* note 127, at 328 (noting that the international intellectual property regime is the product of repeated interactions between an evolving set of currents and crosscurrents).

229. Sylvia Ostry, *WTO Membership for China: To Be or Not to Be—Is that the Answer*, in CHINA AND THE WORLD TRADING SYSTEM: ENTERING THE NEW MILLENNIUM 31, 38 (Deborah Z. Cass, Brett G. Williams & George Barker eds., 2003).

230. Cf. OXFAM INTERNATIONAL, PATENTS VERSUS PATIENTS: FIVE YEARS AFTER THE DOHA DECLARATION I (2006), http://www.oxfamamerica.org/newsandpublications/publications/briefing_papers/patents_patients/Doha5_Final_paper_101106_2.pdf (noting that “little has changed” since the Doha Declaration).

231. See Abbott, *WTO Medicines Decision*, *supra* note 160, at 327 (“Developing as well as

community had been paying growing attention to the human rights implications of intellectual property protection.²³² As the United States' rhetoric was weakened following the "suggestion" of some of its officials and politicians to use compulsory licenses as a response to high drug prices during the post-9/11 anthrax attacks,²³³ the political climate became very favorable to less developed countries. In the Fourth WTO Ministerial Conference in Doha, Qatar, less developed countries pushed for the adoption of the Doha Declaration on the TRIPS Agreement and Public Health, "sen[ding] a clear message that they would take steps to protect and advance their essential interests."²³⁴ The first two paragraphs of the Declaration explicitly "recognize[d] the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics . . . [and] the need for the [TRIPs Agreement] to be part of the wider national and international action to address these problems."²³⁵

In addition, the Declaration extended the deadline for least developed countries to protect pharmaceuticals to January 1, 2016.²³⁶ The Declaration also noted affirmatively that the TRIPs 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."²³⁷ Finally, paragraph 5 of the Declaration underscored the various "flexibilities" reserved for all WTO members under the TRIPs Agreement, which include the following:

- (a) In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.
- (b) Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.
- (c) Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.
- (d) The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.²³⁸

developed countries had interests in items on the Cancún agenda[, and] . . . failure to reach an agreement on public health would virtually ensure a lack of progress on other matters."); *id.* at 349 (explaining why the United States made concession at the Doha Round).

232. See discussion *supra* Part II.C.

233. See Halbert, *supra* note 17, at 280 ("Because of the anthrax controversy, Doha proved to be more successful for the developing world than it otherwise would have been.")

234. F.M. ABBOTT, LEGAL OPTIONS FOR IMPLEMENTING PARAGRAPH 6 OF THE MINISTERIAL DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH (2002) (on file with author).

235. Doha Declaration, *supra* note 13, ¶¶ 1–2.

236. *Id.* ¶ 7.

237. *Id.* ¶ 4.

238. *Id.* ¶ 5.

The only unresolved issue concerning the lack of access to essential medicines in less developed countries was how to address the lack of an indigenous capacity to manufacture pharmaceuticals. Although paragraph 6 of the Doha Declaration “recognized that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement,” it merely instructed the TRIPs Council to devise an “expeditious solution.”²³⁹

B. August 30 Decision

In August 2003, the TRIPs Council issued a decision granting interim waivers to member states that lack an indigenous manufacturing capacity, as well as those that have insufficient capacity to cope with unforeseen situations of national emergency.²⁴⁰ These interim waivers allowed the WTO member states to suspend Article 31(f) of the TRIPs Agreement while they negotiated for a permanent solution, which was not formally proposed until more than two years later. Following the August 30 Decision, the United States, the European Communities, and other developed countries opted out of the system by declaring that they would not use the waivers as importers, while other higher-income countries have stated that they would only use these waivers “in situations of national emergency or other circumstances of extreme urgency.”²⁴¹

The statement by the latter group of countries is especially important. On the one hand, it indicated that the waivers covered not only “situations of national emergency or other circumstances of extreme urgency,”²⁴² but also other situations in which a WTO member state lacked access to essential medicines. Pursuant to the Doha Declaration, member states are free to determine for themselves what constitutes a national emergency or urgency.²⁴³ On the other hand, the opt-out declarations reminded us that the access-to-medicines problem was not limited to less developed countries. Indeed, as demonstrated by the concerns about the high prices of ciprofloxacin following the anthrax attacks in the United States²⁴⁴ and the potential inadequate supply of Tamiflu in the event of an outbreak of the avian flu pandemic,²⁴⁵ even developed countries can suffer from temporarily insufficient manufacturing capacity in unforeseen situations of national emergency.²⁴⁶ When such situations arise, the arguments offered by developed countries will be similar to those made by less developed countries under more widespread public health crises.²⁴⁷ Ironically, the

239. *Id.* ¶ 6.

240. August 30 Decision, *supra* note 11.

241. Chairperson’s Statement, *supra* note 68.

242. *Id.*

243. Doha Declaration, *supra* note 13, ¶ 5(c).

244. *See* Halbert, *supra* note 17, at 280.

245. Manning, *supra* note 16.

246. *See* Abbott, *WTO Medicines Decision*, *supra* note 160, at 334 (“No country is immune from public health problems or insulated from the need for affordable medicines. No country is self-sufficient in the sense of producing the full range of medicines used in its health system.”).

247. *See, e.g.*, Halbert, *supra* note 17, at 280 (“The U.S. lost significant international legitimacy when the overwhelming hypocrisy of its own efforts regarding anthrax were juxtaposed against the efforts of developing countries to secure cheap access to AIDS drugs.”); Susan K. Sell, *TRIPS and the Access to Medicines Campaign*, 20 *WIS. INT’L L.J.* 481, 515–16

availability of generic production in less developed countries may even help alleviate such temporary shortages in the developed world,²⁴⁸ especially if a similar outbreak does not arise in the source countries.

To the disappointment of less developed countries and their supporting intergovernmental and nongovernmental organizations, the chair of the General Council issued a controversial statement along with the decision, partly as a compromise to induce agreement from the United States and other developed countries.²⁴⁹ To prevent countries from using the August 30 decision “to promote national champions in the pharmaceutical sector,”²⁵⁰ the Chairperson’s Statement

(2002) (noting that the series of events surrounding the United States’ response to high drug prices during the anthrax attacks “caught the attention of the access campaign and developing country negotiators, and was on everybody’s minds at Doha”); ‘t Hoen, *supra* note 14, at 43 (“The anthrax scare and the threatened shortage of Cipro forced all WTO Members to ask how much of a prisoner they want to be of their own patent systems.”); Jose Marcos Nogueira Viana, *Intellectual Property Rights, the World Trade Organization and Public Health: The Brazilian Perspective*, 17 CONN. J. INT’L L. 311, 313 (2002) (“U.S. and Canadian approaches to the anthrax scare is precisely what the Brazilian government has been doing over the past two years in response to HIV/AIDS.”).

To be fair, one could distinguish the United States’ response in the anthrax case from the request for compulsory licensing by less developed countries in two respects. First, as the industry has noted, the United States’ response may be better characterized “as an exception, rather than a precedent.” Ragavan, *Jekyll and Hyde Story*, *supra* note 79, at 816 (quoting Robert Armitage, Senior Vice President and General Counsel, Eli Lilly, Address at the “Patent Law, Social Policy, and Public Interest: The Search for a Balanced System” Symposium at Benjamin N. Cardozo School of Law (Nov. 7, 2002)). Even if granted, it is short-term by nature and does not constitute a general long-term compulsory license. Second, in a challenge by Bayer and other pharmaceutical companies, courts may strike down the government’s proposal, even if implemented. Nevertheless, the hypocritical tone of the United States’ proposal has greatly weakened its rhetoric in international fora. *See sources cited supra*.

248. *See Ragavan, The Jekyll and Hyde Story, supra* note 79, at 811 (noting that Canada bought ciprofloxacin from a local generic drug manufacturer).

249. Chairperson’s Statement, *supra* note 68; *see also* Roffe, *supra* note 31, at 24 (discussing the criticism of the Chairperson’s Statement).

250. Roffe, *supra* note 31, at 20; *see also* Communication from the United States, *Comments on Implementation of the 30 August 2003 Agreement (Solution) on the TRIPS Agreement and Public Health*, ¶ 12, IP/C/W/444 (Mar. 18, 2005) (“It is certain that the [Paragraph 6] solution would not have been reached without the Chairman’s Statement.”). Some countries, however, disagreed with the impact of the Chairperson’s Statement. As Rwanda declared:

With regard to the Chairman’s statement, it is important to understand the circumstances in which the statement came into being, so that we can put this statement in its proper context. The reading of the Chairman’s statement, when the Decision was adopted, was more of an attempt to provide comfort language to assuage the concerns of some pharmaceutical industries that generic manufacturers would gain a strong foothold in the pharmaceutical market. During the informal TRIPS Council meetings, some developing and least-developed countries’ delegates had expressed their reservations over the content of the statement, a clear indication that this statement was never intended to form any part of the permanent solution.

The main reason why those countries with reservations agreed to go along with the Chairman’s statement was because they felt an urgent need to make a contribution to the success of the Cancún Ministerial Conference. WTO Members

declared that the system “should be used in good faith to protect public health and . . . not be an instrument to pursue industrial or commercial policy objectives.”²⁵¹ The statement also maintained that “Members recognize that the purpose of the Decision would be defeated if products supplied under this Decision are diverted from the markets for which they are intended” and that “all reasonable measures should be taken to prevent such diversion in accordance with the relevant paragraphs of the Decision.”²⁵²

Taken together, the August 30 Decision and the Chairperson’s Statement have received mixed reactions from commentators.²⁵³ For example, commentators have criticized the interim waivers for being “unduly cumbersome and complex,” citing lack of usage in their more than three years of existence.²⁵⁴ Other criticisms included their lack of legal authority,²⁵⁵ their failure to address the transfer of pharmaceutical technology to less developed countries,²⁵⁶ and their inability to “prevent a private party from blocking the exportation or importation of drugs, if the national laws do not

may recall that there was a strong feeling at that time that a solution, even if it was an interim solution, had to be concluded before the Cancún meeting so that the meeting could focus on other issues and thus have a better chance of success. It was felt by all that a Chairman’s statement would help facilitate the quick conclusion to the interim solution. But it was also the understanding that this would only be for an interim solution, and that a permanent solution would require more careful consideration, taking into account all the aspects, including how the mechanism chosen could be operationalized in practice.

Communication from Rwanda on Behalf of the African Group, *The TRIPS Agreement and Public Health*, ¶¶ 10–11, IP/C/W/445 (Apr. 6, 2005).

251. Chairperson’s Statement, *supra* note 68.

252. *Id.*

253. See Roffe, *supra* note 31, at 22–24 (discussing the reactions to the August 30 Decision).

254. Timmermans, *supra* note 24, at 45; accord CARLOS M. CORREA, RECENT INTERNATIONAL DEVELOPMENTS IN THE AREA OF INTELLECTUAL PROPERTY RIGHTS 4 (2003), http://www.iprsonline.org/unctadictsd/bellagio/docs/Correa_Bellagio2.pdf [hereinafter CORREA, RECENT INTERNATIONAL DEVELOPMENTS] (“The adopted ‘solution’ is so cumbersome for potential suppliers that they will be hardly encouraged to use the Decision, ‘because it is so designed that no generic manufacturer would be able or willing to comply with its provisions.’” (footnote omitted) (quoting D. G. Shah, Indian Pharmaceutical Alliance)); K.M. Gopakumar, *The WTO Deal on Cheap Drugs: A Critique*, 7 J. WORLD INTELL. PROP. 99 (2004).

255. Halbert, *supra* note 17, at 280 (“Because [the Doha Declaration] is not an amendment to TRIPS, the declaration only has moral force.”). *But see* M. Gregg Bloche, *WTO Deference to National Health Policy: Toward an Interpretive Principle*, 5 J. INT’L ECON. L. 825, 842 (2002) (“More plausibly, the Doha Declaration has interpretive weight under the Vienna Convention on the Law of Treaties, as either a ‘subsequent agreement between the parties regarding the interpretation’ of TRIPS or ‘subsequent practice in the application of the treaty which establishes the agreement of the parties regarding its interpretation.’” (footnote omitted) (quoting Vienna Convention on the Law of Treaties art. 31, May 23, 1969, U.N. Doc. A/CONF.39/27)); Sykes, *supra* note 46, at 54 (“[T]he Doha Declaration is primarily interpretive of imprecise obligations in TRIPS, and does not appear to contradict any textual provision. As such, it is likely to be persuasive authority in the interpretation of TRIPS in the event of a dispute.”). This issue may become moot once Article 31*bis* makes the interim waivers permanent.

256. M. Rafiqul Islam, *The General Drug Deal of the WTO from Doha to Cancun: A Peripheral Response to a Perennial Conundrum*, 7 J. WORLD INTELL. PROP. 675 (2004).

specifically permit such exports or imports under compulsory licenses.”²⁵⁷ Nevertheless, the waivers, on balance, represented a promising first step in focusing attention on the public health crises in less developed countries and in reclaiming some of their lost policy space.²⁵⁸

C. Paragraph 6 Solution

Since the August 30 Decision, the TRIPs Council had been actively exploring a permanent replacement for the temporary waivers, as required by Paragraph 6 of the Doha Declaration. Paragraph 11 of the August 30 Decision stated that “[t]his Decision, including the waivers granted in it, shall terminate for each Member on the date on which an amendment to the TRIPs Agreement replacing its provisions takes effect for that Member.”²⁵⁹ In light of the opportunity to reclaim their lost policy space, less developed countries and their supporting intergovernmental and nongovernmental organizations actively advanced proposed templates for this “permanent solution,” while developed countries offered alternative templates to protect the interests of their nationals and exporting industries.

