CONSTRUING INTELLECTUAL PROPERTY RIGHTS AND COMPETITION POLICY CONSISTENTLY WITH FACILITATING ACCESS TO AFFORDABLE AIDS DRUGS TO LOW-END CONSUMERS

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> "Is there a point at which pharmaceutical laws favor research too much, at the expense of the affordability that comes from price competition? How should a proper balance be struck? Is a premium in earnings over what other sectors earn necessary to spur research in the pharmaceutical sector? If so, how big should that premium be? Does increasing the premium through further intellectual property protection always lead to more and better research?"[1]

I. INTRODUCTION

This Article discusses two approaches of conceptualizing and thinking about how best to address the problem of access to and affordability of drugs to low-end consumers facing life threatening illnesses such as AIDS. The first of these approaches explores TRIPS-consistent[2] possibilities of balancing between the interests of the producers of pharmaceuticals on the one hand, and the interests of low-end consumers of pharmaceuticals facing life-threatening diseases on the other. In this first approach, I proceed from an internal inquiry into the possibilities that the TRIPS regime offers both to consumers and producers of intellectual property.

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1. Edward Hore, *A Comparison of United States and Canadian Laws as They Affect Generic Pharmaceutical Market Entry*, 55 FOOD & DRUG L.J. 373, 388 (2000)

2. TRIPS stands for "Trade-Related Aspects of Intellectual Property Rights." Jerome H. Reichman, *From Free Riders to Fair Followers: Global Competition Under the TRIPS Agreement*, 29 N.Y.U. J. INT'L L. & POL. 11, 12 (1996-97). The TRIPS Agreement "established a basic framework for balancing legal incentives to create against the public interest in free competition." *Id*.

The major claim made here is that TRIPS is based on a private property model that exhibits two logics in tension with each other. The first of these logics is that of property as a market commodity. The second is a public policy perspective that proceeds from the view that there are circumstances under which property can be legitimately encumbered with public regulation consistent with TRIPS; for instance, to strike a balance between the interests of producers and consumers of items subject to intellectual property rights (IPR). My claim is that the commodity logic of IPR protection simultaneously and dialectically co-exists with an alternative logic of IPR protection that recognizes as legitimate the accommodation of public policy concerns falling within the purview of the TRIPS agreement. Within this approach, I also examine the scope of discretion that developing countries have in defining standards of patent eligibility, non-obviousness and novelty, thereby leading to the emergence of state practice consistent with certain public policy goals such as facilitating the availability of essential medicines for low-end consumers.[3]

The second approach is an external approach to conceptualizing how best to ensure expeditious access to affordable AIDS drugs. Its basic thesis is that the problems of low-end pharmaceutical consumers facing life-threatening illnesses are related to the FDA's regulatory framework pertaining to the pharmaceutical industry. The FDA's regulatory framework for pre-marketing testing and approval is driven by the need to protect the public by eliminating, or minimizing to the greatest extent possible, drug-related risks. This regulatory framework, which was built largely in response to perverse notions of risk, results in the setting of high barriers for entry into the pharmaceutical industry for small and new companies, as well as for drugs approved in other countries. The effect of the exclusionary impact of this framework is the monopolization of the pharmaceutical industry. My proposed approach thus advocates a consumer-driven, anti-cartelist strategy to end pharmaceutical industry concentration as a strategy for addressing affordability and accessibility of pharmaceutical products for low-end consumers facing life-threatening illnesses. My second major claim therefore is that the FDA's regulatory framework is a form of governmental intervention that constitutes an anti-competitive mechanism.

This second approach is driven by the desire to foster competition in the pharmaceutical industry as the best way of ensuring affordable and accessible pharmaceutical products. This second approach is a good balance, given the property rights-directed commitments of TRIPS. Unlike the property-directed TRIPS, a competition-driven pharmaceutical

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3. *See id.* at 16; *see also* Samuel A. Oddi, *TRIPS-Natural Rights and a Polite Form of Economic Imperialism*, 29 VAND. J. TRANSNAT'L L. 415, 461-69 (1996) (discussing strategies to mitigate the initial economic costs of TRIPS).

industry would ensure a fair return to owners of IPRs, thereby balancing the interests of producers of pharmaceuticals with IPR protection on the one hand and consumers of these pharmaceutical products on the other. Here, I regard full and free competition as the most legitimate pricing mechanism.

In short, my argument is that an increase in intellectual property protection, such as that provided by TRIPS, necessarily involves a reduction in competition.[4] The increase in intellectual property protection provided by TRIPS implies that the framers of that agreement thought that a monopoly period of twenty years for pharmaceuticals would provide the optimal level of incentive to induce innovation and enhance consumer welfare.[5] However, it is arguable that increasing intellectual property protection has not eliminated piracy or even enhanced consumer welfare, and that a competition-driven policy would complement intellectual property protection by enhancing consumer welfare and addressing issues related to piracy and patent infringements.[6] Indeed, as I argue in this Article, violations of competition policy might ameliorate the shortfalls of intellectual property protection. For example, competition can increase consumer welfare by lowering production costs and passing the benefits of technological innovation on to consumers.

Another major innovation in this Article is that it does not argue that antitrust law and trade laws only operate at odds with each other. It is not necessarily the case that antitrust law only protects consumers and trade laws only protect domestic industry from the effects of unfair foreign

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4. *See* Louis Kaplow, *The Patent-Antitrust Intersection: A Reappraisal*, 97 HARV. L. REV. 1815, 1816 (1984).

5. *See generally* Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Masrakesh Agreement Establishing the World Trade Organization, Annex 1C, LEGAL INSTRUMENTS-RESULTS OF THE URUGUAY ROUND vol. 31, 33 I.L.M. 81 (1994) [hereinafter TRIPS].

6. Indeed, the Supreme Court was evenly split on this very point in *K-Mart Corp. v. Cartier, Inc*., 486 U.S. 281 (1988). At issue, in that case, was an interpretation of trademark law by the Customs Department to the effect that United States trademark owners could not bar the importation of genuinely marked goods made by foreign subsidiaries. *Id*. at 285. The Justices were split as to whether a Customs Service regulation designed by the Treasury Department should be based on strong intellectual property protection or on a competition-based policy that would allow gray market imports. *Id*. at 291. The holding of the case is confined to instances in which American corporations consent to the use of trademarks by importers. *See id.* at 293-95. Four Justices (Rehnquist, Blackmun, O'Connor and Scalia) favored a policy based on strong intellectual property protection, which would give trademark holders monopoly power over intrabrand competition. *See id.* at 286-95. Four other Justices (Brennan, Marshall, Stevens and White), favored a competition-based policy that would allow gray-market imports to compete with locally manufactured goods bearing the same trademarks. *See id.* at 287-88, 295-317 (Brennan, J., concurring in part and dissenting in part). Hence, there was a split between those Justices who believed that intellectual property protection would best enhance technological innovation and consumer welfare and those who supported the view that competition would best enhance consumer welfare. *See id.* at 291.

trade.[7] Rather, antitrust law and trade laws complement each other in promoting the interests of industry and consumers.[8] For example, in *Pfizer, Inc. v. India*,[9] the Supreme Court was invited to decide whether it could treat a sovereign nation in the same manner as it did United States citizens and states under the Sherman Act.[10] The governments of India, Iran, and the Philippines, among others, sought damages against Pfizer, alleging price fixing, market division and fraud upon the United States Patent Office involving abroad-spectrum antibiotics.[11] Pfizer brought the case in order to challenge an order of the Federal Trade Commission requiring it and American Cyanamid to grant applicants from India, Iran and the Philippines licenses under patents held by Pfizer and Cyanamid for broad spectrum antibiotics.[12]

The Supreme Court held that the antitrust laws of the United States provide no alternative remedies for foreign nations, as they do for United States citizens and states.[13] As such, a foreign nation can sue for treble damages where it can show that it, like a domestic state, has been injured in its business or property by antitrust violations.[14] Therefore, nations can use antitrust laws to seek remedies for unfair trade practices in the same way that they can under trade laws.[15]

The *Pfizer* case is also very relevant with regard to how the Court reflected upon the use of antitrust laws in foreign commerce. In his dissenting opinion, Chief Justice Burger, who was joined by Justices Powell and Rehnquist, found that statutory language, legislative history

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7. *See* Christopher M. Barbuto, Note, *Toward Convergence of Antitrust and Trade Law: An International Trade Analogue to Robinson-Patman*, 62 FORDHAM L. REV. 2047, 2051-52, 2089-94 (1994).

8. *Id*. at 2051.

9. 434 U.S. 308 (1978).

10. *Id*. at 309.

11. *Id*. at 309-10.

12. *Id*. at 310 n.2.

13. *Id*. at 318.

14. *Id*.

15. *See* Eleanor M. Fox, *Trade, Competition and Intellectual Property—TRIPS and its Antitrust Counterparts*, 29 VAND. J. TRANSNAT'L L. 481, 482 (1996) (arguing that the need to ensure competition-based law does not undermine the obligations of TRIPS); Hans Ullrich, *TRIPS: Adequate Protection, Inadequate Trade, Adequate Competition Policy, in* ANTITRUST: A NEW INTERNATIONAL TRADE REMEDY? 153, 193-95 (John O. Haley & Hiroshi Iyori eds., 1995) (analyzing the relationship between trade and competition policy under TRIPS); Robert D. Anderson, *The Interface Between Competition Policy and Intellectual Property in the Context of the International Trading System*, 1 J. INT'L ECON. L. 655, 655-60 (1998) (exploring the relationship between competition policy and intellectual property rights); Spencer Weber Waller, *The Internationalization of Antitrust Enforcement*, 77 B.U. L. REV. 343, 349-60 (1997) (discussing the failure of international harmonization efforts and the success of regional efforts).

and Supreme Court precedents denied foreign states standing to sue under the Sherman Act. In Chief Justice Burger's view:

> [I]t takes little imagination to realize the dramatic and very real differences in terms of coercive economic power and political interests which distinguish our own States from foreign sovereigns. The international price fixing, boycotts, and other current anticompetitive practices undertaken by some Middle Eastern nations are illustrative of the weapons in the arsenals of foreign nations which no domestic State could ever employ. Nor do our domestic States, in any meaningful sense, have the conflicting economic interests or antagonistic ideologies which characterize and enliven the relations among nation states.[16]

However, as Justice Stewart, writing for the majority, noted:

> While the Chief Justice's dissent says that there are "weapons [such as cartels or boycotts] in the arsenals of foreign nations" sufficient to enable them to counter anticompetitive conduct, . . . such . . . political remed[ies are] hardly available to a foreign nation faced with monopolistic control of the supply of medicines needed for the health and safety of its people.[17]

Indeed, this is the issue in this Article: how best to use the legal options available to countries and communities who face the monopolization of their supply of medicines, not only for the health and safety of their people in general, but specifically for low-end consumers facing life-threatening illnesses.

In Part II, I demonstrate that AIDS drugs offer new hope for AIDS patients and that the experience of industrialized nations can be extended to low-end consumers who are in large measure found in sub-Saharan Africa. In Part III, I show that the place of social policy, such as in the provision of AIDS drugs to low-end consumers, faces an built-in problem of international economic governance. This built-in problem is a public/private split that is biased against the inclusion of public policy goals that are inconsistent with free trade/IPR protection in the GATT/WTO framework. In Part IV, I explore the tension between commodity and public policy-oriented perspectives of TRIPS. This tension is part of the ambiguous legacy of social policy in international economic governance that can be exploited in favor of facilitating access to AIDS

16. *Pfizer*, 434 U.S. at 327-28 (Burger, J., dissenting).
17. *Id*. at 318.

drugs for low-end consumers. In Part V, I examine the variety of barriers to entry of new firms into the pharmaceutical industry as well as to access to affordable AIDS drugs.

II. HIV/AIDS DRUGS COCKTAILS OFFER NEW HOPE

"AIDS, an acronym for acquired immune deficiency syndrome, is an impairment of the body's ability to fight disease. It leaves the affected individual vulnerable to illnesses that a healthy immune system might overcome."[18]

AIDS patients suffer from weakened immune systems that make them susceptible to opportunistic infections caused by fungi (yeasts), viruses, bacteria, and protozoans. Other symptoms of AIDS include unusual pneumonia caused by the protozoan Pneumosystis Carinii, or a rare cancer of the skin known as Kaposi's Sarcoma (KS). AIDS is contracted through blood, breast milk, semen and vaginal/cervical secretions.

The leading cause of death in Sub-Saharan Africa today is AIDS. In southern African countries, the infection rate is as high as 20% of the population. In 1999, for example, Botswana had an infection rate of 35.80%, Swaziland 25.25%, Zimbabwe 25.06%, Lesotho 23.57%, and South Africa 19.94%.[19] By 1999, at least fifteen million Africans had died of AIDS and another twenty-five million in sub-Saharan Africa were living with the disease.[20] Four million sub-Saharan Africans were newly infected in 1999.[21]

AIDS, contrary to the view that it is a death warrant, is a treatable disease. In the United States, for example, drug treatment has quadrupled the median survival time for Americans diagnosed with AIDS from one to four years.[22] This stunning achievement is the result of a combination of initiatives that has galvanized public attention in treating AIDS for about twenty years. Intense public pressure on the government and the pharmaceutical industry by AIDS activists, including the efforts of non-governmental organizations working with AIDS patients, has led to greater availability and accessibility of AIDS drugs, health services and support services for AIDS patients.

Among these initiatives is the availability of a complex combination of drugs known as a cocktail. A cocktail includes protease inhibitors and

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18. AIDS FACTS AND ISSUES 4 (Victor Gang & Norman Rudnick eds., 1986).

19. JOINT UNITED NATIONS PROGRAMME ON HIV/AIDS, REPORT ON THE GLOBAL HIV/AIDS EPIDEMIC 124 (2000) [hereinafter UNAIDS REPORT].

20. Press Release, World Bank, World Bank Steps Up Fight Against AIDS in Africa (Sept. 14, 2000).

21. UNAIDS REPORT, *supra* note 19, at 8.

22. *U.S. Study Finds AIDS Patients Surviving Longer* (Mar. 14, 2001), *at* http://www.cnn.com/2001/HEALTH/conditions/03/14/aids.survival.reut/index.html.

reverse transcriptase inhibitors. These drugs interrupt the cycle of HIV infection, allow an infected person's immune system to rebuild itself, and allow the person to live much longer than the person would without treatment.[23] In the United States, a strict cocktail regimen costs on average between $10,000 and $15,000 per year.[24] These regimens have reduced mortality rates by a phenomenal 75% in the United States.[25] AZT (Zidovudine) has been shown to reduce mother-to-child transmission by up to 70% when administered to the mother during pregnancy or to the child immediately after birth.[26] By contrast, in sub-Saharan Africa and for low-end consumers in general, AIDS has become history's worst pandemic in part because the cocktails that have been used successfully in the United States are too expensive.[27] In addition, the provision of health services has been undermined substantially by reallocation of funds to other sectors of the economy.[28] It seems, therefore, that unless measures are taken to provide affordable drugs to the millions with AIDS in Africa, they may be "already . . . beyond hope."[29]

In Brazil, the government has produced at least five generic AIDS drugs that have been available to its citizens for free since 1997. Brazil's policy of universal access to AIDS drugs has led to dramatic reductions in the rate of AIDS deaths and the incidence of opportunistic infections. While the death rate between 1996 and 1999 fell by about half, the rate of incidence of opportunistic infections fell by 60-80%.[30] The Brazilian government invested over US $339 million in 1999 and over U.S. $462 million in 2000 into the project.[31] In January 2001, the United States

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23. Lawrence O. Gustin & James G. Hodge, Jr., *The "Name Debate": The Case for National HIV Reporting in the United States*, 61 ALB. L. REV. 679, 700 (1998).

24. Linda C. Fentiman, *AIDS as a Chronic Illness: A Cautionary Tale for the End of the Twentieth Century*, 61 ALB. L. REV. 989, 1004 (1998).

25. Bernard Hirschel & Patrick Francioli, *Progress and Problems in the Fight Against AIDS*, 338 NEW ENG. J. MED. 906, 906-08 (1998).

26. Eileen M. Mckenna, Note, *The Mandatory Testing of Newborns for HIV: Too Much, Too Little, Too Late*, 13 N.Y.L. SCH. J. HUM. RTS. 307, 330-31 (1997).

27. Remarkably, the reform programs (reduced public spending and introduction of fees) of the Bretton Woods institutions (the IMF and the World Bank) in the health sector have exacerbated the pandemic, putting an enormous strain on public health delivery. Marc Epprecht, *Investing in Amnesia, or Fantasy and Forgetfulness in the World Bank's Approach to Healthcare Reform in Sub-Saharan Africa*, 31 J. DEVELOPING AREAS 337, 337-56 (1997).

28. MEREDETH TURSHEN, PRIVATIZING HEALTH SERVICES IN AFRICA 114-16 (1999).

29. Barton Gellman, *An Unequal Calculus of Life and Death: As Millions Perished in Pandemic, Firms Debated Access to Drugs*, WASH. POST, Dec. 27, 2000, at A1.

30. UNAIDS REPORT, *supra* note 19, at 101.

31. *Id*. at 102; *see also* Stephen Buckley, *Brazil Becomes Model in Fight Against AIDS*, WASH. POST, Sept. 17, 2000, at A22.

requested that the WTO establish a panel to determine the legality of Brazil's compulsory licensing laws.[32]

As the experience of the United States and Brazil demonstrates, AIDS is a treatable disease, and levels of infection can drop dramatically with increased availability of drugs: the same should be so in Sub-Saharan Africa. While the AIDS problem in Africa is part of a bigger picture of a health sector in crisis,[33] that is no reason not to take action to facilitate access to affordable AIDS drugs in sub-Saharan Africa. There can be no gainsaying that low income levels in sub-Saharan Africa make costs of over $10,000 per year prohibitive. Yet, the pharmaceutical industry has quietly argued that selling AIDS drugs at discounts in sub-Saharan Africa portends doom with respect to the ability to finance further research and development. In effect, it argues that the AIDS crisis in Africa is intractable because providing AIDS drugs, which still enjoy patent protection in Western markets, conflicts with its commercial objectives.[34] The handouts that pharmaceutical companies have announced are laudable, but the existence of such handouts does not address the question of affordability in the long term. In addition, it is possible that these ad hoc responses and the infrequency with which AIDS drugs are consumed in Africa may contribute to the creation of drug-resistant strains of the virus.[35]

However, addressing the needs of low-end consumers is not a problem specific to sub-Saharan Africa. Low-end consumers, or consumers with little or no income, who have HIV, are found in all countries of the world. Thus, while most of these consumers are in sub-Saharan Africa, the problem is an international one, not merely a regional one. In this Article, I join with others in moving from the premise that, since AIDS is treatable, we should vigilantly seek all possible solutions to resolve this problem of unequal access to AIDS drugs between low and high-income HIV patients. I do so in two ways. First, I reframe the TRIPS agreement not only as embodying the intellectual property rights protection of pharmaceutical corporations, but also as incorporating two logics of private property that are in tension with each other: a commodity logic that largely favors industry and a public-oriented logic that legitimizes departures from the

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32. *See* Request for the Establishment of a Panel by the Untied States, WTO Doc. No. WT/DS199/3 9 (01-0093) (2001), *available at* http://www.cptech.org/ip/health/c/brazil/Req4EstabPanel.html.

