

*Comment*

**HUMAN RIGHTS AND THE WORLD TRADE ORGANIZATION:  
THE RIGHT TO ESSENTIAL MEDICINES AND THE TRIPS AGREEMENT**

**CHRISTOPHER BUTLER\***

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**I. INTRODUCTION**

This paper explores the potential of human rights to influence the behavior of member states of the World Trade Organization (WTO) and ultimately effect changes in the laws and norms of the WTO. The issue of access to medicines and the patent protection of pharmaceuticals under the Agreement on Trade-Related Aspects of

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\* L.L.B. (Hons. 1) Sydney Law School, University of Sydney 2006; B. Economics (Social Sciences) (Hons 1), University of Sydney 2004. Thanks to Professor David Kinley, Chair of Human Rights, Sydney Law School, for supervision and comments and Dr. Gavan Butler.

Intellectual Property (TRIPS) is currently the subject of much contention, and so this paper also analyzes the generation and application of norms relating to the human right to essential medicines and the role of strategic actors. These actors include developing countries, non-governmental organizations, and the United Nations' human rights organs, producing change in the form of the 2001 Doha Declaration on TRIPS and Public Health, and ongoing WTO negotiations arising therefrom.

This paper begins by reviewing the policy options available to resource-strapped states to resort to measures such as compulsory licensing and parallel importation to provide affordable access to medicines under TRIPS prior to the 2001 Doha Ministerial Conference, emphasizing the scope of inter-state contestation inside and outside the WTO over patent protection of pharmaceuticals. Within this restrictive policy space, a coalition of developing countries, the UN human rights system, and civil society formulated a human-rights-centered approach to intellectual property protection, thereby challenging the predominant trade-centered conception of intellectual property rights. This human rights approach involves identifying, particularizing, and publicizing the specific content of a human right of access to essential medicines and relating the obligations of states to fulfill this right in international human rights law to the obligations of states under WTO trade law.

The interaction of human rights with multilateral trade systems produces outcomes on three levels. First, WTO law and its interpretation has changed as a result of the negotiations by developing countries that used human rights law and norms to inform and strengthen their bargaining positions at the Doha Ministerial and the negotiations on Paragraph 6 of the Doha Declaration. Secondly, the projection of human rights law onto the issue of access to medicine influenced the behavior of states inside and outside the WTO. The behavioral change was critical both within the member-driven WTO system of negotiations and dispute settlement, and also among inter-state bargaining outside the WTO. Thirdly, the human rights system was able to achieve substantive outcomes outside the WTO with respect to the agreements of pharmaceutical companies to provide low-cost medicines to poor countries. Although this strategy produced normative and substantive changes in the WTO system, the ability of developing countries to balance their obligations to fulfill the right to medicine with obligations to provide patent protection is still hampered by the limited ability of the WTO to mediate interstate bargaining power within the international trade system, and competition between intellectual property and human rights norms. This paper concludes by considering the normative force of human rights in contesting policy space within and without the WTO to enable states to promote human rights generally.

## **II. CHARTING THE POLICY SPACE**

A critical divergence exists among the policy options available to states under the WTO agreements and the policy space of states in the real-world operation of the international trading system. Central to this analysis is the concept of *policy space*, which requires some clarification. The WTO and its constituent agreements create a broad range of policy constraints in the form of positive and negative obligations of states to refrain from or act upon various trade-related measures. These constraints considered together can be understood as defining the range of measures that may be legitimately implemented by each member. The sum of the measures in this range constitutes a *policy*

*space*. These obligations are assumed by assent to the WTO treaty, and are binding upon all states equally. All states have the right to enforce these obligations against other member-states through the dispute settlement mechanism.

The extent to which the enjoyment of rights and the burden of obligations under the WTO are experienced by members varies according to the respective ability of the state to defend or defy the discipline of its commitments. The defense or defiance of WTO discipline focuses on dispute settlement and the contestation of the policy space, yielding interpretations of the WTO agreements and rulings on the permissibility of certain policies. The WTO, however, while representing a robust rules-based system, does not wholly mediate inter-state bargaining, nor does it mitigate the unequal political and economic power of states. As the membership of the WTO includes some of the poorest and weakest states, as well as the strongest and most developed states in the world system, the capacities of each member to defend its rights or defy its obligations differ accordingly.

Thus, the practical policy constraints in the WTO are largely asymmetrical. Strong states continually seek to structure the policy options available to weak states through bilateral pressures outside the WTO, which alters the policy space of states in observable ways. The following Sections chart the policy space under the TRIPS agreement before the Doha Ministerial and reflect on how state behavior at the WTO materially affects the policy constraints experienced by states seeking to implement measures that increase access to medicines.

### **A. *The TRIPS Agreement***

The Agreement on Trade-Related Aspects of Intellectual Property Rights significantly constrains the policy options available to states in regulating the manufacture, trade, and distribution of essential medicines. Section 5 of TRIPS imposes an obligation on states to offer patent protection for any pharmaceutical product or process, regardless of where it was devised,<sup>1</sup> for twenty years.<sup>2</sup> Although TRIPS does not stipulate the criteria for patentability, little flexibility exists with respect to pharmaceuticals.<sup>3</sup> The rule against discrimination as to the field of technology precludes patent laws that discriminate as a matter of fact or law against certain kinds of pharmaceuticals,<sup>4</sup> unless they fall under the exception for diagnostic, therapeutic, surgical methods, or biological processes as non-patentable subjects.<sup>5</sup> States must also confer upon the owners of pharmaceutical patents the enjoyment of exclusive rights to make, use, or trade the drug.<sup>6</sup> Developed countries were obliged to offer these rights by 1996,

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<sup>1</sup> Agreement on Trade-Related Intellectual Property Rights, 15 Apr. 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C art. 27(1) [hereinafter TRIPS] in WORLD TRADE ORGANIZATION, THE LEGAL TEXTS, THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS 354 (1999)

<sup>2</sup> *Id.* Art. 34.

<sup>3</sup> Jayashree Watal, *Access to Essential Medicines in Developing Countries: Does the WTO TRIPS Agreement Hinder It?*, Science, Technology and Innovation Discussion Paper No. 8, CENTER FOR INTERNATIONAL DEVELOPMENT, HARVARD UNIVERSITY 107 (2000).

<sup>4</sup> Panel Report, *Canada – Patent Protection of Pharmaceutical Products (Generic Medicines)*, WT/DS114/R ¶ 7.94 (Mar. 17, 2000).

<sup>5</sup> TRIPS, *supra* note 1, Art. 27(3)(a), (b).

<sup>6</sup> *Id.* Art. 28(1)(a).

developing countries by 2000, and least-developed countries by 2005.<sup>7</sup> Over 40 Members did not offer patent protection to pharmaceuticals when TRIPS came into effect.<sup>8</sup>

Exclusionary patent protection is the core of the TRIPS agreement with respect to pharmaceuticals, however three categories of exceptions exist for non-exclusive use of patented drugs. Article 30 provides for a set of limited exceptions, Article 31 imposes conditions on compulsory licenses and parallel importation, and Article 32 governs the revocation of patents.<sup>9</sup>

Article 30 is available for exceptions to exclusive use that are (1) “limited”; (2) do not “unreasonably conflict with normal exploitation of the patent”, and; (3) do not “unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.”<sup>10</sup> The range of permissible policies available under these exceptions was considered in the Canadian Generic Medicines case<sup>11</sup> in which the WTO Dispute Panel held that testing a drug for the required regulatory period to enable generic manufacture upon patent expiration was permissible under TRIPS, but stockpiling for sale prior to expiration for immediate commercial exploitation was not. This finding upheld the so-called “Bolar exception” for regulatory testing, but did so in very parsimonious terms.<sup>12</sup> Other potential exceptions may include use for private and non-commercial purposes, prior users’ rights and use for research and experimental or teaching purposes.<sup>13</sup>

Article 31 sets out eleven conditions for the grant of compulsory licenses without the authorization of the patent holder, but not the grounds on which compulsory licenses may be granted.<sup>14</sup> Article 31(a) requires governments to consider each compulsory license on its merits. This requirement prevents the automatic licensing of generics—as was the practice under the former patent law of India<sup>15</sup>—but does allow countries broad discretion in determining what merits the grant of a compulsory license. Article 31(b) requires authorization to have been sought on reasonable commercial terms and in a reasonable period of time. This requirement may be waived in the case of a national emergency or under other circumstances of extreme urgency.<sup>16</sup> Article 31(c) limits the permissible scope and duration of licenses to the purpose for which it was authorized. Article 31(f) requires that the use of a compulsory license be predominantly for the supply of the domestic market in which it is granted. This requirement does not rule out exports, but limits the quantities of goods that may be exported. Article 31(h) requires adequate compensation be paid to the rights holder, taking into account the economic value of the authorization, while Article 31(j) provides for judicial review of that

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<sup>7</sup> Paragraph 7 of the *Declaration on TRIPS and Public Health*, WT/MIN(01)/DEC/2 (Nov. 20, 2000) extended the period for implementation by Least Developed Countries until January 1, 2016.

