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Eyal Benvenisti

George W. Downs

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DISTRIBUTIVE POLITICS AND INTERNATIONAL INSTITUTIONS: THE CASE OF DRUGS

Eyal Benvenisti[†] and George W. Downs^{††}

I. Introduction

WTO drug policy is of particular interest to political economists and international legal theorists interested in the distributive politics of international institutions because it embodies so many of what are believed to be the pathologies of globalization. Coercion and brinksmanship by the most powerful developed states has meant that a shared collective purpose among participants is almost totally absent. The policies of the drug regime are widely believed to be redistributive upward to the benefit of only a handful of developed states, and many aspects of the regime are arguably economically inefficient as well. There has been a continued prevalence of extra-institutional bargaining associated with the drug regime since its formation that has taken place outside the formal WTO process and unconnected to any process of collective or democratic decision making. Finally, provisions of the drug regime designed to provide the populations in poor states with broad access to drugs in an emergency have proved difficult to implement in a timely fashion.

In the pages that follow, we explore these problems and the prospects for progress in their solution. Section two provides a brief political history of the drug regime, an examination of the role that coercion has played in its origin and operation, and a description of some of its aspects that make it emblematic of what has become known as the democratic deficit. Section three begins by examining the difficulties that international law and international legal institutions face in trying to limit the role of coercion in the formation of multilateral institutions such as the WTO. It then goes on to address the prospects for ex post reform of the WTO's institutions through democratic reform and via litigation before the Panels and the Appellate Body. We argue that tribunals are institutionally inclined to level the playing field among states, but because their power and prestige depends on the extent to which their decisions are followed by powerful states, this entrepreneurial bent is inevitably held in check to some degree.

[†] Professor of Law, Tel Aviv University Faculty of Law, Director, the Cegla Center for Interdisciplinary Research of the Law.

^{††} Professor of Politics and Dean of Social Science, New York University.

Section four characterizes the evolution of bargaining power among both developed and developing states and the extent to which it appears to be leading to distributive gains. We argue that while the bargaining power of the U.S. has modestly declined, and that of the large middle income states such as China, India, and Brazil has increased, the results of this redistribution, while significant, have been relatively modest. We argue that this has been due in part to the relatively low priority that most states—even the most advanced developing states—place on reforming the drug regime relative to other goals such as agricultural reform and developing northern markets for their manufacturer's products.

Section five discusses the strategies that the U.S. and EU are using to reduce the present and future rate of developing state progress in achieving distributive reforms. These strategies include agreeing to bargain on price during emergencies as a way to isolate developing state victories and preserve the institutional integrity of the drug regime. Other similar strategies are also discussed such as direct investment and the use of bilateral linkages to other areas such as trade. This section ends with a characterization of the difficulties of maintaining heterogeneous linkages in the face of these strategies.

II. The International Politics of Pharmaceutical Products

A. The Coercive Roots of the Intellectual Property Regime

The unilateral roots of the intellectual property components of the WTO are too well known to warrant an elaborate review here. Frustrated by a world trade regime that it believed was increasingly unresponsive to U.S. interests, and worried about political implications of ever mounting trade imbalances with Japan, Congress set out to reform that regime by demanding that other states reduce barriers to U.S. investment and exports and develop rules to protect intellectual property. The principal tools that it employed to accomplish this were the retaliation threats embodied in section 301 of the U.S. Trade Act of 1974, along with subsequent additions to 301 and the special variants provisions of U.S. trade law. Collectively, these permitted, and even attempted to impel, the executive branch to retaliate unilaterally in response to what were thought to be unfair trade practices.

The most visible affect of the application of these tools was that between 1985 and 1992 the United States Trade Representative initiated over ninety specific 301 cases on the basis of complaints by U.S. corporations and trade groups. While the success of the individual cases varied a great deal, the general strategy of unilateralism is credited by a number of analysts with bringing about a number of the reforms

subsequently embodied in the World Trade Organization and even to getting multilateralism “back on track.”¹

Other voices were far more critical. They argued that the United States had shifted unaccountably from being the world’s strongest voice for the use of multinational negotiations, as the principal vehicle for trade liberalization, to being their most strident critic. Its threat to withdraw from the GATT and negotiate bilaterally with prospective trading partners unless the rest of the world capitulated to its demands appeared to many to be nothing short of bullying by a great power, and it violated the two most fundamental principals of GATT, nondiscrimination and MFN, because the typically 100 percent tariff threat that the U.S. used was employed selectively against some states but not others.² However, for critics such as Bhagwati, the best evidence that the actions of the U.S. were coercive, and nothing more than a self-intended purpose to capitalize on the bargaining power that it possessed by virtue of its large markets, was that the U.S. demands promised no reciprocal benefit in return for the concessions it demanded and that it did little to insure that the concessions it exacted were available to other states.³

The U.S. countered that the section 301 cases and the aggressive transformation of its trade law represented a complement rather than a substitute to its traditional multilateral approach. A flagrant disregard of GATT principals by other states was forcing the U.S. to employ its power unilaterally to save the world trade system and multilateralism before it destroyed itself. Carla Hills, the U.S. trade representative, stated that the U.S. was forced to use “a crowbar” to pry open foreign markets.⁴ For our purposes, the motivations that lie behind the United States’ use of section 301-related threats are less important than the fact that the strategy was both undeniably coercive and corrosive to the principals of due process and collective decision making.

B. TRIPS, Economic Efficiency, and Distributional Effects

The proponents of tighter intellectual property rights (IPR’s) at the international level frequently argue that they benefit both developing and developed states by increasing the incentive for research which leads, in turn, to a higher rate of product innovation and a higher level of collective welfare than would exist otherwise. The need for such a tightening, as well as the benefits it offers to developing states, is suggested by the lack of

¹ THOMAS O. BAYARD & KIMBERLY ANN ELLIOTT, *RECIPROCITY AND RETALIATION IN U.S. TRADE POLICY* 3 (1994).

² JAGDESH BHAGWATI, *THE WORLD TRADING SYSTEM AT RISK* 54 (1991).

³ *Id.* at 52-53.

⁴ *Id.* at 49.

research into diseases such as malaria and drug-resistant tuberculosis that primarily affect the developing world where intellectual property rights are the weakest.⁵

This argument is simple enough on the surface, but underneath a host of complexities exist that are extremely difficult to unravel. For example, while it is difficult to take issue with the argument that developing states would benefit by an increased focus on diseases that affect them, it is not obvious that the value of this benefit is greater than the savings that weaker intellectual property rights allow them to enjoy on the cost of existing drugs.

Moreover, even if one grants the argument that intellectual property rights need to be tightened in the developing world, there remains the question of just how tight they should be. Sykes argues that the fact that a twenty year patent protection standard is often found in developed states makes it a sensible standard to employ in the WTO.⁶ Yet, there is reason to be skeptical of this justification. Observers of democratic politics have long contended that states typically engage in the over-protection of important domestic industries. This observation is consistent with Olson's classic argument that small groups are better able to organize to pursue their interests than a diffuse and disorganized public because the transaction costs of doing so are smaller and they are less plagued by free rider problems.⁷ And it is also consistent with the more recent political economists' research on the implications of current campaign finance laws which allows wealthy corporations and individuals the opportunity to purchase influence.⁸ These political economists would see no reason why they should be less skeptical of the welfare implications of twenty year patent protection than of other interest group-oriented policies that no one would begin to defend as collectively efficient, such as steel tariffs, cotton subsidies, and sugar subsidies.

There is also reason to believe that the argument is more complicated than defenders of increased intellectual property rights suggest, and that innovation rates represent only one part of the story. Helpman, who has produced one of the more sophisticated general treatments of the subject, argues that it is important to examine how at least four different dimensions of the problem affect the welfare of developed and developing states.⁹

⁵ Alan O. Sykes, *TRIPS, Pharmaceuticals, Developing Countries and the Doha "Solution,"* 3 CHI. J. INT'L L. 47, 49 (2002).

⁶ *Id.* at 58

⁷ MANCUR OLSON, *THE LOGIC OF COLLECTIVE ACTION: PUBLIC GOODS AND THE THEORY OF GROUPS* 22-36 (1965).

⁸ See GENE M. GROSSMAN AND ELHANAN HELPMAN, *SPECIAL INTEREST POLITICS* 225-32 (2001).

⁹ See Elhanan Helpman, *Innovation, Imitation, and Intellectual Property Rights.* 61 *ECONOMETRICA* 1247, 1249 (1993).