33. The pharmaceutical industry, in particular, makes this argument to blunt criticism that the high cost of drugs is one of the reasons for the spread of the AIDS pandemic. *See* INTERNATIONAL INTELLECTUAL PROPERTY INSTITUTE, PATIENT PROTECTION AND ACCESS TO HIV/AIDS PHARMACEUTICALS IN SUB-SAHARAN AFRICA 53-54 (2000).

34. Gellman, *supra* note 29, at A1.

35. *See* Fentiman, *supra* note 24, at 1006-07.

commodity logic in order to address certain public health concerns such as AIDS. Second, I argue that a competition-based pharmaceutical industry, freed from the barriers to entry put in place by the FDA, would lower drug prices and facilitate their access to low-end consumers.

One normative initiative that complements my proposals for conceptualizing and implementing strategies that facilitate low-end consumers access to affordable AIDS drugs is the emerging international right to health. Although there has not been much attention paid to norm creation in this area,[36] there have been significant developments that have already laid a rights framework to facilitate access to essential medicines to consumers alongside other health-related needs.[37] States have at least three obligations here: to respect, protect, and fulfill the right to health. The duty to respect obligates states not to discriminate in the provision of health care, as well as to remove obstacles and barriers to access.[38] The duty to protect requires the maintenance of policies "conducive to health protection such as effective regulation to preserve or restore clean air and water, reduce exposure to toxic substances, and assure work place safety."[39] Finally, the duty to fulfil obliges governments to have a national health plan with specific targets that aim at progressively realizing a right to basic health care.[40]

However, social rights such as the right to health have not received as high a premium as civil and political rights, especially in the present international context of development, where social goodies are thought to flow from the inexorable forward march of the market.[41] Indeed, economic reform programs under the aegis of the Bretton Woods institutions[42] and bilateral donors have only led to lower budgetary allocations for social spending in areas such as health care.[43] It is in this context that initiatives

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36. *See* Virginia Leary, *The Right to Health in International Human Rights Law*, 1 HEALTH & HUM. RTS. 24, 26 (1994).

37. For an excellent review, see PAUL HUNT, RECLAIMING SOCIAL RIGHTS: INTERNATIONAL AND COMPARATIVE PERSPECTIVES 107-51 (1996).

38. AUDREY R. CHAPMAN, EXPLORING A HUMAN RIGHTS APPROACH TO HEALTH CARE REFORM 28 (1993).

39. *Id*.

40. *Id*. at 51.

41. Cass Sunstein, *Against Positive Rights: Why Social and Economic Rights Don't Belong in the New Constitutions*, 2 E. EUR. CONST. REV. 35, 35-38 (1993).

42. The Bretton Woods institutions are the World Bank and the International Monetary Fund (IMF). They are named for the Brettan Woods Conference of July 1944, at which they were conceived. Chi Carmody, *Beyond the Proposals: Public Participation in International Economic Law*, 15 AM. U. INT'L L. REV. 1321, 1321 n.1 (2000).

43. Epprecht, *supra* note 27, at 337-56. *See generally* James Thuo Gathii, *Good Governance as a Counterinsurgency Agenda to Oppositional and Transformative Social Projects in International Law*, 5 BUFF. HUM. RTS. L. REV. 107 (1999) [hereinafter *Good Governance*]; James Thuo Gathii, *Representations of Africa in Good Governance Discourse: Policing and Containing*

by national governments to address the AIDS crisis and the handouts of AIDS drugs by pharmaceutical companies must be understood.

In addition, delivery of AIDS drugs is also an issue of international trade following the adoption of the TRIPS agreement after the Uruguay Round in 1994. Given that AIDS, like human rights and environmental issues, is a social claim within the context of the WTO, below I explore how social claims have stacked up against trade concerns in the approximately fifty-year history of the international trading framework.

III. THE PLACE OF SOCIAL POLICY IN POST-SECOND WORLD WAR INTERNATIONAL ECONOMIC GOVERNANCE

Social issues have not been well-received by international economic governance structures since the Second World War. TRIPS continues this tradition. In this part of the Article, I examine the history of the social policy's place in the post-Second World War international institutional compromise. In so doing, I demonstrate that the difficulties of construing or framing TRIPS as raising public health issues are deeply embedded in the internal logic of international economic governance.

A. *Historical Context*

In the post-Second World War institutional compromise, the place of social policy in the context of international economic institutions has been ambiguous. There is the classical or traditional view, and there is a modern view. In the context of IPRs, the commodity view neatly fits into the classical or traditional view, while the public policy conception of IPRs fits into the modern view of the place of social policy in international economic governance.

Under the classical view, international economic institutions, such as the International Monetary Fund (IMF) and the World Bank, identify themselves as private as opposed to public institutions. In this universe of international institutions formed following the Second World War, the United Nations is thought of as the public counterpart of the International Monetary Fund, the World Bank and now the WTO. The public mandate of the United Nations is to secure international peace and security. The mandates of the IMF and the World Bank are economic as opposed to political.[44] The United Nations' role was designated as political because the nature of its role is to avoid war and maintain international security.

This post-Second World War settlement between public and private international institutions was not accidental. Rather, it was the result of a

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Dissidence to Neo-Liberalism, THIRD WORLD LEGAL STUD. 65 (1999).

44. *See Good Governance*, *supra* note 43, at 149.

conscious design of the architects who wanted to safeguard the international economy from the whims of politicians. In the view of these architects, politicians had endangered the international economy in the period following the First World War by interfering with exchange rates and imposing high tariff barriers. Hence, it was necessary to impose restrictions on political influence over the international economy by placing power into the hands of technocrats.[45]

This dichotomy between public and private mandates is embodied in the Articles of Agreement of both the World Bank and IMF. The Articles of Agreement of the World Bank, for example, provide that "[t]he Bank and its officers shall not interfere in the *political affairs of any member; nor shall they be influenced in their decisions by the political character of the member or members concerned. Only economic considerations shall be relevant to their decisions, and these considerations shall be weighed impartially. . . .*"[46] The IMF's Articles of Agreement have been interpreted as providing a similar prohibition of engagement in the political affairs of its members.[47]

There is precedent in the history of the World Bank's operations suggesting that it will not comply with decisions of UN bodies on questions of international human rights involving peace and security. In this precedent, the World Bank declined to follow General Assembly and Security Council Resolutions calling for the suspension of lending to South Africa and Portugal in 1969.[48] The resolution was prompted by Portugal's continuation of its colonial policy in Africa and South Africa's continuation of its apartheid policies, both of which were determined to constitute threats to international peace and security by the United Nations.[49] The World Bank adopted this position notwithstanding the fact that its Relationship Agreement with the United Nations provided for the Bank to have due regard to Security Council resolutions.[50]

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45. For an excellent review of this school of thought, see generally Nathaniel Berman, *Economic Consequences, Nationalist Passions: Keynes, Crisis, Culture and Policy*, 10 AM. U. J. INT'L L. & POL'Y 619 (1995).

46. Articles of Agreement of the International Bank for Reconstruction and Development, Dec. 27, 1945, art. IV, § 10, 2 U.N.T.S. 134, 158 (1947) (emphasis added). Article III, section 5(b) provides that "[t]he Bank shall make arrangements to ensure that the proceeds of any loan are used only for the purposes for which the loan was granted, with *due attention to considerations of economy and efficiency and without regard to political or other non-economic influences or considerations*." *Id*. art. III, § 5(b) (emphasis added).

47. Joseph Gold, *Political Considerations Are Prohibited by Articles of Agreement When the Fund Considers Requests for Use of Resources*, IMF SURVEY, May 23, 1983, at 146-48.

48. Samuel A. Bleicher, *UN v. IPRD: A Dilemma of Functionalism*, 24 INT'L ORG. 31, 31 (1970).

49. *Id*.

50. Under Article I, section 2 of that agreement: "By reason of the nature of its international responsibilities and the terms of its Articles of Agreement, the Bank is, and is required to function

Consequently, in the late 1960s and early 1970s, the position adopted by the World Bank's senior management on the role of the World Bank in relation to the International Bill of Human Rights[51] faced serious scrutiny from critics of the development projects the Bank supported.[52] Simply put, this position held that the World Bank's Articles of Agreement did not provide sufficient institutional elasticity to accommodate a larger role and responsibility for claims such as human rights. Under this view, social policy in the context of internationally-protected guarantees of human rights was outside the World Bank's financial and economic mandate. The view of the World Bank's role in human rights during that period is analogous to the position that the WTO is isolated from the rest of public international law today.

At the World Bank General Counsel's office, the objectives of the International Bill of Rights were seen as contradictory to the Bank's financial and economic mandate under its Articles of Agreement.[53] This position adopted by the General Counsel's Office is the traditional or classical position. However, the continued tenability of the position that the Bank's mandate is insufficiently flexible to accommodate what are represented as political and social objectives outside the scope of its mandate has faced innumerable and sustained challenges. The Bank has since redescribed or modernized its mandate in response to various challenges and responses to this classical position.

The redescription of the Bank's mandate that occurred in the 1990s can be described as follows. The World Bank General Counsel's Office, departing from previous interpretations, acknowledged that the Bank's economic and financial mandate accommodates elements of the

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as, an independent international organization." Agreement between the United Nations and the International Bank for Reconstruction and Development, Nov. 15, 1947, art. I, § 2, 16 U.N.T.S. 346 (1948). However, Article VI, section 1 provides that

> [t]he Bank *takes note* of the obligation assumed, under paragraph 2 of Article 48 of the United Nations Charter, to carry out the decisions of the security council through their action in the appropriate specialized agencies of which they are members, and will, in the conduct of its activities, have *due regard* for decisions of the Security Council under Articles 41 and 42 of the United Nations Charter.

Id. art. VI, § 1 (emphasis added).

51. The International Bill of Human Rights is the core instrument of human rights law, comprised of the Universal Declaration of Human Rights, the International Covenant on Economic, Social, and Cultural Rights, and the International Covenant on Civil and Political Rights. Allyn L. Taylor, *Globalization and Biotechnology: UNESCO and the International Strategy to Advance Human Rights and Public Health*, 25 AM. J.L. & MED. 479, 502 (1999).

52. *See Good Governance*, *supra* note 43, at 137.

53. Ibrahim Shihata, *The World Bank and Human Rights: An Analysis of the Legal Issues and the Record of Achievements*, 17 DENV. J. INT'L L. & POL'Y 39, 39 (1988).

International Bill of Human Rights. The Bank's good governance policy, which combines economic and political conditionality, was the avenue through which elements of the International Bill of Human Rights became a part of the Bank's mandate. Under this reinterpretation of its mandate, the Bank took the view that it can take into account "pervasive violations of [human] rights to the extent that they have obvious and significant effects on the economy of the country it assists."[54] This view can be summarized as follows: human rights goals cannot be achieved at the cost of the World Bank's economic and financial mandate.[55]

This reconstruction of the Bank's mandate to incorporate human rights is, in my view, not a story of progress and evolution from the classical to the modern position.[56] Instead, it is my view that both the Bank's Articles of Agreement and the International Bill of Human Rights provide a sufficiently open-ended interpretive arena for the continued redefinition of the role of the Bank with respect to human rights. This possibility of ambiguity in interpreting and reinterpreting the Bank's Articles of Agreement and the International Bill of Human Rights simultaneously empowers and disempowers those involved in this interpretive and strategic work as each side constructs its case.[57] Hence, the Bank's classical position co-exists alongside positions held both within and without the Bank that are substantially dissimilar.

Consequently, human rights activists who support a larger role for the Bank in the protection of human rights have their goals constantly redefined by reference to the Bank's invocation of its classical position. It is this strategic engagement of rights work that has a disempowering effect on human rights activism, as rights claims have to be redefined or reconciled by finding complementarity and compatibility with the economic policies of the World Bank. Consequently, human rights activists, who have sought to use human rights as a means of demanding that the World Bank adopt an approach to development that is more humane, are constantly disappointed by the continued redefinition of their rights claims with countervailing rights claims, all mediated through

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54. Ibrahim Shihata, *Democracy and Development*, 46 INT'L & COMP. L.Q. 635, 640 (1997).

55. *Good Governance*, *supra* note 43, at 107.

56. Indeed, as Roberto Unger, noted: "We have no stake in finding a preestablished harmony between moral compulsions and institutional constraints. We know, moreover, that the received views of institutional propriety count for little except as arguments to use against those who depart too far from professional consensus." ROBERTO MANGABEIRA UNGER, THE CRITICAL LEGAL STUDIES MOVEMENT 19 (1983).

57. See generally, Amr Shalakany, *Arbitration and the Third World: A Plea for Reassessing Bias Under the Specter of Neoliberalism*, 41 HARV. INT'L L.J. 419 (2000) (arguing that legal norms used in determining arbitration disputes are open-ended and therefore could be used for or against third world/first world positions).

reference to the background assumptions of the classical interpretation of the Bank's mandate.[58]

B. *An Ambiguous Legacy on Social Issues Shapes Up at the WTO: A Built-in Problem*

The place of social issues at the WTO, in my view, reflects the same ambiguity that characterizes the World Bank's mandate relative to human rights. At the WTO, there are, of course, the classicists, who are self-defined as consitutionalists. In the view of the consitutionalists, the WTO is a self-contained institution separate from public international law and therefore from social claims such as labor rights.[59] This view is given credibility by the fact that GATT, unlike the Articles of Agreement of the International Bank of Reconstruction and Development, which established the World Bank, has been widely regarded as a contract rather than a treaty.[60] Then there is a countervailing view, which argues that the WTO's mandate cannot be understood outside the context of public international law.[61]

These two opposing views of the WTO's mandate are unsurprising, given that other international economic institutions, such as the World Bank, already face the same legacy of ambiguity in accommodating social policy as part of their self-described economic and financial mandates.[62]

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58. For a good summary of this argument, see James Thuo Gathii, *Human Rights, the World Bank and the Washington Consensus: 1949-1999, in* AMERICAN SOCIETY OF INTERNATIONAL LAW, PROCEEDINGS OF THE 94TH ANNUAL MEETING 144 (2000).

59. *See generally* Jeffrey L. Dunoff, *The Death of the Trade Regime*, 10 EUR. J. INT'L L. 733 (1999) (arguing that, given the institutional constraints facing the WTO panels and the contested nature of issues falling outside the scope of the WTO, these social claims should be excluded from the WTO because they risk delegitimizing WTO procedures); Jeffrey L. Dunoff, *"Trade and": Recent Developments in Trade Policy and Scholarship—And Their Surprising Political Implications*, 17 NW. J. INT'L L. & BUS. 759, 763-68 (1996-97) (raising concerns about the trade regimes expansion into new substantive areas).

60. *See* David Kennedy, *Receiving the International*, 10 CONN. J. INT'L L. 1, 11 (1994) (summarizing this view of GATT as a vision of a "decentralized scheme of interstate bargaining"); Donald M. McRae, *The Contribution of International Trade Law to the Development of International Law, in* RECUEIL DES COURS: COLLECTED COURSES OF THE HAGUE ACADEMY OF INTERNATIONAL LAW 109, 178 (1996) (describing the view that GATT was a contract and not a treaty, and that "[u]nlike other international organizations which surrounded themselves with lawyers, lawyers were notably absent from GATT, indeed often were not welcome, and the role of law in dealing with the economic relations of States was controversial").

61. *See generally* David Palmeter & Petros C. Mavriodis, *The WTO Legal System: Sources of Law*, 92 AM. J. INT'L L. 398 (1998). Similarly, Donald McRae has argued that "it is clear that at least with the advent of the new WTO dispute settlement mechanism, international law is central to the interpretation of international trade law." McRae, *supra* note 60, at 176-77.

62. *See* James Thuo Gathii, *Re-Characterizing the Social in the Constitutionalization of the WTO: A Preliminary Analysis*, WIDENER L. SYMP. J. (forthcoming 2001).

It is unsurprising for two reasons. First, the WTO has adopted a legal and institutional architecture that, like the Bretton Woods institutions, bifurcates its private mandate from its public mandate. Its mandate as a private international economic institution in lowering barriers to trade can only be limited in exceptional instances, which are defined in part under Article XX of GATT.[63] This bifurcation between private and public roles and the restrictions on departures from what was conceived as a private mandate are the outcome of the post-Second World War institutional compromise separating international governance into separate realms—public and private. Yet, this post-Second World War institutional compromise, which is nothing but an accidental constellation of ad hoc responses to events leading to the Second World War, continues to influence international economic governance today. It is therefore plausible to argue that the ambiguous legacy of social issues in the context of international economic institutions is not inevitable, but rather the outcome of the conscious construction of its architects confined within a legal framework that predetermines such an outcome.

One of the primary ways in which GATT has been defined as having a limited social agenda is through the restrictive interpretations of the exceptions listed in Article XX.[64] Article XX potentially allows the balancing of social objectives, such as public health and protection of the environment on the one hand, and free trade on the other. However, that balance has been illusory. For example, in the *Tuna Dolphin Case*[65] the issue was whether the United States could extend its environmental policy of dolphin protection extra-territorially by banning imports of tuna that had been harvested in violation of vague limits on dolphin intake.[66] The United States justified its import ban on the basis of Article XX(b), which provides for protection of animal life as a basis for departure from a

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63. *See* General Agreement on Tariffs and Trade, Oct. 30, 1947, art. XX, 4 T.I.A.S. 669, 55 U.N.T.S. 262 [hereinafter GATT].

64. Article XX provides that nothing in the GATT

> shall be construed to prevent the adoption or enforcement by any contracting party of measures . . . necessary to protect public morals . . . necessary to protect human, animal or plant life or health; . . . relating to the products of prison labour; . . . relating to the conservation of exhaustible natural resources if such measures are made effective in conjunction with restrictions on domestic production or consumption; . . . or . . . essential to the acquisition or distribution of products in general or local short supply.

Id.