<sup>8</sup> WHO-WTO Joint Study, *WTO AGREEMENTS AND PUBLIC HEALTH* 42 (2002).

<sup>9</sup> TRIPS, *supra* note 1, Arts. 30, 31, 32.

<sup>10</sup> TRIPS, *supra* note 1, Art. 30.

<sup>11</sup> *Canada – Medicines*, *supra* note 4.

<sup>12</sup> Robert Howse, *The Canadian Generic Medicines Panel; A Dangerous Precedent in Dangerous Times*, 3 *J. WORLD INTELL. PROP.* 493, 495 (2002).

<sup>13</sup> Watal, *supra* note 3, at 109.

<sup>14</sup> TRIPS, *supra* note 1, Art.31.

<sup>15</sup> International Centre for Trade and Sustainable Development, *Indian Parliament Approves Controversial Patent Bill*, *BRIDGES* 9, 10 (Mar. 23, 2005).

<sup>16</sup> TRIPS, *supra* note 1, Art.31(b).

decision. These particular provisions *prima facie* allow significant latitude for compulsory licensing provided their conditions are satisfied, however, "... some of the crucial conditions are entirely dependent on the purposes for which use without authorization of the right holder are granted in the first place. This gives considerable leeway to policy makers in developing countries to construct the grounds such that the conditions do not become restrictions."<sup>17</sup>

This broad view would include the public interest as a legitimate ground, in terms of whether the market is being supplied, the price of the product, the qualifications of the licensee, and the reasonableness of the terms or sufficiency of local working of the patent. The ambiguity surrounding the legitimate grounds for compulsory licensing provided room for unilateral trade pressures from pharmaceutical exporting countries on those largely dependent on the importation of medicines. These pressures resulted in a more cautious use of Article 31 than would have been employed under a regime with explicit grounds sanctioning the use of compulsory licenses. Compulsory licensing then became the subject of extensive contestation, which climaxed in the 2001 Doha Ministerial Conference, as explored in detail in Part IV below.

Two other contentious provisions are found in Article 39.3, and Article 6. Article 39.3 requires the protection of undisclosed commercial information such as the data from pharmaceutical testing. This data can be used by generic manufacturers to obtain regulatory approval with re-testing. Article 6 precludes the issue of the exhaustion of intellectual property rights from dispute settlement, a critical provision in relation to the parallel importation of medicines patented in the exporting country without the authorization of the patent holder.

It must also be noted that a number of important policy instruments that can affect the affordability of medicines are not covered by the TRIPS agreement, including price controls and voluntary licensing. While the absence of regulation theoretically provides the freedom for such policies, measures are not afforded the protection of multilateral disciplines in practice and are left vulnerable to bilateral pressures.

## **B. *Policy Constraints in the International Trading System***

The discussion in Part II.A. *supra* has sought to establish that the TRIPS agreement, while not hostile to compulsory licensing and parallel importation, is significantly ambiguous in a number of key areas. This ambiguity, rather than providing leeway to developing countries to implement public health policies, has worked in the opposite direction, by allowing protectionist intellectual property norms to constrict policy options, as projected through unilateral pressures from states with established pharmaceutical industries.

The implementation and enforcement of TRIPS has been the subject of considerable pressure by the United States, through the WTO in the TRIPS Council and the Dispute Settlement Mechanism, and outside the WTO through monitoring of TRIPS compliance and unilateral trade pressures. Susan Sell argues that "... architects and beneficiaries of TRIPS seeking to preserve and extend their gains... have embarked on an aggressive strategy to close any existing loopholes, prosecute non-compliance, and to

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<sup>17</sup> Watal, *supra* note 3 at 112.

promote TRIPS-plus intellectual property standards outside the WTO in bilateral, regional and multilateral agreements.”<sup>18</sup>

Inside the WTO, the principal site of contest over the rights and obligations of patent protection in TRIPS has been the dispute settlement mechanism. Patents have been the subjects of eleven of the twenty-three disputes in the WTO concerning TRIPS.<sup>19</sup> The WTO Dispute Table,<sup>20</sup> appended to the end of this comment, lists the eleven disputes directly concerning patents notified to the WTO Dispute Settlement Board since the inception of the WTO.

Dispute settlement inherently favors stronger countries in the WTO. It is a resource-intensive process to commence and contest, and ultimately the enforcement of a finding of violation relies on the penalty of sanctions on trade. For a small trading nation, sanctions do not pose a credible threat. Table 1 shows that the United States has been the major defender of patent rights in the WTO, seven times as a complainant, and twice as a third party to a dispute. WTO dispute settlement is also a dynamic process, in which consultations are a prerequisite to adjudication and create the potential for linkage pressures.<sup>21</sup> Note is taken of the fact that during transitional periods developing countries were not obliged to implement TRIPS, when majority of disputes related to the implementation of Articles 70.8 and 70.9 as transitional provisions requiring mailbox application (a form of retrospective ‘pipeline’ patent protection) and exclusive marketing rights, a further dimension of policy constraint.<sup>22</sup> Additionally, within the WTO, the U.S. has used the TRIPS Council “as an opportunity to educate developing country members as to how these provisions must be implemented in their laws.”<sup>23</sup>

The autonomy of states to implement compulsory licensing or parallel importation has been tightly patrolled by a global system of surveillance of national intellectual property regimes established and operated by the International Intellectual Property Association (IIPA), which is closely linked with national trade retaliation measures. The IIPA is an association of over 1500 corporations whose key business assets are intellectual property and who together, are represented in every national jurisdiction in the world.<sup>24</sup> This network of members reports on intellectual property laws and their enforcement in each country to the central association. The central association then collates this information and makes submissions to national trade representatives, often accompanied by recommendations on trade action.<sup>25</sup>

Between the gaps of the multilateral trade system, states have used a variety of unilateral and bilateral trade pressures to promote the implementation and enforcement of intellectual property rights. In the case of the U.S., the chief measures have been Section 301 of the Trade and Omnibus Act of 1974 and the disciplinary Section 301 Watch Lists,

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<sup>18</sup> Susan Sell, *TRIPS and the Access to Medicines Campaign*, 20 WIS. INT’L L. J. 481, 481 (2002).

<sup>19</sup> Analysis of WTO Dispute Settlement Board tables, *available at* [www.worldtradelaw.net](http://www.worldtradelaw.net).

<sup>20</sup> *See* comment appendix by author.

<sup>21</sup> The Final Act, Annex 2, Understanding on Rules and Procedures Governing the Settlement of Disputes, Article 4(7).

<sup>22</sup> TRIPS, *supra* note 1, Arts. 70.8, 70.9.

<sup>23</sup> OFFICE OF THE U.S. TRADE REPRESENTATIVE, 1998 TRADE POLICY AGENDA AND 1997 ANNUAL REPORT OF THE PRESIDENT OF THE UNITED STATES ON THE TRADE AGREEMENTS PROGRAM 60 (1998).

<sup>24</sup> International Intellectual Property Alliance, About IIPA, *available at* <http://www.iipa.com/aboutiipa.html>.