Among the contentious issues in this “battle of templates” were the scope of diseases, the members’ eligibility for the benefit of the solution, and the choice of the TRIPs provision that would be used to implement the permanent solution.²⁶⁰ Other issues that were discussed and negotiated included the definition of the “pharmaceutical sector,”²⁶¹ protection against trade diversion and abuse,²⁶² the ability

257. CORREA, RECENT INTERNATIONAL DEVELOPMENTS, *supra* note 254, at 3 (emphasis omitted).

258. *But see* Sykes, *supra* note 46, at 68 (“A lack of credible patent rights for pharmaceuticals in the developing world may do far more harm in the long run than their absence can accomplish in the short run.”). For a response to Professor Sykes, see Cotter, *supra* note 91.

259. August 30 Decision, *supra* note 11, ¶ 11.

260. For a discussion of the various proposals, see generally Note by the Secretariat, *Proposals on Paragraph 6 of the Doha Declaration on the TRIPs Agreement and Public Health: Thematic Compilation*, IP/C/W/363 (July 11, 2002); Abbott, *WTO Medicines Decision*, *supra* note 160, at 327–43.

261. *Compare* African Group Proposal, *supra* note 14, ¶ 6(b) (“[T]he phrase ‘pharmaceutical products’ should [be] construed broadly in order to be meaningful, rather than narrowly in a manner that would restrict it to only limited components of treatment or medicines. ‘Pharmaceutical products’ should be understood to include[] medicines, related technical processes, and related technical equipment.”), *and* Communication from the Permanent Mission of Brazil, *Paragraph 6 of the Ministerial Declaration on the TRIPs Agreement and Public Health*, IP/C/W/355 (June 24, 2002) [hereinafter Brazil Proposal] (discussing the need for access to medicines and “public health-related products”), *with* EC Proposal, *supra* note 160, ¶ 11 (“[T]he product scope is to be defined as pharmaceutical products needed to deal with public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.”), *and* Second Communication from the United States, *Paragraph 6 of the Doha Declaration on the TRIPs Agreement and Public Health*, IP/C/W/358, ¶ 31 (July 9, 2002) [hereinafter U.S. Proposal] (mentioning “patented pharmaceutical products”).

262. EC Proposal, *supra* note 160, ¶ 13 (discussing the need to prevent trade diversion and abuse); U.S. Proposal, *supra* note 261, ¶ 20 (“[W]e recommend that Members taking advantage

to create economies of scale,²⁶³ the need for a moratorium on disputes over public health-related remedies in countries with no or insufficient manufacturing capacity,²⁶⁴ and the facilitation of technology transfer and technical assistance.²⁶⁵ The latter is particularly important as a long-term solution to the access-to-medicines problem. As the WHO Commission on Intellectual Property Rights, Innovation and Public Health stated, “[i]n the longer term, the development of innovative capacity for health research in developing countries will be the most important determinant of their ability to address their own need for appropriate health-care technologies.”²⁶⁶

Although the scope of diseases was not a major issue in the discussion leading to the adoption of the proposed Article 31 *bis*, it was one of the more contentious issues in the initial stage of this battle of templates.²⁶⁷ At the outset, less developed countries considered it important to define the new provision “broadly [to] cover their present and future public health needs.”²⁶⁸ While their immediate concerns were HIV/AIDS, malaria, and tuberculosis, they sought recognition that the access-to-medicines problem extended beyond the list of diseases identified in paragraph 1 of the Doha Declaration.²⁶⁹ After all, from the standpoint of less developed countries, “[the] issue

of this proposal inform the TRIPs Council of actions taken under this mechanism. This will also increase transparency and enable other Members to ensure that the medicines being exported actually reach the intended country and are not diverted into other markets.”)

263. See Brazil Proposal, *supra* note 261, ¶ 12 (noting the need to “consider establishing economies of scale that would reduce costs of production and thus provide more affordable prices for the beneficiary countries in situations, for instance, where domestic production in small quantities from a compulsory licence for a particularly high-priced product may be impractical or too costly”).

264. See African Group Proposal, *supra* note 14, ¶ 6(g) (“There should be a comprehensive moratorium on disputes against any Member that takes measures to address the international and national health concerns in countries with insufficient or no manufacturing capacity.”).

265. See *id.* ¶ 6(e) (“[T]he expeditious solution the TRIPs Council is required to find should be part and parcel of a broader implementation of the TRIPs Agreement, taking into account the objectives and principles set out in Articles 7 and 8, as well as Article 66.2 that deals specifically with least developed Members.”); Brazil Proposal, *supra* note 261, ¶ 20 (“[T]he TRIPs Council should also consider measures under Article 66.2 of the TRIPs Agreement in order to encourage the transfer of technology to least developed countries in order to strengthen local manufacturing capacities in their territories.”).

266. COMM’N ON INTELLECTUAL PROP. RIGHTS, INNOVATION AND PUB. HEALTH, WHO, PUBLIC HEALTH, INNOVATION AND INTELLECTUAL PROPERTY RIGHTS 141 (2006), available at <http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf>.

267. Abbott, *WTO Medicines Decision*, *supra* note 160, at 327 (“The so-called scope-of-diseases issue was the most contentious.”).

268. *Id.* at 328.

269. See Communication from Kenya, *Elements of a Paragraph 6 Solution*, IP/C/W/389, ¶ 4 (Nov. 14, 2002) [hereinafter Kenya Proposal] (“The position of the African Group is to retain the expression ‘pharmaceutical sector’ as used in the Declaration, while at the same time explicitly agreeing that the expression should be broadly construed in a manner that gives efficacy to the solution and in accordance with the right of Members to take measures to protect public health as highlighted in the Declaration.”); Communication from the United Arab Emirates, *Paragraph 6 of the Doha Declaration of the TRIPs Agreement and Public Health*, IP/C/W/354, ¶ 9 (June 24, 2002) [hereinafter UAE Proposal] (“The Doha Declaration does not refer just to situations that relate to serious health problems like malaria, HIV/AIDS, tuberculosis, which are certainly very serious problems, but it relates also to all other public health policy problems.”).

had been resolved at Doha by the adoption of a broadly framed declaration . . . [and any] attempts to limit the solution to particular diseases [would] amount[] to an effort to rewrite the Doha Declaration.”²⁷⁰

Meanwhile, the United States feared that less developed countries with manufacturing capacity, like Brazil and India, might use the new provision to export drugs that were not intended to be covered by the Doha Declaration, such as lifestyle drugs like Viagra.²⁷¹ The United States, therefore, embraced a restrictive approach that sought to limit the list to only a few identified diseases. From the standpoint of developed countries, it is important to limit the number of diseases that are subject to a compulsory license, because that number will affect the amount of patented technologies that will be used without the patent holder’s authorization while increasing the industry’s risk of loss of revenues.²⁷²

The second contentious issue concerned the eligibility of countries for the importation of pharmaceuticals under a compulsory license. Although all countries agreed to make the solution available to the least developed countries, it was uncertain whether other WTO members would be eligible for the Paragraph 6 solution. The European Communities, for example, wanted to include only less developed countries, “focusing especially on least developed country Members and low income Members, with no or insufficient domestic manufacturing capacity, or, in case that product is patented in that Member, no or insufficient manufacturing capacity other than that of the patent holder of the product in that Member.”²⁷³ To avoid disputes, the United States preferred to “establish a procedure to clarify which developing country Members can be considered to have insufficient or no manufacturing capacity in the pharmaceutical sector or at least the factors to be taken into consideration.”²⁷⁴

Meanwhile, many less developed countries did not want any limitation at all,²⁷⁵ while others favored the lack of distinction between developing and least developed countries.²⁷⁶ The African Group went even further to propose that “where a request is

270. Abbott, *WTO Medicines Decision*, *supra* note 160, at 328.

271. *See id.* (noting “the U.S. argument that developing countries such as India and Brazil intended to use the negotiations to promote the export of lifestyle drugs such as Viagra”). To alleviate the United States’ concern, “developing country delegations and NGOs suggested the inclusion of negative lists to exclude such drugs, but these proposals were not taken up.” *Id.*

272. *Id.* at 329.

273. EC Proposal, *supra* note 160, ¶ 12.

274. U.S. Proposal, *supra* note 261, ¶ 12.

275. As Brazil noted in its proposal:

Any WTO Member could face difficulties in making effective use of compulsory licences due to insufficient or no manufacturing capacities in the pharmaceutical sector. Therefore, the solution to be considered by the TRIPS Council needs not and should not be limited to a specific category of countries—although developing countries, in particular least-developed countries, might figure among its main beneficiaries.

Brazil Proposal, *supra* note 261, ¶ 4; *accord* Kenya Proposal, *supra* note 269, ¶ 7 (“The African Group believes that all Members should be eligible as importers, on the understanding that they will use the solution only when they need it, that is, in cases where they lack or have insufficient manufacturing capacity.”).

276. UAE Proposal, *supra* note 269, ¶ 11 (“Any solution under the Doha Declaration should be made available to all Members without further distinction or categorization of developing countries.”).

properly made under the solution, *there should be an obligation* on the requested Member to take all measures necessary for the production and exportation to be speedily accomplished.”²⁷⁷ Amidst the negotiation, tension developed among the less developed countries—between countries that have manufacturing capacity, like India and Brazil, and those that do not but want to increase local production capacity, like those in the African group.²⁷⁸ Instead, the latter “believe[d] that the ultimate solution to the paragraph 6 problem [wa]s to build domestic manufacturing capacity and that this should be explicitly agreed and mentioned in the solution.”²⁷⁹ Fortunately for the less developed world, the two groups of countries were able to set aside their differences and joined together to battle the developed countries—perhaps because the African Group realized that, for the foreseeable future, its members would continue to import new drugs from Brazil, China, and India even if they sought to develop their production capacity.²⁸⁰

The last issue concerned whether the WTO member states would amend Article 30 or 31(f) of the TRIPs Agreement.²⁸¹ During the TRIPs Council meeting in March 2002, four basic options were put on the table:

- (i) an authoritative interpretation based on Article 30;
- (ii) an amendment to Article 31 in order to overcome the restriction, under Article 31(f), to the possibility to export products manufactured and/or sold under a compulsory licence;
- (iii) a dispute settlement moratorium with regard to the non-respect of the restriction under Article 31(f); or
- (iv) a waiver with regard to Article 31(f).²⁸²

Initially, less developed countries, the World Health Organization, and nongovernmental organizations, favored a modification of Article 30,²⁸³ partly due to their concerns about potential bureaucratic delay caused by cumbersome compulsory licensing procedures.²⁸⁴ To provide “the most comprehensive approach to solving the

277. Kenya Proposal, *supra* note 269, ¶ 9 (emphasis added).

278. Abbott, *WTO Medicines Decision*, *supra* note 160, at 334.

279. Kenya Proposal, *supra* note 269, ¶ 15(a).

280. Abbott, *WTO Medicines Decision*, *supra* note 160, at 334.

281. It is important to note, however, that regardless of which article was amended, “[t]he article 31(f) restriction on exports does not apply when a compulsory license is issued to remedy an anticompetitive practice.” *Id.* at 319.

282. EC Proposal, *supra* note 160, ¶ 2.

283. See Brazil Proposal, *supra* note 261, ¶ 8 (“Article 30 of TRIPS should be interpreted so as to recognize the right of WTO Members to authorize third parties to make, sell and export patented public health-related products without the consent of the patent holder to address public health needs in another country.” (footnote omitted)).

284. See *id.* ¶ 10 (“An authoritative interpretation of Article 30 of TRIPS would have the major advantage of avoiding burdensome procedures related to the grant of compulsory licences in the exporting country.”); accord Kenya Proposal, *supra* note 269, ¶¶ 10–11 (“Any objective criteria should not be a way of imposing cumbersome domestic pre-conditions for using the solution, and should not limit the existing rights of Members to protect public health in any circumstances. . . . The mechanisms that a Member uses for establishing that this situation exists, should be left to the Member itself.”); see also Abbott, *WTO Medicines Decision*, *supra* note 160, at 339 (“From the standpoint of many developing countries, NGOs, and the WHO, a

problem,”²⁸⁵ the African Group also proposed to modify Article 31 in addition to Article 30, while the United Arab Emirates favored the modification of Article 31 but proposed the interpretation of Article 30 as “an alternative option.”²⁸⁶ Meanwhile, the United States preferred a modification of Article 31 only, and the European Communities soon sided with the United States,²⁸⁷ perhaps “because they concluded that the United States would never accept an Article 30-based solution.”²⁸⁸ Less developed countries eventually yielded to their demands, perhaps because the United States was unlikely to change its position and other issues were far more important than the modification of Article 30.

D. Proposed Article 31bis

On December 6, 2005, shortly before the Hong Kong Ministerial, WTO member states agreed to accept a protocol of amendment to the TRIPs Agreement, making permanent the interim waivers granted in the August 30 Decision.²⁸⁹ Embodied in the proposed Article 31bis, along with an annex and an appendix to the annex, the amendment lays out conditions under which countries can suspend Article 31(f) of the TRIPs Agreement. If ratified before December 1, 2007, the proposed provision will enter into effect.²⁹⁰ Because the proposal represented the first amendment of a core WTO agreement, this Section examines in detail this proposed provision.

Article 31bis(1) provides that “[t]he obligations of an exporting Member under Article 31(f) shall not apply with respect to the grant by it of a compulsory licence to the extent necessary for the purposes of production of a pharmaceutical product(s) and

solution based on Article 30 would have the major advantage of avoiding the need for a compulsory licensing procedure in the country of export.”). James Love, for example, has noted that compulsory licensing provisions *in practice* in many less developed countries are quite different from those that are *in theory*. As he explained:

Existing compulsory licensing laws are often a barrier to access. The standards for issuing compulsory licences may rely excessively upon narrow grounds, such as non-working or difficult-to-establish abuses, exhibit a lack of clarity regarding public policy objectives, or invite litigation over factual issues or legal standards.