65. United States—Restrictions on Imports of Tuna, Sept. 3, 1991, GATT B.I.S.D. (39th Supp.) at 155 (1993).

66. *Id*. ¶ 5.1.

country's commitment under GATT.[67] In finding against the United States, the panel noted that "[t]he United States . . . had not demonstrated that it had exhausted all options reasonably available to it to pursue its dolphin protection objectives through measures consistent with the General Agreement, in particular through the negotiation of international cooperative arrangements."[68]

In the *Thai Cigarette Case*,[69] Thailand argued that its prohibition of imported cigarettes was justified by the objective of reducing cigarette smoking as a way of combating harmful health effects among its citizens.[70] It justified this prohibition of cigarette importation on the basis of Article XX(b) of GATT.[71] The panel found against Thailand, ruling that "a contracting party cannot justify a measure inconsistent with other GATT provisions as 'necessary' in terms of Article XX(d)."[72] Article XX(d) provides an exemption for measures that a party could reasonably be expected to employ and that are not inconsistent with other GATT provisions available to it.[73] The panel provided further limitations on measures taken under the authority of Article XX(d), requiring that "in cases where a measure consistent with other GATT provisions is not reasonably available, a contracting party is bound to use, among the measures reasonably available to it, that which entails the least degree of inconsistency with other GATT provisions."[74]

Hence, in both the *Thai Cigarette Case* and the *Tuna Dolphin Case*, the panel adopted a very restrictive reading of the exceptions under Article XX of GATT. These rulings in effect read out of the treaty limitations on free trade policies based on public health or related concerns that were understood to be beyond the scope of GATT's mandate. This restrictive interpretation requires measures to be consistent with Article XX *if no less trade-restrictive alternative could be imagined to achieve the policy objectives in question*.[75]

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67. *Id*. ¶ 3.6(b).

68. *Id*. ¶ 5.28.

69. Thailand—Restrictions on Importation of and Internal Taxes on Cigarettes, Nov. 7, 1990, GATT B.I.S.D. (37th Supp.) at 200 (1991).

70. *Id*. ¶ 21.

71. *Id*.

72. *Id*. ¶ 74.

73. *Id*.

74. *Id*.

75. Similarly, in another panel report, a measure was found inconsistent with GATT under Article XX(d). *See* United States—Section 337 of the Tariff Act of 1930, Nov. 7, 1989, GATT B.I.S.D. (36th Supp.), at 345 (1990) [hereinafter Section 337]. The panel ruled "that a contracting party cannot justify a measure inconsistent with another GATT provision as 'necessary' in terms of Article XX(d) if an alternative measure which it could be reasonably expected to employ and which is not inconsistent with other GATT provisions is also available to it." *Id*. ¶ 5.26. The panel also found that "in cases where a measure consistent with other GATT provisions is not reasonably

Another way in which the trading regime has been defined as having little to do with social claims is through the claim that it is a self-contained regime, separate from the rest of public international law. This position informs the restrictive interpretations of Article XX noted above. However, following the *Shrimp Turtle Case*,[76] there is hope for a new direction in trade policy, away from the constitutionalist position.[77] A central issue in the *Shrimp Turtle Case* was whether exhaustible resources in Article XX(g) include endangered species.[78] In answering this question, the WTO Appellate Body (AB) abandoned the notion that the WTO is a self-contained system.[79] It did so by examining the question of whether an endangered species was an exhaustible resource under Article XX(g) by reference to international environmental law.[80] The AB, like the panel below it in the *Shrimp Turtle Case*, found against the United States on grounds other than whether or not an environmental policy protecting turtles fell within the exception provided under Article XX(g).[81] The AB ruling, in effect, allowed members to take action to protect exhaustible natural resources in a manner that would have been found invalid under the panel rulings in both the *Thai Cigarette Case* and the *Tuna Dolphin Case*.[82]

This enduring tension of the place of social claims in the international trading regime embodied in the praxis of the GATT/WTO and in the post-Second World War institutional compromise can also be traced to a

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available, a contracting party is bound to use, among the measures reasonably available to it, that which entails the least degree of inconsistency with other GATT provisions." *Id*.

76. United States—Import Prohibition of Certain Shrimp and Shrimp Products, Oct. 12, 1998, 38 I.L.M. 118 (1999) [hereinafter Shrimp Turtle].

77. Similarly, and perhaps hopefully, the Appellate Body in the *Gasoline II* decision found that United States regulations aimed at reducing emissions of toxic and smog-causing agents from motor vehicles fell within the provisional justification of Article XX(g). United States—Standards for Reformulated and Conventional Gasoline, May 20, 1996, 35 I.L.M. 603, 626 (1996). However, it also held that the regulations violated the introductory clauses of Article XX by constituting arbitrary and unjustifiable discrimination. *Id*. at 633-34.

78. Shrimp Turtle, *supra* note 76, at 153-54.

79. *See generally* MAKAU WA MUTUA & ROBERT HOWSE, PROTECTING HUMAN RIGHTS IN A GLOBAL ECONOMY: CHALLENGES FOR THE WORLD TRADE ORGANIZATION (1999).

80. *See* Shrimp Turtle, *supra* note 76, at 154-57.

81. The United States' ban on shrimp imports from countries that were not certified as having Turtle-safe shrimping methods was found to be inconsistent with GATT because it violated the chapeau, or preamble, to Article XX, which prohibits measures applied in a discriminatory manner. *Id*. at 165-69.

82. For recent commentary, see generally Virginia Dailey, Comment, *Sustainable Development: Reevaluating the Trade vs. Turtles Conflict at the WTO*, 9 J. TRANSNAT'L L. & POL'Y 331 (2000); Andres Rueda, Note, *Tuna, Dolphins, Shrimp and Turtles: What About Environmental Embargoes Under NAFTA?*, 12 GEO. INT'L ENVTL. L. REV. 647 (2000); Jackson F. Morril, Comment, *A Need for Compliance: The Shrimp Turtle Case and the Conflict Between the WTO and the United States Court of International Trade*, 8 TUL. J. INT'L & COMP. L. 413 (2000).

disciplinary bias in private international law. This disciplinary bias can be traced to the definition of private international law as an arena free of sovereign controls. This vision of a private international law order comprised of private actors trading across borders without the constraints of sovereignty has animated scholars as far back as Joseph Story in the Nineteenth Century.[83] Similarly, in the period after the Second World War, Harold Koh has argued that "[i]nternational trade has lived the four decades since its curious birth as a legal stepchild, largely unembraced by its sibling fields of public international law [and] domestic administrative law."[84]

International economic theorists thus believe that the trading regime is a private order insulated from public claims or sovereign controls such as those at issue in the *Thai Cigarette Case* and the *Tuna Dolphin Case*. These cases are aligned with the views of economists such as Wilhelm Ropke, who advocated a liberal economic order premised on the largest possible 'depoliticisation' of the economic sphere. For Ropke, depoliticising the economic sphere as such was a safeguard against socialism.[85] Other scholars in this tradition conceptualized social claims not as a form of collectivism or socialism, as did Ropke, but as a form of economic sovereignty that had to be restricted in favor of a rule based on international economic law.[86] Economic sovereignty under this view was dismissed as an attempt by developing countries, through efforts such as the New International Economic Order,[87] to extend the political concept of sovereignty into economic relations, where it did not belong.[88] Still others claim that the trading regime is a liberal constitutional order akin to an invisible hand under which free trade is maximized under a regime of rule-based, minimal governments.[89]

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83. *See generally, e.g.*, JOSEPH STORY, COMMENTARIES ON THE CONFLICTS OF LAWS (1883).

84. Harold Hongju Koh, *The Legal Markets of International Trade: A Perspective on the Proposed United States-Canada Free Trade Agreement*, 12 YALE J. INT'L L. 193, 194 (1987).

85. Wilhelm Ropke, *Economic Order and International Law*, 86 RECUEIL DES COURS 203, 224, 236 (1954).

86. *See, e.g.*, Georg Schwarzenberger, *The Principles and Standards of International Economic Law*, 117 RECUEIL DES COURS 1, 31 (1966).

87. The New International Economic Order refers to a movement in the late 1960s and early 1970s for third world sovereignty over the means and ends of development. The movement was ultimately overshadowed by demand in the late 1970s for international principles governing development. James C.N. Paul, *The United Nations and the Creation of an International Law of Development*, 36 HARV. INT'L L.J. 307, 310-11 (1995).

88. *See* Norbert Horn, *Normative Problems of a New International Economic Order,* 16 J. WORLD TRADE L. 338, 343 (1982).

89. *See generally*, e.g., ERNST-ULRICH PETERSMANN, CONSTITUTIONAL FUNCTIONS AND CONSITUTIONAL PROBLEMS OF INTERNATIONAL ECONOMIC LAW: INTERNATIONAL AND DOMESTIC FOREIGN TRADE LAW AND FOREIGN TRADE POLICY IN THE UNITED STATES, THE EUROPEAN COMMUNITY AND SWITZERLAND (1991).

Clearly, then, the place of social claims in the trading framework has taken shape within an international economic legal framework that displaces it from the onset. This framework thus only accommodates those assumptions consistent with this background assumption.[90] Given that social issues are conceptualized as falling outside the direct mandate of international economic governance, the outcomes in the *Thai Cigarette Case* and the *Tuna Dolphin Case* can be understood. Yet, following the *Shrimp Turtle Case*, there is clearly a different approach that questions the isolation of the trading regime from public international law norms such as human rights and environmental protection.

The purpose of my analysis in this section has been to illustrate that the tension regarding the place of social issues in international economic governance generally is a built-in problem.[91] It is therefore unsurprising that the provisioning of affordable AIDS medicines to low-end consumers faces the same challenges in the context of TRIPS as human rights claims have faced in the context of the Bretton Woods institutions. This built-in problem arises largely from the dichotomy of private and public consequences in international economic governance. Public consequences, such as providing access to affordable AIDS medicines, human rights and environmental protection, are presumed to be controversial and problematic given the WTO's mandate of lowering barriers to trade. The pursuit of freer trade, by contrast, is regarded as less controversial because it depoliticizes international commerce by eliminating sovereign controls over it.

However, the suggestion that private policy goals such as free trade are apolitical and uncontentious is troubling due to its artificiality. The fallacy of this distinction is made evident by the assumption that private international law, as opposed to public law, is apolitical because it does not depend on sovereign controls, as if the absence of sovereign controls constitutes neutrality. It is problematic to presuppose that politics is only found where there are public interventions into civil society (as in protecting human rights) but not where social claims are made (such as provisioning of affordable medicines for AIDS patients) within a regime of private international law—TRIPS. The restrictiveness with which

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90. *See* David Kennedy, *The Disciplines of International Law and Policy*, 12 LEIDEN J. INT'L L. 9, 12-13 (1999) (describing various approaches for identifying bias in law that purports to be neutral and employing a methodological approach that identifies bias in the deep structure of law in terms of its disciplinary sensibility to its own internal contradictions and background assumptions, which preclude it from seeing some things that are not consistent with those assumptions).

91. *See id*. (arguing "that a discipline's blindspots, strategies of evasion, elision, or forgetfulness might be linked to bias of various sorts . . . [such as] elisions or contradictions internal to a disciplinary sensibility with external biases").

TRIPS is construed in the context of providing affordable medicines is not merely the logical apolitical outcome of a private international regime, but the outcome of a process of making choices between alternative visions of TRIPS. Making these choices is not any less political than the forms of economic regulation that are understood as political by WTO constitutionalists.[92] This differs from the vision of private international law as an apolitical legal arena.[93]

IV. THE DIALECTICAL CHARACTER OF PRIVATE PROPERTY RIGHTS UNDER TRIPS

Based on the foregoing analysis of international economic governance, it comes as no surprise that TRIPS is based on a private property model that exhibits two logics in tension with each other.[94] The first of these logics is that of property as market commodity. The role of property under this logic is that of individual preference satisfaction. The underlying rationale of property rights in the commodity conception is based on a view of a society of free individuals engaging in maximally free contracts. Markets operate as utility-maximizing machines, socially optimizing the aggregate sum of satisfaction with scarce resources through mechanisms of choice, supply, demand, and price.[95] In essence, private property rights in this system are important incentives to high productivity because people

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92. Similarly, Adelle Blacket, *Whither Social Clause? Human Rights, Trade Theory and Treaty Interpretation*, 31 COLUM. HUM. RTS. L. REV. 1 (1999), argues that "social clause proponents should be thinking less about a negotiated 'clause' grafted onto the existing GATT framework, and more about a social dimension through treaty interpretation." *Id*. at 5. Making a similar point, David M. Trubek, *Protectionism and Development: Time For a New Dialogue?*, 25 N.Y.U. J. INT'L L. & POL. 345 (1993), stated that "[r]ather than seeking exceptions to general rules, the South may initiate a new dialogue on trade matters by lobbying for greater enforcement of the basic principles and disciplines the developed countries have officially endorsed." *Id*. at 364. For the same debate in the context of whether deep integration leaves room for social justice, see DAVID M. TRUBEK, SOCIAL JUSTICE "AFTER" GLOBALIZATION: THE CASE OF SOCIAL EUROPE 3 (MacArthur Consortium Research Series on International Peace and Cooperation No. 9, 1996).

93. *See* James Thuo Gathii, *Neoliberalism, Colonialism and International Governance: Decentering the International Law of Governmental Legitimacy*, 98 MICH. L. REV. 1996, 2024-27 (2000).

94. *See generally* TRIPS, *supra* note 5.

95. According to Mark Kelman, it is just an assumption that the actual choices embodied in contracts and markets reliably reflect what people truly value. Kelman argues that there is a wide divergence between choice on the one hand and utility—what people actually value—on the other. MARK KELMAN, A GUIDE TO CRITICAL LEGAL STUDIES 127-28 (1987). If we agree with Kelman, the regime of free contracts cannot therefore reliably provide us the optimum of what we actually deem valuable. There are duress and other forms of constraint that limit our choices. Choice does not reflect value choices such as those related to equality and participatory democracy, as these kinds of values would provide market choices and legitimacy by maximizing the similarities rather than the differences between choice and value.

get to keep what they produce. Without property rights, people would produce less because they would get to keep less. Here, there is no room for political controls over individual use of property.[96]

The second logic is a public policy perspective of property rights. Under this second logic of property, there are circumstances under which property can be legitimately encumbered with public regulation, for instance to strike a balance between the interests of producers and consumers of IPRs. This public policy alternative is embedded in the provisions of the TRIPS agreement that contemplates a balance between the rights of producers and consumers of IPRs. It is also implicit in the discretion that TRIPS presupposes that countries have in implementing the treaty. Hence, for example, there is no consensus on certain issues such as subject matter of protection. The status of computer programs and biotechnologies is unclear.[97] In addition, the novelty and nonobviousness standards of eligibility for patents are unclear.[98] All of these unclear areas give developing countries room to develop practices consistent with their goals. These areas of discretion also extend to the exact scope of exclusive rights, as it is unclear whether the doctrine of equivalents applies.[99] Similarly, there is much discretion afforded in the exceptions that TRIPS allows; for example, it is unclear whether a country must declare a national health emergency to invoke compulsory licensing.[100]

The logic of property as commodity has as a central goal the maximization of returns on investments so that owners of IPRs can receive returns on their investments and conduct research and development. The rallying cry of the private sector group that conceptualized the TRIPS agreement came on the coattails of a fair trade debate in the United States. In the context of IPRs, the fair trade debate arose as a way of addressing piracy of American and, in general, Western corporate IPRs in developing and rapidly developing countries. 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.

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96. For critiques of this protectionist, anti-consumer, pro-industry position, see generally Keith Aoki, *(Intellectual) Property and Sovereignty: Notes Toward a Cultural Geography of Authorship*, 48 STAN. L. REV. 1293 (1996). *See generally* Oddi, *supra* note 3.

97. *See* Sean D. Murphy, *Biotechnology and International Law*, 42 HARV. INT'L L.J. 47, 97 (2001).

98. See Curtis M. Horton, *Protecting Biodiversity and Cultural Diversity Under Intellectual Property Law: Toward a New International System,* 10 J. ENVTL. L. & LITIG. 1, 27 (1995).

99. The doctrine of equivalents "means that if two devices do the same work in substantially the same way and accomplish substantially the same result, they are the same, even though they differ in name, form, and shape." BLACK'S LAW DICTIONARY 542 (6th ed. 1990).

100. Reichman, *supra* note 2, at 16-17, 26.

It is my claim that the commodity conception of IPRs is not the only vision of private property embedded in the TRIPS agreement. The TRIPS agreement was seriously debated against a background of at least two visions in tension with each other on the role of private property in international society. Under the commodity conception of private property, TRIPS embodies a form of IPR protection aimed at realizing the maximum profit possible in the marketplace. Under the alternative view, TRIPS can be conceptualized as embodying a vision that balances the returns producers seek for their research and development and the benefits that IPRs extend to society. Here, the focus is much broader than giving producers of IPRs the right to realize the maximum profit possible.[101]

The "maximum profit possible" view of the commodity conception of IPRs is justified on the basis that it is only reasonable and fair to compensate owners of intellectual property for their investment in research and development. Under this view, those who put their effort, labor, and capital into the market should get a return or reward for their input, without the risk of piracy. According to this commodity logic of private property, producers have an incentive to produce only when these returns

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101. In *Munn v. Illinois,* 94 U.S. 113, 135-36 (1876), the Supreme Court held that the Illinois state government has the power to regulate owners' returns on their businesses, which trumps private agreements regarding price and limits investment return on private property. This power, the Supreme Court held, arose where there was a public interest that justified such regulation of private property. *Id*. at 126-27. In other words, where an industry is intertwined with a public interest, state governments have the power to limit profit. *See id.* The law in question in *Munn* was similar to many laws passed in the Midwest at that time to regulate the warehousing and transportation of grain. *See id.* at 125. Defining grain elevators as public warehouses the Illinois statute established maximum rates for grain storage. *Id.* at 113-14. In *Bluefield Water Works & Improvement Co. v. Public Service Commission*, 262 U.S. 679, 692-93 (1923), the Court held that there is "no constitutional right to profits such as are realized or anticipated in highly profitable industries." Hence, on the issue of protection of private property rights, the Court seems to suggest that only a minimum rate of return is constitutionally required; protection of property rights only has to be reasonable and fair. *See id.*; *Munn*, 94 U.S. at 129. There is an implicit protection of the consumer, to the extent that a fair profit also entails a fair price to the consumer. *See Bluefield*, 262 U.S. at 692-93; *Munn*, 94 U.S. at 129. However, note that following the Supreme Court decision in *Chicago, Milwaukee & St. Paul Ry. v. Minnesota*, 134 U.S. 418 (1890), a doctrine shift from *Munn* occurred. In that case, the Court invalidated a statute that made railroad rates that a commission had established without a hearing conclusive in judicial proceedings to enforce them. Such absence of an investigation, the Court held, was a deprivation of the company's lawful use of its property. Hence, in *Milwaukee*, the Supreme Court departed from *Munn* in holding that even businesses affected with a public interest had a due process right to check legislative power to regulate railroads for reasonableness. Eventually, in *Smyth v. Ames*, 169 U.S. 466 (1898), the Supreme Court, in holding as unconstitutional a Nebraska statute imposing rate reductions averaging 29.5% on intrastate shipments, completed its doctrinal shift away from *Munn*. Following *Smyth*, a "corporation's opportunity to realize profits for private benefit, even as to firms that were licensed to serve the public interest," was raised to a constitutional level. GREGORY ALEXANDER, COMMODITY AND PROPRIETY: COMPETING VISIONS OF PROPERTY IN AMERICAN LEGAL THOUGHT 270 (1997).

are guaranteed. This view proceeds from a very strong view in favor of the sanctity of property. This view further justifies intellectual property protection as a necessary precondition for promoting transfers of technology to developing countries.