<sup>25</sup> *Id.*

as well as the adjustment of preferential trading benefits under the Generalized System of Preferences.<sup>26</sup> E.H. Smith is quoted by Sell as saying that Section 301 “has done more than any other provision of U.S. trade law to improve the level of worldwide protection of U.S. products embodying copyright.”<sup>27</sup> GSP benefits act as a powerful incentive for compliance with U.S. pressures, as shown by the withdrawal of 50% of Argentina’s GSP benefits worth about \$260 million which prompted the National Congress of Argentina in 1999 to make amendments to establish the exclusivity of test data.<sup>28</sup>

In the case of the Thailand, the expiration in 1998 of safety monitoring periods and pipeline protection for U.S.-patented HIV anti-retroviral drugs (protection of which was granted under duress of U.S. trade pressure in the period 1992-1993) created the opportunity for compulsory licensing or parallel importing, upon approval by the Thai Pharmaceutical Patent Review Board.<sup>29</sup> The opportunity was, however, foreclosed by USTR threats of withdrawal of GSP benefits and sanctions on core Thai exports of wood products and jewelry, and which further forced the repeal of compulsory licensing laws and the disbanding of the review board.<sup>30</sup>

In 1997, South Africa boldly introduced a generic medicines scheme by amendment to Article 15(c) of the Medicines and Medical Devices Regulatory Authority Act to allow the revocation of patents, parallel importation and compulsory licensing of generic anti-retroviral drugs.<sup>31</sup> The constitutionality and TRIPS compliance of this legislation was immediately challenged by 39 local licensees of international pharmaceutical companies, despite the amendment being based on a draft legal text from WIPO’s Committee of Experts.<sup>32</sup> Enormous pressure was brought to bear by various U.S. state agencies, as all of South Africa’s GSP benefits were withdrawn and it found itself on the ignominious 301 Watch List.<sup>33</sup>

Free trade agreements and bilateral investment and intellectual property treaties have been another powerful form of securing compliance with the demands of developed countries for intellectual property protection, and considered further at the conclusion of Part IV, *infra*.

Lastly, the normative framework underlying the protection of intellectual property in the WTO has been pronounced and pervasive in justifying strong state pressures for implementation and enforcement of intellectual property rights. Two main norms infuse the debate. The first is the importance of intellectual property protection to securing the revenues needed for research into new medicines. This norm was at the forefront of the developed countries negotiating position leading up to and during the Doha Ministerial conference, as discussed in Part IV, *infra*. This contest of norms is grounded in the

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<sup>26</sup> Susan Sell, *Intellectual Property as a Trade Issue: From the Paris Convention to the GATT*, 13 LEGAL STUD. F. 407, 415 (1989).

<sup>27</sup> Sell, *supra* note 18 at 493.

<sup>28</sup> Wendy S. Vincentre, *Questionable Victory for Coerced Argentine Pharmaceutical Patent Legislation*, 19 U. PA. J. INT’L ECON. L. 1101, 1108 (1998).

<sup>29</sup> Médecins Sans Frontières, *Access to HIV/AIDS Medicines in Thailand*, MSF REPORT TO THE NATIONAL AIDS COMMITTEE OF THAILAND (Aug. 1, 1999).

<sup>30</sup> *Id.*

<sup>31</sup> South Africa, Medicines and Medical Devices Regulatory Authority Act, Art. 15(c).

<sup>32</sup> Sell, *supra* note 18 at 501.

<sup>33</sup> See generally Patrick Bond, *Globalisation, Pharmaceutical Pricing and South African Health Policy: Managing Confrontation with U.S. Firms and Politicians*, 29 INT’L J. HEALTH SERVICES 768 (1999).

transnational sectoral competition between research-based pharmaceutical companies, based mainly in the developed world, whose marginal costs include large research components, and the generic pharmaceutical industries, based mainly in large developing countries such as India, Brazil, Mexico, Argentina, China, and South Africa. The second norm is the equation of breaches of intellectual property with piracy or theft of legitimate property rights, and which reinforces the status of intellectual property as a normative property right. It would be these norms that became the subject of contestation by alternative conceptions of knowledge embodied in intellectual property as relevant to human rights.

### **III. A HUMAN-RIGHTS-CENTERED APPROACH TO INTELLECTUAL PROPERTY**

With the formation of the WTO and the coming into force of TRIPS, the restrictive dimensions of the policy space facing developing countries became progressively apparent. In response, there arose a campaign for affordable access to medicines that developed a human rights-centered approach to intellectual property protection in the WTO that could challenge the primacy of intellectual property norms, and so leverage greater policy autonomy for developing countries. This movement drew together a broad coalition of actors who variously developed analytical frameworks that elaborated the specific content of the human right of access to medicines, and the responsibility of governments in international law to fulfill that right. The elucidation and elevation of this human right enabled linkage to intellectual property protection in the WTO. Prior to 1996, the right to health and the responsibility of governments for public health, though indisputably recognized as a human right, was undeveloped and lacked normative and legal shape. Part III of this paper reviews the movement which fleshed out a right to access essential medicines and pitched it against intellectual property interests and their state sponsors in the forum of the TRIPS Agreement. This movement produced two distinct conceptions of the relationship between intellectual property rights and human rights that variously affected norm-creation and the substantive outcomes of the process. One set of norms emphasized the primacy of human rights when in conflict with intellectual property rights as trade rules. A second set of norms sought to reconcile competition between rights, emphasizing the importance of mutual balancing of rights and state obligations. Different actors and agendas emphasized these alternately, but together, they contributed to the accretion of soft law and norms, which supported the developing country members' efforts to negotiate revisions of TRIPS in the WTO, as discussed in Part IV, *infra*.

As this paper reviews a timeline of the agency of particular strategic actors in developing and operationalizing the right to medicines, it describes a snowballing effect in terms of identifying, publicizing, and particularizing the issue of access to medicines, and casting it as a human rights approach to intellectual property norms. The struggles of developing countries as outlined in Part II, *supra*, began the ball rolling. Health-based NGOs started to mobilize against U.S. trade policy and the transnational pharmaceutical industry, attacking the norms which underpinned intellectual property rights, and proposing new frames through which to view the issue. In turn, NGOs interacted with developing country policy makers and UN human rights agencies, while health and trade experts and academics developed further theoretical frameworks to explore the issue. The progression is not simply linear, but described an accumulation of activities; a loose

process of norm-creation and diffusion. An element of strategy attributable to various actors is evident in this process, found in the coordination of NGOs in the Campaign for Access to Medicines and the agenda set by the UN Sub-Commission on Human Rights. The process and objectives of these strategies were essentially the development and application of human rights to effect change in the policy constraints to effective action on public health crises. Human rights as a normative force in this case was directed against the states and industries that constructed, defended and extended the policy constraints created by the TRIPS Agreement and its normative framework.

**A. *The Right to Health and the Right to Medicines***

Article 25.1 of the Universal Declaration of Human Rights affirms that “Everyone has the right to a standard of living adequate for the health of himself and of his family, including food, clothing, housing and medical care and necessary social services.”<sup>34</sup> This declaration was incorporated into a legally binding obligation for state parties to the International Covenant on Economic, Social and Cultural Rights (ICESCR) at Article 12, which recognizes;

1. The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.
2. The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for:  
...  
(c) prevention, treatment and control of epidemic, endemic, occupational and other diseases;  
(d) creation of conditions which would assure to all medical service and medical attention in the event of sickness.<sup>35</sup>

Article 2 of ICESCR further exhorts governments “to take steps... to the maximum available resources, with a view to achieving the progressive realization of the rights,” including those recognized in Article 12.<sup>36</sup> Over 100 countries have incorporated the right to health into their national constitutions.<sup>37</sup>

Despite the clear status of the right to health as a human right, it received limited analysis and little elaboration in respect of the right of access to medicines within UN human rights agencies prior the mid-1990s. The World Health Organization (WHO), established in 1948, has been the main intergovernmental organization for discussions of international health policies, including medicines policy, but the exploration of accessibility of patented medicines under the TRIPS agreement did not surface in the WHO until 1996.<sup>38</sup> In view of later actions in the WHO by countries with intellectual property interests (discussed below), this may be due to the efforts of developed countries

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<sup>34</sup> Universal Declaration on Human Rights (UDHR) Art. 25.1.

<sup>35</sup> International Covenant on Economic, Social, and Cultural Rights (ICESCR) Art. 12.

<sup>36</sup> *Id.* Art. 2.

<sup>37</sup> Hans Hogerzeil, *Is Access to Essential Medicines as Part of the Fulfilment of the Right to Health Enforceable Through the Courts?*, 368 LANCET 305, 311 (2006).