This has caused some governments to delay or reject requests for compulsory licences despite enormous problems over access to patented medicines.

Love, *supra* note 42, at 241, 242; *see also* Scherer & Watal, *supra* note 18, at 924 (“The longer the issuance of compulsory licenses is delayed after patented drugs enter the marketplace, the less time licensees have to recover their start-up costs and the more difficult it is to achieve effective competition among multiple generic substitute suppliers.”).

285. Abbott, *WTO Medicines Decision*, *supra* note 160, at 340.

286. *See* UAE Proposal, *supra* note 269, ¶ 17.

287. *See* EC Proposal, *supra* note 160, ¶ 5 (“The addition of . . . a new paragraph to Article 31 of the TRIPs Agreement offers the best guarantees for a sustainable, balanced and workable solution to the problem raised under paragraph 6 of the Doha Declaration.”).

288. Abbott, *WTO Medicines Decision*, *supra* note 160, at 340.

289. *See* WTO Press Release, *supra* note 10.

290. The temporary waivers will remain in force until two-thirds of the WTO membership ratifies the proposed Article 31bis of the TRIPs Agreement. *See* December 6 Decision, *supra* note 9. As of April 5, 2007, only seven countries (United States, Switzerland, El Salvador, South Korea, Norway, India, and Philippines) have ratified the proposed amendment. WTO, Countries Accepting Amendment of the TRIPs Agreement, http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm (Apr. 5, 2007).

its export to an eligible importing Member(s).²⁹¹ This provision uses the phrase “to the extent necessary” to reflect the limited circumstances under which the provision should be used, and thereby reminds member states that the provision “should be used in good faith to protect public health and . . . not be an instrument to pursue industrial or commercial policy objectives.”²⁹²

Article 31 *bis*(2) sets out the parameters for remuneration to the patent holders.²⁹³ The provision first states that adequate remuneration will be paid in the exporting member state “taking into account the economic value” to the importing member state of the authorized use.²⁹⁴ It then discusses the situation in which compulsory licenses exist in both the importing and exporting countries. To avoid double remuneration in that situation, the provision will exempt the importing country from paying remuneration if a compulsory license has already been paid for in the exporting country.²⁹⁵

Article 31 *bis*(3) extends the coverage of the provision to countries belonging to a regional trade agreement.²⁹⁶ As Part I discussed, market aggregation of various less developed countries may be needed to generate enough purchasing power to make the development of an indigenous pharmaceutical industry attractive. By allowing products produced or imported under a compulsory license to be exported to other less developed countries through a regional trade agreement, the provision, therefore, will help “harness[] economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products.”²⁹⁷ It also paves the way for the creation of regional supply centers,²⁹⁸ “the development of systems providing for the grant of regional patents,” and the provision of technical cooperation.²⁹⁹

It should be noted, however, that the provision limits its benefits to African countries, as it specifically requires that at least half of the membership of the regional agreement in question be least developed countries. While it is troubling that the provision excludes countries in Asia and South America that are facing equally serious public health crises,³⁰⁰ the limitation is partly a legacy of the August 30 Decision³⁰¹ and

291. General Council, *Protocol Amending the TRIPS Agreement*, in December 6 Decision, *supra* note 9, art. 31 *bis*(1) [hereinafter TRIPs Amendment].

292. Chairperson’s Statement, *supra* note 68.

293. TRIPs Amendment, *supra* note 291, art. 31 *bis*(2).

294. *Id.*

295. *Id.*

296. *Id.* art. 31 *bis*(3).

297. *Id.*

298. See Jerome H. Reichman, Remarks at “Saving Profits, Saving Lives: A Comprehensive Discussion of the Social, Legal, and Economic Implications of Reverse Engineering and Parallel Importing on the Pharmaceutical Industry” Symposium at the University of North Carolina School of Law (Feb. 25, 2006) (exploring the prospects of creating regional pharmaceutical supply centers using a compulsory license permitted under the proposed Article 31 *bis* of the TRIPs Agreement).

299. TRIPs Amendment, *supra* note 291, annex ¶ 5.

300. See Abbott, *WTO Medicines Decision*, *supra* note 160, at 345 n.202 (“The restriction of regional flexibility to Africa is not easy to explain from the standpoint of regions such as the Caribbean, Central America, and East Asia, where there are very serious public health problems and limited pharmaceutical-manufacturing capacity.”); *id.* at 331 (noting that United States

partly reflects the United States' earlier failed attempts to limit the Doha Declaration and the paragraph 6 solution to the African continent—perhaps due to concerns about the generic manufacturing capacity in Argentina, Brazil, China, India, and Thailand.

Article 31*bis*(3) also specifically mentions Article XXIV of the GATT³⁰² and the Decision of 28 November 1979 on Differential and More Favourable Treatment, Reciprocity and Fuller Participation of Developing Countries.³⁰³ Notwithstanding these explicit acknowledgements, the provision does not resolve the growing debate about whether the benefits of bilateral and regional trade agreements signed by WTO members would be extended to all members through the most favored nation treatment as stated in Article 4 of the TRIPs Agreement.³⁰⁴ While some commentators have cited the North American Free Trade Agreement (NAFTA) to illustrate that Article XXIV of the GATT has made a special exception for the establishment of trade agreements, others have suggested that obligations created by those agreements will be extended not just to the relevant parties, but to all WTO member states.³⁰⁵

Article 31*bis*(4) prohibits members from initiating non-violation complaints over measures enacted to implement this amendment.³⁰⁶ This prohibition is particularly

Trade Representative Robert Zoellick indicated in a ministerial meeting in Tokyo that “the United States might be willing to concede on the scope of diseases if the [paragraph 6] solution were limited to Africa”). It is important to note that Brazil specifically stated the importance of economies of scale in its proposal on behalf of less developed countries in South America and Asia. As the proposal stated:

Members should bear in mind that legal solutions based on Article 30 will be best achieved if grounded in economic solutions. In many situations, a public health problem might affect more than a single country (as in the case of—but not limited to—HIV/AIDS, tuberculosis, malaria and several tropical diseases). Therefore, in implementing such solutions, countries may consider establishing economies of scale that would reduce costs of production and thus provide more affordable prices for the beneficiary countries in situations, for instance, where domestic production in small quantities from a compulsory licence for a particularly high-priced product may be impractical or too costly.

Brazil Proposal, *supra* note 261, ¶ 12.

301. See August 30 Decision, *supra* note 11, ¶ 6(i).

302. General Agreement on Tariffs and Trade art. XXIV, Oct. 30, 1947, 61 Stat. A3, 55 U.N.T.S. 188 [hereinafter GATT].

303. Differential and More Favourable Treatment, Reciprocity and Fuller Participation of Developing Countries, Nov. 28, 1979, GATT B.I.S.D. (26th Supp.) at 203 (1980).

304. See JOHN R. THOMAS, INTELLECTUAL PROPERTY AND THE FREE TRADE AGREEMENTS: INNOVATION POLICY ISSUES CRS-21 (2005), http://digital.library.unt.edu/govdocs/crs//data/2005/upl-meta-crs-8252/RL33205_2005Dec21.pdf.

305. Compare Judy Rein, *International Governance Through Trade Agreements: Patent Protection for Essential Medicines*, 21 Nw. J. INT'L L. & BUS. 379, 382 (2001) (“The exception provided within the GATT, permitting customs unions and free trade areas, will probably be applied to World Trade Organization (“WTO”) agreements.”), with Abbott, *WTO Medicines Decision*, *supra* note 160, at 357 n.286 (“It may at least be worth exploring whether some developing country generic producers may be suffering de facto MFN discrimination by importing members of FTAs as a consequence of the new FTA rules, which may effectively grant preferences to originator companies principally based in a few WTO members.”).

306. TRIPs Amendment, *supra* note 291, art. 31*bis*(4) (“Members shall not challenge any measures taken in conformity with the provisions of this Article and the Annex to this Agreement under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994.”). As Frederick Abbott explained:

important because the threat of being targeted with non-violation complaints remains an important issue for less developed countries in the public health area.³⁰⁷ Given the limited resources and legal expertise in these countries,³⁰⁸ the fear of becoming the target of such a complaint may create a chilling effect, further hindering their ability to develop policies to address the access-to-medicines problems within their borders.

At the end of the protocol is a proposed annex to the TRIPs Agreement, which “set[s] out terms for using the system, and cover[s] such issues as definitions, notification, avoiding the pharmaceuticals being diverted to the wrong markets, developing regional systems to allow economies of scale, and annual reviews in the TRIPs Council.”³⁰⁹ Paragraph 1(a) expands the term “pharmaceutical product” to cover “active ingredients necessary for [the] manufacture [of the pharmaceutical product] and diagnostic kits needed for its use.”³¹⁰ Paragraph 1(b) limits country eligibility to “any least-developed country Member, and any other Member that has made a notification to the TRIPs Council of its intention to use the system set out in Article 31*bis* and this Annex . . . as an importer.”³¹¹ It remains interesting to see whether countries that had already opted out of the August 30 Decision would be able to opt in should unforeseen situations of national emergency arise.³¹² Finally, to reduce the risk of trade diversion of imported pharmaceutical products under the compulsory license, paragraph 3 requires the importing countries to “take reasonable measures within their means, proportionate to their administrative capacities and to the risk of trade diversion to prevent re-exportation of the products that have actually been imported into their territories under the system.”³¹³

The document concludes with a proposed appendix to the annex to the TRIPs Agreement, detailing ways to factually establish the absence or insufficiency of manufacturing capacity³¹⁴ as required under paragraph 2 of the Annex, which sets out

In a nonviolation nullification or impairment action, a member does not seek to challenge the conformity of another member’s measures or actions with the terms of the relevant agreement (e.g., GATT 1994), but contends that the measures or actions adversely affect the benefits it expected to receive based on a negotiated exchange of concessions.

Abbott, *WTO Medicines Decision*, *supra* note 160, at 346 n.209.

307. See Abbott, *Cycle of Action*, *supra* note 15, at 35 (“Apart from dealing with the FTA problem, resolution of the non-violation question may be the most important single item on the WTO agenda from a TRIPs and public health standpoint.”) (citation omitted); Dreyfuss & Lowenfeld, *supra* note 172, at 285–88 (discussing non-violation complaints).

308. Dreyfuss, *TRIPs—Round II*, *supra* note 2, at 25 (“[I]t requires either that a country have experience with intellectual property protection or sufficient human capital (in the form of legal talent) to codify wiggles into law. Many developing countries lack both.”); Gregory Shaffer, *Recognizing Public Goods in WTO Dispute Settlement: Who Participates? Who Decides? The Case of TRIPs and Pharmaceutical Patent Protection*, 7 J. INT’L ECON. L. 459, 473–76 (2004) (discussing the limited legal expertise in less developed countries).

309. WTO Press Release, *supra* note 10.

310. TRIPs Amendment, *supra* note 291, annex ¶ I(a).

311. *Id.* ¶ 1(b).

312. Commentators remain divided on the issue. Frederick Abbott, for example, has suggested that “countries opting out directly in the text of the Decision are not free to modify their status, as contrasted with those that merely stated their intention to the General Council.” Abbott, *WTO Medicines Decision*, *supra* note 160, at 336 n.130.

313. TRIPs Amendment, *supra* note 291, annex ¶ 3.

314. *Id.* annex app.

the terms for importing and exporting countries to notify the TRIPs Council regarding their use of a compulsory license.³¹⁵ Although no approval is required and the notification requirement seems to be introduced to promote transparency,³¹⁶ paragraph 2 requires a confirmation that “the eligible importing Member in question, other than a least-developed country Member, has established that it has insufficient or no manufacturing capacities in the pharmaceutical sector for the product(s) in question in one of the ways set out in the Appendix to this Annex.”³¹⁷ This confirmation is likely to be problematic, costly, and burdensome for many less developed countries.³¹⁸ The fact that the notification may be subject to the WTO dispute settlement process also may deter some less developed countries from taking full advantage of these provisions.³¹⁹

315. *Id.* annex ¶ 2.

316. As the European Communities noted, transparency is very important to rights holders and the exporting countries:

The application of the proposed exception would lead to the specific situation that a product sold in one country (in certain cases pursuant to a compulsory licence) would have been produced in another country under a compulsory licence. One would indeed have to deal with a special situation where patent protected products would cross the borders while covered by compulsory licences in both the country of production and the country of consumption (except in those cases where the product in question is not patented in the country of consumption). In view of this situation it will be of paramount importance to ensure full transparency of the process and to ensure that the patent holder(s) and other WTO Members remain fully informed of the steps undertaken in view of granting the authorization. Furthermore, transparency would also contribute to preventing trade diversion: by being informed of the use of the exception, other Members will be able to increase their vigilance with regard to possible (re)importation of the products concerned.

EC Proposal, *supra* note 160, ¶ 15.