The foregoing view however, understates the invariable tensions that this commodity logic of private property generates in the context of public policy. Hence, for example, early in the negotiations on TRIPS and immediately after it came into force following the Uruguay Round, the United States was greatly opposed to reading flexibility (or limitations on IPR protection) into TRIPS. However, there has seemed to be a recognition of the need to be flexible in implementing TRIPS in the last two years. Hence, in May 2000 President Clinton signed an Executive Order ordering the United States Trade Representative (USTR) not to impose trade sanctions under section 301 of the Trade Act of 1974 or revoke any intellectual property laws or policies of sub-Saharan African countries related to promoting access to HIV/AIDS pharmaceuticals or medical technologies to affected populations.[102] Similarly, in United States constitutional jurisprudence, the Supreme Court has stopped short of treating rate regulation as a deprivation of property without due process.[103]

I therefore argue that there is no single tradition of intellectual property protection in TRIPS. My claim is that the commodity logic of IPR protection simultaneously and dialectically co-exists with an alternative logic of IPR protection that recognizes as legitimate the accommodation of public policy concerns as falling within the purview of the TRIPS agreement. In essence, the TRIPS agreement is predicated on an implicit balance between the interests of producers and consumers of IPRs.[104]

One of the reasons that the dialectical character of intellectual property protection has been understated over the last several years has to do with the success of the classical economic vision of free markets in shaping the production of legal doctrine relating to IPRs. I claim that the production of legal doctrine in the context of TRIPS was also heavily influenced by discourse about markets and therefore by the commodity view of private property rights. This free market rhetoric that has characterized debates about free trade and globalization under the aegis of neo-liberal economics

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102. Exec. Order No. 13,255, 65 Fed. Reg. 30,521, 30,522 (2000). This executive order also required sub-Saharan African countries to provide adequate and effective intellectual property protection as a precondition for increasing access to HIV/AIDS drugs. *Id*. at 30,521.

103. In *Munn*, 94 U.S. at 125, Chief Justice Waite noted that under certain circumstances, price regulation may constitute a deprivation of property without due process. However, in the context of pharmaceuticals under the TRIPS agreement, there is no parallel to price deregulation, especially following the wave of deregulation that has accompanied the wave of globalization since the late 1980s. *See also supra* note 101.

104. For a preliminary attempt to articulate this sense of balance in the trading regime in general, see Gathii, *supra* note 62.

over the last several years has given the commodity logic of private property rights enormous credibility while simultaneously de-legitimating governmental limitations on private property.[105] Yet, this vision of free markets with its attendant subscription to a model of property as commodity is only one of the contending visions of intellectual property that has characterized debates on the ideal international IPR regime.

Hence, while TRIPS evidences the success of those committed only to the commodity vision of private property, this vision has been in severe contention and tension with an alternative vision of IPRs. That alternative vision is characterized by the assertion that public policy issues such as human rights, environmentalism, and public health issues like AIDS have a legitimate place in TRIPS. This tension is partly a reflection of the significance of seeing the TRIPS regime within the context of prevailing social, political, and economic circumstances. These circumstances in turn influence the construction and interpretation of the legal norms of the TRIPS regime and, as such, produce a tension with the prevalent commodity conception of IPRs.[106] Seeing TRIPS this way demonstrates the nature of its built-in public/private dichotomy, which is most evident when we start considering the policy options and choices it provides for or forecloses.

In this part, I aim to clarify this tension in the construction and interpretation of different logics of property under the TRIPS regime. Only one of the private property logics of TRIPS, the commodity logic, has been

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105. However, as Duncan Kennedy reminds us, the role of law has been simply to transpose from equally presumptuous economics the "idea of respect for the labor of others" by defining private property as embodying the legal equivalent or repository of the labor of others. Duncan Kennedy, *The Role of Law in Economic Thought: Essays on the Fetishism of Commodities*, 34 AM. U.L. REV. 939, 955 (1985). Hence, "[c]lassical legal thought conceived the legal system as designed to guarantee everyone that they could safely embody their labor in commodities and freely exchange them. This idea was essential to the classical economists' claim that the distributive process merely compensated economic actors for their labor inputs." *Id*. at 956. Further, Kennedy notes that

> [c]lassical legal thought supported the classical economists' claim that the outcome of economic processes was 'natural' by showing that state intervention could be organized in accord with natural law, rather than as a distorting activity. If all rational men must agree, not only that property was sacred and *pacta sunt servanda*, but that a code could be deduced from those abstractions, then state activity in enforcing the code could hardly be described as artificial.

Id.

106. This does not in any way suggest that international legal regimes like TRIPS do not have an autonomy of their own, independent of prevailing circumstances.

well developed and articulated, while the contending public policy-oriented perspective has not been articulated as well in the literature.[107]

The contribution my Article makes in developing a public policy-oriented perspective of private property rights is guided by the principle that private property rights have a social as well as a political character, apart from their economic character in seeking the highest returns for owners of private property. Private property is valued not only as an end and right in and of itself, but also in terms of its social utility, which comes from political demands such as those related to accessibility and affordability of IPR protected products that will help to meet public health needs of low-income individuals.[108]

Indeed, it seems that Western governments, which have most vehemently advocated a commodity logic of intellectual property based on maximizing profits to producers of IPRs, have in certain cases back-tracked. For example, as noted above, the United States has adopted a policy of allowing sub-Saharan African governments discretion to adopt laws and policies facilitating access to AIDS drugs without fear of imposition of sanctions under Section 301 of the Trade Act of 1974.[109] This, in addition to the political demands associated with dramatic moments such as the Seattle protests,[110] complemented by public policy constructions and interpretations of the TRIPS agreement, can be characterized as constituting and indeed beginning to crystallize a public policy-oriented conception of intellectual property rights.

Similarly, on September 17, 1999, the United States and South Africa reached a common understanding on the relationship between pharmaceuticals and public health.[111] While both governments committed

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107. Some works with aspirations in this direction include: JAMES BOYLE, SHAMANS, SOFTWARE, AND SPLEENS: LAW AND THE CONSTRUCTION OF THE INFORMATION SOCIETY (1996); Aoki, *supra* note 96; Keith Aoki, *The Stakes of Intellectual Property Law*, *in* THE POLITICS OF LAW: A PROGRESSIVE CRITIQUE 259 (David Kairys ed., 1998) [hereinafter *Stakes*]; Samuel Murumba, *Globalizing Intellectual Property: Linkage and the Challenge of a Justice Constituency*, 19 U. PA. J. INT'L ECON. L. 435 (1998); Oddi, *supra* note 3; Ruth Gana Okediji, *Toward an International Fair Use Doctrine*, 39 COLUM. J. TRANSNAT'L L. 75 (2000); Ruth Gana Okediji, *Copyright and Public Welfare in Global Perspective*, 7 IND. J. GLOBAL LEGAL STUD. 117 (1999); Reichman, *supra* note 2.

108. JOSEPH WILLIAM SINGER, THE EDGES OF THE FIELD: LESSONS ON THE OBLIGATIONS OF OWNERSHIP 20 (2000), notes that property law "is highly protective of the prerogatives of owners, but it also recognizes that ownership may impose vulnerabilities on others and limits the rights of owners when their actions impinge on the legitimate interests of other." *Id*.

109. *See supra* note 102 and accompanying text.

110. In November 1999, a diverse group of demonstrators gathered in Seattle to protest the negative aspects of international trade and globalization. Peter L. Fitzgerald, *Massachusetts, Burma and the World Trade Organization: A Commentary on Blacklists, Federalism, and Internet Advocacy in the Global Trading Era*, 34 CORNELL INT'L L.J. 1, 2-3 (2001).

111. Steven Lee Myers, *South Africa and U.S. End Dispute Over Drugs*, N.Y. TIMES, Sept.

themselves to the TRIPS agreement, they nevertheless acknowledged the need to address the AIDS epidemic as a public health emergency.[112] However, one must also not forget that the planned actions of the United States with respect to Brazil and Argentina indicate a tendency the other way.

A. *The Commodity Logic of Private Property Embodied in TRIPS: The Background for Aggressive IPR Protection*

The TRIPS agreement evidences the success of a coalition of private, American high-technology firms in linking intellectual property protection to trade and to the GATT/WTO framework. This coalition, known as the Intellectual Property Committee (IPC), was formed in the early 1990s with two major aims. The first was to make IPR protection a central part of United States foreign trade policy. The second was to use this new prominence of IPR protection in the domestic foreign trade policy context to improve international IPR protection, primarily through new internationally-binding minimum standards that would be adopted in the course of the Uruguay Round and enforced by the WTO. The strategy of the thirteen member IPC,[113] under the leadership of then-Pfizer Chairman and CEO Edmund T. Pratt, was to forge an alliance with European and Japanese high-technology industries, as well as with the governments in Europe, Japan and the United States. Their goal was motivated in part by the desire to gain leverage in the creation of the GATT/WTO framework under negotiation in Uruguay, and to achieve IPR protection.

A primary impetus behind this privately sponsored initiative was the shift in the United States' comparative advantage with respect to products and services with a market value that is greatly dependent on international intellectual property protection. For example, the value of United States exports produced with IPR protection rose from 9.9% in 1947 to 27.4% in 1986, a 17.5% percentage point increase in about four decades.[114] Given this trend, the new locus of the United States' competitiveness now largely depends on its capability not only to generate research, software designs, entertainment, engineering concepts, advertising, marketing, styling, legal and financial innovations and information-based inventions, but also to

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18, 1999, at A8.

112. *See id*.

113. These thirteen members were: Pfizer, General Electric, Merck, IBM, Du Pont, Warner Communications, Hewlett-Packard, Bristol Myers, FMC Communications, General Motors, Johnson and Johnson, Monsanto, and Rockwell International.

114. INTELLECTUAL PROPERTY RIGHTS: GLOBAL CONSENSUS, GLOBAL CONFLICT? 4 (R. Michael Gadbaw & Timothy J. Richards eds., 1988). The products measured in 1947 were chemicals, books and electrical machinery, while in 1986 they included those items and computers. *Id*.

protect these forms of intellectual property as rights. Such protection would in turn secure the competitive edge of United States intellectual property exports.

However, as a central part of United States foreign trade policy, the shift in the United States' comparative advantage from an advantage solely in terms of industry, technology, and resources to an advantage in transforming or producing conceptual notions into intangible flows of ideas and money was the result of private sector lobbying. The backdrop against which the high-technology sector in the United States raised the need for more prominence of IPR protection in foreign trade policy was the debate on fair trade. One of the rallying cries of the fair trade debate characterized United States IPRs as particularly vulnerable to piracy at the hands of developing countries. There was a particular concern regarding countries such as Japan and those of Southeast Asia, which had achieved dramatic levels of growth based on imitation and mimicry of the high technology of United States corporations. The following factors fueled the fair trade debate: the trade deficit, especially with Japan; unemployment losses, which were somewhat directly related to declining export levels, and lobbying especially by organized labor.[115]

This perception further held that foreign competition from Third World countries had increasingly made it harder for the United States and developed countries in general to maintain their standards of living, or even their high rates of economic growth. Japanese growth was an initial impetus of this perception in the 1980s. These perceptions congealed into claims of unfairness that propelled United States unilateralism and leadership in the Uruguay Round of GATT. The debate was structured somewhat around the claim that the United States had progressively opened its border to international trade without a concurrent reciprocity on the part of its trading partners. One consequence the trade debates of this era was the quest by the United States to pry open foreign markets that had been perceived to have been closed to United States commerce.[116]

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115. On the complex relationship between unemployment and international trade, see JAGDISH BHAGWATI, TRADE AND WAGES: A MALIGN RELATIONSHIP (Department of Economics, Columbia University, Discussion Paper No. 761, 1995). Bhagwati argues that it is not entirely clear that the low wages in developed countries can easily be accounted for solely by labor-saving technologies and skills-biased technological changes, and that the effects of globalization in and of themselves cannot account for the loss of these jobs. However, Dani Rodrik argues that there is a probable relationship between the loss of labor's bargaining power in the United States and globalization because globalization increases the substitution of labor across national boundaries much easier. *See* DANI RODRIK, HAS GLOBALIZATION GONE TOO FAR? (1997).

116. For an excellent discussion of these issues, see generally AGGRESSIVE UNILATERALISM: AMERICA'S 301 TRADE POLICY AND THE WORLD TRADING SYSTEM (Jagdish Bhagwati & Hugh T. Patricks eds., 1990).

Edmund Pratt Jr., Chairman and CEO of Pfizer, was at the time of this debate and since 1979 a member of President Carter's Advisory Committee on Trade and Policy Negotiations (ACTPN). The mandate of this private sector group was to review and to report to Congress on the policies of the USTR's Office, as well as to advise the USTR on trade policy. As the ACTPN chair from 1981, Pratt led not only the IPC but also the ACTPN in making IPR protection a central part of United States foreign trade policy. This turned into a remarkable conceptual and policy success. Conceptually, the acknowledgement of IPRs as a trade issue heralded a new era of United States trade policy, shifting from merely advocating open markets for trade to actively prying open foreign markets for United States goods (particularly IPRs) while simultaneously seeking aggressive international legal protections for IPRs in these new markets. It is noteworthy that Pratt and IBM Chairman John Opel jointly chaired the intellectual task force of the ACTPN at the time when these changes were taking place.[117]

Another policy success of the ACTPN initiative institutionally was the formation of a new office of Assistant USTR for International Investment and Intellectual Property in the early 1980s. Congressional action also followed suit with significant changes made to the Trade Act of 1974. In 1984, Section 301 of the Trade Act of 1974 was amended to authorize the USTR, without a showing of injury by the industry, to take retaliatory action against countries failing to give adequate protection to intellectual protection.[118] Section 303 was amended to authorize the USTR to report on barriers to trade in countries throughout the world.[119] Section 501 was amended to authorize the President to consider the adequacy of intellectual property protection in deciding whether a developing country should be granted tariff preferences under the United States Generalized System of Preferences.[120]

In 1988, the Trade Act of 1974 was further amended, by the Omnibus Trade and Competitiveness Act of 1988, through the passage of Special

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117. Some startling statistics from a variety of industries on the losses they had sustained as a result of lax, inadequate, or non-existent IPR protection in developing countries gave further impetus to the claims of unfairness. Among the industries that alleged piracy were pharmaceutical as well as copyright-based industries such as the movie, publishing and software industries. In 1986, for example, the United States International Trade Commission estimated that inadequate intellectual property protection had cost United States firms between $43 and $61 billion in 1986 alone. PFIZER: GLOBAL PROTECTION OF INTELLECTUAL PROPERTY 9 (Harvard Business School, Case No. 9-392-073, 1995).

118. *See* Trade and Tariff Act of 1984, Pub. L. No. 98-573, § 301, 98 Stat. 3000 (1984) (codified as amended at 19 U.S.C. § 2411 (1988)).

119. *See id.* § 303(a), 98 Stat. at 3001-02 (codified as amended at 19 U.S.C. § 2241 (2001)).

120. *See id*. § 501, 98 Stat. at 3001-02 (codified as amended at 19 U.S.C. §§ 2461-2465 (2001)).

301.[121] Special 301 is a unilateral trade power that requires the USTR to identify foreign states denying intellectual property protection to United States firms and to designate the most important of these as "Priority Foreign Countries."[122] The designation of a country under the priority list requires the USTR to initiate an investigation within thirty days to determine whether the foreign practices involved violated United States rights under a trade agreement or were unreasonable or discriminatory.[123] The enhancement of the USTR's jurisdiction, as well as the unilateral jurisdiction of the United States that was apparent on the face of these amendments, reflected a major policy shift of United States trade policy towards retaliation rather than reciprocity in securing foreign markets for United States goods and services.

The increased authority of the USTR in the area of IPRs in turn laid the stage for the United States to unilaterally single out countries opposed to the TRIPS agreement for punitive action unless they complied with United States law. The threat of unilateral sanction was also used to push developing countries to support TRIPS at the Uruguay Round. The countries placed on the Priority Watch List in 1989 in this effort included India, Brazil, Taiwan, and Thailand, which all opposed the inclusion of IPR protection in the Uruguay Round in general and TRIPS in particular. The actions against Brazil and India, two of the biggest members of the developing country coalition, a group of seventy-seven countries, played a major role in splitting the coalition and in securing acquiescence to TRIPS by developing countries.

In 1988, the IPC issued its "Basic Framework" document, which embodied the outlines of the TRIPS agreement.[124] Building consensus with European governments and corporations was problematic, especially in view of the emerging tendency towards United States unilateralism. European countries, for example, were inclined towards a multilateral approach that embodied considerations such as special and differential treatment for their former colonies. The European Union member countries and industries wanted a Code on Intellectual Property Rights that would eventually become a part of GATT.

The American-led IPC wanted a system of intellectual property protection that was binding on all nations, not only those that had ratified such a Code, as had been the practice under similar GATT codes. The Japanese government and Japanese industry, like their European

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121. *See* 19 U.S.C.§ 2242(a)(1)(A) (2001).

122. *See id.* § 2242(a).

123. *Id*. § 2412(b)(2)(A).

124. *See generally* INTELLECTUAL PROPERTY COMMITTEE ET AL., BASIC FRAMEWORK OF GATT PROVISIONS ON INTELLECTUAL PROPERTY—A STATEMENT OF THE VIEWS OF THE EUROPEAN, JAPANESE, AND UNITED STATES BUSINESS COMMUNITIES (1988).

counterparts, were reluctant to proceed with the IPC's proposals. To overcome these hurdles to an IPR agreement, the IPC used its relationship with the United States federal trade establishment to increase bilateral pressures through the enhanced powers under Section 301, among others. In addition, the IPC suggested that the United States should condition debt forgiveness to Latin American countries on adequate patent protection.

The bilateral pressures of the United States, which were based primarily on its unilateral retaliatory powers, were critical in leveling opposition to TRIPS in the Uruguay Round Working Group on Intellectual Property. Whereas the IPC's basic framework did not anticipate all the differences the United States, the European Union, and Japan haggled over during the Uruguay Round, it undoubtedly put IPRs on the international trade agenda. The success of industry in making IPRs a part of the GATT/WTO framework is evident in the definition of IPRs.

The industry's success in bringing IPRs to the WTO was further enhanced by the United States' conditional acceptance of the Uruguay Round agreements on the acknowledgment of its unilateral power under Section 301 of the Trade Act of 1974, as amended. Consequently, the United States has reserved the authority to enforce the Uruguay Agreements where members of the WTO's Dispute Settlement Understanding did not comply with their obligations at the end of the dispute settlement process.[125]

TRIPS is unprecedented because it is the first international treaty to embody a regime of private rights with minimal attention to the underlying public policy issues underlying IPR protection. Traditionally, trade and economic treaties have created rights for private parties indirectly through their respective public authorities. However, TRIPS departs from this norm by providing an elaborate international private law regime with remedies such as injunctive remedies,[126] border measures against counterfeiting[127] and penalties for infringement.[128]

TRIPS is also unique in the way it has influenced and will continue to influence distributional benefits disproportionately in favor of Western or,

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125. A WTO panel has found that sections 301-310 of the Trade Act of 1974 are consistent with United States obligations under the WTO. United States—Sections 301-310 of Trade Act of 1974, WTO Doc. No. WT/DS152/R (99-5454) (1999). At the 2000 Annual Meeting of the American Society of International Law (ASIL), Robert Howse argued that this decision was consistent with international legal principles allowing countries to engage in unilateral actions in their foreign relations as set out in *Nuclear Tests* (*Austl. v. Fr.*), 1974 I.C.J. 253 (Dec. 20). However, Petros Mavriodis argued that this case raised the possibility that the panel was mistaken to the extent that section 23 of the Dispute Settlement Understanding is the cornerstone of the multilateral system of dispute settlement at the WTO.