<sup>38</sup> Based on the author’s analysis of WHA and WHO resolutions and reports.

to keep the issue of patent protection off the WHO agenda by using their leverage as major donors to the organization.

### **B. *The Role of NGOs and the Campaign for Access to Medicines***

A broad NGO movement on access to medicines is identified by Sell as effectively coordinating and conducting a campaign against TRIPS and U.S. trade policy by animating a human rights approach to intellectual property rights.<sup>39</sup> This campaign was critically important in influencing U.S. trade policy, public opinion, and motivating action within WHO and eventually UN human rights bodies. In Sell's review of the campaign, the catalyzing actor was the U.S.-based, Consumer Project on Technology (CPTech), led by James Love and former presidential candidate Ralph Nader, who mobilized in response to the slavish promotion of pharmaceutical industry interests by U.S. trade policy.<sup>40</sup> In 1996, the framework of an NGO coalition was created at a joint meeting with Health Action International (HAI), a global NGO focused on rational medicine use and access.<sup>41</sup> Médecins Sans Frontières (MSF) would join in November 1998, creating their own Neglected Diseases Group of experts, along with Oxfam International in 1999 and an increasing array of other trade and health based NGOs.<sup>42</sup> The activities and activism of this nascent network were first galvanized by the negotiations for 'TRIPS-plus' provisions in the Free Trade Area of Americas Agreement and the U.S. pressures on South Africa and Thailand's plans to manufacture generic medicines under compulsory licenses in the period 1997-1999. In the case of South Africa, Sell discusses the role of activists in thwarting the complicity of the then-Vice President, Al Gore in escalating U.S. trade pressure to pander for campaign financing from PhRMA for the 2000 presidential elections, until public campaign interruptions of activists from 'ACT UP' NGOs and the prospect of the African-American vote saw him critically change his allegiances, and terminate U.S. trade pressures.<sup>43</sup>

### **C. *The World Health Organization***

The World Health Organization, under its mandate of realizing the highest attainable state of human health, became the first inter-governmental forum for contestation on the issue of access to drugs under WTO agreements. The first consideration of the WTO at the World Health Assembly (WHA) was found in the 1996 Resolution 49.14.2(1), which requested that the Director-General report on the impact of the work of the WTO with respect to national drug policies and essential drugs and make recommendations for collaboration between WTO and WHO, as appropriate.<sup>44</sup> In 1998, the WHO released the report requested in the 1996 Resolution, which *inter alia*, provided members with recommendations on the implementation of TRIPS to mitigate negative

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<sup>39</sup> Sell, *supra* note 18 at 498.

<sup>40</sup> Sell, *supra* note 18 at 499-504.

<sup>41</sup> *Id.*

<sup>42</sup> *Id.*

<sup>43</sup> *Id.*

<sup>44</sup> Resolution on Revised Drug Strategy, Forty-ninth World Health Assembly, W.H.A. Res. 49.14 ¶ 2(1) (1996).

effects of patent protection.<sup>45</sup> The U.S. and EC tried unsuccessfully to suppress this publication.<sup>46</sup> Further momentum gained by the NGO campaign spilled into the World Health Assembly of 1998. Sell argues that HAI and CPTech were instrumental in influencing developing country representatives<sup>47</sup> during the drafting of the WHO's 'Revised Drug Strategy' relating to the essential medicine lists, which recognized "the impact of relevant international agreements, including trade agreements, on local manufacturing capacity and on access to and prices of pharmaceuticals in developing and least developed countries."<sup>48</sup> The rotating absence of the U.S. from the Executive Board in 1998 led to this resolution being adopted, however an attempt to confer to WHO a role in monitoring international trade agreements however, was strongly opposed by the U.S. who threatened to withdraw WHO funding.<sup>49</sup> In May of 1999, at the 52<sup>nd</sup> WHA, the Revised Drug Strategy was adopted, urging members "to ensure that public health interests are paramount in pharmaceutical and health policies" and to "review their options under relevant international agreements, including trade agreements, to safeguard access to essential drugs."<sup>50</sup>

During this process, the NGO network had consolidated its organization, and continued to push the agenda along under the banner of the Campaign for Access to Essential Medicines, boosted by the donation by MSF of the \$1 million prize money from the Nobel Prize it won in October of 1999 through its Neglected Diseases Fund.<sup>51</sup> It further pushed the agenda by distributing an open letter to all WTO states on 8 November 1999<sup>52</sup> and promulgating the Amsterdam Statement, arising from a campaign conference, both which called on states to recognize the WHA resolution and consider TRIPS flexibilities at the Seattle WTO Ministerial Conference commencing on 30 November 1999.<sup>53</sup>

#### **D. *U.S. Antipathy Short-Circuited***

It was amidst the hurly-burly of the Seattle Ministerial Conference that U.S. President Bill Clinton announced a change in tack of U.S. trade policy. With U.S. based NGOs publicizing the objects of U.S. trade policy on TRIPS and aligning public opinion against TRIPS enforcement, Clinton declared U.S. support for sub-Saharan African countries' access to HIV/AIDS drugs and on May 10, 2000 issued Executive Order

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<sup>45</sup> Germán Velásquez & Pascale Boulet, *Globalization and Access to Drugs: Implications of the WTO/TRIPS Agreement* (rev. ed. 1999), WHO Doc. WHO/DAP/98.9 at 16.

<sup>46</sup> Paul Benkimoun, *Agressions et Menaces Centre un Responsable de l'OMS Défenseur de l'Access du Tiersmonde aux Medicaments*, LE MONDE, Aug. 23, 2001.

<sup>47</sup> Sell, *supra* note 18 at 504.

<sup>48</sup> REPORT BY THE CHAIRMAN OF THE AD HOC WORKING GROUP, WHO EXECUTIVE BOARD, REVISED DRUG STRATEGY, EB103/4 ¶ 9 (Nov. 25, 1998) available at <http://www.cptech.org/ip/health/who/rds-report.html>.

<sup>49</sup> Médecins Sans Frontières, *supra* note 17.

<sup>50</sup> Resolution on the Revised Drug Strategy, Fifty-second World Health Assembly, WHA52.19 ¶ 1(3) (May 24, 1999).

<sup>51</sup> Doctors Without Borders, Press Release (Dec. 9, 1999) available at [http://www.doctorswithoutborders.org/pr/1999/12-09-1999\\_1.cfm](http://www.doctorswithoutborders.org/pr/1999/12-09-1999_1.cfm).

<sup>52</sup> Open Letter to WTO Member States on TRIPS and Access to Health Care Technology, Médecins Sans Frontières, available at [http://www.wto.org/english/forums\\_e/ngo\\_e/posp9\\_e.htm](http://www.wto.org/english/forums_e/ngo_e/posp9_e.htm).

<sup>53</sup> Text of Open Letter to WTO Member States, *ibid.*, available at <http://www.cptech.org/ip/health/wto-99-signon.txt>.

13155 prohibiting any § 301 trade pressure on TRIPS standards in intellectual property laws in Africa.<sup>54</sup>

The activation of public opinion through the reframing of intellectual property protection as an issue of human need and rights was central to the brake on the long-standing championship of the U.S. government for U.S. intellectual property interests. Nominal U.S. support was now apparent, and the cumulative effect of these activities began to manifest in the UN human rights system, which responded by clarifying and consolidating the core rights that underpinned the campaign for access to medicines.

### **E. *UN Human Rights Bodies***

There had been some activity in the UN outside of the WHO on the issue of access to essential drugs before 2000, especially in UN development agencies, such as UNCTAD and UNDP who had noted in various reports the potential tensions with TRIPS.<sup>55</sup> The Joint UNAIDS Program was instituted in 1996 to take over from the decade-old WHO Global Strategy Against AIDS. In May of 2000, the UNAIDS Program concluded the ‘Accelerating Access Initiative’ with the largest pharmaceutical companies to lower prices of HIV/AIDS drugs by up to 80%, and in some case freely donate drugs.<sup>56</sup> NGOs and other commentators skeptically received the Accelerating Access Initiative as a pre-emptive attempt by drug companies to avoid compulsory licenses being issued against the same drugs.