317. TRIPs Amendment, *supra* note 291, annex ¶ 2(a)(ii).

318. See Jorge A.Z. Bermudez, Maria Auxiliadora Oliveira & Gabriela Costa Chaves, *Intellectual Property in the Context of the WTO TRIPS Agreement: What Is at Stake?*, in *INTELLECTUAL PROPERTY IN THE CONTEXT OF THE WTO TRIPS AGREEMENT: CHALLENGES FOR PUBLIC HEALTH* 23, 56 (Jorge A. Z. Bermudez & Maria Auxiliadora Oliveira eds., 2004) (“Poor countries of Africa, Asia, and Latin America have to go through unnecessary red tape to prove that they do not have manufacturing capacity”), available at http://www.who.int/intellectualproperty/submissions/Trips_ingles%20nova%20versao%202005.pdf; see also Abbott, *WTO Medicines Decision*, *supra* note 160, at 353 (“Ambiguous pharmaceutical-related rules raise serious problems when procurement officials try to do their work”). James Love of Knowledge Ecology International (formerly the Consumer Project of Technology) has even compared Article 31*bis* to the Appendix to the Berne Convention, which has been largely unused by less developed countries due to its cumbersome requirements. Interview with James Love, Director, Knowledge Ecology International, in Durham, N.C. (Feb. 25, 2006); see also RUTH L. OKEDIJI, *FOSTERING ACCESS TO EDUCATION, RESEARCH AND DISSEMINATION OF KNOWLEDGE THROUGH COPYRIGHT* 9–10 (2005), http://www.iprsonline.org/unctadictsd/bellagio/docs/Okideji_Bellagio4.pdf (discussing the cumbersome requirements of the Berne Appendix).

319. See U.S. Proposal, *supra* note 261, ¶ 29 (“Because a country would only have full legal certainty after the conclusion of a dispute process—a situation that we would like to avoid—we are concerned that an interpretation or amendment will not deliver the legal certainty and security sought by many WTO Members”). *But see* Kenya Proposal, *supra* note 269, ¶ 21 (“The African Group takes the view that notification should serve the purpose of information sharing but must not constitute a notification obligation.”).

In sum, the proposed Article 31 *bis*, along with the annex and appendix to the annex, was an apparent compromise between developed and less developed countries. It was significantly different from the one-size-fits-all template for which the United States or the European Communities has been pushing. While the less developed countries were able to prevail on the scope-of-diseases and country eligibility issues, the United States was successful in limiting the amendment to Article 31. Nevertheless, the proposed amendment did not allow less developed countries to reclaim their lost policy space or to roll back the recent expansion of intellectual property rights. Thus, if they are to reclaim this lost space and to further resist the international enclosure movement, they need to understand the root causes of the movement and devise strategies accordingly to resist or even roll back the enclosure attempts.

IV. THE RECLAMATION OF POLICY SPACE

From the TRIPs Agreement to bilateral and regional trade agreements, developed countries have been fairly successful in inducing their less developed trading partners to adopt a rich-country intellectual property system despite their limited economic development and technological capabilities. To understand why developed countries were successful in enclosing the policy space of less developed countries, this Part advances three explanations. First, this Part argues that the significant disparity in power between developed and less developed countries has given the less-powerful countries no choice but to adopt harmful rich-country transplants. Second, this Part underscores the incentive-investment divide between national and foreign intellectual property policies and explains how the linkage between trade and intellectual property has caused policymakers to focus unduly on the protection of trade interests while ignoring the importance in harnessing local conditions to promote innovation. Finally, this Part shows that the transformation of the international intellectual property system from a patchwork coordination system to a supranational, harmonized code forces countries to adopt legal standards that ignore local economic, social, cultural, and technological conditions. As intellectual property protection becomes increasingly globalized, it spills over into other areas. A reexamination of the design of the international intellectual property system is, therefore, in order. Following the discussion of each explanation, this Part offers suggestions on how countries can reform the international intellectual property system to preserve the autonomy needed to tailor policies to local conditions and how less developed countries can reclaim their lost policy space to facilitate greater access to essential medicines.

A. Power Asymmetry

More than ten years have passed since the establishment of the TRIPs Agreement. By now, it is apparent that the power asymmetry in the international trading system has been projected into the intellectual property arena. Just as IP-irrelevant factors affect the access-to-medicines problem, TRIPs-irrelevant factors equally affect the implementation of the TRIPs Agreement and the overall design of the existing international intellectual property system.³²⁰ Although the international intellectual property system initially focused on the differences between what would today be

320. Thanks to Debora Halbert for making this suggestion.

considered developed countries, its nature changed as a large number of less developed countries joined the system in the post-colonial era. As less developed countries realized the hard way, the changes required by the TRIPs Agreement were not only dramatic, but also went beyond just intellectual property to affect other areas, such as agriculture, health, the environment, education, and culture.³²¹ Even worse for less developed countries, while they have to modify their intellectual property systems or risk sanctions under the WTO, they are unable to use the WTO dispute settlement process to change the behavior of their more powerful trading partners, like the European Communities or the United States. The recent bilateral and regional trade agreements initiated by the European Communities and the United States have also forced less developed countries to ratchet up intellectual property protection even though they have yet to successfully adjust to the heightened protection required by the TRIPs Agreement.

Although commentators have described the TRIPs Agreement as “coercive,”³²² it is not as one-sided as many commentators have claimed, especially when viewed in the international trade context.³²³ Indeed, despite commentary suggesting that some less developed countries might have been ignorant of the importance of intellectual property when they signed on to the TRIPs Agreement,³²⁴ there was sufficient evidence to suggest that negotiators in those countries might have negotiated to the best of their ability under the circumstances and considering the inequitable nature of the geopolitical system. Indeed, one could view the TRIPs Agreement as a complex bargain in which each party obtained its preferred benefits.³²⁵ While developed countries received stronger protection for intellectual property rights and a reduction in restrictions against foreign direct investment, less developed countries obtained lower tariffs on textiles and agriculture and protection, via the mandatory dispute settlement process, against unilateral sanctions imposed by their more-powerful counterparts. To some negotiators, the complete WTO package might provide a net gain to their countries, even though the TRIPs Agreement was a loss.

From the international trade perspective, this bargain narrative makes a lot of sense. Although intellectual property rules are technical, the negotiation of these rules “do[es] not take place in isolation from other trade and finance negotiations.”³²⁶ Today, many less developed countries remain “highly dependent on the developed countries as the source of capital, whether it is provided through the IMF or World Bank, or through investment bankers and securities exchanges.”³²⁷ As Peter Gerhart noted, “international intellectual property regimes are not made through a search for the right balance between incentives and access because the states that make the regime are not,

321. See Yu, *Currents and Crosscurrents*, *supra* note 127, at 365.

322. See sources cited in Peter K. Yu, *Toward a Nonzero-sum Approach to Resolving Global Intellectual Property Disputes: What We Can Learn from Mediators, Business Strategists, and International Relations Theorists*, 70 U. CIN. L. REV. 569, 580 n.70 (2002).

323. Yu, *TRIPs and Its Discontents*, *supra* note 193, at 374–75.

324. See *id.* at 375–76 (discussing the ignorance narrative of the TRIPs Agreement).

325. See *id.* at 371–73 (discussing the bargain narrative of the TRIPs Agreement).

326. Frederick Abbott, *The Future of IPRs in the Multilateral Trading System*, in *TRADING IN KNOWLEDGE*, *supra* note 7, at 36, 43.

327. *Id.*; see also Roffe, *supra* note 31, at 15 (“[I]t may need substantial courage for a small country to issue a compulsory licence on a drug patented in the US or in a European Union . . . Member State.”).

individually, looking for that balance in the international sphere. Each state is looking for an international regime that reflects that state's interests."³²⁸

However, when the Agreement is viewed in the context of intellectual property protection (or public health) alone, there is no denial that the TRIPs Agreement is biased against less developed countries. The fact that it is not intentionally biased in the international trade context does not reduce the seriousness and impact of its bias in the intellectual property area. Neither is it helpful to note that the WTO package as a whole provides a net gain to the country or that some sectors within the nation may have benefited from the package. Without a transfer of payments from one sector to another, gains in one sector will do nothing to alleviate the problems of those sectors that have lost out, such as the generic manufacturers or the poor consumers who cannot afford to pay higher drug prices. As Frederick Abbott noted:

The problem with . . . using net economic gains or losses as the developing country benchmark is that gains for a developing country's textile or agricultural producers do not directly translate into higher public or private health expenditures. Salaries for part of the workforce may increase and government tax revenues may rise, and this may indirectly to help offset pharmaceutical price increases. However, in order for the health sector not to be adversely affected, there must be some type of transfer payment, whether in the form of increased public health expenditures on pharmaceuticals, by providing health insurance benefits, or other affirmative acts. In a world of economic scarcity, the prospect that governments will act to offset increases in medicines prices with increased public health expenditures is uncertain.³²⁹

Moreover, some of the gains are more aspirational than empirically grounded.³³⁰ While the TRIPs Agreement requires less developed countries to strengthen

328. Peter M. Gerhart, *Introduction: The Triangulation of International Intellectual Property Law: Cooperation, Power, and Normative Welfare*, 36 CASE W. RES. J. INT'L L. I, 11–12 (2004).

329. Abbott, *Cycle of Action*, *supra* note 15, at 33 (citation omitted); see MUSUNGU & OH, *supra* note 12, at xi (“[The] net gains analysis presumes that earnings in agriculture or other sectors due to increased market access . . . would automatically translate into ability to afford higher priced medicines.”); Gerhart, *supra* note 328, at 16 (“[W]hen we think of the welfare aspects of intellectual property we normally do not think of the distributive dimension—that is, we do not think about how the gains and losses from policy design are distributed.”); see also JACK DONNELLY, *UNIVERSAL HUMAN RIGHTS IN THEORY AND PRACTICE* 201 (2d ed. 2003) (“[B]ecause markets distribute the benefits of growth without regard to short-term deprivations—those who suffer ‘adjustment costs’—lost jobs, higher food prices, inferior health care—acquire no special claim to a share of the collective benefits of efficient markets.”).

330. As David McGowan noted about the current intellectual property debate:

It is easy for each side to poke holes in the other side's positions. It is hard for either side to make an affirmative, instrumental case for their views. For this reason, and because scholars favor consequentialist rhetoric, the debate often consists of competing narratives that use hunches and conjectures to link the result an author desires to the policy the author favors. Because the evidence in such arguments is so weak, the legal endgame is to place the burden of proof on the other side. Whoever has to prove the unprovable facts is likely to lose.

David McGowan, *Copyright Nonconsequentialism*, 69 MO. L. REV. I, 2 (2004); see also IPR COMMISSION REPORT, *supra* note 6, at 166 (“As the rules [of the intellectual property system]

intellectual property protection, it guarantees the prospects of neither technical assistance nor increased foreign investment from developed countries. As one commentator noted, “to pass and enforce the laws that create the US\$60 billion a year obligation is a bound obligation; however, the implementation assistance and the impact on investment and innovation are not.”³³¹

Indeed, the lack of technical assistance in developing intellectual property laws that are sensitive to local conditions, as well as the lack of indigenous expertise to do so, have hurt less developed countries. Due to such a lack, less developed countries often have to directly transplant the TRIPS requirements onto their domestic laws, and exceptions that the Agreement does not mention explicitly are unlikely to find their way to the intellectual property system. As Rochelle Dreyfuss pointed out in the case of trade secret protection, “since TRIPS does not mention a right to reverse engineer [which exists in the United States], transcription would create a level of protection surpassing that found in the United States, where the right to copy is privileged.”³³² To make matters worse, appeals by less developed countries for guidance and technical assistance are often met by those having a different orientation, or even a different agenda.³³³ Even if the assistance represents a well-intentioned effort to assist in the use of intellectual property laws to promote economic development, there is no guarantee that the advisor understands the local conditions.

Legal transplants that are not tailored to local conditions are problematic for several reasons. First, because of the differences in economic conditions, imitative capacity, and research and development productivities,³³⁴ an innovative model that works well in developed countries often does not suit the needs and interests of less developed countries.³³⁵ Unquestioned adoption may not only fail to result in greater innovative efforts, industrial progress, and transfer of technology, but may also drain away the resources needed for dealing with socio-economic and public health problems. Such adoption might also exacerbate the dire economic plight of less developed countries by allowing foreign rights holders to crush local industries through the threats of litigation, or even actual litigation.³³⁶

evolve, it is important that their actual and potential impact be properly understood if policymaking is to be more firmly based on evidence, and less on preconceptions of the value or otherwise of these rules to developing countries.”); Penrose, *supra* note 112, at 772 (noting that the arguments for and against the effect of a domestic patent system on invention and innovation generally is “primarily ‘testimony’” and that “there are very little ‘hard’ empirical data”).

331. J. Michael Finger, *Introduction and Overview*, in POOR PEOPLE’S KNOWLEDGE: PROMOTING INTELLECTUAL PROPERTY IN DEVELOPING COUNTRIES 1, 4 (J. Michael Finger & Philip Schuler eds., 2004), available at http://www.worldbank.org/rcsearch/Poor_Peoples_Knowledge.pdf.

332. Dreyfuss, *TRIPS—Round II*, *supra* note 2, at 25.

333. *Id.* (“[T]he countries in a position to provide assistance do so on their own terms; that is, they help implement highly protectionist regimes, without regard for the actual needs of developing nations.”).

334. Claudio R. Frischtak, *Harmonization Versus Differentiation in Intellectual Property Rights Regime*, in GLOBAL DIMENSIONS OF INTELLECTUAL PROPERTY RIGHTS IN SCIENCE AND TECHNOLOGY 89, 93–97 (Mitchel B. Wallerstein, Mary Ellen Moguee & Roberta A. Schoen eds., 1993).