126. TRIPS, *supra* note 5, art. 44.

127. *Id*. arts. 51-60.

128. *Id*. art. 46.

at the very least, large corporations with enormous resources, which have the necessary expertise to take advantage of its provisions.[129] One of the most significant ways in which TRIPS narrows distributional gains is by its overwhelming reliance on a notion of original authorship. Hence, through a conceptual shift, science, commerce, and research are re-constituted solely as information, as opposed to being appreciated for their underlying value as scientific, commercial and educational resources, and the knowledge that they bring. For example, TRIPS protects control over expressions rather than ideas.[130] Similarly, it protects the information value contained in patents rather than inventions that have been reduced to practice.[131] Trademarks have similarly expanded the scope of exclusive control over marketplace signals in commerce, thereby departing from their signaling function in the marketplace.[132]

This conceptual shift towards original authorship in turn leads to the underprotection and underappreciation of indigenous knowledge, culture, dances, artifacts and physical resources.[133] Hence, where indigenous knowledge forms the basis for new pharmaceutical products, such indigenous knowledge is uncompensated because it is regarded as merely being raw material, which only acquires IPR value once it is transformed by scientific intervention. This shift in terms of conceiving forms of knowledge as information heavily favors the Western industrialized countries in general, and owners of technologies in those countries in particular, as they hold the industrial, technological, and resource advantage in transforming or producing conceptual notions into intangible flows of ideas and money.

Yet, while the significance of the medium grows, the product cost devoted to producing the medium drop; however, that saving in cost of production is not passed on to the consumer. Hence, as the price of producing a diskette or even a drug drops, the price of the diskette or of licensing the patent for it grows under the regime created by TRIPS.[134] The exclusivity of control of information under the TRIPS regime, contrary to the notions of its most ardent supporters, will therefore "diminish the

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129. To take one small example that has potential to weigh heavily in favor of Western multinationals, the TRIPS agreement adopts a first-to-file as opposed to a first-to-invent system for determining IPR protection. This seemingly insignificant change favors "large corporate research and development departments with staffs of patent lawyers working on time consuming and complex patent applications." Stakes, *supra* note 107, at 271.

130. *See* TRIPS, *supra* note 5, art. 9 § 2.

131. *See id.* art. 27.

132. *See id.* arts. 15-21.

133. For an inquiry into this issue, see Ruth L. Gana Okediji, *Has Creativity Died in the Third World? Some Implications of the Internationalization of Intellectual Property*, 24 DENV. J. INT'L L. & POL'Y 109, 125-37 (1995).

134. BOYLE, *supra* note 107, at 7.

availability of our cultural heritage, inhibit artistic innovation, and restrict public debate and free speech" in a manner that will undermine innovation and scientific progress.[135]

B. *The Public Policy-Oriented Logic of Intellectual Property Rights*

A public policy conception stands in tension with the commodity logic of IPRs in TRIPS. Although this public policy oriented conception of IPRs is overshadowed by the prevalence of the commodity conception in commentary on TRIPS, it nevertheless co-exists with the commodity conception. One central tension between the commodity and public policy conceptions of IPRs is as follows: the commodity oriented impulse towards the liberty interest of producers of IPRs to realize profits on the one hand is in tension with the interests of consumers of IPRs in receiving a fair price and accessibility to products subject to IPRs on the other.

According to proponents of the public policy perspective of IPRs, the pre-TRIPS protection of international IPRs balanced the interests of consumers and producers of IPRs. IPRs were, in the pre-TRIPS period, understood as being intended to support public uses for information that scientists, teachers, students, business people, librarians, and others need. Private use was guaranteed to the extent that it fulfilled these public purposes. TRIPS, by contrast, has created a catalogue of extensive liabilities that compromise these public uses of intellectual property rights. In fact, TRIPS seems to be predicated on the notion that any uncompensated use of IPRs is subject to sanctions. TRIPS has thus upset

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135. *Id*. at 124-25; *see also* WILLIAM ALFORD, TO STEAL A BOOK IS AN ELEGANT OFFENSE: INTELLECTUAL PROPERTY LAW IN CHINESE CIVILIZATION (1995) (arguing that Chinese history undermines the thesis that there is a historical correlation between economic development and respect for intellectual property rights); William Alford, *How Theory Does–And Does Not—Matter: American Approaches to Intellectual Property Law in East Asia*, 13 UCLA PAC. BASIN L.J. 8, 16-19 (1994); Bhupinder S. Chimni, *The Philosophy of Patents: Strong Regime Unjustified*, 52 J. SCI. & INDUS. RES. 234, 234-39 (1993) (questioning the idea that a hard notion of property rights is necessarily consistent with higher productivity). According to Alford, intellectual property rights cannot be implemented successfully in isolation from other rights. Hence, he suggests that concerns about human rights are indispensable to the attainment of intellectual property protection. He bases this view on the premise that serious copyright protection depends upon political and economic pluralism and independent legal institutions capable of vigorously enforcing citizens' rights. Alford, *supra*, at 18.

Even Friedrich A. von Hayek, the conservative free market commentator, has expressed skeptical views on the relationship between large investments in research and development, which should justify increased levels of IP protection on the one hand and innovation on the other. According to Hayek, "recurrent re-examinations of the problem [of intellectual property] have not demonstrated that the obtainability of patents of invention actually enhances the flow of new technical knowledge rather than leading to wasteful concentration of research on problems whose solution in the near future can be foreseen. . . ." FRIEDRICH A. VON HAYEK, THE FATAL CONCEIT: THE ERRORS OF SOCIALISM 37 (W. W. Bartley III ed., 1988).

that balance by overprotecting the rights of producers at the expense of the interests of consumers and, indeed, even of other producers of IPRs by constricting an arena of social and commercial space for uncompensated "fair uses."[136]

Proponents of TRIPS, as noted above, claim that developing countries are stealing the intellectual property rights of Western innovators, thereby compromising future productivity. This, the argument goes, is critical because America's economy presently stands on its competitive advantage in intellectual property. However, there is clearly a countervailing view. This countervailing view regards it as imperative to maintain a "balance" in a country's popular, legal, and technical conceptions of intellectual property. In the United States, this balance is founded in the Constitution's Patent and Copyright Clause.[137] This clause implies a *balance between intellectual property and an intellectual commons* and, if the balance tilts too heavily in one direction, the public loses its constitutionally protected right to a vigorous public domain.[138] Similarly, a variety of developing countries adopted policies that excluded pharmaceutical and agricultural products from IPR protection with a view towards maintaining their public health and food needs through affordable medicines and food.[139]

In the pre-TRIPS era, international protection of IPRs was embodied in a number of international treaties.[140] There were two underlying principles related to international IPR protection in the pre-TRIPS regime. First, IPR protection was based on the principle of national treatment.

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136. *See* Aoki, *Stakes*, *supra* note 107, at 270-71.

137. U.S. CONST. art. I, § 8, cl. 8.

138. *See* LAWRENCE LESSIG, CODE AND OTHER LAWS OF CYBERSPACE (1999). However, courts in the United States have expanded the scope of American intellectual property rights in ways that undermine that implicit constitutional balance. In *Diamond v. Chakrabarty*, 447 U.S. 303, 318 (1980), for example, the Supreme Court ruled that non-naturally occuring manufacture (or genetically created micro-organisms or life forms) qualify as patentable subject matter. In *State St. Bank & Trust Co. v. Signature Financial Group*, 149 F.3d 1368 (Fed. Cir. 1998), the United States Court of Appeals for the Federal Circuit similarly extended the scope of patentable subject matter by holding that "the mere fact that a claimed invention involves inputting numbers, calculating numbers, out putting numbers, and storing numbers, in and of itself, would not render it nonstatutory subject matter, unless . . . its operation does not produce 'a useful, concrete and tangible result.'" *Id*. at 1373 (quoting *In re* Alappot, 33 F.3d 1526, 1544 (Fed. Cir. 1994)). In *Feist Publications, Inc. v. Rural Telephone Service Co.*, 499 U.S. 340, 360 (1991), the Supreme Court apparently opened the door to copyrighting compilations of information if there is a degree of creativity in the selection and compilation of the data.

139. *See* Vandana Shiva, *Farmers' Rights and the Convention on Biological Diversity*, *in* BIODIPLOMACY: GENETIC RESOURCES AND INTERNATIONAL RELATIONS 107, 114-15 (Vincente Sanchez & Calestous Juma eds., 1994).

140. *See generally, e.g.*, Paris Convention for the Protection of Industrial Property, Mar. 20, 1883, 21 U.S.T. 1583 (as revised on July 14, 1967 in Stockholm); Berne Convention for the Protection of Artistic and Literary Works, Sept. 9, 1886, 25 U.S.T. 1341 (as revised on July 24, 1971 in Paris).

Under this principle, each country was bound to protect the IPRs of other countries in a manner that was no worse than the manner in which it protected its own. That is, every country was only obliged to protect the IPRs of other countries as it protected its own. Second, under the principle of national treatment each country retained its sovereignty in determining its own level of IP protection, except in a few instances in which international treaties included substantive protections.[141]

In essence, TRIPS is unprecedented. It is unprecedented because it is the first treaty that provides a minimum international substantive regime of IPR protection. Unlike any other WTO agreement, TRIPS also departs from the norm of regulatory diversity. Hence, GATT, for example, provides general principles such as most-favored-nation status (MFN) and national treatment for determining whether countries are proceeding with trade liberalization.[142] Each member country then can choose how best to meet the goals of liberalization. However, TRIPS is the first example of an international trade treaty that aims at deep integration, as it is not premised on achieving trade goals through regulatory diversity.

The departure of the TRIPS agreement from the principle of national treatment, as well as from regulatory diversity, has had both procedural and substantive consequences for IPR protection. Procedurally, TRIPS sidestepped the role of the World Intellectual Property Organization (WIPO) as the international institution through which international protection of IPRs was to be coordinated. The WIPO, the United States argued, with the prodding of the IPC, had to be avoided as the institutional home for international IPR enforcement. GATT, with the promise of the WTO and an enhanced dispute resolution machinery, was the forum with more promise of international IPR enforcement.

It is important to mention that the national treatment principle is indeed preserved under the provisions of TRIPS in Article 3.[143] Under Article 3, the exceptions allowed under the pre-existing intellectual property conventions of the WIPO are also allowed under TRIPS.[144] Where these exceptions allow material reciprocity, a consequential exception to MFN treatment is also permitted.[145] Trips also provides for certain other limited exceptions to the MFN obligation.[146]

Substantively, TRIPS came to embody the interests of the IPC-led Western coalition. A primary example of how TRIPS overprotects the interests of Western countries, particularly those of the United States, is

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141. *See* GATT, *supra* note 63, art. III, § 4.
142. *See id*. art. I, § 1, art. III, § 4.
143. TRIPS, *supra* note 5, art. 3.
144. *Id*.
145. *See id.*
146. *See id.*

that IPRs are defined as only those forms of knowledge that are capable of industrial application.[147] This definition reflects the sector in which the United States has the largest export sales. It excludes all sectors that produce and innovate outside the industrial mode of production. Profits and capital accumulation through industrialization are recognized as the only ends to which IPRs can be put.[148] In addition, IPR protection in TRIPS is non-derogable, meaning that, unlike public international law treaties, such as the International Covenant on Civil and Political Rights,[149] countries cannot make reservations to TRIPS without the consent of all signatory state parties.[150] It would be difficult to get such consent.

The sovereignty that countries had in the pre-TRIPS era to determine how far to extend IPR protection was lost. (For example, in the pre-TRIPS era, a variety of developing countries had decided not to extend patent protection to pharmaceuticals. The reason was to ensure the availability of medicines to their citizens at affordable prices.) In other words, some countries had chosen not to extend monopoly protection to certain products in the public interest.

The post-TRIPS international environment narrowed the sovereignty of countries bound by TRIPS to determine appropriate levels of IPR protection. Unlike GATT, for example, TRIPS does not embody the principle of special and differential treatment. Under this principle, developing countries were entitled to preferential trading relationships. For example, while developed countries trade on the basis of the norm of reciprocity or unconditional MFN status, developing countries do not enjoy the same level of obligations as industrialized nations. Hence, a developing country in trading with a developed country does not have to extend the trading privileges it extends to that developed country to all members of GATT.

The developed country, by contrast, is obliged to extend all the privileges it extends to its trading partners to all members of GATT. This in essence gave developing countries a chance to participate in international trade with countries with much higher levels of economic achievement. In addition, the developing countries also received trading privileges such as preferential access for their imports in the markets of developed countries. However, as noted above, such preferential access for developing country imports in the United States under the Generalized

147. Article 27 (1) of TRIPS provides that, "patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application."

148. Shiva, *supra* note 139, at 110, 115-16.

149. *See generally* International Convention Civil and Political Rights, Dec. 19, 1966, 999 U.N.T.S. 171.

150. *Id*. art. 72.

System of Preferences was conditioned on developing countries signing on to TRIPS.[151] In addition, other cross-conditionalities or cross-retaliatory measures require developing countries to protect the IPRs of the United States without the risk of suffering retaliatory sanctions under Section 301 of the Omnibus Trade Act of 1988.[152]

So what is left of the public policy-oriented conception of IPRs in TRIPS? There is a prospect that the multiple extra-TRIP voluntary arrangements entered into between developing countries and pharmaceutical companies to provide pharmaceuticals on concessional terms evidence a recognition by pharmaceutical corporations of the large public policy concerns underlying international IPR protection.

Various provisions of TRIPS embody a sense of balancing the protection of intellectual property rights on the one hand, and the underlying public policy objectives that the protection of intellectual property rights requires on the other. More importantly, the inclusion of policy objectives and the various exceptions to IPR protection reflect the flexibility with which the commodity conception of private property rights embedded in TRIPS ought to be construed and applied.

Article 7 provides that the protection and enforcement of intellectual property rights should contribute both to the promotion of technological innovation, which is much to the advantage of developed countries, and to the transfer and dissemination of technology to developing countries.[153] This sense of balance is also provided in Article 7 in its provision to the effect that IPR protection is not an end in itself.[154] This article contextualizes IPR protection, first to the mutual advantage of producers and users of technological knowledge, and second to the promotion of social and economic welfare and to the balancing of rights and obligations.[155]

Article 8 recognizes the rights of members to adopt measures for public health and other public interest reasons and to prevent the abuse of intellectual property rights, provided that such measures are consistent with the provisions of the TRIPS Agreement.[156] Article 8, section 2 further provides that "[a]ppropriate measures, provided that they are consistent with the provisions of [TRIPS], may be needed to prevent abuse of intellectual property rights by right holders or the resort to practices which

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151. *See supra* note 120 and accompanying text.

152. *See supra* notes 118-23 and accompanying text.

153. *See* TRIPS, *supra* note 5, art. 7.

154. *See id.*

155. This article should be read in conjunction with the preamble, which reproduces the basic Uruguay Round negotiating objectives established in the TRIPS area by the 1986 Punta del Este Declaration and the 1988-89 Mid-Term Review. *See id.*, preamble.

156. *Id.* art. 8.

unreasonably restrain trade or adversely affect the international transfer of technology."[157]

The WTO recently endorsed this view of balancing between the interests of producers and consumers of intellectual property rights in its background paper to the African Trade Ministers conference in Libreville late last year.[158] Hence, I claim that the exclusivity of patent protection, especially in the pharmaceutical industry, ought to be seen in the context of balancing the interests of the industry in recovering its investments on the one hand, and the interests of consumers, and especially low-end consumers suffering from life threatening illnesses, on the other.

Indeed, if TRIPS is read as an inflexible regime of exclusive IPR protection, that would legitimize a market failure in the provision of drugs, particularly for low-end consumers suffering from life threatening diseases such as AIDS. That is to say, TRIPS exacerbates the lack of access to and the lack of affordability of AIDS drugs, especially for low-end consumers, in light of the already prevailing anti-competitive international pharmaceutical industry.

In addition, there are a variety of other provisions in TRIPS that contemplate a balancing of the interests of producers and users of IPRs. Whereas these provisions are hedged with limitations requiring consistency with protection of IPRs, they nevertheless give governments some discretion in realizing certain public policy objectives. Article 6, for example, makes provision for the principle of international exhaustion, which allows parallel imports.[159] Article 30 permits members to provide limited exceptions to the exclusive rights conferred by a patent in instances relating to experimental uses and noncommercial uses.[160] However, such an exception would be subject to the proviso that it must "not unreasonably conflict with a normal exploitation of the patent and [must] not unreasonably prejudice the legitimate interests of the patent owner, *taking account of the legitimate interests of third parties.*"[161] Article 27, section 3(b) allows for the nonpatentability of substances existing in nature and, to an arguable extent, of animals and plants.[162] Article 13 arguably allows for an exception to copyright protection under the fair use or private use exception.[163] Article 31 allows compulsory licensing, although it is

157. *Id*. art. 8, § 2.

158. Libreville 2000—Meeting of African Trade Ministers, WTO Doc. No. M/LIB/SYN15 (Oct. 23, 2000), *available at* http://www.itd.org/Libreville/docs/MMLIBSYN15.doc.

159. TRIPS, *supra* note 5, art. 6.

160. *Id*. art. 30.

161. *Id*. (emphasis added).

162. *Id*. art. 27, § 3(b).