These dimensions include (a) the terms of trade; (b) the interregional location of manufacturing; (c) product availability; and (d) R&D investment patterns.

In terms of trade and the location of manufacturing, Helpman argues that tighter IPR's shift production from less developed to more developed states, leading to higher profits for developed state drug firms. This improves welfare in the north and decreases it in the south. However, the fact that drugs are then manufactured in developed states, where the wages are highest, increases the cost of drugs which tends to reduce the welfare of both regions. This suggests that in terms of these two dimensions of the problem, tighter IPR's always operate to reduce the welfare of developing states, and they may or may not be to the advantage of the developed states that favor them. The answer for developed states depends on the degree to which the welfare benefits of the increased level of drug firm manufacturing is offset by the impact of the increases in the higher costs that developed state consumers have to pay.

Helpman presents an analysis which shows that when the rate of imitation is relatively low (i.e., when the rate of illegal copying is modest) tight IPR's operate to the disadvantage of developed states and developing states alike because the higher profits achieved by developed state drug firms are more than offset by the higher costs of drugs. This is not likely to stop drug firms in the north from pushing for tighter intellectual property standards (a fact to which we will later return); but a welfare-minded democratic government would have good reason not to respond to this pressure. Only when the rate of imitation is high should drug firms and voters both be on the side of tighter intellectual property rules.

Helpman argues that the innovation rate and the number of products available to consumers—the benefits that the drug lobby traditionally equates with stricter intellectual property standards—is also complicated. He shows that while a tightening of IPR's initially leads to an increase in the innovation rate, this rate subsequently declines to a level that is less than it would have been had the tightening not taken place. This is because the drug company has less of an incentive to find more effective substitutes for its existing products. The same process leads to the availability of fewer drugs in the long run.

In short, while it appears that northern consumers sometimes benefit, and northern drug firms always benefit from the tightening of intellectual property standards in the pharmaceutical area, the south never benefits. All the south gets are higher prices, fewer manufacturing jobs, and fewer drugs to choose from in the long run.¹⁰

¹⁰ But See Ellen 't Hoen, *TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way from Seattle to Doha*, 3 CHI. J. INT'L L. 27, 35-38 (2002) (arguing changing attitudes among global players have contributed to stronger intellectual property protections in developing countries).

The actual details of the pharmaceutical provisions that are embedded in the GATT/WTO have another provocative feature apart from their redistribution upward: they display little evidence of compromise apart from an adjustment period for generic drug firms in developing states. As we have seen, the length of patent protection was set at twenty years—the exact duration that had been proposed by U.S. drug firms—and a period that appears designed to extract the most revenue from the poorest states and destroy the emerging drug industry in states such as India and Brazil. It is true that the harshness of this effect is mitigated by a substantial adjustment period for these states, but this seems more designed to insulate southern politicians from negative political fallout of signing on to the agreement than to protect the long term interests of southern consumers.

C. The Politics of AIDS Drugs

For many, the tension between the drug provisions contained in the TRIPS agreement and the twin demands of the south for access to life preserving drugs and a voice in determining the rules by which the world trade regime is organized is best exemplified by the controversy over the availability of AIDS drugs in poor countries. At least on paper, it is a conflict that perhaps need not have happened. While the twenty years of patent protection contained in the original TRIPS agreement was obviously destined from the start to raise the drug prices in the south and restrict access, it did contain a number of provisions that were designed to help developing states deal with a public health crisis such as AIDS. The two most prominent of these mechanisms were compulsory licensing and parallel importing.

Compulsory licensing permits the production of a drug without the owners consent when such production is warranted by public interest. The holder of the license can be a different drug firm or the government itself. Licenses can be granted for noncommercial use of the drug, to produce drugs during an emergency at very low prices, and to prevent anti-competitive practices. In the event that a drug is sold, a reasonable royalty is to be paid to the patent holder.¹¹

Parallel imports involve importing drugs from another state where they are available more cheaply, and then reselling them without the consent of the original producer. Since the prices of drugs vary dramatically from one state to another and many, if not most, developing states lack the capacity to produce their own drugs under compulsory licensing, parallel imports can potentially provide a powerful tool for lowering prices and increasing access. We say potentially because the precise conditions under which one

¹¹ C.P. Chandrasekhar & Jayati Ghosh, *WTO drugs deal: Does it really benefit developing countries?*, The Hindu Business Line, available at <http://www.thehindubusinessline.com/2003/09/09/stories/2003090900140900.htm> (Sept. 09, 2003).

state is justified in permitting the export of drugs which are still under patent protection is not defined in WTO. As Sykes points out, Article 6 of TRIPS explicitly holds that nothing in the agreement addresses the issue regarding the extent to which the patent holder maintains any control over the resale rights of a product once it has been sold.¹²

Despite the theoretical availability of these options, developing states have been reluctant to use these tools for fear that it would lead to retaliation by the United States and Europe, both of which possess enormous bargaining leverage by virtue of the fact that they are the chief importers of developing state goods. "This is why developing countries were keen on explicit recognition in the WTO that public health requirements could permit the legal implementation of loopholes that already existed in the TRIPS document. All the subsequent activity has been devoted to nothing more ambitious than a restatement of that basic right."¹³

As a result of the technical complexities and political problems, developing states became increasingly frustrated that their public health needs did not enjoy a status comparable to that accorded them in other areas of the GATT. Thus, while the GATT Article XX stated that "[n]othing in this Agreement shall be construed to prevent the adoption or enforcement of by any contracting party of measures necessary to protect human, animal, or plant life or health," the TRIPS agreement added a significant restriction.¹⁴ It allowed members to adopt measures necessary to protect public health and nutrition only "provided that such provisions are consistent with the provisions of this Agreement."¹⁵

The Doha declaration on TRIPS and public health represented some progress toward the restatement of rights desired by developing states. It acknowledged the right of each state to grant compulsory licenses in an emergency and to determine what represented an emergency. What it did not do was grant states the same power of self-determination in connection with establishing the grounds for parallel importing. This is significant because the compulsory licensing provision is meaningless for those states in the south that do not contain drug firms capable of manufacturing generic products. Their only hope for access to sophisticated AIDS drugs lies in working out purchasing arrangements with generic drug firms in states such as India and Brazil. Instead of providing a simplified process for doing this, the final version cleared in August 2003 actually constituted a significant retreat from a draft statement that had been previously

¹² Sykes, *supra* note 5, at 53 (discussing patent protection exhaustion, Sykes also raises the prospect that parallel importing may lead drug manufacturers to raise the price of drugs for those states which re-export them in order to reduce the problem).

¹³ Chandrasekhar & Ghosh, *supra* note 11.

¹⁴ *Id.*

¹⁵ *Id.*

negotiated in 2001, but was subsequently held up by the U.S. government on behalf of the drug lobby for fear that it would allow generic firms in states such as India and Brazil to flood the market with cheap copies. In the eyes of some observers, the result is an agreement that "is patently imbalanced in favor of large multinational patent holders [and] so restrictive and so unworkable for exporters and importers of generic drugs."¹⁶

"The suspicion must be that this agreement, which had been held up for so long by the developed countries (especially the U.S.) and the multinational drug lobby, has now been hammered down the throats of the unfortunate developing country negotiators, simply in order to show some results before the Cancun meeting. If this is so, it augurs badly for the outcome of other trade negotiations in Cancun."¹⁷

Fortunately, the situation was more complicated and less bleak from the standpoint of at least some developing states than the diplomatic history of Doha seems to suggest. During the same period that negotiators were wrangling over language in the WTO, Latin American states were conducting their negotiations with U.S. and European drug firms regarding access to low cost AIDS drugs. While Brazil engaged in its own negotiations with the drug firms, ten other states including Argentina, Mexico, and Chile rejected the prices offered by developed state multinationals and entered into an agreement with a group of generic manufacturers from middle income developing states and Abbott labs, at a price less than half of the cost negotiated in 2002 by a group of Caribbean states with the major multinational firms. At around the same time, the multinationals offered roughly comparable or lower prices to a number of African countries.

D. Bargaining on Price and Extra-institutional Policymaking

The Glivec case has received far less attention than the AIDS case in the news media, but it is important both for what it reveals about the interstate bargaining that typically surrounds the marketing of a new high profile drug, and because it illustrates the emerging battle over access to drugs that is taking place between drug producing states and those middle income states that possess a substantial middle class, such as South Korea and Brazil.