335. See sources cited in Yu, *From Pirates to Partners I*, *supra* note 120, at 233 n.502.

336. See ‘t Hoen, *supra* note 14, at 30–31 (discussing the lawsuit major pharmaceutical

Second, from the development standpoint, those less developed countries that suffer from the imbalance created by a rich-country intellectual property system are often those that lack an indigenous capacity to develop and manufacture pharmaceuticals. Although commentators and policymakers have explained at length why stronger patent protection in these countries may help stimulate indigenous inventive activities, significant empirical evidence shows that, while stronger protection may benefit those possessing strong imitative capacity and technical expertise, it does not work well for countries that do not have similar conditions.³³⁷

Third, the high costs of pharmaceuticals and heavy medical expenses would take away the needed resources to put in place mechanisms to correct an out-of-balance intellectual property system. Although commentators have emphasized the importance of a counter-balancing competition system,³³⁸ it remains disturbing that many less developed countries do not have the resources to put together at the same time *both* a patent system and a competition system; instead, they often have to choose between the two. Many of these countries also may not have the ability to put in place a correction mechanism once they have exhausted their financial and human resources to update or strengthen their intellectual property system.³³⁹ Even worse, because reforms based on foreign models always incur political costs on those pushing the reforms, policymakers may have limited political capital to put in place further “correction” reforms once their initial reforms fail.

Finally, from the standpoint of intellectual property rights holders, unquestioned transplants of foreign laws are unlikely to result in sustained development of intellectual property protection in a country that lacks a tradition or a legal culture of such protection, which takes considerable time to build. As I pointed out in the case of China, it was not until the development of local stakeholders that the Chinese leaders became interested in offering stronger protection of intellectual property rights without

manufacturers brought against the government of South Africa).

337. See KEITH E. MASKUS, *INTELLECTUAL PROPERTY RIGHTS IN THE GLOBAL ECONOMY* 116–19 (2000).

338. See, e.g., Jonathan Berger, *Advancing Public Health by Other Means: Using Competition Policy*, in *NEGOTIATING HEALTH*, *supra* note 15, at 181, 182 (exploring how less developed countries can use competition policy to “increase access to a sustainable supply of affordable essential medicines”); Ernst-Ulrich Petersmann, *International Competition Rules for Governments and for Private Business: A “Trade Law Approach” for Linking Trade and Competition Rules in the WTO*, 72 *CHI.-KENT L. REV.* 545, 563 (1996) (“[D]eveloping countries with underdeveloped national competition and intellectual property rights laws . . . will need more systematic rules on the protection of competition among trade-related intellectual property rights and on the prevention of their anticompetitive abuse.”); 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, 52–58 (1997) (proposing to use “competition law to curb the abuse of market power” as a pro-competitive strategy for implementing the TRIPs Agreement in less developed countries).

339. See IPR COMMISSION REPORT, *supra* note 6, at 4 (“[W]e consider that, if anything, the costs of getting the IP system ‘wrong’ in a developing country are likely to be far higher than in developed countries. Most developed countries have sophisticated systems of competition regulation to ensure that abuses of any monopoly rights cannot unduly affect the public interest.”); MASKUS, *supra* note 337, at 237 (noting that developed countries “have mature legal systems of corrective interventions” where “the exercise of [intellectual property rights] threatens to be anticompetitive or excessively costly in social terms”).

the presence of foreign pressure.³⁴⁰ If intellectual property protection is to be strengthened, an endogenous approach that seeks to develop local stakeholders and to undermine resistance against stronger protection will be very important.³⁴¹

Thus, if we are to facilitate greater access to essential medicines in less developed countries, we have to correct the imbalance in the current international intellectual property system. The length of this Article does not allow me to engage in an elaborate discussion of what less developed countries need to do to take advantage of the TRIPs Agreement and to reform the international intellectual property system. The following list, therefore, only recapitulates the eight courses of action I proposed and discussed elsewhere:

1. Develop a pro-development interpretation of the TRIPs Agreement.
2. Explore the public interest safeguards in the TRIPs Agreement.
3. Take advantage of the WTO dispute settlement process.
4. Add explicit access rights to the TRIPs Agreement.
5. Explore the use of alternative international regimes.
6. Facilitate coalition building.
7. Understand the tension between the European Communities and the United States.
8. Assess the compatibility of the free trade agreements with the multilateral WTO system.³⁴²

For illustrative purposes, consider the need for less developed countries to build coalitions to resist pressures on public health.³⁴³ While the United States was actively developing its divide-and-conquer strategy to reward those who were willing to work with the country, Brazil, India, and other members of the Group of 20 successfully established a united negotiating front for less developed countries.³⁴⁴ This coalition eventually led to the collapse of the Fifth WTO Ministerial Conference in Cancún, in which developed countries failed to obtain new legal standards on investment, competition policy, government procurement, and trade facilitation.³⁴⁵ In light of the

340. See Yu, *From Pirates to Partners I*, *supra* note 120, at 140–54 (discussing the cycle of futility and criticizing the U.S. foreign intellectual property policy toward China in the late 1980s and early 1990s).

341. See Peter K. Yu, *The Copyright Divide*, 25 *CARDOZO L. REV.* 331, 431–33 (2003) (discussing the need to create local stakeholders).

342. Yu, *TRIPS and Its Discontents*, *supra* note 193, at 386–410 (delineating eight courses of action to reform the international intellectual property system).

343. See Abbott, *Cycle of Action*, *supra* note 15, at 33 (noting the importance of “[t]he formation of counter-coalitions committed to resisting pressures on public health”); Yu, *TRIPS and Its Discontents*, *supra* note 193, at 403–06 (discussing coalition-building strategies).

344. Yu, *TRIPS and Its Discontents*, *supra* note 193, at 403 (discussing coalition-building strategies used by the Group of 20). The twenty-one current members of the G-20 are: Argentina, Bolivia, Brazil, Chile, China, Cuba, Egypt, Guatemala, India, Indonesia, Mexico, Nigeria, Pakistan, Paraguay, Philippines, South Africa, Tanzania, Thailand, Uruguay, Venezuela, and Zimbabwe. The website of the G-20 is available at <http://www.g-20.mre.gov.br/>.

345. See Elizabeth Becker, *Poorer Countries Pull Out of Talks Over World Trade*, *N.Y. TIMES*, Sept. 15, 2003, at A1; Editorial, *The Cancun Failure*, *N.Y. TIMES*, Sept. 16, 2003, at A24.

increasing proliferation of bilateral and regional trade agreements, this coalition-building strategy has become even more important.³⁴⁶

Although the international system remains state-centered, coalition-building efforts are not limited to states. Today, private actors have played an increasingly important role. Thus, it is important for generic drug companies to pursue multicountry strategies that help “reduce the problems of intimidation and direct confrontation that might inhibit single developing countries to hold strong positions when negotiating with the US, the EU or a TNC [transnational corporation].”³⁴⁷ It is also important for less developed countries “to work consistently with US and European political allies to alter the US and European domestic political contexts.”³⁴⁸ In doing so, generic manufacturers will be able to “enhance the prospects of their success [by convincing] other US and European constituencies [to] offset the pharmaceutical industry’s pressure on US and European trade authorities to aggressively advance industry interests.”³⁴⁹

B. The Incentive-Investment Divide

The TRIPs Agreement not only imposed intellectual property laws on less developed countries, but for the first time linked intellectual property with trade at the multilateral level. Commentators widely agreed that including intellectual property in the trade agreement was one of the greatest achievements of the Uruguay Round.³⁵⁰ As Michael Ryan noted, such bargain linkage has allowed member states to “achieve treaties in diplomatically and politically difficult areas in which agreement would otherwise be elusive.”³⁵¹ Without such linkage, the developed and less developed countries might not have been able to resolve the deadlock developed since the 1981 Diplomatic Conference in Nairobi.³⁵²

Notwithstanding these achievements, the linkage between trade and intellectual property has greatly distorted the decision-making process concerning the development of international intellectual property policies. Due to the enormous disparity in volume, trade interests often take over intellectual property interests. Because trade negotiators often have to negotiate intellectual property interests as part of a package trade deal, they are keener on protecting the foreign investment of their nationals and exporting industries than on striking the appropriate balance in the intellectual property system in either the target country or the international community as a whole.³⁵³ As a result, there

346. See Abbott, *Cycle of Action*, *supra* note 15, at 34 (noting the urgency for less developed countries to respond to the bilateral and regional free trade agreements).

347. Rovira, *supra* note 84, at 239.

348. Shaffer, *supra* note 308, at 479.

349. *Id.* at 480.

350. See, e.g., Dreyfuss & Lowenfeld, *supra* note 172, at 276–77 (considering the TRIPs Agreement as one of the two major achievements of the Uruguay Round).

351. MICHAEL P. RYAN, *KNOWLEDGE DIPLOMACY: GLOBAL COMPETITION AND THE POLITICS OF INTELLECTUAL PROPERTY* 12 (1998).

352. See *supra* Part II.A (discussing the deadlock between developed and less developed countries in the diplomatic conference in Nairobi).

353. See Carlos M. Correa, *Internationalization of the Patent System and New Technologies*, 20 *WIS. INT’L L.J.* 523, 524 (2002) (“During the last century, a new shift in emphasis took place towards a system mainly concerned with the encouragement of the *investment* required to

is increasingly an incentive-investment divide between national and foreign intellectual property policies, and intellectual property protection has become a mere bargaining chip among the many other trade items in a calculus of the country's international trade bottom line.

Consider, for example, the recent United States-Australia Free Trade Agreement. Although Australia's chief negotiator, Stephen Deady, "told the Senate Estimates Committee that the Australian economy would receive an economic boost from the copyright term extension . . . [he confessed] that the Government had not engaged in any economic research of its own into the impact of the copyright term extension."³⁵⁴ Other officials have, likewise, dismissed the importance of the copyright term extension requirement amidst the many bargaining items in the Agreement. When questioned about the economic benefits of the copyright term extension, a spokesman for Australian Trade Minister Mark Vaile explained, "Our position was that we did not think we needed to go the extra 20 years . . . but in the context of the overall agreement we were happy to."³⁵⁵

The position of the Australian government was understandable. As Michael Geist noted:

Australia may recognize the importance of a balanced copyright policy to both their cultural and economic policies, but they are increasingly willing to treat intellectual property as little more than a bargaining chip as part of broader negotiation. Since most trade deals are judged by an analysis of the bottom-line, economic benefits that result from the agreement, and since quantifying the negative impact of excessive copyright controls is difficult, the policy implications of including copyright within trade agreements is [sic] often dismissed as inconsequential.³⁵⁶

produce and exploit inventions."); Correa, *Unfair Competition Under the TRIPS Agreement*, *supra* note 167, at 72 ("[T]est data protection is a reward for the investment in data production, rather than for the creativity or inventiveness involved."); Gathii, *Construing Intellectual Property Rights*, *supra* note 40, at 748 ("Although fair trade was the chosen means of the advocates of the TRIPS agreement to combat IPR piracy, the true goal of these advocates in adopting a private property model was to maximize profits and returns on investment for the purpose of research and development of IPRs."); Ruth L. Okediji, *Back to Bilateralism? Pendulum Swings in International Intellectual Property Protection*, 1 U. OTTAWA L. & TECH. J. 125, 130 (2004) ("[I]t is important to understand the new bilateralism, both its structure and its pervasiveness, as a significant expression of the enduring project of the post-colonial assimilation of developing countries and peoples into an international legal order that privileges private capital, particularly through the agency of transnational corporations.").

354. Matthew Rimmer, *Robbery Under Arms: Copyright Law and the Australia-United States Free Trade Agreement*, FIRST MONDAY, Mar. 2006, at http://www.firstmonday.dk/issues/issue11_3/rimmer/index.html.

355. *Id.* (quoting Fergus Shiel, *Libraries Caught in Copyright Changes*, AGE (Melbourne), Feb. 11, 2006, at A5, available at <http://www.theage.com.au/articles/2004/02/10/1076388365432.html>).

356. Michael Geist, *Why We Must Stand on Guard Over Copyright*, TORONTO STAR, Oct. 20, 2003, at D3; see also Kevin Outterson, *Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets*, 5 YALE J. HEALTH POL'Y L. & ETHICS 193, 243 (2005) ("USTR may succeed in raising drug prices in the least appropriate places. The greatest success will be found in the poorest countries, or other smaller countries desperately seeking preferential access to the U.S. market. Small, poor countries offered a free trade deal

Given the fact that the negotiators had considered intellectual property protection as merely one of the many bargaining chips in international trade, it is, therefore, no surprise that Australia agreed to adopt TRIPs-plus and TRIPs-extra measures without asking hard questions about whether these changes strike an optimal balance in the Australian intellectual property system.³⁵⁷ Nevertheless, the Australian example foreshadows the difficulty confronting less developed countries in their dealings with more powerful trading partners. Because Australia is one of the larger economies in the world,³⁵⁸ if it did not find it beneficial to resist the United States's demands in the intellectual property area, one can only imagine how effective less developed countries can be in resisting those demands.

To make matters worse, less developed countries were equally blinded by their concern about compliance with their international obligations. As Keith Maskus and Jerome Reichman have pointed out, many of these countries are "compliance oriented." Concerned about using the intellectual property system to attract foreign direct investment, technology transfer, inward trade flows, and human capital,³⁵⁹ many of these countries have yet to "treat intellectual property as an integral part of national or regional systems of innovation."³⁶⁰ Just as developed countries are obsessed with the protection of the *investment* made by their exporting industries, less developed countries are also obsessed with international compliance and the acquisition of foreign direct *investment*. In the end, both groups of countries focus so much on investment that they pay little attention to innovation and its needed incentives.

Consider the implementation of Article 39(3) of the TRIPs Agreement as an illustration. Although the provision requires member states to protect only undisclosed information against unfair commercial use, recent bilateral and regional trade agreements have pushed for stronger protection that allows pharmaceutical companies to prevent their competitors from using clinical trial data submitted to authorities for regulatory approval.³⁶¹ As the pharmaceutical industry claimed, "the development and bringing to market of a new drug requires the originator to conduct extensive chemical, pharmacological, toxicological and clinical research and testing, at an average cost of US\$800 million, and taking 10 to 15 years to complete."³⁶² Thus, the industry contends

with the United States may well agree to provisions which undermine health in order to serve commercial interests.") (footnote omitted); Shira Perlmutter, *Future Directions in International Copyright*, 16 CARDOZO ARTS & ENT. L.J. 369, 378 (1998) (contending that, for many countries, "the trade-related benefits that may be obtained from joining a club like the WTO can outweigh any perceived drawbacks of adopting a new copyright law").