163. *Id*. art. 13. However, see Okediji, *supra* note 107, at 78-79.

qualified by at least eight preconditions.[164] Article 28 provides for parallel imports.[165]

The coercive bargaining framework within which TRIPS was accepted has been acknowledged as a primary reason for reading flexibility into it. There was overwhelming pressure to have TRIPS embody the commodity conception of IPR protection. One outcome of the dominance of Western countries, and the United States in particular, in promoting a vision of IPR protection heavily biased towards developed countries was that the underlying public policy issues were significantly understated. That explains why the foregoing provisions of TRIPS are hedged with requirements for consistency with what is really the commodity version of IPRs.[166]

In addition, little attention was paid to the costs of developing countries benefiting from this new legal framework, TRIPS, without the fiscal and institutional wherewithal to realize its benefits. In essence, TRIPS was designed to benefit the interests of industries in developed countries, which have the resources and experience to take advantage of this new agreement. In addition to private businesses in developing countries standing to lose from TRIPS, the governments of developing countries may fare no better, as they continue to suffer high compliance costs in implementing required policy changes.[167] It is now clear, in retrospect, that TRIPS was negotiated under circumstances that understated the significance of public policy and the development implications of IPRs. The Uruguay Round was too focused on trade in and of itself, as if removing border restrictions on trade was necessary for developing countries to solve their development problems. As J. Michael Finger noted, the WTO is still moving in this same direction; only this time its clarion cry seems to be that of shaping all domestic regulatory and legal

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164. TRIPS, *supra* note 5, art. 31. These conditions include: (1) that authorization of the use without the consent of the patent owner must be considered on its individual merits; (2) that efforts to obtain a voluntary license on reasonable terms and conditions must first be made (except for government use, which only requires notification); (3) that the scope and duration of the use must be limited to the purpose for which it was authorized; (4) that the use must be nonexclusive; (5) that the use must be authorized predominantly for the supply of the domestic market of the member authorizing the use; (6) that the authorization of use can be terminated if and when the circumstances which led it to cease to exist are unlikely to recur; (7) that the patent owner must be paid adequate remuneration, taking into account the economic value of the authorization and the decisions relating to authorization; and (8) that remuneration must be subject to judicial review or other independent review by a distinct higher authority within that member. *Id*.

165. *Id*. art. 28.

166. CHAKRAVARTHI RAGHAVAN, RECOLONIZATION: GATT, THE URUGUAY ROUND AND THE THIRD WORLD 69-80 (1990).

167. Under Article 67 of TRIPS, developed countries committed themselves to providing technical and financial support to developing and least developed countries, with a view towards assisting them in implementing TRIPS. TRIPS, *supra* note 5, art. 67.

systems—from the institutional infrastructure of the economy to the export interests of the developed world.[168] There are at least five reasons for cautious optimism for a public policy-oriented perspective having a place on the table alongside the perspective of those who support exclusivity of patent protection.

First, like South Africa, Thailand has also benefited from such an understanding by the United States with regard to its compulsory licensing laws. Writing to Thailand, the USTR's office noted:

> We encourage Thai officials to explore all options for extending access to effective treatments, including ongoing direct dialogue with pharmaceutical manufacturers. But the final choice is one for Thailand to make. If the Thai government determines that issuing a compulsory license is required to address its health care crisis, the United States will raise no objection, provided the compulsory license is issued in a manner fully consistent with the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS).[169]

This retreat by the United States is instructive to the extent that it provides a role for public policy with regard to AIDS as it relates to patents. Although unsurprisingly encumbered with a proviso that Thailand must engage in compulsory licensing consistent with TRIPS, it represents a departure from a prior policy that seemed impervious to policy claims in the context of the AIDS epidemic.

In addition, the use of Section 337 of the Tariff Act of 1930[170] by the United States in the Thailand AntiAids Drug Case, which was subsequently invalidated by a GATT panel, provides a hopeful precedent.[171] In that case, a Thai patent law allowing for compulsory

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168. J. Michael Finger, The Uruguay Round North South Bargain: Will the WTO Ever Get Over It?, delivered at the Conference on the Political Economy of International Trade Law in Honor of Professor Robert E. Hudec, (Sept. 15-16, 2000). Chakravarthi Raghavan, *The World Trade Organization and its Dispute Settlement System: Tilting the Balance Against the South* (Trade and Development Series No. 9, 2000), at http://www.twnside.org.sg/title/tilting.htm, similarly argues that the WTO's dispute resolution mechanism is a complex and expensive proposition for developing countries.

169. Letter from Joseph S. Papovich to Mr. Paisan Tan-Ud (Jan. 20, 2000), *at* http://www.cptech.org/ip/health/c/thailand/ustrletterjan27.html.

170. Tariff Act of 1930, Pub. L. No. 71-361, § 337, 46 Stat. 590, 703 (1930) (codified as amended at 19 U.S.C. § 1337 (2001)) (allowing for seizure and destruction of patent-infringing goods).

171. *Id*. For a description of the facts and points of law at issue; *see also* RALPH H. FOLSOM ET AL., INTERNATIONAL BUSINESS TRANSACTIONS 798-823 (1995). Note that the United States moved to comply with the Panel's findings in Section 337 when it incorporated the Uruguay Round

licensing of patents that had not been used in the country was at issue.[172] Pfizer had only recently succeeded in pushing the TRIPS agreement through and registering its patents on Tetracine and AntiAids in Thailand. Thailand informed Pfizer that, because it had not established local processing of these drugs, it would invoke compulsory licensing with a view towards addressing a rapidly growing rate of HIV infection.[173] To safeguard its interests in Thailand, Pfizer filed a complaint with the United States International Trade Commission under Section 337 of the Tariff Act of 1930 requesting preliminary and permanent relief for the importation of drugs manufactured in Thailand in contravention of Pfizer's patents.[174] Section 337 proceedings were at the time extremely attractive to United States companies and burdensome to foreign companies because they had relaxed standards of evidence (including hearsay) and relatively short periods of discovery and trial (limited to seventy days), compared to a proceeding in a federal district court.[175]

In 1989, a GATT panel ruled that Section 337 violated the national treatment provisions of Article III, section 4 of GATT.[176] The panel noted that imported goods were treated less favorably than domestic goods under Section 337, and the GATT council adopted the decision.[177] Subsequently, the United States amended Section 337 to allow counterclaims in proceedings initiated under its authority.[178] While this may have been a limited victory since there are several other arenas where the battle over pharmaceuticals was playing out, it illustrates that there are spaces within the present structure of GATT/WTO law for accommodating actions such as compulsory licensing.

The second reason for hope involves the recent South African controversy, which also relates to compulsory licensing. South Africa passed legislation titled the South African Medicines and Related Substances Control Amendment Act 90 of 1997, which is similar to

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commitments into its domestic legislation. *See* U.S. Trade Policy Review Body of the WTO, Fourth Review of the United States Trade Policies Conducted on 11 and 12 November, 1996–Press Release/Press/T PRB/46 Oct. 31, 1996 *available at* http://www.wto.org/wto/english/tratop_e/tpr_/tp46_e.htm.

172. *See supra* note 172.

173. *Id*.

174. *Id*.

175. *See* William A. Zeitler, Book Review, *Federal Unfair Competition Action: Practice and Procedure Under Section 337 of the Tariff Act of 1930*, 86 AM. J. INT'L L. 238, 239 (1992).

176. Section 337, *supra* note 75, ¶ 6.3.

177. *Id*.

178. Uruguay Round Agreements Act of 1994, Pub. L. No. 103-465, 108 Stat. 4814 (codified as RALPH H. FOLSOM & MICHAEL W. GORDON, INTERNATIONAL BUSINESS TRANSACTIONS § 18.4 (1995)).

Thailand's law allowing compulsory licensing.[179] Soon thereafter, the USTR put South Africa on the watch-list under super 301 of the Trade Act, which authorizes the USTR to commence investigations with a view towards establishing violations of United States IPRs, which would in turn form the basis for retaliatory action.[180]

After intense public protest in South Africa, around the world, and in the United States, then-Vice President Al Gore formed a commission, which he jointly chaired with President Thabo Mbeki of South Africa. On September 17, 1999, as noted above, South Africa and the United States reached an understanding that accommodated South Africa's concerns relating to the AIDS crisis as well as the United States' concerns regarding patent protection.[181] The USTR thus withdrew South Africa from the watch list. The success of public pressure on a senior administration official demonstrates room for administrative interventions, which may create room, albeit in minimal ways, for advancing a public policy oriented view of IPRs. Subsequently, the big pharmaceutical companies withdrew a suit against the South African government for passing legislation that is in part inconsistent with the government's commitments under TRIPS.

The third reason for hope is an Executive Order signed by President Clinton in 2000 ordering the USTR not to impose trade sanctions against a sub-Saharan African country pursuing a policy or law aimed at addressing the AIDS epidemic.[182] As noted above, this Executive Order also seeks to give such countries an incentive to comply with TRIPS. Some administration officials, such as Secretary of State Madeline Albright, took the view that the AIDS crisis constituted a situation that involved the national security interests of the United States. That view was explored in January 2000, when Richard Holbrooke, the United States Permanent Representative to the UN, addressed a forum convened as part of the United Nations' focus on Africa that month.[183]

Fourth, Bristol Myers-Squib, which together with Yale University, owns patent rights for Zerit, an AIDS drug, announced in March 2000 that it will waive those patent rights in South Africa. In effect, Bristol-Myers Squib and Yale University have opened the door for a drug still enjoying a patent monopoly in countries other than South Africa for marketing as

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179. *See* Zachie Achmat, *We Can Use Compulsory Licensing and Parallel Imports: A South African Case Study*, *at* http://www.hri.ca/partners/alp/tac/license.shtml.

180. *See* Omnibus Trade and Competitiveness Act of 1988, Pub. L. 100-418, § 1302, 102 Stat. 1107 (1988) (codified as 19 U.S.C. § 2420 (2001)).

181. *See supra* notes 111-12 and accompanying text.

182. *See supra* note 102 and accompanying text.

183. *Gore Vows AIDS Help for Africa: Security Council Addresses Crisis*, MONITOR CHRON., Jan 11, 2000, at A12.

a generic.[184] Bristol Myers-Squib also announced that it would sell its AIDS drugs, Videx and Zerit, to any African country for the cost of one dollar per day per dosage, eighty five cents for Videx and fifteen cents for Zerit.[185] The announcement by Bristol Myers-Squib came very shortly after Merck announced that it would sell two of its AIDS drugs, Crixivan and Stocrin, to poor countries at about one-tenth the United States price.

However, in March 2000, both Bristol Myers-Squib and Merck were part of a five company (together with Boehringer Ingelheim, Glaxo Welcome (now GlaxoSmithkline) and F. Hoffman La Roche) initiative with UNAIDS that unsuccessfully sought to reduce prices of anti-retrovirals by eighty-five percent. Critics of this initiative have called it a public relations gimmick, and one hopes that these new arrangements do not fail to come through as well.[186] In addition, Bristol Myers-Squib, in late 2000, pulled out and eventually scaled back its own commitment of a $100 million charitable initiative it dubbed "Secure The Future" to fight AIDS in Africa. In withdrawing the commitment, Bristol-Myers was acknowledging an internal debate on what moral obligations the company had towards sick people who could not afford medicines and how such obligations would be reconciled with the company's commercial objectives.[187]

Another hopeful effort on the horizon is an offer by Cipla, an Indian company that manufactures generics, to supply AIDS drugs to developing countries at extremely low prices. It has announced its willingness to sell generic versions of eight of the fifteen anti-HIV drugs, which, in varying combinations, are used in the cocktails, at a nominal fee of $600 per year per patient — a small fraction of the $10,000 to $15,000 that high-income consumers pay.[188] Cipla has also made an offer to supply these drugs at $350 per year per patient to Doctors Without Borders. Cipla hopes that its initiative will bring down the price of AIDS drugs by breaking their monopoly pricing.[189]

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184. According to John L. McGoldrick, Bristol Myers' Executive Vice President, "This is not about patents; it's about poverty and a devastating disease. . . . We seek no profits on AIDS drugs in Africa and we will not let our patents be an obstacle." Karen DeYoung & Bill Brubaker, *Another Firm Cuts HIV Drug Prices*, WASH. POST, Mar. 15, 2001, at A1.

185. *Id*.

186. Dagi Kimani, *Why Not Take Up Offer of Cheaper AIDS Drugs*?, DAILY NATION, Feb. 24, 2001; *see also* Barton Gellman, *A Turning Point That Left Millions Behind: Drug Discounts Benefit Few While Protecting Pharmaceutical Companies' Profits*, WASH. POST, Dec. 28, 2000, at A01.

187. Bill Brubaker, *The Limits of $100 Million: Epidemic's Complexities Curb Impact of Bristol-Myers's Initiative*, WASH. POST, Dec. 28, 2000, at A1.

188. Sheryl Gay Stolberg, *Africa's AIDS War*, N.Y. TIMES, Mar. 10, 2001, at A1.

189. Donald G. McNeil, Jr., *Indian Company Offers to Supply AIDS Drugs at Low Cost in Africa*, N.Y. TIMES, Feb. 7, 2001, at A1.

Fifth, and significantly, is the discretion that developing countries have in complying with the TRIPS agreement. At the outset, clearly Article 7 of TRIPS provides for safeguard provisions, and Article 8 provides for public interest exceptions.[190] Under these provisions, as well as under provisions allowing compulsory and parallel licensing, developing countries can legally depart from TRIPS in order to address public health emergencies such as the AIDS epidemic.[191] Some scholars have suggested that these countries should adopt high standards of patentability so that only revolutionary, as opposed to merely improving, inventions are granted patents.[192] Another method might be to allow prior art form to defeat novelty. This might be very useful in cases in which developing countries contend that a patent claim is based on pre-existing indigenous knowledge. All of these instances would be justifiable, as there is no consensus on an international standard of absolute novelty.[193]

Ultimately, it seems very plausible that one of the ways in which compliance with TRIPS would best be achieved is by ensuring an international consensus on the core values underlying it.[194] This would imply balancing public and private uses of IPRs as well as balancing the needs and imperatives of capital with basic needs such as affordable and accessible foods and medicines for the world's low-end consumers. A threat-based TRIPS agreement cannot balance these interests in a way that guarantees its legitimacy.

C. *The Dialectics of Competing Conceptions of Property in TRIPS*

The public policy perspective of IPRs both affirms and contradicts the private property logic as well as the free trade goals of the WTO. It affirms the free trade goals of the WTO because the forms of flexibility under Articles 7 and 8 of the TRIPS Agreement are required to be consistent with protection of IPRs. Hence, although there are limits to IPR protection, these limits are carefully circumscribed. The commodity conception of IPRs leaves limited room for the underlying public policy goals embedded in TRIPS.[195]

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190. TRIPS, *supra* note 5, arts. 7-8.

191. *See* James Love, *Access to Medicine and Compliance with the WTO TRIPS Accord: Models For State Practice in Developing Countries* (paper for United Nations Department Programme, 2001), *at* http://www.cptech.org/ip/health/recommededstatepractive.html.

192. *See* Oddi, *supra* note 3, at 464-65.

193. *See* Reichman, *supra* note 2, at 30.

194. Michael W. Smith, *Bringing Developing Countries' Intellectual Property Laws to TRIPs Standards: Hurdles and Pitfalls Facing Vietnam's Efforts to Normalize an Intellectual Property Regime*, 31 CASE W. RES. J. INT'L L. 211, 235 (1999).

195. There is some case law in the United States suggesting that courts will not protect holders of patents against infringement when a patent has been misused. This is an exercise of equitable

Yet, in another respect, the commodity conception of IPRs in TRIPS contradicts the public policy goals underlying TRIPS by circumscribing public policy goals to the narrow confines of consistency with IPR protection. In the same respect, to the extent that the public policy limitations of IPR protection are a part of TRIPS, they are inconsistent with IPR protection.

In short, it is not entirely implausible to observe that recognizing the commodity conception of IPRs, as well as the social and political character of IPRs, would be laden with contradictions, but also have room for complementarity. The public policy oriented vision of IPRs contradicts the market oriented property vision of IPRs because it acknowledges that limitations on the commodity-oriented conception are necessary and reasonable.

V. FDA CARTELIZATION OF THE PHARMACEUTICAL INDUSTRY AND ITS IMPLICATIONS FOR LOW-END CONSUMERS

My thesis in this part of the article is that the FDAs high standards of drug safety and effectiveness, which are embodied in pre-marketing testing and approval requirements, result in the cartelization of the pharmaceutical industry. The FDAs cartel effect is the indirect and unintended result of a regulatory regime for drug approval that is heavily driven by perverse notions of risk. In addition, this regulatory regime acts as an insurance mechanism for the pharmaceutical industry to avoid the high costs associated with product liability for unsafe and ineffective drugs. In short, these high standards of drug approval have the result of cartelizing the pharmaceutical industry.

This regulatory environment exacerbates an already restrictive international IPR protection regime, which leaves little flexibility for public policy demands. Two examples will suffice to illustrate how TRIPS exacerbates the restrictiveness of FDA regulation. First, TRIPS does not allow departures or reservations from IPR protection except with the consent of all countries that have signed onto it.[196] Second, notwithstanding the potential in TRIPS for balancing the interests of producers and consumers of IPRs as discussed in Part III above, trade

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discretion, and as such, "courts . . . may appropriately withhold their aid where the plaintiff is using the right asserted contrary to the public interest." Morton Salt Co. v. G.S. Suppiger Co., 314 U.S. 402, 492 (1942). A leading United States antitrust authority, the late Phlilip Areeda, opined that, although what is contrary to the public interest is open-ended, "[i]t does seem clear . . . that conduct offensive to the antitrust laws is a misuse." PHILLIP AREEDA & LOUIS KAPLOW, ANTITRUST ANALYSIS: PROBLEMS, TEXT, CASES 183 (4th ed. 1988).

196. TRIPS, *supra* note 5, art. 72.

agreements have been construed so narrowly as to rule out those public policy concerns.[197]

The FDA's high standards of drug approval, exacerbated by TRIPS, act as a barrier for entry of new competitors into the pharmaceutical industry, leading to the cartelization of the pharmaceutical industry. Thus, according to the United Nations Development Program, 35% of the $297 billion industry in 1998 was controlled by the top ten pharmaceutical companies.[198] In 1999, the median return on equity for the twelve pharmaceuticals members of the Fortune 500 was 35.8%, which was more than double the median return of 15.2% for the Fortune 500 as a whole.[199] These returns were net, taking into account the sector's large research expenses.[200] The pharmaceutical industry also ranked first in return on assets as well as return on revenues.[201]

Cartelization in the pharmaceutical industry has at least three consequences, all at which are detrimental to the access and affordability of AIDS drugs. First, it impedes competition in the international pharmaceutical industry by deterring new entrants into the industry. Second, it is directly related to the high cost of AIDS drugs, which have become unaffordable for terminally-ill, low-end consumers. Third, it limits expeditious access to AIDS drugs.

The United States Government's anti-competitive action, to wit its participation in the cartelization of the pharmaceutical industry through its statutory regime of drug approval, is arguably contrary to a general principle of international law that favors free competition. While the imprimatur of a government shields it from antitrust liability, particularly in the intellectual property realm, the anti-competitive effect of governmental action in cartelizing the pharmaceutical industry violates antitrust law.

A. *FDA Regulation: Pre-marketing Testing and Approval*

The FDA's regulatory framework is the cumulative result of legislative responses to drug-related tragedies such as the thalidomide scare of the 1950s.[202] The stricter regulation of drug approval that has come about as a result of drug scares in part reflects how perverse notions of risk inform policy. While tightening drug approval is critical for public confidence in

197. *See supra* notes 64-90 and accompanying text.

198. UNITED NATIONS DEVELOPMENT PROGRAMME, HUMAN DEVELOPMENT REPORT 67 (1999).

199. *How the Industries Stack Up*, FORTUNE, Apr. 2000, at F27.

200. *Id*.

201. *Id*.