Glivec is a drug that is used in treating various leukemia and other types of solid tumors and possesses the twin virtues of greater effectiveness and fewer side effects than other alternatives. Its chief limitation is cost. Glivec costs about \$27,000 a year per patient in the United States, a price

¹⁶ *Id.*

¹⁷ *Id.*

that makes it both extremely profitable and inaccessible for the vast majority of the world's population.¹⁸

Cookson and Dyer argue that, faced with declining profitability in the European market in recent years, drug firms of potentially high profit drugs such as Glivec are increasingly turning to growing middle income markets in Asia and Latin America to make up the difference. They quote an Oxfam official who remarks that it is this market, rather than the market for AIDS drugs in the poorest countries, that the drug companies really care about.¹⁹ To win this battle, Glivec's developer and the developer of similar drugs need to fight off possible competition from the generic manufacturers that currently exist in these countries already or which could be created overnight. It is only natural that the northern drug firms turn to their governments for help in this battle, and it is only politically expedient for the states to respond.

One high profile dispute occurred in South Korea, where South Korea wanted to be able to provide the drug for a lower price than the drug company charged in the U.S. The drug company refused and the U.S. government stepped in to pressure South Korea to pay a price equal to the average price among the Group of Seven countries, and to agree to reject an application for a compulsory license to be issued for the drug which would have opened the way for generic production. Interestingly, the U.S. appears to have taken this step not so much to maximize the profits for Glivec's manufacturer—a Swiss firm—but to prevent a precedent that might eventually damage the profitability of products manufactured by its own firms.

Cookson and Dyer say that this dispute over Glivec is typical of the "strong-arm" tactics that the U.S. government uses to defend its drug industry. "The U.S. government does not control the price of drugs in its own country but it is telling Korea what they should charge," says Jamie Love of the Consumer Project on Technology.²⁰

Yet interestingly, the outcomes and the strategies that are employed are not always the same. The Brazilian government threatened to issue a compulsory permit that would have permitted the generic manufacture of Glivec unless it got a substantial price reduction from the G-7 price that South Korea had agreed to pay. Brazil won. Its citizens now pay \$13 dollars per dose compared to the \$19 dollars per dose charged South Koreans. According to Cookson and Dyer, Natco, an Indian generics firm that has already launched a generic version of Glivec, expects to be able to reduce the price even lower.

¹⁸ Clive Cookson and Geoff Dyer, *A Drugs Deal for the World's Poorest: now the fight is over patents and cheap medicines in middle income countries*, FIN. TIMES, Sept. 2, 2003 at 19.

¹⁹ *Id.*

²⁰ *Id.*

Whatever the human significance of these outcomes in these three cases, it is noteworthy from a political point of view that they are the product of bilateral bargaining between a middle income state and either the drug firm that holds the patent, or the U.S. government. They appear to have been little influenced by any multilateral decision or dispute resolution process despite the fact they fall within the province of the WTO.

III. Challenges for International Law and the WTO

In general, the above analysis suggests that despite the high hopes that the WTO would help curb the coercive effects of economic concentration in the hands of a few northern states, there has been little progress in connection with pharmaceutical products. In this section, we first examine the relevant international law norms that affect states' ability to resort to coercion. We then explore to what extent these norms are, or can be, modified by the contemporary regime of trade law and by the WTO treaty bodies.

A. The Legal Background

To date, international law has made little explicit attempt to constrain powerful states from using economic coercion to elicit concessions from weaker states. In fact, it provides two basic ground rules that facilitate such behavior. The first is the principle that states have freedom of action unless it is limited by international law. This principle may be called the Lotus principle (because it was pronounced in the famous Lotus case).²¹ This is equivalent to saying that unless states can overcome the collective action problems involved in prescribing and then enforcing regulation of the market, the default rules of the international trade regime are the rules of the free and unregulated market. Thus, until southern states agreed to the strict TRIPS obligations, they did not violate any international law by producing generic drugs. Similarly, until the northern states agree to impose upon themselves restrictions on price-fixing and other cartelistic behavior, they may continue to engage in anti-competitive measures.²²

The second principle is the non-intervention in the internal affairs of states, which actually does not prohibit external economic pressures. Article 2(7) of the UN Charter reiterates this principle: "nothing contained in the present Charter shall authorize the United Nations to intervene in

²¹ The Lotus Case (*Fr. v. Turk.*), PCIJ Reports, Series A, No. 10 (1927), at 18, 19.

²² See Eleanor M. Fox, *International Antitrust and the Doha Dome*, 43 VA. J. INT'L L. 911 (2003); Andrew T. Guzman, *International Antitrust and the WTO: The Lesson from Intellectual Property* 43 VA. J. INT'L L. 933 (2003) (discussing the need to regulate international anti-competitive activities).

matters which are essentially within the domestic jurisdiction of any state.” Although on the surface this principle declares the relative immunity of states to outside intervention, it fails to specify what types of interventions are proscribed. As a result, the nature of what constitutes “intervention” remains contested. Stronger states claim that external economic pressure does not constitute “intervention” as long as the institutions of the state in question are the ones that formally decide. The fact that there may have been undue duress involved is immaterial. Southern states, not surprisingly, tend to see this debate differently.²³ Among many of them the concern about economic interference is quite strong. For example, Article 15 of the Charter of the Organization of American States (OAS), which proscribes outside intervention in the internal affairs of a state, emphasizes that this principle prohibits not only armed force but also any other form of interference or attempted threat against the personality of the State or against its political, economic, and cultural elements.²⁴

The International Court of Justice (ICJ) appears to have combined the first principle with the interpretation of the second, preferred by powerful states, to reject the claim that economic coercion constitutes intervention in internal affairs. In a suit brought by Nicaragua against the United States before the ICJ, Nicaragua asserted that the United States had violated the principle of nonintervention by cutting off economic aid, by reducing Nicaragua's sugar quota by 90 percent, and by imposing a comprehensive trade embargo. While the ICJ also ruled that the United States had violated customary international law by training and arming the anti-government contras, the majority was unable to find a breach of the law by imposing economic sanctions. As the court explained: “[T]he Court has merely to say that it is unable to regard such action on the economic plane as is here complained of as a breach of the customary-law principle of non-intervention.”²⁵

If general international law does not proscribe economic pressure to elicit compliance, could then the law of treaties contain strategic behavior by nullifying agreements concluded through coercion? The debate in this context is about the availability of a doctrine on economic coercion in the

²³ James Thuo Gathii, *Neoliberalism, Colonialism and International Governance: Decentering the International Law of Governmental Legitimacy*, 98 MICH. L. REV. 1996, 2033 (2003) (book review).

²⁴ Diana E. Moller, *Intervention, Coercion, Or Justifiable Need? A Legal Analysis Of Structural Adjustment Lending In Costa Rica*, 2 SW. J. OF L. & TRADE AM. 483, 518 (1995) (arguing that economic coercion renders treaties void and is a breach of the norm of non-intervention in the inter American context) (quoting Charter of the Organization of American States, Apr. 30, 1948, 2 U.S.I. 2394, 119 U.N.T.S. 3, as amended by Protocol of Buenos Aires, Feb. 27, 1967, 21 U.S.T. 607, 789 U.N.T.S. 287, art. 15) (emphasis same as original).

²⁵ *Military and Paramilitary Activities in and Against Nicaragua (Nicar. v. U.S.)*, 1986 I.C.J. 14, at 126 (June 27).

law on treaties. Article 52 of the Vienna Convention on the Law of Treaties defines coercion as “the threat or use of force in violation of the principles of international law embodied in the Charter of the United Nations.”²⁶ This concept of coercion that was adopted after a long debate constituted a novelty in international law: Article 52 signified a break from the old law that recognized the validity of treaties even though they resulted from gunship diplomacy and actual subjugation through force. Not surprisingly, the developed countries objected to the introduction of the concept of coercion to international treaty law,²⁷ but had to agree that what was illegal under the UN Charter, i.e. aggressive use of force, could not give rise to valid treaty obligations.