The Committee on Economic, Social and Cultural Rights (CESCR), as the authoritative interpreter of the ICESCR, issued its first General Comment on Implementation of the Right to Health on May 11, 2000. The CESCR interpreted the right to health as not the right to be healthy, but the “right to the enjoyment of a variety of facilities, goods, services and conditions necessary for the realization of the highest attainable standard of health.”<sup>57</sup> This was declared a “core obligation”<sup>58</sup> which includes the availability, accessibility and quality of essential drugs, as defined by the WHO Action Programme on Essential Drugs. Economic accessibility, i.e. affordability, is identified as an essential element of the right to health.<sup>59</sup> The right to prevention, treatment and control of diseases includes “individual and joint efforts to, *inter alia*, make available relevant technologies.”<sup>60</sup> Violations of the obligation to fulfill these rights may occur by omission of State Parties to adopt measures that ensure the right to enjoy health, including the distribution of health goods, such as drugs.<sup>61</sup> This General Comment provided a detailed elaboration on the content of the right to access medicines as a component right to that of the enjoyment of health.

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<sup>54</sup> President of the United States, Executive Order 13155, May 10, 2000.

<sup>55</sup> *See generally*, United Nations Conference on Trade and Development, *The TRIPs Agreement and Developing Countries*, New York and Geneva, U.N. Doc. UNCTAD/ITE/1 (1996); United Nations Development Programme, *Human Development Report 1999* (Oxford U. Press 1999).

<sup>56</sup> International Federation of Pharmaceutical Manufacturers, Accelerating Access Initiative Fact Sheet, available at [http://www.ifpma.org/site\\_docs/Health/AAI\\_Factsheet\\_Jan\\_07\\_Q3\\_2006.pdf](http://www.ifpma.org/site_docs/Health/AAI_Factsheet_Jan_07_Q3_2006.pdf).

<sup>57</sup> U.N. CESCR, 22d Sess., General Comment 14, *The Right to the Highest Attainable Standard of Health*, ¶¶ 9, 17, U.N. Doc. E/C.12/2000/4 (May 11, 2000).

<sup>58</sup> *Id.* ¶¶ 43(d), 44(c).

<sup>59</sup> *Id.* ¶ 12(b).

<sup>60</sup> *Id.* ¶ 16.

<sup>61</sup> *Id.* ¶ 52.

This was soon followed by Resolution 2000/7 in the UN Sub-Commission on Human Rights, which was adopted without a vote on August 17, 2000.<sup>62</sup> The resolution took TRIPS head-on, setting out a wide-ranging agenda for action by UN agencies, and *inter alia*;

- Noted that actual or potential conflicts exist between TRIPS and realization of economic, social and cultural rights, including “restrictions on access to patented pharmaceuticals and the implications for the enjoyment of the right to health”;<sup>63</sup>
- Reminded all Governments of the primacy of human rights obligations over economic policies and agreements, and requested them to integrate into their legislation and policies, provisions, in accordance with international human rights obligations and principles, that protect the social function of intellectual property;<sup>64</sup>
- Called upon the WTO, and particularly the Council on TRIPS during its ongoing review of the TRIPS Agreement, to take fully into account the existing State obligations under international human rights instruments;<sup>65</sup>
- Asked the Office of the UN High Commissioner of Human Rights to undertake an analysis of the human rights impacts of the TRIPS agreement;<sup>66</sup>
- Asked WIPO, WHO, UNDP, UNCTAD, UNEP and other UN agencies to ‘deepen their analysis of the TRIPS agreement’;<sup>67</sup>
- Asked its UN Special Rapporteurs on ‘Globalization and its impact on the full enjoyment of human rights’ to include consideration of the human rights impact of the implementation of the TRIPS Agreement in their next report;<sup>68</sup>
- Noted the Human Development Reports in 1999 and 2000 which had identified circumstances attributable to the implementation of the TRIPS Agreement which contravened international human rights law, and the WIPO-UN High Commissioner of Human Rights Panel Discussion of 9 November 1998 on the subject of Intellectual property and human rights;<sup>69</sup>
- Encouraged CESCR to clarify the relationship between intellectual property rights and human rights by drafting a general comment;<sup>70</sup> and
- Asked the UN Secretary-General to provide a report on this question at the Sub-Commission's next session in August 2001.<sup>71</sup>

The effect of this Resolution was to shake all the limbs of the UN human rights system into action on the issue of TRIPS, while consolidating the body of norms that had accumulated in the WHO, UNDP and CESCR amongst others. Responses included;

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<sup>62</sup> U.N. Sub. Comm’n Hum. Rts., 25th Sess., Res. 2000/7, *Intellectual Property and Human Rights*, U.N. Doc. E/CN.4/Sub.2/RES/2000/7 (Aug. 17, 2000).

<sup>63</sup> *Id.*, preamble, para. 2.

<sup>64</sup> *Id.* ¶ 5.

<sup>65</sup> *Id.* ¶ 8.

<sup>66</sup> *Id.* ¶ 10.

<sup>67</sup> *Id.* ¶ 12.

<sup>68</sup> *Id.* ¶ 9.

<sup>69</sup> *Id.* preamble.

<sup>70</sup> *Id.* ¶ 11.

<sup>71</sup> *Id.* ¶ 15.

- **19 August 2000** - a joint informal workshop held on by CESCR and the International NGO Committee on Human Rights in Trade and Investment which dealt, in part, with intellectual property and human rights, focusing particularly on the TRIPS Agreement;
- **13-14 December 2000** – Further discussions in the 24<sup>th</sup> session of CESCR, resulting in a Statement on Human rights and intellectual property, which then formed the basis for General Comment No. 17 on Article 15.1(c) of ICESCR<sup>72</sup>;
- **20 April 2001** – Commission on Human Rights resolution 2001/3 on the ‘Access to medication in the context of pandemics’,<sup>73</sup> sponsored by Brazil and unanimously adopted, which called on states to use full measures to combat AIDS in accordance with international agreements;
- **31 March 2001** – A second, more strongly worded edition of WHO’s *Globalisation, TRIPS and Access to Pharmaceuticals*, which refers to the Sub-Commission Resolution and CESCR General Comment and asserts “[a]ccess to essential drugs is a human right” which justifies full use of flexibilities in TRIPS;
- **14-22 May 2001** - 54<sup>th</sup> World Health Assembly Resolution WHA 10 ‘Scaling up the Response to HIV/AIDS’,<sup>74</sup> and the ‘WHO Medicines Strategy’,<sup>75</sup>;
- **14 June 2001** - UN Secretary General’s Report, which was composed of TRIPS-critical responses from Brazil, Pakistan, UNCTAD and NGOs and TRIPS-supportive responses from the WTO and other NGOs<sup>76</sup>;
- **27 June 2001** – UN General Assembly Special Session Declaration on HIV/AIDS, which though not legally binding, contained clear statements of commitments and deadlines, including discussion of policy options under TRIPS, and recognizing the importance of access to medicines<sup>77</sup>. The U.S. withdrew its WTO complaint regarding Brazil’s pharmaceutical laws on the day discussions began;
- **27 June 2001** - The Report of the High Commissioner of Human Rights, ‘The Impact of TRIPS Agreement on Human Rights’, which *inter alia* recommended;

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<sup>72</sup> U.N. CESCR, 24th Sess., 77th mtg., U.N. Doc. E/C.12/2000/SR.77 (Dec. 13, 2000); U.N. CESCR, 27th Sess., U.N. Doc. E/C.12/2001/15 (Dec. 14, 2001); U.N. C.E.S.C.R. 35<sup>th</sup> Sess., General Comment No. 17 (2005): *The Right of Everyone to Benefit from the Protection . . . (Article 15, Paragraph 1(c) of the Covenant)*, U.N. Doc. E/C.12/GC/17 (Jan. 12, 2006).

<sup>73</sup> Comm’n on Hum. Rts. Res. 2001/3, *Resolution on Access to Medication in the Context of Pandemics*, U.N. Doc. E/CN.4/RES/2001/33 (Apr. 20, 2001).

<sup>74</sup> W.H.A. Res. 54.10, World Health Assembly 54th Sess., *Scaling up the Response to HIV/AIDS* (May 22, 2001).

<sup>75</sup> W.H.A. Res. 54.11, World Health Assembly 54th Sess., *WHO Medicines Strategy* (May 22, 2001).