202. *See infra* notes 227-31 and accompanying text.

available drugs on the market,[203] no regulatory regime could entirely eliminate all risk given the uncertainties of scientific evidence. This being the case, any regulatory regime will involve a choice as to the level of risk that can be adopted. However, in view of the FDA's responsiveness to at times irrational public perceptions of risk, its regulatory environment is tilted towards eliminating risk at the expense of other legitimate public policy goals. Such goals include expeditious access to affordable drugs for terminally ill patients. In addition, given that there is bound to be imperfect competition in any industry, including the pharmaceutical industry, the choice of a regulatory framework is one between imperfect regulation (insofar as it is impossible to eliminate all risk) and imperfect competition.

The FDA's authority to approve drugs for safety and effectiveness falls into four stages: Pre-clinical testing; Investigational New Drug (IND) Testing; New Drug Application (NDA) Testing; and Post-Market Surveillance. The following is a brief discussion of each.

1. Pre-Clinical Testing

The purpose of this stage is to determine whether a drug is sufficiently safe and promising to justify human clinical testing. To make this determination, the drug sponsor must engage in pre-clinical testing. The drug sponsor must then file an Investigational New Drug Application (IND) with the FDA.[204] The IND application must contain all of the active ingredients of the drug to be tested, a summary of any previous human experience with the drug, a description of the overall investigation plan, identification of phases of clinical investigation, a list of possible risks and side effects, a protocol for each study to be conducted, and a summary of pharmacological and toxicological effects of the drug on animals.[205] It is estimated that pre-clinical testing takes about thirty months.

2. Investigational New Drug (IND) Testing

If the FDA does not object to IND Testing, the applicant then proceeds to clinical testing on human subjects. This stage comes in three phases. Although these phases are not required under the law, the FDA recognizes them as part of the process for establishing the safety and effectiveness of drugs.[206] Phase I, which lasts approximately six months, involves testing

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203. There is also the possibility that product liability law also acts as a background against which the FDA's regulatory environment has grown. In other words, a tough regulatory environment serves as a form of insurance against product liability for the pharmaceutical industry.

204. 21 C.F.R. § 312.23(a) (2001).

205. *Id*. § 312.23.

206. *See* Investigational New Drug, Antibiotic, and Biological Drug Product Regulations;

the drug's safety on about twenty to eighty volunteers. The subjects are tested for the safe dosage level of the drug, tolerance to the drug, how the drug is administered, and how the drug is eliminated from the body. Phase II, which involves several hundred subjects, tests the drug's safety and effectiveness and could last up to eighteen months. Phase III takes place only in cases where there is reasonable evidence about the drug's safety and effectiveness. In this phase, the drug applicant has to administer the drug under circumstances in which a physician would prescribe the drug. The aim is to further the assessment of the safety and effectiveness of the dosage and its effectiveness in treatment. A drug under consideration takes three years to pass Phase III. The FDA has authority to terminate clinical testing at any phase if it believes that the drug is unsafe and ineffective.[207]

3. NDA Testing and Post-Market Surveillance

Where an applicant can show the FDA promising results through Phase III, it may submit a New Drug Application (NDA) to the FDA for approval to market the drug. This stage, which involves hundreds to several thousand patients, takes an average of five years. The FDA may also condition its NDA approval upon the submission of post-marketing approval studies.[208] The post-marketing approval study stage is also known as Phase IV. Only manufacturers, rather than physicians, are required to report suspected adverse drug reactions. While post-marketing surveillance is not a statutory requirement, it is now customary for the FDA to require it with a view towards monitoring a drug's ongoing safety and efficacy. FDA approval requires substantial evidence of a drug's safety and effectiveness, as established through adequate and well-controlled investigations.[209]

4. Terminally-Ill and AIDS Related Exceptions to FDA Regulation

There are several ways in which terminally-ill AIDS patients benefit from shortened processes of FDA pre-market testing. In 1987, for example, the FDA began the Treatment Investigational New Drug program (Treatment IND), which allows physicians to prescribe unapproved experimental drugs to terminally ill patients. The FDA stipulates that physicians may prescribe unapproved, experimental drugs only when no

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Procedures for Drugs Intended to Treat Life-Threatening and Severely Debilitating Injuries, 53 Fed. Reg. 41,518 (Oct. 21, 1988).

207. 21 C.F.R. § 312.44 (2001).

208. Marion J. Finkel, *Phase IV Testing: FDA Viewpoint and Expectations*, 33 FOOD DRUG COSM. L.J. 181, 183-84 (1978).

209. 21 U.S.C. § 355(d) (2001).

comparable or satisfactory alternative drug or therapy is available.[210] The Treatment IND program is an example of the FDA's acknowledgment of the need for speedy development of safe and effective drugs for terminally-ill patients. However, the requirement that an illness be "immediately life threatening" restricts the program's utility to individuals suffering from HIV-related opportunistic diseases.[211]

The Treatment IND program was expanded in the early 1990s to improve expedited approval of AIDS drugs through a "parallel track" mechanism.[212] This mechanism allows drug sponsors to conduct parallel studies without the use of experimental controls, which ensure quality controls. Expedited approval is facilitated through the provision of experimental drugs to those enrolled in the parallel studies. Such terminally-ill patients would not have had access to these drugs under standard FDA pre-marketing approval trials, as only those enrolled in FDA clinical trials have access to experimental drugs. In short, the "parallel track" mechanism allows expanded availability of experimental drugs through parallel studies conducted by the sponsor. However, only patients for whom there is no alternative treatment available and who are ineligible to participate in FDA trials can participate in expedited access to experimental drugs under the "parallel track" mechanism.[213]

Another mechanism providing for an accelerated process of drug approval is the "fast track" process. Since 1988, the FDA has reserved the power to eliminate Phase II testing to facilitate a faster process of establishing the safety and efficacy of a drug. Under this process, the FDA evaluates requests for expedited approval after Phase II testing by examining the risks and benefits of the drug, the severity of the disease, and the availability of alternative remedies.[214] Under the fast track process, drugs that meet the FDAs safety and effectiveness criteria can be approved without Phase III testing.[215] The fast track process is an incentive for terminally-ill patients not to participate in risky, underground, unapproved, and uncontrolled studies. Under this process, an applicant can apply for FDA approval to conduct clinical trials without the use of placebo control

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210. 21 C.F.R. § 312.34(b)(iii) (2001).

211. *See* Lisa Terrizzi, *The Need for Improved Access to Experimental Drug Therapy: AIDS Activists and Their Call for a Parallel Track Policy*, 4 ADMIN. L.J. 589, 609-10 (1991).

212. Expanded Availability of Investigational New Drugs Through a Parallel Track Mechanism for People with AIDS and Other HIV-Related Disease, 57 Fed. Reg. 13,250, 13,258 (Apr. 15, 1992).

213. Stuart L. Nightingale et al., *Access to Investigational Drugs for Treatment Purposes*, 50 AM. FAM. PHYSICIAN 845, 845 (1994).

214. 21 C.F.R. § 312.84 (2001).

215. *Id*. § 312.80.

groups if alternative effective therapies can be used for comparison and control.[216]

Another exception, which has been in force since 1989, for the use of drugs that have not received FDA approval is the Personal Use Exception Program. Under this program, unapproved drugs that are for the treatment of threatening or serious conditions and that do not pose a significant health risk may be brought into the United States by an individual or through the mails. Although the Personal Use Exception Program was initially intended for AIDS and cancer patients, it now covers a variety of drugs.[217] This program, which is the result of AIDS activism, has been criticized as being only available to patients who can afford to import unapproved drugs. In addition, the availability of this option has been cited as a disincentive for terminally-ill patients to participate in FDA-approved clinical trials, which could affect the accuracy of FDA drug safety and effectiveness information.[218]

Another controversial avenue through which the FDA allows early approval of new drugs for the treatment of serious or life-threatening diseases, such as AIDS and Alzheimer's disease, is the application of surrogate markers. A surrogate marker is defined by the FDA as a "laboratory measurement or physical sign that is used in therapeutic trials as a substitute for a clinically meaningful endpoint that is a direct measure of how a patient feels, functions, or survives and that is expected to predict the effect of therapy."[219] Surrogate markers therefore measure a drug's safety and effectiveness indirectly, unlike standard FDA procedures.

However, the FDA's approval in such instances is conditional. First, the FDA requires post-marketing clinical studies of drugs approved based on surrogate markers,[220] and, second, a failure to conduct such studies with due diligence or a failure to verify clinical benefit will result in the FDA's withdrawal of approval.[221] The controversy surrounding surrogate markers reflects a primary theme of this article: while surrogate markers are intended to expedite drug approval by short-circuiting costly and time-consuming clinical trials, it is arguable that they could result in compromising a drug's safety and efficacy.[222] Ultimately, the question is

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216. *Id*. § 312.83.

217. Audrey A. Hale, Note, *The FDAs Mail Import Policy: A Questionable Response to the AIDS Epidemic*, 16 RUTGERS COMPUTER & TECH. L.J. 169, 169-70, 180 (1990).

218. *See, e.g.*, Beth E. Myers, *The Food and Drug Administration's Experimental Drug Approval System: Is It Good For Your Health*?, 28 HOUS. L. REV. 309, 309-10 (1991).

219. New Drug, Antibiotic, and Biological Drug Product Regulations, Accelerated Approval, 57 Fed. Reg. 13,234, 13,235 (Apr. 15, 1992).

220. *Id.* at 13,235.

221. Accelerated Approval of New Drugs for Serious and Life-Threatening Illnesses, 21 C.F.R. § 314.530 (2001).

222. Marsha F. Goldsmith, *HIV/AIDS Early Treatment Controversy Cues New Advice But*

not whether all risk can be eliminated,[223] but what types of risks terminally-ill patients are willing to accept in return for access to affordable drugs. This also raises the question of paternalism.[224] Does the government's regulatory framework for drug approval compromise the rights of terminally-ill patients to decide what products to use and therefore what risks to assume?

One of the most significant initiatives enacted by the FDA in response to critics, who stated that pre-market testing procedures resulted in lengthy approval times, is charging pharmaceutical companies a user fee when it reviews their NDAs.[225] With this money, the FDA was able to hire more drug reviewers and to shore up its resources with a view towards expediting the drug approval process. The alliance of pharmaceutical companies and AIDS activists hoped that user fees would substantially reduce the time within which drugs were approved.[226]

B. *The FDA's Regulatory Framework as a Barrier to Entry, Access, and Affordability*

Although the FDA's regulatory framework provides for a number of exceptions, which provide for expeditious approval of AIDS drugs, the rigorous requirements described above nevertheless act as barriers for new entrants into the pharmaceutical industry. The following are some of the most important issues in terms of ease of entry into the pharmaceutical industry.

1. Lengthy Approval Times

The foregoing process of drug approval takes at least seven years. In particular, the Kefauver-Harris Amendments of 1962[227] imposed a variety of clinical tests to establish drug safety and effectiveness. These amendments came immediately after the Thalidomide scare, when the FDA repeatedly declined to approve a sedative given to pregnant women

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Questions Remain, 270 J. AM. MED. ASS'N 295, 296 (1993); *Step By Step*, ECONOMIST, Nov. 26, 1994, at 93-94.

223. *See* Paul Stephen Dempsey, *Market Failure and Regulatory Failure As Catalysts for Political Change: The Choice Between Imperfect Regulation and Imperfect Competition*, 46 WASH. & LEE L. REV. 1, 23 (1989).

224. Marion Smiley, *Legalizing Laetrile*, *in* ETHICS AND POLITICS CASES AND COMMENTS 310, 313 (Amy Gutman & Dennis Thompson eds., 1997).

225. *See* Prescription Drug User Fee Act of 1992, Pub. L. No. 102-571, § 101, 106 Stat. 4491, 4491 (1992).

226. Jon Hamilton, *Unclogging the Drug Pipeline: What the New FDA Policy Means to You*, 8 AM. HEALTH: FITNESS OF BODY & MIND 78, 78 (1993).

227. Drug Amendments of 1962, Pub. L. No.87-781, 76 Stat. 780 (1962) (codified as amended at 21 U.S.C. § 301-81 (2001)).

because of a lack of sufficient evidence of its safety and effectiveness.[228] In Europe at the same time, Thalidomide was blamed for the incidence of phocomelia, a condition causing babies to be born with deformities and missing limbs.[229] Although the drug did not receive FDA approval, its American sponsor had distributed it to over 1200 doctors for experimental testing.[230] A small outbreak of phocomelia occurred, leading to the Kefauver-Harris Amendments, which tightened and thereby lengthened the FDA's drug approval process.[231] The various initiatives such as the Treatment IND program that allow accelerated approval of drugs for patients suffering from life-threatening diseases, validate the idea that lengthy approval times are a problem.

2. Elimination of Risks in a Risk Averse Society as a Driving Force of FDA Regulation

The legislative response to the Thalidomide scare illustrates how the public perception of risk can shape FDA policy. Besides the thalidomide scare, other public responses to drugs have shaped the FDA's authority. Indeed, the Food and Drug Act of 1906 was in a large part a victory of the progressive movement's concern about widespread food and drug impurities.[232] The inadequacy of the 1906 law did not receive legislative attention until 1937, when a drug-related tragedy propelled reform. In this instance, it was Elixer Sulfanilamide, a drug approved for use in the United States in pill form. In its liquid form, however, the solvent had not been tested for toxicity, and it resulted in 107 deaths.[233] This spurred the passage of the 1938 Food, Drug and Cosmetic Act, which required safety testing and government approval of new drugs prior to commercial marketing.[234] The next major legislative changes were in response to the thalidomide scare.[235]

It seems credible to argue that designing regulatory structures, such as that of the FDA, with a view towards achieving a risk-free society would adversely affect the allocation of resources for other purposes, such as

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228. PETER TEMIN, TAKING YOUR MEDICINE: DRUG REGULATION IN THE UNITED STATES 123-24 (1980).

229. *Id*. at 123.

230. *Id*.

231. *Id.* at 124.

232. *See* Pure Food and Drug Act of 1906, Pub. L. No. 384, ch. 3915, 34 Stat. 768 (1906) (repealed 1938).

233. David F. Cavers, *Food, Drug and Cosmetic Act of 1938: Its Legislative History and Its Substantive Provisions*, 6 L. & CONTEMP. PROBS. 2, 20 (1939).

234. Food, Drug and Cosmetic Act of 1938, Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. § 301-95 (2001)).

235. *See supra* notes 227-31 and accompanying text.

providing health care. Indeed, some studies illustrate a mismatch between regulatory costs and risk reduction.[236] Yet, the FDA's mandate for health and safety regulation has arisen largely in response to public health scares. The public hence reacts more emphatically and dramatically to risks related to food supply and drugs than to incremental risks, such as those related to coal. The thalidomide scare is a good example of such perverse responses to risk. Cass Sunstein, therefore, argues that justifying government action by collective action in instances involving the regulation of risk in food supply, and also drugs, might yield outcomes such as regulatory regimes that proceed from a sort of innate human inaccuracy of risk assessment.[237] Similarly, Stephen Breyer notes that Congress has a penchant for trying to solve social and economic problems by passing laws and regulations based on moral conviction rather than economic analysis.[238] Hypothetically, one can therefore argue that, even if the public were persuaded that free market forces and product liability laws were sufficient to prevent the sale of unsafe food and drugs, the public would still probably insist on government screening of new products before they were sold.

3. Stringent Requirements for Acceptance of Foreign Data

The FDA accepts foreign clinical data as evidence of safety and efficacy of drugs where the clinical studies were "well designed, well conducted, performed by qualified investigators, and conducted in accordance with ethical principles acceptable to the world community."[239] There are two categories under which foreign clinical data is accepted by the FDA: foreign clinical studies that are not conducted under an IND, and approval based on clinical data alone. Under the first category, data is accepted as primary evidence of approval of a new drug provided that it meets the specification noted above.[240] Under the second category, the data must be applicable to the United States population and current medical practice; it must be performed by qualified clinical investigators; and the data can be considered valid without the need for on-site inspection, or if the FDA considers such an inspection necessary, it can validate the data through on-site inspection or other appropriate means.[241]

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236. *See, e.g.*, W. KIP VISCUSI, FATAL TRADEOFFS: PUBLIC AND PRIVATE RESPONSIBILITIES FOR RISK 5 (1992).

237. CASS SUNSTEIN, AFTER THE RIGHTS REVOLUTION: RECONCEIVING THE REGULATORY STATE 53 (1990).

238. STEPHEN BREYER, REGULATION AND ITS REFORM 3, 8, 378 (1982).

239. 21 C.F.R. § 312.120(a) (2001).

240. *Id*.

241. *Id*. § 314.106.

While the conditions imposed on acceptance of foreign data in the United States are primarily targeted at protecting the public from dangerous and ineffective drugs, the European Union (EU) directives on the sale and approval of medicinal products are aimed at protecting public health while encouraging research and trade in the pharmaceutical industry.[242] The Committee for Proprietary Medicinal Products (CPMP) has the authority within the EU to harmonize uniform and consistent data acceptance policies between member states. The CPMP's guidelines have facilitated inter-agency collaboration within the EU, thereby shortening the process of drug approval. The FDA's stringent requirements, by contrast, do not facilitate the easy exchange of clinical data. FDA requirements therefore lead to wasteful duplication of resources, as drugs approved abroad often have to go through the United States regulatory process. This means that approval of drugs takes comparatively longer and the cost of drugs is comparatively higher in the United States than in the European Union.[243]

In 1991, the President's Council on Competitiveness proposed measures to enhance United States recognition of foreign drug approvals. For example, countries that have reciprocity agreements with the United States can have their data automatically accepted. The Council has also made efforts towards developing common research and drug approval standards between countries.[244] Other proposals call for allowing the use of animal test data from Japan and the EEC in FDA review processes[245] and joint review of drugs by the FDA and foreign counterpart agencies in Japan, Australia and the EEC.[246]

4. High Costs Associated with the Lengthy Approval Process

The focus on protecting the public from risks related to unproven drugs and the various departures from this regulatory regime, which increase the time frame within which AIDS patients can get access to new drugs, are costly to drug companies as well as to consumers. For example, Mark A.

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242. *See* O.J. EUR. COMM. (No. L 22) 369 (1965), *reprinted in* COMMISSION OF THE EUROPEAN COMMUNITIES, I THE RULES GOVERNING MEDICINAL PRODUCTS IN THE EUROPEAN COMMUNITY 23 (1989); John J. Gorski, *An FDA-EEC Perspective on the International Acceptance of Foreign Clinical Data*, 21 CAL. W. INT'L L.J. 329, 345-46 (1990-91).

243. Although Congress has enacted legislation to encourage international cooperation in addressing the AIDS crisis, the FDA's requirements for drug approval have remained intact. This new law also aims at promoting international research through institutions such as the World Health Organization towards treatments and cures for AIDS. 22 U.S.C. § 6802 (2001).

244. *Recommendations to Speed Drug Approvals Issued*, [1990-1991 Transfer Binder] Food Drug Cosmetic L. Rep. (CCH) 44,603, 43,617 (1991).