The text of Article 52 could therefore be seen as a compromise. The rich countries' concession put off any formal acknowledgement on their part that economic coercion amounted to “threat or use of force in violation of the principles of international law embodied in the Charter of the United Nations.” Yet, the door was left open for the south to try to link economic coercion to the prohibition under the UN Charter to use force. Again, the rather apprehensive Latin American states tried to develop a theory according to which the “force” prohibited under the UN Charter included also economic force. Already in 1945, in the San Francisco Conference, Brazil introduced an amendment to Article 2(4) of the Charter which, if adopted, would have prohibited not only the “threat or use of force” but also the threat or use of economic coercion.²⁸ Since then, “the narrow interpretation of the concept of ‘force’ has generally prevailed among Western states, while the Communist bloc and most of the Third World countries have favored a broader construction of Article 2(4) embodying also economic coercion.”²⁹

We should note that the compromise was presented in rather technical terms. In its 1963 report, the International Law Commission's Rapporteur, Sir Humphrey Waldock, explained the difficulties with the introduction of economic coercion:

“[I]f ‘coercion’ were to be regarded as extending to other forms of pressure upon a State, to political or economic pressure, the door to the evasion of treaty obligations might be opened very wide; for

²⁶ Vienna Conventions on the Law of Treaties, May 23, 1969, art. 52, U.N. Doc.A/CONF.39/27.

²⁷ “The United States figured prominently among the delegations opposed to allowing a claim of economic coercion to invalidate a treaty.” See Jon Hinck, *The Republic of Palau and the United States: Self-Determination Becomes the Price of Free Association* 78 CALIF. L. REV. 915, 962-967 (1990).

²⁸ Text of the Brazilian amendment (Doc. 215, I/1/10, 6 U.N.C.I.O. Docs. 558-559 (1945)) discussed in, Domingo E. Acevedo, *The U.S. Measures Against Argentina Resulting From The Malvinas Conflict* 78 AM. J. INT’LL. 323, 327 n.13 (1984).

²⁹ *Id.* at 327-28 n.13

these forms of 'coercion' are much less capable of definition and much more liable to subjective appreciations. Moreover, the operation of political and economic pressures is part of the normal working of the relations between States, and international law does not yet seem to contain the criteria necessary for formulating distinctions between the legitimate and illegitimate uses of such forms of pressure as a means of securing consent to treaties."³⁰

Waldock's position made a great deal of sense at the time. It is no easy matter to come up with a robust definition of what constitutes the distinction between the legitimate and illegitimate use of economic force that is not liable to a wide range of subjective appreciations. Today, however, the concern with subjective appreciations may be addressed institutionally via recourse to dispute resolution under the WTO dispute resolution proceedings—a topic with which we will deal in the next section. Whether such rulings will exhibit much independence from the preferences of powerful states and whether they will be accepted and complied with by powerful states if they do are, of course, other questions which Waldock deftly side-stepped with the cryptic note that political and economic pressure "is part of the normal working relations between States." We will return to the latter questions later in the paper. First, however, we want to look at the case for hoping that the WTO's Dispute Settlement Body ("DSP") might be able to blunt some the problems described earlier.

B. The WTO as the Potential Venue for the Evolution of the Law

The relatively elaborate norms of the GATT, and the quite effective dispute resolution mechanism of the WTO focus the attention of states and scholars on the possibility that trade law, as interpreted and applied by the WTO Dispute Settlement Body, will transform the regime of economic relations between states from essentially a laissez-faire system to a more regulated one: a system which links trade rules to other obligations states have, such as the obligations to protect human rights and the environment. This is a question of substance, which faces an initial legal difficulty, namely to what extent can the GATT law be viewed as a self-contained regime that is immune to the influence of other areas of international law, including human rights law, labor law, and environmental law. In addition to this question of substance, there is also a question concerning process: to what extent should the decision-making processes within the WTO (both in the DSB and the multinational renegotiation rounds) be more democratic, allowing for smaller, less economically powerful states and non-governmental voices to represent the wider spectrum of global interests. This section outlines the debate (subsections 1 and 2) and assesses (in

³⁰ Humphrey Waldock, Special Rapporteur, Second report on the Law of Treaties, Doc. A/CN.4/156 1963, rep. in II Yearbook of the International Law Commission 1963, 36, at 52.

subsection 3) the responses offered so far by the Appellate Body (AB) of the WTO.

1. Substance: Trade Law and Its Potential Links to other Areas of Law

Several issues have been raised in the context of the possible regulation of international trade. These include the interface between trade and human rights, between trade and international environmental law, as well as the proscription of economic coercion or anti-competitive measures in international relations. These issues share two fundamental questions. The first and more general question is whether international trade law *should* or *should not* provide only for a laissez-faire regime and remain indifferent to the domination by the more powerful even at the cost of inefficiency or unfairness. The second more specific question is whether the existing law of the GATT can be interpreted as supporting one or the other interpretation.

The second question has preoccupied many legal scholars resulting in the emergence of two camps arguing for or against the view that the GATT law is a so-called self-contained regime. Beyond the assessment of the different interpretations, however, it is interesting to explore the views expressed by state parties before WTO treaty bodies, and the decisions taken within this institution. Curiously, both camps – the north and the south – respond in two voices to the general question. Both the developed northern states and the developing south seek to impose constraints on international markets. Both the north and the south stand for opposing such constraints. Of course, each camp advocates the imposition of norms in exactly those areas where the other camp resists them. These inconsistencies suggest that neither side truly purports to attain collective goals. Yet, at the same time they suggest that an all-inclusive compromise may not be completely out of the question.

The north champions the human rights and labor rights of the workers within the southern states. It also maintains that the southern states' compliance with their obligations under international environmental treaties is part and parcel of their free trade obligations. In both spheres the northern claim is that unacceptably low standards of human and labor rights and environmental protection are themselves unfair trade practices. Southern governments demur, of course, against what they see as intervention in domestic affairs prompted by northern concern about competition. They regard what the north refers to as their lower standards as their relative advantage, often the only advantage they have. At the same time the south puts forward different claims for the regulation of international transactions. It argues that the protection of IP under TRIPS is excessive and threatens the basic interests of their citizens; that the opportunities for suppliers of northern products to abuse their monopolistic

positions must be checked, and that economic coercion must be recognized as illegal, thereby voiding agreements concluded through the use of such coercion.

At the same time, in some areas both the north and the south call for the *non*-regulation of international transactions. The north, who would like the developing south to be more conscious of domestic human and labor rights, refuses to control monopolistic behavior when it is directed only against foreign markets, and rejects the notion of economic coercion as too vague and dangerous. Some of the southern states, those who have natural resources they export—particularly the oil producing states—reject international limitations on their sovereign rights to dispose of their natural resources, even by way of cartelization and embargos.³¹

For the purposes of this essay, one striking aspect of the debate is that the human rights discourse that is espoused by the north in the context of labor rights is dismissed by the north as irrelevant to the claim of the developing countries that AIDS victims and others have a right to receive life-saving treatment at manageable cost. Why should a southern state be obliged—under international human rights law—to provide its citizens with decent working conditions, but not have the right and duty, based on the same law, to provide them with decent medical treatment when they become ill?

The explanation favored by northern states lies in a neat distinction that runs through international human rights law. Human rights law applies traditionally to the relationship between a state and the individuals subject to its “effective control.” This “effective control” test has so far been interpreted as applying only in areas subject to the direct control of the state organs. Therefore, under this doctrine, a state is not responsible for the protection of human rights of foreign citizens situated outside its jurisdiction. Under certain circumstances, the state *may* come to the support of foreign nationals—by, for example, imposing sanctions on the foreign government, or by the so-called humanitarian intervention. But there is no *obligation* to do so. So, while the north may impose sanctions on southern states that do not respect the southern citizens’ rights, the north has no obligation to care for those citizens when they are too poor to obtain life saving medicines.

³¹ Ibrahim F. I. Shihata, *Arab Policies and the New International Economic Order*, 16 VA. J. INT’L L. 261, 267-68, (1976): “The embargo [on oil supplies in 1973] and accompanying production cutbacks were in full conformity with customary international law ... Arab oil-exporting States were ... only exercising their recognized sovereign right to dispose of their natural resources in the manner which best suited their legitimate interests.”