<sup>76</sup> The Secretary General, *Report of the Secretary General on Intellectual Property Rights and Human Rights, delivered to the Sub-Commission on the Promotion and Protection of Human Rights*, U.N. Doc. E/CN.4/Sub.2/2001/12 (June 14, 2001).

<sup>77</sup> G.A. Res. S-26, U.N. GAOR, 26th Special Sess., *Declaration of Commitment on HIV/AIDS*, U.N. Doc. A/RES/S-26/2 (Aug. 2, 2001).

- Respect for Article 15 of ICESCR so as to strike the private/public balance;<sup>78</sup>
- Promotion of public health in amending patent laws for pharmaceuticals;<sup>79</sup>
- Implement competition law to prevent abuse of intellectual property rights such as restrictive licensing or high prices;<sup>80</sup>
- Consider cultural rights of indigenous peoples and local communities;<sup>81</sup>
- National legislation to protect affordable access to drugs through use of compulsory licensing, parallel importation and regimes for international exhaustion of intellectual property rights;<sup>82</sup>
- International cooperation and technological transfer pursuant to Article 66(2) of TRIPS for supply of affordable drugs;<sup>83</sup>
- No TRIPS-plus agreements without considering impacts on human rights;<sup>84</sup>
- A recommendation to modify Article 7 of TRIPS to make express reference to human rights<sup>85</sup>;
- **15 January 2002** – Report of UN Special Rapporteur on Globalisation and the Impact on the Full Enjoyment of Human Rights.<sup>86</sup>

#### **F. *Normative Dimensions of the Right to Medicines***

Helfer categorizes this UN agenda as producing two schools of norms alternatively positing the conflict and the co-existence of human rights with intellectual property; the first emphasizing the primacy of human rights, the second the need for mutual balancing of obligations to TRIPS and human rights.<sup>87</sup> A further subset of the co-existence school emphasizes the need for reconciliation between the research objects of intellectual property protection and the relevance of Article 15.1(c) of ICESCR with other human rights, emphasizing their indivisibility.<sup>88</sup>

The first school is characterized by the UN Sub-commission resolution, which adopted an “antagonistic approach to TRIPS . . . stressing actual or potential conflicts” . . . motivated by the principle that human rights must be given “primacy over economic policies and agreements”.<sup>89</sup> The second approach identifies shared goals and attempts to

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<sup>78</sup> The High Commissioner, *Report of the High Commissioner of Human Rights on the Impact of TRIPS Agreement on Human Rights* ¶¶ 69-70, delivered to the Sub-Commission on the Promotion and Protection of Human Rights, U.N. Doc. E/CN.4/Sub.2/2001/13 ¶ 61 (27 June 27, 2001).

<sup>79</sup> *Id.* ¶ 63.

<sup>80</sup> *Id.* ¶ 64.

<sup>81</sup> *Id.* ¶ 65.

<sup>82</sup> *Id.* ¶ 66.

<sup>83</sup> *Id.* ¶ 67.

<sup>84</sup> *Id.* ¶ 69.

<sup>85</sup> *Id.* ¶ 68.

<sup>86</sup> Special Rapporteur, *Report of U.N. Special Rapporteur on Globalisation and the Impact on the Full Enjoyment of Human Rights, delivered to the Sub-Commission on the Promotion and Protection of Human Rights*, UN Doc. E/CN.4/sub.2/2001/10, (Jan. 15, 2002).

<sup>87</sup> Lawrence Helfer, *Human Rights and Intellectual Property Rights; Conflict or Co-existence?*, 5 MINN. INTELL. PROP. REV. (2003), page 47.

<sup>88</sup> *Id.*

<sup>89</sup> *Id.* at 55-56.

“articulate a human rights approach to TRIPS that reconciles states treaty obligations”<sup>90</sup> as a project of rational harmonization of internationally recognized rights, such as embodied by the Committee for Human Rights Resolution 2001/3.<sup>91</sup> Helfer argues that the conflict school pressed human rights bodies to develop specific interpretations of rights to compete with the clearly defined rules in TRIPS, encouraging the jurisprudential evolution of economic, social, and cultural rights. This paper builds on Helfer’s analysis and argues that the conflict approach was manifested in the activism of NGOs, CESCR, and the UN Sub-Commission on human rights, and influenced the initial negotiating position of developing countries seeking to confirm clear exceptions in TRIPS for public health policies. Furthermore, such conflict norms are strategically relevant in structuring the live issue of minimum-maximum intellectual property standards that arises in the context of TRIPS-plus bilateral agreements. Helfer speculates that “these objections may, for the first time, begin to impose a ceiling on the upward drift of intellectual property standards that has accelerated over the past few decades.”<sup>92</sup> Part V, of this paper will evaluate this conclusion in a review of recent developments. Ultimately, this paper finds that the co-existence approach was predominant in the negotiations at the Doha Ministerial Conference and the content of the Doha Declaration, as explored in Part IV, *infra*.

#### **IV. WINDOWS INTO THE WTO**

The central argument of this paper is that the elaboration of human rights in relation to an urgent policy crisis can be effective in influencing state behavior in multilateral trade negotiations, which in turn promote change in the normative and substantive content of WTO rules. The following section reviews the normative effect of the developments in Part III, *supra*, particularly the effect of the two sets of norms identified above, in the negotiations at the 2001 Doha Ministerial Conference.

##### **A. WHO-WTO Workshop**

The first window opened into the WTO came in the form of a WHO-WTO expert workshop on the pricing and financing of essential medicines in April of 2000, hosted by the Norwegian Foreign Affairs Ministry and organized by the Global Health Council, a U.S. health based-NGO, and joined by the secretariats of WTO and WHO.<sup>93</sup> The meeting was closed to the media, and the executive summary of discussions<sup>94</sup> did not directly refer to the effect of patent protection on prices under TRIPS, but did allude to the impacts on competition from generic medicines and the compatibility of differential pricing with TRIPS. One may suspect that the involvement of the WTO secretariat

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<sup>90</sup> *Id.*

<sup>91</sup> U.N. Sub. Comm’n on Human Rts., *supra* note 62.

<sup>92</sup> Helfer, *supra* note 87.

<sup>93</sup> World Trade Organization, Press Release 213, (May 15, 2001); World Health Organization, Press Release WHO/5 (May 18, 2001).

<sup>94</sup> GLOBAL HEALTH, EXECUTIVE SUMMARY OF REPORT ON WORKSHOP ON DIFFERENTIAL PRICING AND FINANCING OF ESSENTIAL DRUGS, *available at* <http://www.globalhealth.org/assets/pdf/ExecSumEnglish.pdf>; World Trade Organization, Press Release 220 (Apr. 11, 2001); World Health Organization, Press Release WHO/20 (11 Apr. 11, 2001).

inhibited the executive summary in this regard, while Abbott comments that; “[t]he WTO Secretariat has been less than entirely cooperative with the WHO on TRIPS matters. A portion of the WTO Secretariat resistance may be attributable to normal inter-institutional competition for jurisdictional primacy.”<sup>95</sup>

### **B. *Discussions in TRIPS Council***

Developing member-states, in particular the African Group,<sup>96</sup> are the most likely parties to force the matter of TRIPS flexibilities onto the WTO agenda. At the request of Boniface Chidyausiku, Chairman of the African Group on April 5, 2000, the TRIPS Council scheduled a special session for discussions on June 20, 2001.<sup>97</sup> The African Group led the negotiating bloc of developing countries on this issue, receiving briefings and technical assistance from the same NGOs at the heart of the Campaign for Access to Medicines, which enabled them to enter negotiations on this issue on an informed basis with strong common objectives. The African Group’s position paper prepared prior to discussions argued for full flexibility for public health measures under TRIPS, and emphasized the importance of the objectives and principles in Articles 7 and 8 in interpreting the broadest flexibilities for compulsory licensing and the importance of the international exhaustion of rights for the legitimating of parallel importation schemes.<sup>98</sup> Significantly, the African Group recognized the “careful attention” of intergovernmental organizations and civil society, citing MSF, CPTech and Oxfam on the issue,<sup>99</sup> affirmed the proper mandate of the WHO on public health issues, evidencing the flow on effects of the positive action in WHO on TRIPS in regards to access to medicines. The same paper cited the Commission on Human Rights 2001/33<sup>100</sup>, the 54<sup>th</sup> WHA Resolutions on *Scaling Up the Response to HIV/AIDS* and *WHO Medicines Strategy*,<sup>101</sup> the Secretary General’s Report<sup>102</sup> and the prospective UNGA Special Session on UNAIDS as the normative basis for their position.<sup>103</sup>

The European Communities and U.S. papers exhorted the need for balancing objectives in TRIPS, supporting compulsory licensing for epidemics, while insisting on the necessity of Article 31 safeguards, offering an alternative interpretation to enable parallel importation, but resisting any broadening of the limited exceptions in Article 30 and exclusivity of data protection in Article 39.3.<sup>104</sup>

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<sup>95</sup> Frederick Abbott, *Doha Declaration on the TRIPS Agreement and Public Health; Lighting a Dark Corner at the WTO*, 5 J. INT’L. ECO. L. 2, 475 (2002).