357. These measures include an extension of the copyright term, the adoption of an anti-circumvention provision, and a ban on the parallel importation of cheap generic drugs. U.S.-Australia FTA, *supra* note 204, ch. 17.

358. List of countries by GDP (nominal), WIKIPEDIA, http://en.wikipedia.org/wiki/List_of_countries_by_GDP_%28nominal%29 (last visited Apr. 11, 2007).

359. See Peter K. Yu, *Intellectual Property, Economic Development, and the China Puzzle*, in INTELLECTUAL PROPERTY, TRADE AND DEVELOPMENT: STRATEGIES TO OPTIMIZE ECONOMIC DEVELOPMENT IN A TRIPS PLUS ERA (Daniel J. Gervais ed., forthcoming 2007) [hereinafter Yu, *Intellectual Property, Economic Development*], available at <http://ssrn.com/abstract=978301>.

360. Maskus & Reichman, *supra* note 43, at 18.

361. See sources cited *supra* note 206.

362. IFPMA REVIEW, *supra* note 166. Commentators, however, have queried the oft-cited \$800 million figure. As Marcia Angell explained:

that additional protection, other than what it has already received under the patent system, is needed to enable them to recoup the high costs of data collection.

However, as commentators and economists have pointed out, the need for such protection is at best dubious from an economic standpoint.³⁶³ Although the costs of clinical trials remain high and could make up for a major portion of the research and development costs of new drugs,³⁶⁴ companies already have large incentives under the current patent system as well as public funding support to conduct research and development. To be certain, many of these companies need incentives to obtain market approval for the product, even if they have already obtained incentives from the patent system to invent it in the first place.³⁶⁵ However, unless the regulatory authorities require different clinical trials, most of the marketing costs are already included in the total costs that are used to justify stronger patent protection. If additional incentives are provided by the data exclusivity regime, one has to wonder whether patent protection should be weakened proportionally to reflect the additional incentives.

In addition, there is no evidence that a data exclusivity system within developed countries will not enable the pharmaceutical companies to recoup their investment. Because “developing countries provide a small share of the global pharmaceutical market and their policy choices have a minimal impact upon the R&D investment decisions of multinational pharmaceutical companies,” ratcheting up protection in the form of data exclusivity in less developed countries is unlikely to result in greater foreign direct investment in those countries.³⁶⁶ If the need for data exclusivity is not supported by empirical evidence, one has to wonder whether the regime is justified for any reason other than the desire to protect the pharmaceutical exports of developed countries. As Peter Drahos noted, “[e]ven within some developed countries, the tendency to espouse a protectionist IP agenda seems more a reflection of policy capture than a reasoned attempt to balance domestic needs.”³⁶⁷

Today, the trade deficit has figured largely in the discussion of any international intellectual property agreement. Viewed through this lens, one can easily understand

[The Tufts estimate of \$802 million] is not the actual out-of-pocket cost at all, even for the special group of drugs considered. That cost was \$403 million per drug. The \$802 million is what the authors call the “capitalized” costs—that is, it includes the estimated revenue that might have been generated if the money spent on R&D had instead been invested in the equity market. It’s as though drug companies don’t *have* to spend any money at all on R&D; they could invest it instead. . . . This theoretically lost revenue is known as the “opportunity cost,” and the Tufts consultants simply tacked it on to the industry’s out-of-pocket costs. That accounting maneuver nearly doubled the \$403 million to \$802 million.

ANGELL, *supra* note 19, at 44–45.

363. See, e.g., Carlos M. Correa, *Protecting Test Data for Pharmaceutical and Agrochemical Products Under Free Trade Agreements*, in NEGOTIATING HEALTH, *supra* note 15, at 81; Aaron Xavier Fellmeth, *Secrecy, Monopoly, and Access to Pharmaceuticals in International Trade Law: Protection of Marketing Approval Data Under the TRIPs Agreement*, 45 HARV. INT’L L.J. 443, 469 (2004); Pugatch, *supra* note 48; Robert Weissman, *Data Protection: Options for Implementation*, in NEGOTIATING HEALTH, *supra* note 15, at 151 [hereinafter Weissman, *Data Protection*].

364. See Henry Grabowski, *Increasing R&D Incentives for Neglected Diseases: Lessons from the Orphan Drug Act*, in INTERNATIONAL PUBLIC GOODS, *supra* note 43, at 457.

365. Thanks to Aaron Fellmeth for raising this important question.

366. Weissman, *Data Protection*, *supra* note 363, at 154.

367. Maskus & Reichman, *supra* note 43, at 10.

why policymakers and negotiators have been particularly concerned about the foreign investment of their nationals and exporting industries. Indeed, trade agreements, including those in the intellectual property area, can be increasingly considered as investment treaties. As Frederick Abbott has noted:

A patent is essentially a financial instrument that entitles its bearer to achieve greater than competitive market rates of return on investment. The Pharma companies are market-oriented enterprises that seek to maximize shareholder returns on investment. Pharma treats potential intrusion on the security of the patent and regulated regulatory support as a threat to return on investment. Pharma justifies its rent seeking as necessary to the funding of research and development for new medicines. . . . The Pharma companies demand rules and enforcement that will protect their income streams, justifying a high return on investment as necessary to drug development.³⁶⁸

Because trade negotiators focus more on the protection of investment by their nationals than the economic efficiency of and the welfare gain in the intellectual property system, they are more likely to request the development of a system that is biased toward foreign investors and that does not take into consideration the public interest, the local innovative environment, and the country's social-economic conditions. Indeed, although it has been shown that countries need to have different patent systems due to their varying economic, social, cultural, and technological conditions,³⁶⁹ the international patent system has increasingly focused on the development of a one-size-fits-all template. Such a "universal" template seeks to offer maximum protection to the investment of exporting industries based in developed countries, regardless of whether such investment makes economic sense or represents a windfall to the investors.³⁷⁰

Moreover, while commentators have discussed how intellectual property can enhance foreign direct investment,³⁷¹ they have yet to provide concrete evidence

368. Abbott, *Cycle of Action*, *supra* note 15, at 36.

369. See Graeme B. Dinwoodie & Rochelle C. Dreyfuss, *TRIPS and the Dynamics of Intellectual Property Lawmaking*, 36 CASE W. RES. J. INT'L L. 95, 95 (2004) ("As new industries emerge and mature, nations must have the flexibility to modify their intellectual property rules to readjust the balance between public and private rights."); Yu, *Intellectual Property and the Information Ecosystem*, *supra* note 211, at 9 ("[P]olicymakers in less developed countries often find themselves confronted with contradictory intellectual property policies."); Peter K. Yu, *Still Dissatisfied After All These Years: Intellectual Property, Post-WTO China, and the Avoidable Cycle of Futility*, 34 GA. J. INT'L & COMP. L. 143, 153 (2005) [hereinafter Yu, *Still Dissatisfied After All These Years*] (noting that China is likely to be "schizophrenic" over its intellectual property policies, due to its preference for stronger protection for entertainment, software, biotechnology, and semiconductors while having lower protection for pharmaceuticals, chemicals, and foodstuffs).

370. See Assafa Endeshaw, *The Paradox of Intellectual Property Lawmaking in the New Millennium: Universal Templates as Terms of Surrender for Non-Industrial Nations; Piracy as an Offshoot*, 10 CARDOZO J. INT'L & COMP. L. 47 (2002) (criticizing the application of universal templates to non-industrial nations); Peter K. Yu, *World Trade, Intellectual Property and the Global Elites: An Introduction*, 10 CARDOZO J. INT'L & COMP. L. 1, 2-3 (2002) (criticizing the requirement that less developed countries adopt a one-size-fits-all intellectual property system).

371. Josh Martin, *Copyright Law Reforms Mean Better Business Climate*, J. COM., Mar. 7,

concerning the correlation between intellectual property protection and such investment. Studies, indeed, have shown that many companies that are doing business in China are not particularly concerned about intellectual property issues.³⁷² Rather, foreign companies set up operations in the country either to take advantage of the lower production costs, the large growing market, or the preferential treatment of foreign investors.³⁷³

To correct the imbalance in the intellectual property system, this Part proposes three courses of actions. First, policymakers need to delink intellectual property from trade in their policy assessment and carefully evaluate the need for intellectual property protection outside the trade context. While this Article advocates the delinking of intellectual property from trade when the need for particular intellectual property protection is assessed, it does not call for a delinking of intellectual property from trade in the international intellectual property system. Linking intellectual property and trade has its benefits, including getting both developed and less developed countries to reach an agreement in the first place.³⁷⁴ Notwithstanding these benefits, such linkage is likely to result in an inaccurate assessment of the need for intellectual property protection.

By contrast, an independent evaluation would allow countries to develop a balanced system that helps protect the interests of intellectual property rights holders while facilitating the much needed access to essential medicines (as well as meeting other public access needs). It would also allow countries whose economic sectors are growing at a different pace to avoid making a difficult choice that will benefit only some of the sectors. For example, emerging countries like China, Brazil, and India are likely to be “schizophrenic” over their intellectual property policies. While they want strong protection of intellectual property rights in such sectors as entertainment, software, biotechnology, and semiconductors, they prefer lower protection in other areas, such as pharmaceuticals, chemicals, and foodstuffs.³⁷⁵ Unfortunately for these countries, which “generate substantial trade surpluses with OECD countries, arguments in favour of price concessions on pharmaceuticals may become less compelling in a wider political arena,”³⁷⁶ even though the poor in these countries continue to suffer from high prices and the resulting inaccessibility of drugs.

To undertake an independent inquiry that delinks intellectual property and trade, policymakers need to explore whether the protection is needed in the first place—for example, whether it would generate the optimal level of incentives to promote

1996, at 2C (reporting about a World Bank survey of major U.S. companies that demonstrated the correlation between intellectual property rights and foreign investment).

372. See Paul Tackaberry, *Intellectual Property Risks in China: Their Effect on Foreign Investment and Technology Transfer*, J. ASIAN BUS., Fall 1998, at 1, 26, quoted in Yahong Li, *The Wolf Has Come: Are China's Intellectual Property Industries Prepared for the WTO?*, 20 UCLA PAC. BASIN L.J. 77, 79 n.9 (2002); see also Carlos A. Primo Braga & Carsten Fink, *The Relationship Between Intellectual Property Rights and Foreign Direct Investment*, 9 DUKE J. COMP. & INT'L L. 163, 164 (1998) (“[T]he available empirical evidence does not conclusively establish the relationship between IPRs and FDI decisions.”).

373. Yu, *Intellectual Property, Economic Development*, *supra* note 359.

374. See RYAN, *supra* note 351, at 12 (noting that bargain linkage allowed member states to “achieve treaties in diplomatically and politically difficult areas in which agreement would otherwise be elusive”).

375. Yu, *Still Dissatisfied After All These Years*, *supra* note 369, at 153.

376. Abbott, *Cycle of Action*, *supra* note 15, at 29.

innovative activities and consumer welfare.³⁷⁷ The fact that the pharmaceutical industry is spending millions of dollars on collecting clinical trial data does not mean that it deserves protection unless such protection will result in therapeutic advances and the further development of pharmaceutical products. Indeed, as pointed out above, there is insufficient empirical evidence to warrant the recent expansion of intellectual property rights. An inquiry based on intellectual property protection alone, therefore, would force policymakers to ask hard questions about why they need to introduce additional protection in the first place.

Objections can be raised about the difficulty in proving or disproving the benefits of a patent system through empirical analyses. As Fritz Machlup remarked famously in his critical examination of the American patent system: "If we did not have a patent system, it would be irresponsible, on the basis of our present knowledge of its economic consequences to recommend instituting one. But since we have had a patent system for a long time, it would be irresponsible, on the basis of our present knowledge, to recommend abolishing it."³⁷⁸ Thus, if intellectual property rightsholders are concerned about the paradox alluded to by Professor Machlup, policymakers could perhaps lower the burden of proof in the inquiry. While it may be difficult to obtain conclusive proof, such difficulty does not mean that policymakers should not undertake the inquiry at all. Rather, it means that they should be cautious in undertaking such an inquiry.

Some may also be concerned that many less developed countries do not have the needed expertise or resources to conduct impact studies. In addition, as Rochelle Dreyfuss and others have pointed out, the empirical approach tends to favor the retention of an undesirable status quo.³⁷⁹ To alleviate these concerns, policymakers could further adjust the burden to reflect the interests and development needs of less developed countries—for example, by focusing on the upward ratchet while keeping in mind the special nature of protection for traditional knowledge, folklore, and indigenous materials. They could even require developed countries or

377. Some commentators have pointed out the inefficiency of the R&D strategy used by the pharmaceutical industry by focusing on the marginal costs of drug production. However, due to the high fixed costs involved in drug production, the pharmaceutical industry is one of those sectors in which a calculation based on marginal costs would not fully reflect the risks and investment involved. As one commentator explained:

Perhaps [the industry's] most differentiating characteristic is that it is particularly intensive in fixed costs. . . . Once those fixed costs are expended, the remaining costs of drug marketing, manufacturing, and distribution—while far from insignificant—are relatively small. The model of price-setting in a perfectly competitive market suggests that prices are based upon marginal costs. But this model obviously does not apply for pharmaceuticals, for if they were priced according to their marginal costs, they would be very inexpensive, but in the long run no expenditures on R&D would be made.