245. *Id*. at 42,806.

246. *Id*. at 43,126.

Kassel has argued that the FDA's refusal to expeditiously approve effective drugs that are available in other countries has resulted in mortality and morbidity costs that were avoidable.[247]

Another cost passed on to the public, in addition to the FDA's goal of maximum public safety, is product liability law.[248] For example, the Third Restatement on Torts permits courts and juries to second-guess FDA determinations on effective drug design. Hence, under the restatement, a manufacturer could be held liable for prescription drugs and medical devices whose risks outweighs their benefits, so that a health care provider knowing these risks would not prescribe the product for any class of patient.[249] A 1991 American Law Institute report also concluded that ever-increasing safety controls do not always enhance social welfare, because the incremental, typically diminishing, benefits of greater stringency may be swamped by mounting costs including the loss of useful products.[250] In addition, because the FDA has sole authority over the labeling of prescription drug products, pharmaceutical companies are exposed to product liability suits in states in which the adequacy of a prescription drug product's labeling is subject to jury resolution. The FDA justifies this stringent control on the need to ensure that all labeling be supported by reliable scientific evidence.[251]

The use of prescription drug use fees is also regarded as potentially imposing financial impediments to research and development in general, as well as impeding market entry for new start-up biotechnology firms that do not have the financial resources to meet this requirement. Such an outcome is possible notwithstanding the fact that there are exceptions for small business, as these exceptions limit, but do not eliminate, only one of three kinds of fees payable to the FDA.[252]

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247. Mark A. Kassel, Note, *Getting There With the Best: The Need to Shorten the Prescription Drug Approval Process*, 27 VAL. U. L. REV. 95, 99-102 (1992).

248. *See* Louis Lasagna, *The Chilling Effect of Product Liability on New Drug Development*, *in* THE LIABILITY MAZE: THE IMPACT OF LIABILITY LAW ON SAFETY AND INNOVATION 334, 336 (Peter W. Huber & Robert E. Litan eds., 1991); W. Kip Viscusi et al., *Deterring Inefficient Pharmaceutical Litigation: An Economic Rationale for the FDA Regulatory Compliance Defense*, 24 SETON HALL L. REV. 1437, 1452-55 (1994).

249. RESTATEMENT (THIRD) OF TORTS § 8 (tentative Draft No. 2, 1995).

250. I AMERICAN LAW INSTITUTE, ENTERPRISE RESPONSIBILITY FOR PERSONAL INJURY (1991).

251. For example, in *Wooderson v. Ortho Pharmaceutical Corp.*, 681 P.2d 1038, 1057 (Kan. 1984), a manufacturer of oral contraceptives, based on some adverse reports, had asked the FDA to permit a labeling change to warn consumers about a serious reaction that could cause kidney failure. The FDA refused to permit the change. The Kansas Supreme Court rejected the FDA's determination because the FDA's communication to the manufacturer could not determine that consumers should not be warned that the drug could cause kidney failure. *Id*. at 1058.

252. *See* Danni Sabota, *Biotech Firms Brace for New FDA User Fees*, HOUS. BUS. J., Oct. 19, 1992, at 1.

5. Comparing the FDA to the British Experience

To appreciate the FDA's authority in its mandate of pre-market testing of drugs for safety and effectiveness, it is important to briefly compare and contrast this mandate with those at the equivalent British agencies. The main difference between the British and the American process of drug approval is that, while in the American system safety and effectiveness are required through pre-marketing studies, under the British system they are required through post-marketing surveillance. Pre-marketing testing in the British system therefore takes a much shorter time.[253]

The agency for drug approval in Great Britain is the Medicines Division of the Department of Health and Social Services. Drug approval is pre-conditioned on a showing of safety, quality, and efficacy both before and after approval. The pre-approval process requires animal testing, a series of safety studies, as well as a six month period of chronic toxicity study.[254] The Medicines Division issues Clinical Trial Certificates, which authorize human use of drugs. A Clinical Trial Certificate expires after two years unless it is renewed. A Product License allows for the marketing of new drugs and is issued for five years unless it is reviewed. The licenses impose a mandatory reporting system, which requires physicians to report to the Committee on the Review of Medicine all adverse reactions to drugs. This reporting system in turn lays the foundation for the Committee on the Review of Medicines' mandate to take action to prevent similar adverse reactions to a drug.[255] For example, the Committee on the Review of Medicines can advise the Medicines Division to issue warnings to the public or to revoke the drug's marketing license.[256]

This is one of the main differences between British and United States drug regulation, as the American system requires safety and effectiveness to be shown prior to approval. This results in lengthy and costly pre-marketing clinical trials. By contrast, in the British system, a drug's adverse effects, safety information, as well as safety and efficacy, are demonstrated by post-market surveillance.[257]

Critics argue that one of the downsides of the British system is that it cannot reveal long-term adverse effects, which would require long-term, FDA-type pre-market testing.[258] Assuming that such FDA-type testing

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253. *See* Rosemary Pierce Wall, *International Trends in New Drug Approval Regulation: The Impact on Pharmaceutical Innovation*, 10 RUTGERS COMPUTER & TECH. L.J. 317, 323-26 (1984) [hereinafter Wall, *International Trends*].

254. Julie C. Reliban, Note, *Expediting FDA Approval to AIDS Drugs: An International Approach*, 13 B.U. INT'L L.J. 229, 245 (1995).

255. *See id.* at 245-47.

256. *See generally* DAVID C. GREEN, MEDICINES IN THE MARKETPLACE (1987).

257. *See* Wall*, International Trends, supra* note 253, at 324-26.

258. *See, e.g., id.* at 325.

would reveal such long-term and perhaps serious reactions, the British system postpones discovery of such reactions until the post-marketing stage. The British system's relatively narrower threshold for drug certification and licensing extends to its exceptions. Hence, for example, there is an exception to certification of new drugs for therapeutic purposes in cases of terminally-ill patients.[259] However, under this exception, no clinical testing is required, unlike under the FDA's Treatment IND program.[260]

The British process of drug certification and licensing, unlike the United States system, is not driven by the public's perceptions of risk as a result of drug related tragedies. The British process is also insulated from pharmaceutical industry and government pressures due to the use of independent advisory committees. The advent of the AIDS crisis in Britain has resulted in a balancing of governmental intrusion to address the health crisis with the need to maintain the certification and licensing authorities' autonomy.[261]

Overall, drug approval is cheaper and faster in Britain than in the United States in at least three respects. First, the British experience gives post-market surveillance a higher premium. Second, the British process incorporates independent review committees. Third, it also provides for accelerated access to new and experimental drugs to treat life-threatening illnesses. As seen above, the FDA has taken steps to address this lengthy and expensive approval process with a variety of exceptions.[262] These measures have, however, not led to decreases in the importation of unapproved drugs into the United States.[263]

C. *A Summary of the Implications of the FDA's Regulatory Framework in the Pharmaceutical Industry for Terminally-Ill, Low-End Consumers*

The FDA's regulatory framework is "lengthy and bureaucratically rigid relative to those of other nations."[264] This is further exacerbated by product liability law. The implications for consumers and pharmaceutical companies include increased costs of manufacturing new drugs, higher prices of drugs for consumers, and long waiting times for new drugs,

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259. Reliban, *supra* note 254, at 246.

260. *Id*.

261. *Id*.

262. *See generally* Kenneth I. Kaitin et al., *The Drug Lag: An Update of New Drug Introductions in the United States and Britain, 1977 Through 1987*, 46 CLINICAL PHARMACOLOGY & THERAPEUTICS 121 (1989).

263. Steven R. Salbu, *Regulation of Drug Treatments for HIV and AIDS: A Contractarian Model of Access*, 11 YALE J. ON REG. 401, 417 (1994).

264. *Id*. at 404.

especially for terminally-ill patients. In the United States, these factors have led to a thriving underground market of unapproved drugs from other countries, leading terminally-ill patients such as those with AIDS to encounter unknown levels of risk exposure.

This state of affairs is not inevitable. Given the territorial manner in which drug approval agencies work, it is not surprising that there are vastly different regulatory frameworks from country to country. However, international cooperation to resolve the AIDS crisis through measures such as the acceptance of foreign data that demonstrates safety and efficacy could greatly reduce duplication of research initiatives.[265] Although there may be grounds for skepticism as to the validity of foreign data, the lack of international cooperation to resolve the AIDS crisis is a reflection of how jealously countries safeguard sovereign control of drug approval.[266]

1. FDA Cartelization is Contrary to Antitrust Law

In the United States, state or governmental action is immunized from antitrust scrutiny. However, anti-competitive state or governmental action is not exempt from antitrust scrutiny. In the United States, there is a two-part test for determining whether otherwise uncompetitive conduct is immune under the state action doctrine.[267] Under this test, the challenged restraint must be "clearly articulated and affirmatively expressed as state policy" and "'actively supervised' by the State."[268] The supervision requirement prevents states from frustrating federal competition policy by casting a "gauzy cloak of state involvement over what is essentially a private price fixing agreement."[269]

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265. Reliben, *supra* note 254, at 248.

266. *See* James O'Reilly, *Three Dimensions of Regulatory Problems: United States, European Economic Community and National Laws*, 41 FOOD & DRUG COSM. L.J. 131, 132 (1986).

267. Cal. Retail Liquor Dealers Ass'n v. Midcal Aluminum, 445 U.S. 97, 105 (1980).

268. *Id*. (quoting City of Lafayette v. La. Power & Light Co., 435 U.S. 389, 410 (1978)); *see also* S. Motor Carriers Rate Conference, Inc. v. United States, 471 U.S. 48, 58-59 (1985). Another exception to the immunity of state action against antitrust violations relates to instances in which the state is acting as a commercial participant. However, it does not apply in this instance. *See* Robert Wai, *The Commercial Activity Exception to Sovereign Immunity and the Boundaries of Contemporary International Legalism*, *in* TORTURE AS TORT: COMPARATIVE PERSPECTIVES AND THE DEVELOPMENT OF TRANSNATIONAL HUMAN RIGHTS LITIGATION 213 (C. Scott ed., 2001).

269. 324 Liquor Corp. v. Duffy, 479 U.S. 335, 345 (1987) (quoting *Cal. Retail Dealers*, 445 U.S. at 106). It is also arguable that anticompetitive governmental conduct violates a general principle of international law. Under Article 38(1)(c) of the Statute of the International Court of Justice, "general principles of law recognized by civilized nations" are a source of international law. Since international law is based upon consent of states, general principles of law found in a majority of the national systems of states could very well be indicative of principles of public international law. A general principal of international law need not be found in all states, but only in most of them.

With regard to the FDA, there may be a question as to whether a legislative scheme that acts as a bar to entry may constitute state policy.[270] However, courts in the United States are only interested in establishing precedent if the regulatory scheme is a by-product of state action. According to the Supreme Court:

> Our decisions make clear that the purpose of the active supervision inquiry is not to determine whether the State has met some normative standard, such as efficiency, in its regulatory practices. Its purpose is to determine whether the State has exercised sufficient independent judgement and control so that the details of the rates or prices have been established as a product of deliberate state intervention, not simply by agreement among private parties.[271]

Hence, the only inquiry the Court makes in such a case is whether the regulation is a by-product of state action. Yet, although courts have been reluctant to interfere with state regulatory authority, there are instances in which anti-competitive state action, in limiting entry to various trades or callings, has been prohibited.[272] However, given that the FDA is a federal regulatory body, it is not entirely clear the extent to which courts would respond to claims that its mandate in establishing the safety and effectiveness of drugs circumscribes the countervailing public interest in free competition in the pharmaceutical industry.

Yet, there are a variety of reasons that the FDA's regulatory framework will increase the susceptibility of the pharmaceutical industry to cartelization. First, the patent regime creates a twenty-year monopoly in the pharmaceutical industry. This monopoly places returns on investment in research and development above competition as the best policy to serve consumer welfare. Hence, although pharmaceuticals are very easy to re-engineer, there is almost no gray market for pharmaceuticals, unlike products enjoying copyright and trademark protection.

Subha Ghosh has argued that patent protection explains the lack of a gray market in pharmaceuticals. Such gray markets, which allow intrabrand competition, have resulted in lower consumer products prices in products other than pharmaceuticals. In a sense, therefore, patent protection, which is exacerbated by the FDA's mandate, results in the cartelization of the pharmaceutical industry in a manner that raises drug prices substantially. Drugs also take longer to get to consumers because of

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270. *See* Town of Hallie v. City of Eau Clair, 471 U.S. 34, 43 (1985).

271. FTC v. Ticor Title Ins. Co., 504 U.S. 621, 634-35 (1992); *see also* New England Motor Rate Bureau, Inc. v. FTC, 908 F.2d 1064, 1074 (1st Cir. 1990).

272. *See, e.g.*, Olsen v. Smith, 195 U.S. 332, 344-45 (1904).

the lengthy drug approval times. Hence, only high-end consumers can afford drug prices that result from the regulatory environment, which raises pharmaceutical research and development costs substantially.[273]

It is now considered a truism that monopolists and oligopolists can accommodate economic downturns better than small firms within an industry: a benefit for consumers if this happens.[274] However, while it is also true that such market power gives these firms more flexibility in their pricing policies so that they can recoup their research and development costs, the inability of small firms to compete effectively with big firms may act as a disincentive for further research and development. This is especially the case where patents and other contract restrictions inhibit smaller firms from entering an industry.[275]

Arguably, the patent monopoly thus raises the cost of drugs further, as it reduces competition in the pharmaceutical industry. By contrast, competition in the steel and automobile industries, which do not have operation costs or barriers of entry as high as the pharmaceutical industry, led to a lowering of prices. Competition in the pharmaceutical industry is also circumscribed by the FDA's regulatory environment, which imposes on new entrants and small firms in the industry the risk of enormous costs that threaten their ability to survive with the market leadership of big firms.

In essence, big firms have no incentive to produce for low-end markets that cannot afford drugs sold in high-end markets. Unlike other industries, like the automobile industry and the computer industry, which have grown by and large by re-engineering and recombining ideas, new entrants in the pharmaceutical industry face the costs of intellectual property infringement, which keep drug prices high.

There is also a collective action problem. No firm would be willing, without the cooperation of other firms, to lower the prices of their drugs for low-end markets. However, in the recent past, individual firms have made commitments to reduce drug prices for AIDS patients in Africa. These announcements, however, came after the Pharmaceutical Industry Initiative, which was agreed to under the auspices of UNAIDS in 2000, failed to produce an industry-wide initiative. The incentives for individual

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273. Shubba Ghosh, *State Creation of Gray Markets as a Limit on Patent Rights*, 53 FLA. L. REV. 789 (2001).

274. *See generally* FRED WESTON, CONCENTRATION AND EFFICIENCY: THE OTHER SIDE OF THE MONOPOLY ISSUE (1978).

275. *See* Geoff Tansey, Trade Intellectual Property, Food and Biodiversity: A Discussion Paper 12 (1999), *available at* Quaker Peace e service website: http://hostings.diplomacy.edu /quaker, *cited in* John H. Barton, *The Impact of Patent Law on Plant Biotechnology Research*, *in* INTELLECTUAL PROPERTY RIGHTS III GLOBAL GENETIC RESOURCES: ACCESS AND PROPERTY RIGHTS (Steve A. Eberhart et al. eds., 1998).

companies to make their individual announcements of price cuts to accommodate pressure on the industry are a reflection of a lack of more thorough initiatives; this situation has come about as a result of the lack of incentives to cooperate in finding a sustainable solution to the crisis.

A case could be made that pharmaceutical firms in situations of upward growth could sell their drugs at cost to low-end consumers without undermining their efficiency or bottom-line. Indeed, recent research shows that these companies expend a lot of money marketing their AIDS drugs unnecessarily, as they have such a discrete market in which information on available cocktails is very well-known especially in high-end markets. Marketing costs rose following the FDA's 1997 relaxation of a rule that prohibited direct-to-consumer advertising. In 1998, "America's pharmaceuticals report[ed] spending $24 billion on research and development but almost three times that amount, $68 billion, on marketing, advertising and administration."[276] These expenditures could be misdirected, given that cocktails are very individualized in the sense that they depend on an individuals' medical histories and other personal attributes. In essence, the resources unnecessarily spent on advertising AIDS drugs could be redirected towards either reduced prices of drugs for low-end markets or other similar solutions, such as increasing drug production to lower prices. Given that a primary purpose of antitrust law today is to maximize consumer welfare in terms of lower prices, the issue of inefficient competition between small firms does not arise in a period of upward growth in the pharmaceutical industry. It is clear that competition in the pharmaceutical industry between the upwardly-mobile, big pharmaceutical companies and small competitors will help bring prices down, as the example of Cipla, the Indian company, demonstrates.[277] Needless to say, spending on AIDS drugs has expanded enormously by 1146%, from $129.2 million in 1993 to $1.48 billion in 1998.[278] It could be argued that having so benefited from the AIDS pandemic, the pharmaceutical industry is morally indebted to AIDS patients around the world.[279]

VI. CONCLUSION

There is a built-in tension regarding the place of social issues in international economic governance. This built-in problem dichotomizes private from public consequences in international economic governance.

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276. Daniel Zingale, Silence=$, at http://www.thebody.com/aac/jul2099.html (July 20, 1999).

277. *See supra* notes 188-89 and accompanying text.

278. Zingale, *supra* note 276.

279. *See generally* MICHAEL SANTORO, PROFITS AND PRINCIPLES: GLOBAL CAPITALISM AND HUMAN RIGHTS IN CHINA (2000).

Public consequences, such as providing access to affordable AIDS medicines, human rights and environmental protection, are presumed to be controversial and problematic within the WTO's mandate of lowering barriers to trade. The pursuit of freer trade, by contrast, is regarded as less controversial because it de-politicizes international commerce by eliminating sovereign controls over it.

In this Article, I have advocated two strategies of provisioning AIDS drugs to low-end consumers. The first of these strategies exploits the tension inherent in the WTO's mandate with regard to the place of social issues alongside its mandate to lower barriers to trade. I exploit this tension by examining exceptions to the exclusivity of patent protection, such as through Articles 7 and 8 of TRIPS, as well as the possibilities for compulsory and parallel licensing embedded in TRIPS. In addition, developing countries have discretion in implementing TRIPS to set very high standards for patentability, thereby legally excluding from patent protection products or processes that would be inconsistent with a country's legal standards.

Second, I advocate a competition-based critique of the operation of the pharmaceutical industry as one of the reasons for the lack of expeditious access to affordable AIDS drugs for low-end consumers. That is, the FDA has placed a high premium on safety and effectiveness of AIDS drugs without taking into account their access and affordability, especially to low-end consumers. I have argued that changes at the FDA, such as acceptance of foreign data to prove safety and efficacy of drugs approved in countries with which the United States has reciprocity treaties, could increase access to affordable drugs. In addition, it is plausible to argue that increased competition in the pharmaceutical industry, which might result in adopting a hybrid framework between the present framework and the British experience, would have a desirable outcome for low-end consumers facing life-threatening diseases.