<sup>96</sup> The African Group, in addition to African nations, includes Barbados, Bolivia, Brazil, Dominican Republic, Ecuador, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka, Thailand and Venezuela.

<sup>97</sup> Ellen ‘t Hoen, *TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way From Seattle to Doha*, CHI. J. INT’L L. 38 (2002)

<sup>98</sup> World Trade Organization, Submission of the African Group on TRIPS and Public Health, IP/C/W/296 (a), (b), (c) (Jun. 29, 2001).

<sup>99</sup> *Id.* ¶ 14.

<sup>100</sup> *Id.* ¶ 9.

<sup>101</sup> *Id.* ¶¶ 10, 11.

<sup>102</sup> *Id.* ¶ 12.

<sup>103</sup> *Id.*

<sup>104</sup> World Trade Organization, Working Paper Submitted by the European Communities, IP/C/W/280 (Jun. 12, 2001).

At the first session in the TRIPS Council, developing countries presented individual country statements, all of which called for a Ministerial Declaration, the extension of implementation deadlines for developing and least-developed countries, a moratorium on dispute actions relating to public health, and hoisted the issue faced by countries without manufacturing capacities in using compulsory licenses for the import of generic medicines, an issue which would remained at the masthead of the debate leading up to and after the Doha Ministerial.<sup>105</sup> The U.S. and Switzerland defended the necessity of intellectual property protection for the development of new medicines. The developed countries, while accepting HIV/AIDS as a “national emergency” in the meaning of Article 31.1(b) and the suitability of compulsory licensing for public health, stood firm in other areas.<sup>106</sup> Ultimately, agreement that the issue should be the subject of a Ministerial Declaration at Doha was reached, with WTO Director-General Mike Moore commenting that the issue was “a deal-breaker” for Doha<sup>107</sup> and further discussions in the TRIPS Council were scheduled for later in the year. In the meantime, the U.S. position at the WTO was compromised by the U.S. government’s response to the anthrax attacks, which killed seven postal workers in the wake of the terrorist attacks of 9 November 2001.<sup>108</sup> The U.S. State Department threatened to issue compulsory licenses for the anti-anthrax antibiotic, Ciprofloxacin, in order to negotiate deep price cuts with the German patent holder, Bayer, with Canada immediately issuing compulsory licenses for generic manufacture of Cipro.<sup>109</sup> Abbott believes that the affair, “...illustrated the common-sense understanding lying at the heart of the developing country draft declaration... that no responsible government with a choice would place the public health of its citizens below the interests of a few patent holders.”<sup>110</sup>

The second session of discussions in the TRIPS Council were held from September 19 to 21 of 2001, and focused on the reconciliation of competing drafts of the Ministerial Declaration. The fundamental position of the African Group draft sought agreement that “nothing in the TRIPS Agreement shall prevent Members from taking measures to protect public health.”<sup>111</sup> The fourteen-point draft demanded freedom to allow parallel imports and to determine the grounds for issuing compulsory licenses, including medicines imported under compulsory license, abbreviated periods of test data exclusivity, a commitment from developed countries to refrain from imposing or

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<sup>105</sup> Statements of developing member-states reviewed included: Bolivia, Intervencion de la Delgacion de Bolivia, N. Propiedad intelectual y el acceso a los medicamentos, 21 de junio del afto 2001; Brazil, Council for TRIPS, TRIPS and Access to Medications, 20 June 2001; India, Statement of India at the TRIPS Council Meeting on 20 June 2001 on Public Health and Access to Medicines; Kenya, Statement of Kenya on the Impact of TRIPS Agreement on Public Health; Indonesia, Statement by the Indonesian Delegation, WTO-Council Meeting, Geneva 18-22 June 2001; Philippines, Statement of the Philippines; South Africa, Special Discussion on TRIPS and Public Health, 20 June 2001; Sri Lanka, Statement of Sri Lanka Delegation at TRIPS Council Meeting on 20 June 2001 on Public Health & Access to Medicines.

<sup>106</sup> World Trade Organization, News Item, June 20, 2001, *available at*

[http://www.wto.org/english/news\\_e/news01\\_e/trips\\_drugs\\_010620\\_e.htm](http://www.wto.org/english/news_e/news01_e/trips_drugs_010620_e.htm).

<sup>107</sup> David Banta, *Public Health Triumphs at WTO Conference*, 286 J. AM. MED. ASSOC. 21 (2001).

<sup>108</sup> Sell, *supra* note 18, at footnote 143.

<sup>109</sup> Kristen Jensen, *Thompson May Seek to Void Cipro Patent if Talks Fail*, BLOOMBERG NEWS SERVICE, Oct. 23, 2001, at 23.

<sup>110</sup> See Abbott, *supra* note 95 at 488.

<sup>111</sup> World Trade Organization, Draft Ministerial Declaration, Proposal by the Africa Group, IP/C/W/312, WT/GC/W/450 (Oct. 4, 2001).

threatening to impose sanctions within and without the WTO, restraint in WTO disputation over health measures, longer transition periods for developing countries, and continuous monitoring in the TRIPS Council.<sup>112</sup> The third and fourth paragraphs of the preamble clearly reflected the human rights approach to TRIPS reviewed in Part III, *supra*, emphasizing state obligations to

“... protect and promote the fundamental human rights to life and the enjoyment of the highest attainable standard of physical and mental health, including the prevention, treatment and control of epidemic, endemic, occupational and other diseases and the creation of conditions which would assure to all medical service and medical attention in the event of sickness, as affirmed in the International Covenant on Economic, Social and Cultural Rights...”<sup>113</sup>

The paper prepared by the developing countries was comprehensive, including a long preamble and a detailed list of provisions, reflecting their united and informed position.<sup>114</sup> It stood in stark contrast to the incomplete and reactive draft-reply of a group of developed countries.<sup>115</sup> This reply lacked any clarification provisions and contained only preambular language on the treatment of pandemics, as opposed to general public health grounds for compulsory licensing, emphasizing the importance of research and development financed by patent protection and the range of economic, social, and health policies necessary for the provision of access to essential medicines.<sup>116</sup> It was this divergence on the legitimate grounds for compulsory licenses that would prove the sticking point for negotiations and cause a divided draft to be forwarded on from these TRIPS Council discussions to the negotiations at Doha. The chair of the WTO General Council, Stuart Harbinson summarized these competing positions.<sup>117</sup> The developing countries draft at paragraph four read,

*[n]othing in the TRIPS Agreement shall prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement shall be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health, and in particular to ensure access to medicines for all. In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement which provide flexibility for this purpose.*<sup>118</sup>

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<sup>112</sup> *Id.*

<sup>113</sup> *Id.*

<sup>114</sup> World Trade Organization, Draft Ministerial Declaration, Proposal by the Africa Group, IP/C/W/312, WT/GC/W/450 (Oct. 4, 2001).

<sup>115</sup> World Trade Organization, Draft Ministerial Declaration, Proposal from a Group of Developed Countries, IP/C/W/313 (Oct. 4, 2001).

<sup>116</sup> *Id.*

<sup>117</sup> World Trade Organization, Draft Declaration on Intellectual Property and [Access to Medicines][Public Health], JOB(01)/155 (Oct. 27, 2001).

<sup>118</sup> 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, 39-40 (2002) (emphasis added).