SCHWEITZER, *supra* note 40, at 8–9.

378. STAFF OF S. COMM. ON THE JUDICIARY, 85TH CONG., AN ECONOMIC REVIEW OF THE PATENT SYSTEM 80 (Comm. Print 1958) (prepared by Fritz Machlup).

379. Rochelle Dreyfuss has raised her concerns along this line. See Justin Hughes, *Of World Music and Sovereign States, Professors and the Formation of Legal Norms*, 35 LOY. U. CHI. L.J. 155, 199 (2003).

intergovernmental organizations, like WIPO or the WTO, to provide financial support and technical assistance for these studies.

Once policymakers find protection is warranted, they need to explore whether there are alternative strategies that are *less restrictive* to the access to essential medicines. This proposal calls for a “less restrictive” standard, as compared to the “least restrictive” standard used often in constitutional law, because the latter would impose too heavy a burden on those seeking protection, significantly reducing incentives for innovation.

In the past few years, commentators have advanced many different proposals, and it is time we seriously evaluate whether these proposals would offer a less restrictive means to protect intellectual property. For example, Tim Hubbard and James Love proposed a treaty that sought to help revamp the way governments fund research and development while alleviating concerns by the United States and other major countries over the free-riding problem.³⁸⁰ The late Jean Lanjouw offered a proposal that requires pharmaceutical companies that develop a patented product for a global disease to “choose either protection in the rich countries or in the poor countries but not in both.”³⁸¹ Led by Yochai Benkler, researchers at Yale Law School have also advocated an open licensing approach for university innovations to address global health inequities.³⁸² In addition, commentators have proposed the establishment of international purchase funds for vaccines and essential medicines.³⁸³ There are also numerous research and case studies about the use of public-private partnerships to enhance access to medicines in less developed countries.³⁸⁴

In the context of clinical trial data, Jerome Reichman has explored the use of a cost-sharing or liability-rule approach, as compared to the data exclusivity approach, to enable pharmaceutical companies to receive compensation for the high costs of the clinical trials used to obtain market approval for pharmaceuticals.³⁸⁵ He also advanced a proposal to treat clinical trials as a global public good, as compared to “a private-sector obligation whose results and outcomes must necessarily be rendered artificially

380. Tim Hubbard & James Love, *A New Trade Framework for Global Healthcare R&D*, 2 PLOS BIOLOGY 147 (2004), available at http://biology.plosjournals.org/archive/1545-7885/2/2/pdf/10.1371_journal.pbio.0020052-S.pdf; see also JOHN BARTON, PRESERVING THE GLOBAL SCIENTIFIC AND TECHNOLOGICAL COMMONS 4 (2003), http://www.ictsd.org/dlogue/docs/tech_transfer_dialogue.pdf (noting the need for “a treaty that defines rules freeing scientific/technological exchange and establishes procedures for negotiating regular improvements and expansions of those rules”).

381. Jean O. Lanjouw, *A New Global Patent Regime for Diseases: U.S. and International Legal Issues*, 16 HARV. J.L. & TECH. 85, 90–91 (2002).

382. See Amy Kapczynski, Samantha Chaifetz, Zachary Katz & Yochai Benkler, *Addressing Global Health Inequities: An Open Licensing Approach for University Innovations*, 20 BERKELEY TECH. L.J. 1031 (2005).

383. For a list of some of these proposals, see Operbeck, *supra* note 77, at 530.

384. See Maskus, *supra* note 31, at 576 (discussing various “innovative research programs within private firms or among collaborative ventures, with substantial shares of funding coming from governments, NGOs, and multilateral organizations”); Obijiofor Aginam, *From the Core to the Peripheries: Multilateral Governance of Malaria in a Multi-Cultural World*, 3 CHI. J. INT’L L. 87, 90–91 (2002) (discussing the development of public-private partnerships as a response to malaria).

385. See Reichman, *International Legal Status*, *supra* note 167, at 144–48.

scarce in order to appropriate returns from investment.”³⁸⁶ Meanwhile, Aaron Fellmeth has proposed a very interesting readjustable royalties model that allows “for the calculation of royalty payments to the initial registrant by subsequent registrants.”³⁸⁷

In exploring all of these alternatives, it is particularly important to examine whether the proposals can be compatible with existing treatments in less developed countries, such as the use of traditional medicine. As one commentator noted, “[i]n developing countries, up to 80 percent of the population relies on traditional medicine to meet its health-care needs. Such medicine is not only affordable, but it is also widely available and trusted.”³⁸⁸ Indeed, “[e]thnomedical knowledge of plants by indigenous people across societies and cultures has ‘long served as [a] crucial source[] of medicines either directly as [a source of] therapeutic agents, as [a] starting point[] for the elaboration of more complex semi-synthetic compounds or as synthetic compounds.’”³⁸⁹

As traditional medicines become more important and patented medicines become more costly and unaffordable, it is no surprise that many less developed countries have raised issues about biopiracy of indigenous knowledge and resources.³⁹⁰ As Peter Drahos noted, “significant numbers of pharmaceutical products that have been released onto the market over the years have their lineage in, and can be traced back to, traditional origins. Yet, property rights protection in these assets does not match the kind of intellectual property rights protection available to companies for their compounds and processes of treatment.”³⁹¹ Most recently, less developed countries have put forward a proposal that requires the disclosure of the source and origin of genetic material as part of the patent application process.³⁹² The proposal, introduced as a draft Article 29*bis* of the TRIPs Agreement, thus far has faced strong resistance from the patent community in the developed world, including Japan, Korea, and the United States.

386. *Id.* at 147.

387. Fellmeth, *supra* note 363, at 483. For a discussion of the model, see *id.* at 482–99.

388. Nanda & Lodha, *supra* note 30, at 586; see also Aginam, *supra* note 384, at 93 (“[E]thnomedical therapies for malaria may be readily available at a cost the community can afford while orthodox (Western) malaria medicines may not be.”). For a discussion of legal issues concerning traditional medicine, see generally Carlos M. Correa, *Protection and Promotion of Traditional Medicine Implications for Public Health in Developing Countries* (2002), <http://www.southcentre.org/publications/traditionalmedicine/traditionalmedicine.pdf>.

389. Aginam, *supra* note 384, at 93.

390. For discussions of biopiracy, see, for example, VANDANA SHIVA, *BIOPIRACY: THE PLUNDER OF NATURE AND KNOWLEDGE* (1997); Keith Aoki, *Neocolonialism, Anticommons Property, and Biopiracy in the (Not-So-Brave) New World Order of International Intellectual Property Protection*, 6 *IND. J. GLOBAL LEG. STUD.* 11 (1998); Peter Drahos, *Indigenous Knowledge, Intellectual Property and Biopiracy: Is a Global Bio-Collecting Society the Answer?*, 2000 *EUR. INTEL. PROP. REV.* 245 (2000); Paul J. Heald, *The Rhetoric of Biopiracy*, 11 *CARDOZO J. INT’L & COMP. L.* 519 (2003); Ikechi Mgbeoji, *Patents and Traditional Knowledge of the Uses of Plants: Is a Communal Patent Regime Part of the Solution to the Scourge of Bio Piracy?*, 9 *IND. J. GLOBAL LEG. STUD.* 163 (2001); Remigius N. Nwabueze, *Ethnopharmacology, Patents and the Politics of Plants’ Genetic Resources*, 11 *CARDOZO J. INT’L & COMP. L.* 585 (2003); Naomi Roht-Arriaza, *Of Seeds and Shamans: The Appropriation of the Scientific and Technical Knowledge of Indigenous and Local Communities*, 17 *MICH. J. INT’L L.* 919 (1996).

391. Drahos, *Intellectual Property and Pharmaceutical Markets*, *supra* note 5, at 403–04.

392. See Abbott, *Cycle of Action*, *supra* note 15, at 35 (discussing the proposal).

Finally, it is important to require impact studies before a further expansion of intellectual property protection. For example, during an intergovernmental meeting on the WIPO Development Agenda, Bahrain proposed that “WIPO . . . prepare studies on intellectual property, in cooperation with Member States, to demonstrate the economic, social and cultural impact of the use of intellectual property systems in Member States, with particular emphasis on the contribution of cultural industries to national economies.”³⁹³ Other international fora, like the human rights regime, have called for similar assessment. In a recent interpretive comment, the CESCR stated that “States parties should . . . consider undertaking human rights impact assessments prior to the adoption and after a period of implementation of legislation for the protection of the moral and material interests resulting from one’s scientific, literary or artistic productions.”³⁹⁴ Such assessment is important, because it not only will provide the needed information for all member states to consider, but also will ensure that nationals and policymakers of the *demandeur* countries are aware of the development-related impact of the policies for which they are pushing. The study will also provide helpful information to enable policymakers to make informed judgment in the face of heavy lobbying by intellectual property rights holders.

C. Globalization of Intellectual Property Rights

When the international intellectual property regime was established, the intention of the member states was to coordinate protection to a level that would reduce infringement and commercial piracy. As a result, they focused on anti-discrimination tools, like the national treatment provision. Although the Paris Convention includes some minimum standards of protection in a small number of areas, it reserves to each member state considerable autonomy to develop its own intellectual property policies based on local needs and conditions. Indeed, although some members preferred to have greater harmonization of the intellectual property system, “practical impracticality” prevented them from obtaining their preferred system.³⁹⁵

As protection becomes more uniform in the developed world, however, countries have found it important to have greater harmonization of intellectual property rights. Led by the United States and members of the European Communities, developed countries have pushed for a harmonization process that transformed the international intellectual property system from a patchwork system that coordinates varying national

393. *Proposal by the Kingdom of Bahrain on the Importance of Intellectual Property in Social and Economic Development and National Development Programs*, WIPO Doc. IIM/2/2 (June 14, 2005); see also Frederick M. Abbott, *Toward a New Era of Objective Assessment in the Field of TRIPS and Variable Geometry for the Preservation of Multilateralism*, 8 J. INT’L ECON. L. 77, 79 (2005) (contending that “new [intellectual property rights] and associated regulatory provisions be subject to objective impact assessment”).

394. *General Comment No. 17*, *supra* note 196, ¶ 35.

395. See Beier, *supra* note 134, at 8 (“In view of the large variety of national laws and interests, . . . [the] idealistic concept of an international uniform law [under the Paris Convention] proved too utopian. And in fact, the idea of a ‘world patent’ or ‘world trademark,’ which was subsequently revived still remains a castle in the sky.”); see also Sam Ricketson, *The Birth of the Berne Union*, 11 COLUM.-VLA J.L. & ARTS 9, 19 (1986) (discussing the political difficulty in creating uniform protection in the Berne Convention).

systems³⁹⁶ to a global “supranational code” that imposes obligations on the different members of the system.³⁹⁷ Because of power asymmetry, this harmonization process eventually became a Westernization, or Northernization, process. At times, when multilateral efforts failed, developed countries have resorted to the use of bilateral and regional trade agreements to fill in the gaps and to achieve what their harmonization efforts could not.³⁹⁸

To add to the plight of less developed countries, the TRIPs Agreement was designed with a focus on setting only the floor, rather than the ceiling, of protection. Article 1 of the TRIPs Agreement stipulated specifically that “[m]embers may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement.”³⁹⁹ Thus, although the Agreement includes a considerable number of minimum standards, it has very limited maximum standards.⁴⁰⁰

This misguided focus on floor setting and minimum standards has two negative effects on the international intellectual property system. First, it fails to retain the balance commonly found in domestic intellectual property systems, in which limitations and exceptions are arguably as important as the grants of rights.⁴⁰¹ By having an undue focus on the floor, countries ignore the fact that policymakers may not be able to protect their own industries and nationals by balancing the additional protection through the inclusion of exceptions and public interest safeguards. Indeed, such exceptions would likely be viewed with disfavor by their richer and more powerful trading partners (and the multinational corporations that heavily lobbied those countries).

Second, it has made it difficult for countries to take a holistic perspective and offer package legislation that includes strengthened protection and public interest offsets, especially when the rules are scrutinized by the WTO dispute settlement panels. As Rochelle Dreyfuss and Graeme Dinwoodie noted:

Th[e] “discrete” approach to adjudication (by which we mean that discrete parts of legislative compromises are broken out for individual assessment) can produce perverse consequences. Not only does it unravel carefully negotiated legislative deals, it does so in a systematic way. Because TRIPS sets only minimum standards, WTO dispute resolution operates as a one-way ratchet: complaints can lead to the invalidation of measures that reduce the level of intellectual property protection, but they never reach measures that increase protection. Thus, compromises will always unravel in the same direction, requiring nations to

396. See generally Paul Edward Geller, *From Patchwork to Network: Strategies for International Intellectual Property in Flux*, 9 DUKE J. COMP. & INT’L L. 69 (1998) (discussing the move from the patchwork model to the network model).

397. Jane C. Ginsburg, *International Copyright: From a “Bundle” of National Copyright Laws to a Supranational Code?*, 47 J. COPYRIGHT SOC’Y U.S.A. 265 (2000); see also Yu, *Currents and Crosscurrents*, *supra* note 127, at 354–75 (discussing the transformation from international agreements to a supranational code).