2. Process: The Democratization of the WTO

As noted earlier, “democratization” in the context of the WTO and other international institutions typically refers to participatory rights in the decision-making process, such as the right to receive and impart information, rather than the right of individuals to elect representatives. The strong connection between democracy and the transparent and accessible decision-making process within the international institution was emphasized by the German Constitutional Court, when it explained why Germany’s ratification of the Maastricht Treaty did not signify the abdication of the Germans’ right to democracy.³² In an integrated European Union, reasoned the Court, the demand for democracy will be satisfied if the union will provide an “ongoing free interaction of social forces, interests, and ideas, in the course of which political objectives are also clarified and modified, and as a result of which public opinion moulds political policy.”³³ Since the creation of the WTO, there has been growing NGO demand for more transparency in decision-making. The norm-setting process within the WTO involves all member states. This is mainly an informal, behind-the-scenes process of negotiations and consultations. The official website of the WTO suggests that such “informal consultations within the WTO play a vital role in bringing a vastly diverse membership round to an agreement.”³⁴ This informal prescriptive process remains opaque to civil society. Indeed, NGOs representing diverse interests can sometimes use this opacity to present their views and gather information,³⁵ but this influence remains a matter of discretion for states who find it opportune to support some NGOs on a certain matter under discussion.

The plenary sessions of the Ministerial Conferences were open to observers since the first Conference held in Singapore in 1996.³⁶ In July 1996, the General Council adopted Guidelines for Arrangements on Relations with Non-Governmental Organizations.³⁷ The guidelines recall

³² Federal Constitutional Court Decision concerning the Maastricht Treaty, 33 I.L.M. 388, 420 (1994).

³³ *Id.*

³⁴ See “Understanding the WTO: Whose WTO is it anyway?,” at http://www.wto.org/english/thewto_e/whatis_e/tif_e/org1_e.htm (last visited Oct. 27, 2004).

³⁵ See Jeffrey L. Dunoff, *The Misguided Debate over NGO Participation at the WTO*, 1 J. INT’L ECON. L. 433 (1998). For a recent appraisal of the debate, see Eric Stein, *International Integration and Democracy: No Love at First Sight*, 95 AM. J. INT’L L. 489, 504-09 (2001).

³⁶ The number of NGOs attending the plenary sessions has grown from 108 at the Singapore Ministerial Conference in 1996 to 686 at the Seattle Ministerial Conference in 1999. See Communication from Hong Kong, China, *WTO: External Transparency*, WT/GC/W/418 (Oct 31, 2000).

³⁷ Guidelines for Arrangements on relations with Non-Governmental Organizations, WT/L/162 (July 23, 1996) [hereinafter WT/L/162].

Article V:2 of the Marrakesh Agreement establishing the WTO, which provided that “the General Council may make appropriate arrangements for consultation and cooperation with non-governmental organizations concerned with matters related to those of the WTO.”³⁸ In these guidelines, the Council members “recognize the role NGOs can play to increase the awareness of the public in respect of WTO activities.”³⁹ They further acknowledge that NGOs are “a valuable resource [that] can contribute to the accuracy and richness of the public debate.”⁴⁰ The Members therefore agree to improve transparency and develop communication with NGOs.⁴¹ For this purpose, the guidelines call upon members to “ensure more information about WTO activities in particular by making available documents which would be derestricted more promptly than in the past.”⁴² The WTO Secretariat is requested to provide on-line computer access to such documents. The Secretariat is instructed further to “play a more active role in its direct contacts with NGOs . . . through various means such as *inter alia* the organization on an ad hoc basis of symposia on specific WTO-related issues, informal arrangements to receive the information NGOs may wish to make available for consultation by interested delegations and the continuation of past practice of responding to requests for general information and briefings about the WTO.”⁴³

At the same time, however, the guidelines reflect the concern many governments have with more formalized decision-making procedures that may increase transparency and voice to other governments and to NGOs. Article 6 emphasizes “the special character of the WTO, which is both a legally binding intergovernmental treaty of rights and obligations among its Members and a forum for negotiations,” and points out the “broadly held view that it would not be possible for NGOs to be directly involved in the work of the WTO or its meetings.”⁴⁴ The intergovernmental character of the WTO implies, according to the guidelines, that the appropriate level for NGOs’ direct participation is the national level: “Closer consultation and cooperation with NGOs can also be met constructively through appropriate processes at the national level where lies primary responsibility for taking into account the different elements of public interest which are brought to bear on trade policy-making.”⁴⁵

³⁸ Agreement Establishing the World Trade Organization (1994), art. V(2).

³⁹ WT/L/162 *supra* note 37.

⁴⁰ *Id.* at art. IV.

⁴¹ *Id.* at art. II.

⁴² *Id.* at art. III.

⁴³ *Id.* at art. IV.

⁴⁴ *Id.* at art. VI.

⁴⁵ *Id.*

In the years since 1996 impressive efforts have been made, particularly by the Secretariat, to provide accessible information including documents to the general public by posting it on the WTO website. A few northern members have come up with suggestions for improved transparency. Canada, Norway, and the United States suggested inter alia that General Council and other committee meetings be open to observers, including Trade Policy Review meetings, where members' policies are reviewed for conformity with WTO rules.⁴⁶ Other suggestions included the establishment of fora to enable open dialogue between WTO bodies and NGOs, the inclusion of advice of legislators from member states and of experts in specialized areas, and the creation of ad-hoc advisory boards to provide non-binding NGO advice on a variety of issues.⁴⁷ Such northern suggestions are not well-received by the developing southern countries that stand to lose from a more active role for NGOs that represent the interests of the relatively well-off societies seeking to maintain high levels of welfare and environmental protection. As a result, developing members often work to restrict public participation to the passive role of receiving information from WTO bodies rather than communicating it to the WTO.⁴⁸

The main area of attention in this respect has so far been the procedures within the judicial organs themselves. In contrast to most other international adjudication procedures, the WTO procedures maintain

⁴⁶ See General Council Informal Consultations on External Transparency, Submission from the United States, WT/GC/W/413 (Oct. 13, 2000) [hereinafter U.S. Submission]; WTO External Transparency, Informal Paper by Canada, WT/GC/W/415 (Oct. 16, 2000) [hereinafter Canada Paper]; External Transparency, Communication from Norway, WT/GC/W/419 (Nov. 2, 2000).

⁴⁷ See Canada Paper, *supra* note 46.

⁴⁸ Note the position of Hong-Kong, China on this matter, elaborating on the distinction between external transparency and direct participation:

"8. In our view, enhancing "external transparency" of the WTO means keeping the public informed and educated of the WTO's work, enriching their understanding and awareness of the Organization and the multilateral trading system, and thereby improving the ability of the public to reflect views to their governments. On the other hand, "participation" in the WTO by non-Members implies a right to take part in the decision-making process of WTO, a right to make representations of interest in the formal WTO setting and in the process prejudice the outcome of discussions. 9. While we are prepared to consider those proposals aiming at improving transparency, we are not convinced of the desirability of adopting proposals which seek to make provisions for direct participation of the civil society in the Organization in this exercise. Such proposals go against the inter-governmental nature of the WTO, risk politicising the operations of the Organization due to sectoral and electoral interests, and undermine the rights and obligations of individual WTO Members." See Communication from Hong Kong, China, *supra* note 36.

secrecy. Litigation before the Panels and the Appellate Body are closed to WTO members who are not parties to the litigation and to the general public. Calls for transparency focus therefore on making all parties' submissions available to the public and on enabling the general public to observe the proceedings using various tools, including web casting.⁴⁹ Moreover, suggestions for enabling the flow of communication from the public to the adjudicators concentrate on the possibility of submitting amicus briefs to the panel and the appellate bodies.

Northern members tend to strongly support open and accessible proceedings. The United States is the most ardent supporter of transparency and communication in the dispute settlement process.⁵⁰ It, apparently, believes it has the most to gain from such openness. In fact, it was the first and so far the only state that presented NGO briefs as an integral part of its brief while defending its environment-friendly unilateral restrictions on trade against the complaint of India, Malaysia, Pakistan, and Thailand.⁵¹

In general, however, we believe that the promise of opening up WTO decision processes and linking trade to other normative constraints is limited. Greater transparency and NGO participation can lead to greater public awareness of policies, but as the AIDS drugs case suggests, there are significant limitations on the role that international public opinion actually plays. The pharmaceutical companies are doubtless well aware of this and so do not insist on limiting public access to the process.

3. Responses by the WTO Dispute Resolution Bodies

The DSP is active both in creating linkages and in opening up the decision making process to nongovernmental voices. The Appellate Body (AB) accepted a link between trade and the protection of the environment in the Shrimp-Turtle case.⁵² The question is open with respect to the AB's attitude towards a possible link between trade and human rights.⁵³ The AB has also opened up its dispute settlement process to third states and NGOs. It has shown a clear inclination to consider amicus briefs of third states and

⁴⁹ See U.S. submission, *supra* note 46.