398. See *supra* Part II.D.

399. TRIPs Agreement, *supra* note 8, art. 1.

400. See sources cited in Yu, *TRIPS and Its Discontents*, *supra* note 193, at 402 n.138 (2005).

401. JAMES BOYLE, SHAMANS, SOFTWARE & SPLEENS: LAW AND THE CONSTRUCTION OF THE INFORMATION SOCIETY 138 (1996).

change those features of their legislation that benefit user groups while protection-enhancing provisions stay in place.⁴⁰²

Noting that the panel struck down the Fairness in Music Licensing Act, which expanded the unauthorized use of music by restaurants, bars, retail stores, and other small business establishments, while leaving alone the copyright term extension legislation that was enacted under the same package deal,⁴⁰³ Professors Dreyfuss and Dinwoodie cautioned us that the discrete approach taken by the panels might have the perverse effect of encouraging intellectual property rights holders “to agree to provisions that reduce the level of protection in exchange for the protection-enhancing legislation that they want, knowing that the reductions will be successfully challenged at the international level.”⁴⁰⁴

It is high time that we reconsider the way the international intellectual property system is developed. If the system has been transformed from an international system that uses patchwork treaties to harmonize protection to a global one that imposes protection and obligations on all of the member states, there is a strong need to strike a balance between proprietary interests and public access needs in an intellectual property system, taking into consideration both the public interest and distribution concerns.⁴⁰⁵ To do so, countries need to consider both endogenous and exogenous limits.⁴⁰⁶

For example, commentators have articulated the need for access rights to provide endogenous limits. They have noted the need for the creation and use of early working exceptions,⁴⁰⁷ like the Bolar exception in the United States,⁴⁰⁸ which “makes it legal for

402. Dinwoodie & Dreyfuss, *supra* note 369, at 99–100 (emphasis omitted).

403. *See id.* at 99.

404. *Id.* at 100.

405. As Peter Gerhart explained:

[W]e normally think of normative welfare within a country, where we can rely on the tax and spend power of government to address the distributive values that cannot be reached through the intellectual property system. If some people are too poor to have access to essential patented medicines, for example, the government can subsidize their purchase in order to provide access that the intellectual property system would otherwise deny. . . .

In the international system, however, the institutional infrastructure for making such distributive decisions is missing; we have no institutional structure for making the welfare decisions that determine, across states, whether and how those who gain from a particular policy should compensate those who lose from the policy. Accordingly, in the international system, distributive values must be embedded in the international intellectual property system itself, through the provisions of intellectual property systems that provide for fair use or other access rights—otherwise these values will be ignored. Simply put, in the international arena, there is no good mechanism for taking into account the inability of poor countries to pay for the knowledge goods that they need in order to enhance their own welfare, and if distributional goals are to have any salience, the goals must be forthrightly addressed.

Gerhart, *supra* note 328, at 16.

406. *See* Yu, *TRIPS and Its Discontents*, *supra* note 193, at 396–401 (discussing literature that calls for the creation of explicit access rights).

407. *See* IPR COMMISSION REPORT, *supra* note 6, at 50 (recommending less developed

a generic producer to import, manufacture and test a patented product prior to the expiry of the patent in order that it may fulfil the regulatory requirements imposed by particular countries as necessary for marketing as a generic."⁴⁰⁹ In light of the increased patenting of research tools, commentators have also noted the need for research exemptions for those tools, lest scientific progress be stifled.⁴¹⁰ In addition, commentators have underscored the importance of Articles 31(k) and 40 of the TRIPs Agreement, which permit member states to take appropriate measures to curb "an abuse of intellectual property rights having an adverse effect on competition in the relevant market."⁴¹¹

Exogenous limits are equally important. Commentators have already noted how international human rights,⁴¹² in particular the right to health,⁴¹³ have provided

countries to "include an appropriate exception for 'early working' to patent rights in their legislation, which will accelerate the introduction of generic substitutes on patent expiry"); Timmermans, *supra* note 24, at 52 (noting the need to "ensure that . . . a 'Bolar provision' . . . [is] incorporated within the national patent law, and that [it applies] to bio-pharmaceuticals as well as to conventional pharmaceuticals").

408. See Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 21 U.S.C. § 355 (2000)).

409. IPR COMMISSION REPORT, *supra* note 6, at 50.

410. See Timmermans, *supra* note 24, at 52 (noting the need for "a research exemption"). For discussions of the experimental use exemption, see generally Rochelle Dreyfuss, *Protecting the Public Domain of Science: Has the Time for an Experimental Use Defense Arrived?*, 46 ARIZ. L. REV. 457 (2004); Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017 (1989); Janice M. Mueller, *No "Dilettante Affair": Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools*, 76 WASH. L. REV. 1 (2001); Janice M. Mueller, *The Evanescent Experimental Use Exemption from United States Patent Infringement Liability: Implications for University and Nonprofit Research and Development*, 56 BAYLOR L. REV. 917 (2004); Katherine J. Strandburg, *What Does the Public Get? Experimental Use and the Patent Bargain*, 2004 WIS. L. REV. 81.

411. TRIPs Agreement, *supra* note 8, art. 40. As commentators have pointed out, many less developed countries "may decide against investing resources in giving effect to competition policy unless and until required to do so." Berger, *supra* note 338, at 196; see also Dreyfuss, *TRIPs—Round II*, *supra* note 2, at 31 (noting that although "[t]he TRIPs Agreement recognizes that members may need law to control the abuse of intellectual property rights, . . . countries that did not have enforceable intellectual property laws prior to joining the WTO had little reason to develop competition law to control right holders" (footnote omitted)). Nevertheless, some commentators, like Jonathan Berger, believed that "developing countries will most likely at some point in the future be required to commit to the enforcement of competition policy as part of the ultimate resolution of the 'Singapore issues,' either as a result of the Doha Development Round or regional and bilateral trade agreements." Berger, *supra* note 338, at 196 (footnote omitted).

412. See generally Bloche, *supra* note 255, at 827 ("The WTO system . . . has come to treat protection for health as a *de facto* interpretive principle when disputes arise over members' treaty obligations."); Audrey R. Chapman, *The Human Rights Implications of Intellectual Property Protection*, 5 J. INT'L ECON. L. 861 (2002) (discussing the human rights implications of intellectual property protection); Helfer, *Toward a Human Rights Framework*, *supra* note 189 (outlining a human rights framework for intellectual property rights); Yu, *Reconceptualizing Intellectual Property Interests*, *supra* note 189 (examining ways to develop a human rights framework for intellectual property rights).

413. For a discussion of the right to health and the international normative and legal

language that may trump intellectual property protection. In the Resolution 2000/7 on "Intellectual Property Rights and Human Rights," for example, the United Nations Sub-Commission on the Protection and Promotion of Human Rights urged national governments, intergovernmental organizations, and civil society groups to give human rights "primacy . . . over economic policies and agreements."⁴¹⁴ In a recent interpretative comment on the ICESCR, the CESCR also stated that "States parties are . . . obliged to strike an adequate balance between their obligations under article 15, paragraph 1 (c), on one hand, and under the other provisions of the Covenant, on the other hand, with a view to promoting and protecting the full range of rights guaranteed in the Covenant."⁴¹⁵ The other human rights with which the TRIPs Agreement may present conflicts include the right to food, the right to health, the right to education, the right to self-determination, the right to freedom of expression, the right to cultural participation and development, and the right to the benefits of scientific progress.⁴¹⁶

To "codify" the principle of human rights primacy, countries can consider negotiating for a treaty provision that allows public health concerns to trump other concerns, such as the protection of intellectual property. Uma Suthersanen recently proposed to amend Article 13 of the TRIPs Agreement by adding the phrase "taking note of the need to maintain a balance between the rights holders and the larger public interest, particularly education, development and access to information" at the end of the provision.⁴¹⁷ One could make an analogous change by amending Article 30 of the TRIPs Agreement by adding the following phrase: "taking note of the need to maintain a balance between the rights holders and the larger public interest, particularly development and access to essential medicines." Such a provision would allow policymakers to focus on the promotion of public health, rather than on creating benefits for either the pharmaceutical industry or generic manufacturers.⁴¹⁸ The

standards defining such a right, see generally Audrey R. Chapman, *Conceptualizing the Right to Health: A Violations Approach*, 65 TENN. L. REV. 389 (1998); Eleanor D. Kinney, *The International Human Right to Health: What Does This Mean for Our Nation and World?*, 34 IND. L. REV. 1457 (2001).

414. Helfer, *Toward a Human Rights Framework*, *supra* note 189; see also Chon, *supra* note 223, at 2886 (proposing to integrate a principle of substantive equality "throughout intellectual property globalization decision-making via a legal rule akin to the strict scrutiny doctrine in U.S. constitutional law"). As the U.K. Commission on Intellectual Property Rights noted in its chapter on health:

Our starting point in this analysis is that healthcare considerations must be the main objective in determining what IP regime should apply to healthcare products. IP rights are not conferred to deliver profits to industry except so that these can be used to deliver better healthcare in the long term. Such rights must therefore be closely monitored to ensure that they do actually promote healthcare objectives and, above all, are not responsible for preventing poor people in developing countries from obtaining healthcare.

IPR COMMISSION REPORT, *supra* note 6, at 30.

415. *General Comment No. 17*, *supra* note 196, ¶ 35.

416. Yu, *Reconceptualizing Intellectual Property Interests*, *supra* note 189, at 1148; Peter K. Yu, *Ten Common Questions About Intellectual Property and Human Rights*, 23 GA. ST. U. L. REV. (forthcoming 2007), available at <http://ssrn.com/abstract=979193>.

417. UMA SUTHERSANEN, THE FUTURE OF COPYRIGHT REFORM IN DEVELOPING COUNTRIES: TELEOLOGICAL INTERPRETATION, LOCALIZED GLOBALISM AND THE "PUBLIC INTEREST" RULE 24 (2005), http://www.ipronline.org/unctadictsd/bellagio/Bellagio2005/Suthersanen_final.pdf.

418. See *supra* text accompanying notes 57–58.

provision is particularly important in light of the public health crises in less developed countries and in light of the lack of a special public health exception in the TRIPs Agreement.⁴¹⁹ Unfortunately, the history of the development of the Paragraph 6 solution suggests that the United States is very unlikely to welcome such a change.

Thus, a more politically feasible approach is to locate exogenous limits outside the intellectual property regime. As Laurence Helfer explained in the context of regime shifting, exogenous limits can come initially in the form of “counterregime norms”⁴²⁰ and then be incorporated into the intellectual property system as “revisionist norms.”⁴²¹ As he explained, “[t]he value of counterregime norms for developing countries is grounded in two fundamental characteristics of the international legal system. The first is the disaggregated and nonhierarchical structure of that system, and the second is the frequent use of nonbinding norms to guide the behavior of states and private parties.”⁴²² Because the impact of intellectual property protection is now spilling over into other areas, such as agriculture, health, the environment, education, culture, free speech, and democracy, the need to locate limits outside the intellectual property regime is becoming more important.

Despite the importance of these limits, one should remember that the exportation of these limitations could be as dangerous as the exportation of substantive rights. Indeed, commentators have been concerned about such exportation and have argued for the retention of the original international intellectual property system, which included only limited minimum standards. While this Article takes the view that it is no longer politically feasible to retain such a system, it is important to underscore the fact that limits that ignore local conditions—for example, limits on the protection of traditional knowledge—could be as problematic as rights that ignore local conditions. Intellectual property is a means to an end, rather than the end itself. The limits that make it difficult for less developed countries to innovate will ultimately defeat the purpose of having the limits in the first place.

CONCLUSION

Although this Article focuses on the access-to-medicines problem, the analysis is equally applicable to other intellectual property-related problems, such as access to

419. Commentators and policymakers have sought to increase such an exception through other exceptions for the protection of “*ordre public*,” TRIPs Agreement, *supra* note 8, art. 27(2), “public interest,” *id.* art. 8(1), and national security. *See id.* art. 73 (stipulating an exception for member states to pursue their essential security interests and to fulfill obligations under the United Nations Charter in relation to the maintenance of international peace and security); *see also* David P. Fidler, *Constitutional Outlines of Public Health’s “New World Order,”* 77 TEMP. L. REV. 247, 251–53 (2004) (discussing public health in the context of national security). One could also locate a special exception in Article XX of the GATT, which allows for “measures necessary to protect human, animal or plant life or health.” GATT, *supra* note 302, art. XX (emphasis added).

420. Professor Helfer defined *counterregime norms* as “binding treaty rules and nonbinding soft law standards that seek to alter the prevailing legal landscape.” Helfer, *Regime Shifting*, *supra* note 193, at 14.

421. Laurence R. Helfer, *Mediating Interactions in an Expanding International Intellectual Property Regime*, 36 CASE W. RES. J. INT’L L. 123, 127 (2004).

422. *Id.*

educational materials; access to computer software and information technology; the protection of traditional knowledge, folklore, and indigenous materials; the promotion of biological diversity; and the preservation of culture and freedom of expression. This analysis is also important to understanding other trade-related problems that create tensions between developed and less developed countries as well as problems that are within developed countries.

Nationwide decisions are inherently complex. Countries, as a result, need wide policy space regardless of their economic development and technological capabilities. With the establishment of the TRIPs Agreement and the proliferation of bilateral and regional trade agreements, the policy space of less developed countries has been drastically reduced. While commentators and policymakers have expressed grave concerns about the enclosure of the public domain and devise responses to address this enclosure, they also need to pay attention to a different, and perhaps more important, enclosure movement. The international enclosure movement will not only take away the policy space individual countries have in their attempts to respond to problems within their borders, but will also limit their abilities to independently resist and respond to the enclosure of the public domain.

Despite the importance and urgency to resist the international enclosure movement, the cessation of the movement does not guarantee the end to intellectual property-related problems confronting less developed countries. In fact, some forms of enclosure, such as those pushed by the WTO Development Agenda, can be beneficial to these countries and promote economic development there (although developed countries could see those initiatives as an enclosure of their own policy space). Thus, if we are to fully understand the implications of the international enclosure movement, we need to separate *contextualized* enclosure from *decontextualized* enclosure—the type of enclosure that ignores local conditions. It is the latter that makes the movement particularly dangerous to both developed and less developed countries.