⁵⁰ *Id.*

⁵¹ The complaint criticized the U.S. prohibition on the importation of certain shrimp and shrimp products caught in methods considered by the U.S. to adversely affect the population of sea turtles. WTO Appellate Body, United States – Import Prohibition of Certain Shrimp and Shrimp Products, WT/DS58/AB/R (Oct. 12, 1998) [hereinafter Shrimp Report].

⁵² *Id.*

⁵³ Werner Meng, *International Labor Standards and International Trade Law*, in *THE WELFARE STATE, GLOBALIZATION, AND INTERNATIONAL LAW* 371, 387 (Eyal Benvenisti & Georg Nolte Eds., 2004).

NGOs thereby rendering the process more transparent and accessible.⁵⁴ In a decision that enraged numerous southern states, the AB invited third parties to submit briefs and then denied their requests to do so without explanation in the face of furious reactions to its decision.⁵⁵ Interestingly, however, despite the strong political reaction to its invitation, the AB did not retract its principled approach, but rather left open the door for future requests for third party intervention, and actually enabled them in a subsequent case.⁵⁶ The AB also recognized the “due process” rights of foreigners vis-à-vis a state that imposes constraints on trade that affect them. These foreigners have a right of hearing during national legislation proceedings for potentially affected foreign interest groups to grant.⁵⁷

What can we learn from these initial decisions of the AB? As other tribunals before it, such as the European Court of Justice and the International Court of Justice, the AB has taken the liberty of translating the silence of the treaty and general international law into authorization to progressively develop the law. Such bodies reason that the state parties always have the option of undoing the tribunal’s ruling if they wish. Thus, for example, when the AB opened the door for third parties’ briefs, it defended the action by noting the silence of the lawmakers in connection with the issue:

“[N]othing in the DSU or the Working Procedures specifically provides that the Appellate Body may accept and consider submissions or briefs from sources other than the participants and third participants in an appeal. On the other hand, neither the DSU nor the Working Procedures explicitly prohibit[s] acceptance or consideration of such briefs. . . . Therefore, we are of the opinion that as long as we act consistently with the provisions of the DSU and the covered agreements, we have the legal authority to decide whether or not to accept and consider any information that we believe is pertinent and useful in an appeal.”⁵⁸

⁵⁴ For analyses of the Panels’ and Appellate Body’s authority to consult amicus briefs see Robert Howse, *Adjudicative Legitimacy and Treaty Interpretation in International Trade Law: The Early Years of WTO Jurisprudence*, in *The EU, the WTO, and the NAFTA* 35, 48-51 (Joseph H.H. Weiler, ed., 2000), Petros C. Mavroidis, *Amicus Curiae Briefs Before The WTO: Much Ado About Nothing*, Jean Monnet Paper No. 2/01 (2002) available at <http://www.jeanmonnetprogram.org/papers/papers01.html>.

⁵⁵ WTO Appellate Body, *European Communities – Measures Affecting Asbestos and Asbestos-Containing Products*, WT/DS135/9 (March 12, 2001).

⁵⁶ WTO Appellate Body, *European Communities – Trade Description of Sardines*, WT/DS231/AB/R, paras. 153-170 (Sept. 26, 2002).

⁵⁷ *Shrimp Report*, *supra* note 51.

⁵⁸ WTO Appellate Body, *United States – Imposition of Countervailing Duties on Certain Hot-Rolled Lead and Bismuth Carbon Steel Products Originating in the United Kingdom*, WT/DS138/AB/R, para. 39 adopted (emphasis added) (May 10, 2000).

This formal explanation reveals an important aspect of international lawmaking that is responsible for overcoming discord among states. The “legislative impasse” among states at the level of treaty-making and collective bargaining, which prevented the adoption of thicker rules and more formal decision-making procedure, can at least under some circumstances effectively relegate authority to the judicial organs to develop the law in line with what they perceive to be global interests. The question is, what are those circumstances? There is a general sense in the legal community that one critical prerequisite for judicial entrepreneurship is the expectation that the ruling will be accepted. International tribunals like domestic courts are acutely aware of their own status and reputation. They have a keen sense of the limits on their enforcement and managerial powers, and do not want their reputation and prestige to be damaged by judgments that go ignored by powerful actors.⁵⁹ This suggests that the entrepreneurship of courts tends to be greatest when there is relatively little power disparity among actors and when the affected actors have little ability to threaten the institution of which the court is a part with exiting or the withholding of funds.⁶⁰ This dynamic also suggests that international tribunals have an institutional interest themselves in trying to level the playing field between the participating state actors as much as they can. The more power is balanced, the more the tribunal will enjoy independence and actual legislative powers. The difficulty is that the ability of courts to do this is usually rather modest, especially when the power disparities are relatively large. Hence our expectation is that the ability of judicial entrepreneurship to level the playing field to increase its own rule making authority depends first and foremost on the evolution of a favorable pattern of power relations among states. In the meantime, however, there is every indication that we can count on international decision-makers, in particular on the WTO judges, to remain acutely aware of these relations and to continuously test the waters.

IV. Evolution in the Bargaining Power of Developing States

Of course, it is one thing to argue that the entrepreneurial range of the judiciary is critically dependent on the power disparities among the states, and quite another to accurately characterize how these disparities are evolving and why. In recent years, international legal scholars have looked to international relations theory for such guidance, but many have come to realize that international relations is as contested a field as any with which

⁵⁹ This may suggest that to date the evolving jurisprudence of the AB does not conflict with stronger states’ interests as much as is sometimes assumed. That is, that greater transparency has had relatively little effect on actual policy outcomes except in those few cases where judges have correctly calculated that even the stronger states have more to lose by undermining the authority of the tribunal than they do by complying with it.

⁶⁰ The ICJ litigation in the claim of Nicaragua against the U.S. is one rare example for the limits of power.

they themselves are familiar. Each of the dominant theoretical perspectives is well-armored against falsifiability by an endless assortment of ambiguities and abstractions that can be operationalised in any number of ways by those who adhere to each theory. The fact that the major theories tend to focus on different issues and different variables only increases the difficulty of making comparative judgments. Rather than attempt to review the landscape of international relations theory and evaluate the extent to which each are capable of explaining the historical developments in WTO drug policy, we think it would be more useful to examine informally how the distributive politics of drug policy is evolving through the lens of a hybrid perspective that we consider most appropriate.

Often referred to as political economy, this approach contains elements of each of the traditional schools of realism, institutionalism, liberalism, and is no more well-defined or homogeneous than they are, but its applications tend to possess a number of things in common. First, much of the analytic apparatus is drawn from economics. Individual actors are assumed to act purposefully and strategically based on rational expectations but not necessarily narrowly: the nature of what goes into determining a given actor's utility function is globally undefined and context specific. Uncertainty and discount rates are also important and game theory is widely employed as an analytic tool. Second, relative power plays an important role in determining differences in the bargaining power and strategic behavior of actors, and the range of possible outcomes. However, what constitutes the nature of relative power in a given context is also highly contextual. Military power does not possess the supremacy that it does in realism and various forms of economic power, and positional power derived from the nature of the institutional context are taken quite seriously. Third, domestic politics play a critical role in determining the priorities of national actors just as it does in liberalism.

The most striking aspect of the history of drug policy and the intellectual property regime generally is the extent to which the nature of the original agreement was dominated by the interests of the United States, and to a somewhat lesser extent those of the EU. Indeed, it is difficult to see how they could have done much better. True, there were two provisions for dealing with emergencies and promises of progress in the area of agricultural policy, but the practical effect of the safeguard provisions on the profitability connected with the property rights that were granted has been modest and the liberalization of agricultural policy has yet to be realized. It seems relatively clear that the reason that the intellectual property rules of the WTO are so one-sided is because at the time they were negotiated, the United States—and only the U.S.—was able to credibly threaten to exit the regime and negotiate separate trade agreements bilaterally. The fact that it had already embarked on a program of unilateralism in connection with Section 301 had convinced other states that it was serious about its threats. Also, given the mismatch in economic

power between the U.S. and the vast majority of other states, bilateral negotiations represented a grim prospect that other states wanted very much to avoid.

Of course, once the intellectual property rules were made and progress had also been achieved in the area of reducing non-tariff barriers, the U.S. had a far greater investment in the success of the WTO than it had had previously. Its bargaining power was reduced somewhat, and arguably, it could now no longer threaten to credibly exit the trade regime because the opportunity costs of doing so had grown enormously. Quite the contrary, it now had to worry about maintaining the integrity of the intellectual property regime in the face of what over time were sure to be challenges from states capable of producing and marketing generic versions of its firm's most popular and profitable drugs.

The politics of the intellectual property regime in the area of drugs has continued to evolve. The continued economic development of states such as China, Brazil, and India, with their increasingly large numbers of middle class consumers, now creates the backdrop against which the democratization of the WTO, and other international institutions willing to engage in redistribution, is taking place. What is less clear is the extent to which this is likely to lead to more democratic policymaking in the WTO generally, and a drug regime that provides more distributive benefits for developing states.

To date there has been some modest progress and it has tended to involve either one of the largest of the most advanced developing economies, or a coalition of developing states. This is true both in the AIDS and Glivek cases. Recall that in the case of AIDS drugs, both Brazil and a consortium of ten other middle income Latin American states including Argentina, Mexico, and Chile rejected the prices offered by U.S. and European drug firms. Instead, they negotiated a deal with Abbot labs that was half the cost negotiated a year earlier by a group of Caribbean states, and which was comparable to what was being offered at the time to African countries. Considering that the Latin American market was prospectively far more lucrative than the African or Caribbean markets because the ability of consumers in Latin America to pay was much higher, this was a remarkable outcome.

In the case of Glivek the outcome was more complicated but not dissimilar. South Korea attempted to negotiate a price that was significantly lower than the drug company wanted to charge, but soon found itself being pressured by the U.S. government to agree to a price that was equal to the average price that was being charged to consumers in Group Seven countries. The United States also urged South Korea to reject a license that would have allowed a generic South Korean firm to produce its own version of the drug at a lower cost. The Brazilian government had considerably better luck. When it threatened to issue a compulsory license, the price of the drug was quickly dropped to \$13 dollars per dose, six

dollars less than what South Korean consumers found themselves having to pay.

Large, middle income developing countries and to a growing role for coalitions get a better deal than poorer countries because they have the power to produce generic versions of U.S. drugs anytime they desire, and they either contain or potentially contain lucrative middle class markets that U.S. firms can't afford to lose or alienate. South Korea probably possesses far more capacity to produce its own generic drugs than does Brazil, but Brazil possesses more middle class consumers for U.S. products than Korea, and it is less dependent on the U.S. for its security and for a market for its own exported products.

This trend of an increasing empowerment of large middle income states shows every sign of accelerating in the future as the wealth and middle classes of states like China, Russia, India, and Brazil continue to grow. There is every reason to believe that they will continue to press for lower drug prices when there is a public health emergency and shorter patent periods of patent protection for their generic drug firms. States such as India, that will soon have to face the prospect of watching its generic firms destroyed as its period of negotiated grace comes to an end, can be expected to launch an aggressive campaign to either extend the grace period further or secure a permanent change in the rules.

It would, however, be a mistake to overestimate the bargaining power that these large, middle income developing states possess, or the likelihood that they will be willing to invest it in a vigorous campaign to alter the character of the WTO's drug regime. While their economies are large compared to those of other developing states, they are many times smaller than that of the U.S. or EU and their economies continue to be more dependent on the developed states than the developed states are dependent on them. Moreover, except during the wake of an extraordinary crisis such as the AIDS epidemic which affects a significant portion of the population and has extremely high political visibility, these states each have a host of economic concerns that have a far greater political priority than reducing the cost of cutting edge drugs that often affect only a tiny proportion of citizens. Most of these states have no significant drug industry. Even India, the developing state that stands the most to gain from a loosening of the intellectual property rules connected with drugs, is unlikely to jeopardize the enormous gains that it has made with U.S. firms in other areas by adopting an overly confrontational stance in connection with drugs.

In such an environment where individual developing states have neither the power nor the interest necessary to mount a long term campaign to reform the drug regime, it would seem to make sense for them to pursue their collective interest by creating a coalition. We have seen that this has been done on a number of occasions, but the significance and effectiveness of this trend toward coalition building is also unclear. It is true that one of a

consortium of ten Latin American countries managed to obtain a concession on the price of AIDS drugs, but that price does not appear to be lower than that obtained by the largest and most economically powerful state in the region acting alone. The Caribbean and African countries that formed coalitions seem to have been somewhat less successful.

There is also the concern that up to this point the coalitions have been ad hoc and oriented toward the goal of obtaining lower prices in connection with a specific drug. There is nothing surprising in the fact that the initial focus of these coalitions has been narrow; the initial focus of what was to become the European Community was also narrow. But the lack of permanency is concerning because it suggests that the states involved are more concerned with short term problem solving than they are in creating some entity that could pursue their collective long term interest in altering the fundamental character of the drug regime.

In sum, these cases give us good reason to expect that the formation of coalitions of states for the purpose of bargaining will become increasingly common, but less reason to believe that they will be strikingly successful in reforming the regime. The differences in the success that was achieved by the Latin American coalition, which was led by Argentina, Mexico, and Chile, compared to that led by the African and Caribbean states certainly suggests that the success of a coalition depends critically on the membership and leadership of one or more of the larger and economically advanced developing states. However, in none of the cases has a coalition established the institutional roots necessary to counterbalance the role of those developed state interests that support the status quo.

V. Developed State Strategies for Slowing Distributive Progress

While developing state progress toward achieving a more equitable drug regime has so far been modest, the impressive rates of economic growth currently being achieved by states such as China, Russia, and India would seem to argue for the eventual evolution of a system that is much less dominated by the interests of the U.S. and EU. However, to embrace this conclusion too quickly is to ignore the fact that the most economically powerful northern states have developed and refined any number of institutional strategies to “lock in” the advantages that they currently enjoy. The nature and composition of the UN Security Council, which has perpetuated a post-war distribution of power for over fifty years, is only one particularly prominent example of such a strategy. There are many others.

The phenomenon of “bargaining on price” that has played such a central role in the discussion up to this point is a good example of one of the more subtle strategies employed, and one which has received little or no attention in the literature of intellectual property generally. At first glance it appears to be a developing state strategy that is designed to chip away at

the foundations of the drug regime. Some might even argue that it provides the most tangible evidence available that the regime is evolving in response to changes in the relative economic power of the more advanced developing countries.

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

Bargaining on price thus provides an effective strategy for the U.S. and EU to deal with the growing power of the large, economically advanced developing states while they further institutionalize the regime. Developing states do benefit, of course. Patients receive a given drug more cheaply than they otherwise would, and some patients who would not have access to the drug at all are able to obtain it. Politicians in developing states are able to reap the domestic political benefits of being able to claim that they have secured far lower prices for their country than those that are available to citizens of neighboring countries.⁶¹ But the developed states have achieved the larger victory of deflecting growing political pressure for reform while maintaining an extremely profitable regime.⁶²

Over time the largest and most scientifically advanced of the developed states such as India, Russia, and China may decide that price breaks are not enough, or the U.S. and EU may decide to reduce prices either because they feel that they are costing too much or because there is growing pressure from developing states for price parity. Should this occur, the U.S. and EU will almost certainly resort to other regime preserving strategies.

One such strategy involves the use of a bilateral linkage strategy where the developed state signs a second treaty in which it agrees to provide the

⁶¹ Of course, this will do little to lower the prices for the citizens of developing states generally, but it will take an exceptional leader to pass up the short term political benefits in his home country to pursue a policy that primarily will benefit the citizens of poorer states and will involve the political risks associated with confronting an economic superpower.

⁶² Negotiating prices separately for each drug might seem to involve too many transaction costs for both large developing states and the drug companies, but over time these will be reduced through the use of the same standard operating procedures that are now applied to states with different national health systems.

developing state with improved access to its markets via a Free Trade Agreement, or an increased military assistance in exchange for the developing state agreeing not to seek to renegotiate certain provisions of the intellectual property regime, or to recommit itself to maintaining the highest standards of intellectual property protection within its borders.⁶³ This strategy enables the U.S. or EU to incrementally and unobtrusively gain a commitment on the part of the developing state to ratchet upward its intellectual property standards beyond those currently embodied in TRIPS at the modest cost of providing the developing state with a benefit that it is likely to want to provide in the future anyway.

For their part the politicians of the developing state obtain the substantial political benefit of being able to say that they have achieved a degree of access to U.S. or EU markets that the rest of the developing states have not been able to collectively achieve to date at Doha. The fact that the monetary value of this increased access to the citizens of the developing state will fall over time as the developed states sign comparable agreements with other developing states, and that the costs associated with extending intellectual property are likely to rise sharply tends to be ignored in favor of the short term political victory.

Alternatively, the U.S./EU could attempt to win a developing state's support of the intellectual property regime by giving it a direct stake in the regime's success. This could be done through the device of purchasing generic drug companies in the developing state and continuing to operate them there, or by outsourcing the manufacture of drugs under U.S./EU patents to generic firms in the developing states. This is not a strategy that can be employed too widely because it is predicated on the expectation that the foreign firms that are owned or contracted with are large enough and powerful enough to be a significant political force in the politics of the developing state. This condition is unlikely to be met in more than a handful of economically advanced developing states, but it is important to note that these states are also the ones most likely to be the most vocal and politically powerful.

These same strategies can just as easily be employed to "break" a coalition of developing states as deal with one or more of the most economically powerful developing states because the task is basically the same. This would not be the case if all developing states were the same size and there was a large coalition that the U.S./EU had to bargain with. Simply inducing one or two of the twenty-five or thirty states in the coalition would have little effect, and the U.S./EU would face the prospect

⁶³ This strategy is closely related to the "regime shifting" and "regime blocking" strategies discussed by Braithwaite and Drahos. See PETER DRAHOS & JOHN BRAITHWAITE, *INFORMATION FEUDALISM: WHO OWNS THE KNOWLEDGE ECONOMY?* 85-107 (2003). In this case, the developed state has shifted from the venue of intellectual property and trade talks in the WTO to a bilateral negotiation.

of either having to dilute the current regime in significant ways or of having to pay a heavy price to maintain it.

Unfortunately for the developing states, they are an extremely heterogeneous group whose ability to bargain effectively with the developed states appears to be dependent on the leadership of a small subset of states that are large and more economically developed than the rest. This fact operates to reduce the task of the U.S. and EU in dealing with coalitions to the near-equivalent of what has just been described. The existence of the coalition is likely to somewhat increase the cost of reaching an agreement with one or more large developing states that are leading the coalition, and it could conceivably delay the reaching on an agreement for sometime if the large state places a high value of being the leader of the developing world. However, there is no evidence to date that suggests that U.S./EU strategies such as bargaining on price and bilateral bargaining will be ineffective against coalitions. It is worth noting that in the case of AIDS drugs, the Argentina led coalition of ten Latin American states does not appear to have wrested a better deal from the drug companies than Brazil was able to procure by acting alone. Even more significantly, there appears to be little evidence that any developing state coalition is even actively pursuing a reform goal that is more ambitious than a one time price reduction.

VI. Conclusion

With its coercive origins and its distributionally perverse effects, the TRIPS regime constitutes one of the most salient manifestations of the democratic deficit in the WTO. As such, the political history of TRIPS provides a good opportunity to examine the kinds of challenges that will have to be overcome if the developing world's expectations for more democratic policy making and greater redistribution are going to be met in the future. In this paper we have focused on the drug regime. The drug regime is particularly interesting from a political standpoint because its benefits are not only redistributed upward like the rest of TRIPS, but they are also arguably inefficient and threaten to undermine human rights in the area of public health.

Given the role that economic coercion, in the form of institutional brinksmanship, played in the origin of the regime and arguably continues to play, we began by looking at the prospect that such coercion is likely to be contained via international legal institutions in the near future. We argued that contemporary international law has made little attempt to do this despite arguments from both the north and the south that some limits on economic power are needed and appropriate. Although international tribunals, in particular the Appellate Body of the WTO, have evidenced an appetite for increasing their lawmaking function to level the international economic playing field, their ability to make any real progress in doing so

has been constrained by the fear of willful and visible noncompliance of the United States and the European Union which could greatly damage their prestige and influence.

We argued that the existence of this constraint testifies to the importance of achieving a better balance in the bargaining power within developed states and between the developed states and the large middle income developing states such as China, Brazil, and India, which have both more acute public health demands than do developed states and the potential capacity to produce generic versions of virtually any drug should they decide to do so. Unfortunately, while such an improved balance in bargaining power is a necessary precondition for distributive progress, it is far from being a sufficient one especially in the short term. The problem is the potential for institutional "lock-in," or the creation of institutional rules to perpetuate a particular distribution of bargaining power long after it has eroded.

Recognizing the gradual emergence of the large developing states and inferring its possible long term consequences in renegotiating the current regime, the large developed states together with their drug firms have taken a number of steps to institutionally lock in the present regime so that it will be difficult to reform. One particularly effective strategy for doing this is to respond to developing state discontent by bargaining on the price of individual drugs in order to allay discontent before it reaches the point where states begin to push for more fundamental (and distributionally democratic) reforms that would threaten the underpinnings of the regime. As a consequence, while the price reductions that have been achieved in connection with AIDS drugs and Glivec have been important in human terms, their institutional impact in terms of insuring that the TRIPS's drug regime will be more responsive to southern interests in the future have been negligible.

Bargaining on price is only one of the strategies that the developed states and their drug companies appear to be employing to perpetuate the status quo. Developed states can approach developing states bilaterally and offer to negotiate free trade agreements in exchange for a commitment on the part of the developing state to maintain the highest standards of intellectual property protection. Alternatively, developed state drug companies can purchase generic drug firms or otherwise outsource the production of drugs to developing states in order to give the largest and most economically powerful developing states a modest stake in maintaining the current regime. Neither strategy offers much real value to the populations of the developing states in the long run, but they do improve the political prospects of the politicians in power in the short run, and this makes them extremely effective. This effectiveness makes them a particularly useful tool for developed states to use when attempting to prevent coalitions of developing states from forming, or in dividing those that have formed.

Does this mean that there is little or no prospect of reforming the drug regime? For those interested in distributive justice, the democratic deficit, public health, and legitimacy of what is one of the world's most prominent international institutions in the developing world—this would be a very dim prospect. There are, however, reasons to be at least moderately hopeful. A major source for hope lies in the drug regime collapsing due to political over-reach on the part of EU and U.S. drug company executives. If history is any guide, their own preoccupation with their short term interests will eventually lead them to overplay their hand and destroy the regime that they have so tirelessly engineered.⁶⁴

There are some scattered signs that this is already starting to happen. For example, the seemingly endless push within the United States to patent not only end products such as drugs, but myriad processes, chemical compounds, and every piece of genetic material as it is identified threatens to raise the “overhead” associated with innovation to the point where it threatens the productivity and profitability of broad segments of U.S. industry.⁶⁵ Almost inevitably, it will pit the interests of large U.S. research universities against the drug industry in a battle that could easily leave the drug industry losing control of the drug patent process and dramatically increasing its own overhead costs. If either occurs, the international community and developing states could be the beneficiary of revised rules.

Another source for hope lies with the continued development of the large middle income states. Even if the U.S. and EU succeed in delaying reform for a number of years, it seems likely that a small coalition of the most technologically-oriented states with the largest consumer markets will eventually find themselves in a position to demand a renegotiation of some of the regimes most regressive components such as the twenty year life on patents. The upcoming expiration of the grace period for generic firms in India should provide one indication of the pace with which things are changing. While the drug firms will be anxious to hold firm to the current deadlines in order to eliminate an important thorn in their side, the growing

⁶⁴ Political blunders are common in industries that have invested heavily in securing political influence. According to a recent article in the *New York Times*, Abbott Laboratories decided to quintuple the price of the annual dosage costs of its important AIDS drug Norvir from \$1500 to \$7800. The fact that Norvir was developed with federal money during the 1990's (which has earned Abbott more than one billion dollars already), coupled with the fact that the price increase will result in thousands of Americans paying ten times the price Europeans pay, quickly made the case a focal point for AIDS and consumer activists and the focus of a federal hearing. Gardiner Harris, *Price of AIDS Drugs Intensifies Debate on Legal Imports*, N.Y. TIMES, Apr. 14, 2004, at A1.

⁶⁵ See Keith E. Maskus & J. H. Reichman, *Mini-Symposium: International Public Goods and the Transfer of Technology under a Globalized Intellectual Property Regime* (paper given at the Conference on International Public Goods and the Transfer of Technology under a Globalized Intellectual Property Regime, Duke University School of Law, Durham, N.C.) (Apr. 24-26, 2003).

economic and political importance of India could well lead the U.S. government to agree to an extension of the grace period. Should it do so, it could well be the harbinger of even more significant compromises in the future.