Whereas the developed countries draft read,

[w]e affirm a Member's ability to use, to the full, the provisions in the TRIPS Agreement, *which provide flexibility to address public health crisis such as HIV/AIDS and other pandemics, and to that end, that a Member is able take measures necessary to address these public health crises, in particular to secure affordable access to medicines.* Further, we agree that this Declaration does not add to or diminish the rights and obligations of Members provided in the TRIPS Agreement. With a view to facilitating of this flexibility by providing greater certainty, we agree on the following clarifications . . . .<sup>119</sup>

The developed countries strategy of seeking to limit TRIPS flexibilities only for use against epidemics was rehashed in the subsequent negotiations on the implementation of Paragraph 6 of the Doha Declaration,<sup>120</sup> however the consensus on the particular necessity of policy autonomy to take measures to secure affordable access to medicines represents the measure of success of human rights norms in influencing state behavior at the WTO. That success was translated into WTO law.

### **C. *The Doha Declaration on TRIPS and Public Health***

At the Fourth WTO Ministerial Conference, held in Doha from November 9 to 13, 2001, in which negotiations continued, and were reportedly resolved by a closed session between U.S. and Brazil negotiators.<sup>121</sup> The Declaration was confirmed by consensus on November 14, 2001, along with a comprehensive Ministerial Declaration that contained statements on registration of geographical indications.<sup>122</sup> The declaration also included a future review in the TRIPS Council of the patent protection of plant varieties and non-patentability of biological processes under Article 27.3(b), and the relationship of TRIPS to the Convention on Biological Diversity and the protection of traditional knowledge and folklore, all of which have potential human rights dimensions.<sup>123</sup> Although that declaration only provided a mandate for review of these issues and no binding course of action, their very appearance owes much to similar process of norm generation as those described here. In the course of negotiations, developing countries received technical assistance from the key NGOs from the campaign, all of whom attended Doha for the Conference.<sup>124</sup>

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<sup>119</sup> *Id.* (emphasis added).

<sup>120</sup> See Part IV.E., *infra*.

<sup>121</sup> Abbott, *supra* note 95 at 488.

<sup>122</sup> World Trade Organization, Ministerial Declaration of 14 November 2001, ¶ 18, WT/MIN(01)/DEC/1 (Nov. 20, 2001).

<sup>123</sup> See Caroline Dommen, *Raising Human Rights Concerns in the WTO: Actors, Process and Possible Strategies*, HUM. RTS. Q., 24, 1-50 (2002); Helfer, *supra* note 87 at 47. See also David Weissbrodt & Kell Schoff, *Human Rights Approach to Intellectual Property Protection: The Genesis and Application of Sub-Commission Resolution 2000/7*, 5 MINN. INTELL. PROP. REV. 3 (2003).

<sup>124</sup> 647 NGOs attended the Doha Ministerial Conference; see NGO Information Page for Fourth Ministerial Conference, [http://www.wto.org/english/thewto\\_e/minist\\_e/min01\\_e/min01\\_ngo\\_e.htm](http://www.wto.org/english/thewto_e/minist_e/min01_e/min01_ngo_e.htm).

**D. Content of the Doha Declaration**

The final form of the Doha Declaration on TRIPS and Public Health<sup>125</sup> saw the concerns of the developing countries prevail. The language of the declaration was broad, and Paragraph 4, so contested in the TRIPS Council, ultimately reflected the developing countries main objective; that WTO members "... agree that the TRIPS agreement does not and should not prevent Members from taking measures to protect public health."<sup>126</sup> This objective was underpinned by the affirmation that the TRIPS agreement is "supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all."<sup>127</sup>

It has been the central thesis of this paper that the identification and elaboration of the right to health and the right to essential medicines was effective in influencing WTO law and norms. The structure of Paragraph 4 reflects both the general relevance and the specific application of the human right to health, while the first three preambular paragraphs also reflect the influence of the human rights centered approach outlined in Part III, *supra*. Paragraph 1 of the declaration recognizes the gravity of the public health problems of the developing world, a recognition that owes much to the activism of NGOs and UN agencies.<sup>128</sup> Paragraph 2 stresses the need for TRIPS to be part of the wider national and international action to address these problems, echoing the call of the UN Sub-Commission Resolution 2000/7 for inter-agency cooperation, the coordinated approach of the Joint UNAIDS Program, and the active role of the WHO.<sup>129</sup> Paragraph 3 reflects the approach of balancing norms of intellectual property protection for research, and the concerns about its effect on prices.<sup>130</sup> Abbott argues that Paragraph 3 is a "relatively weak way of acknowledging that patents have negative consequences in the form of higher prices, in the form of a "controversial juxtaposition" in which patents are "important" and high prices are only a "concern."<sup>131</sup>

Paragraph 5 is composed of four provisions which clarify the policy space available to Member states under TRIPS including; (a) the relevance of the purposes, objectives and principles for interpretation of the agreement in accordance with customary rules of interpretation; (b) the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted; (c) the right to determination of national emergencies or other circumstances of extreme urgency, with the understanding that public health crises, including epidemics can represent such circumstances; and (d) the non-challengeable discretion of Members to establish regimes for the exhaustion of intellectual property rights.<sup>132</sup> Paragraph 7 reaffirms developed countries' commitment to provide incentives for technology transfer and extends the

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<sup>125</sup> World Trade Organization, Ministerial Declaration on TRIPS and Public Health, WT/MIN(01)/DEC/2, (Nov. 20, 2001).

<sup>126</sup> *Id.* ¶ 4.

<sup>127</sup> World Trade Organization, Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2 ¶ 4 (Nov. 20, 2001).

<sup>128</sup> *Id.* at 1.

<sup>129</sup> *Id.* at 2.

<sup>130</sup> *Id.* at 3.

<sup>131</sup> Abbott, *supra* note 95 at 491.

<sup>132</sup> WTO, *supra* note 127 ¶ 5.

transitional period for implementing protection for patents and test data by least-developed countries to January 1, 2016.<sup>133</sup> Paragraph 6 refers the issue of WTO members with no or insufficient pharmaceutical manufacturing capacities in utilizing compulsory licensing to the TRIPS Council for resolution by 2002.<sup>134</sup> Truculence on the part of the U.S. ensured that this issue would not be resolved until August of 2003.<sup>135</sup>

**E. *Negotiations on Implementation of Paragraph 6 of the Doha Declaration***

Three core issues obstructing consensus emerged in the course of negotiations.

1. SCOPE OF DISEASES

Despite the fact that the scope of diseases was extensively discussed at Doha, and the consensus text rejected any limitations,<sup>136</sup> the U.S., Switzerland and Japan insisted that the availability of compulsory licenses for export be limited to set list of epidemics of infectious diseases, concerned to prevent the generic manufacture and export of lifestyle drugs such as Viagra.<sup>137</sup> By December 16, 2002, a broad consensus had emerged around the Motta text<sup>138</sup>, which was joined by Japan and Switzerland, but the U.S. maintained their objections and negotiations broke down. NGOs waded in once more with a flood of criticism,<sup>139</sup> and after an EU proposal to refer the decision over eligible diseases to the WHO did not float by August 23, 2003, U.S. recalcitrance became untenable, and agreement was reached over a broad definition of *pharmaceutical product*.<sup>140</sup>

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<sup>133</sup> *Id.* ¶ 7.

<sup>134</sup> *Id.* ¶ 6.

<sup>135</sup> See Part IV.E., *infra* (elaborating on this proposition).

<sup>136</sup> World Trade Organization, Paragraph 6 of the DOHA Declaration on the TRIPS Agreement and Public Health, Communication from the African, Caribbean and Pacific Group of States, IP/C/W/401 (May 28, 2003).

<sup>137</sup> OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, U.S. ANNOUNCES INTERIM PLAN TO HELP POOR COUNTRIES FIGHT HIV/AIDS AND OTHER HEALTH CRISES (2002) available at [http://www.ustr.gov/Document\\_Library/Press\\_Releases/2002/December/US\\_Announces\\_Interim\\_Plan\\_to\\_Help\\_Poor\\_Countries\\_fight\\_HIV-AIDS\\_other\\_Health\\_Crises.html?ht](http://www.ustr.gov/Document_Library/Press_Releases/2002/December/US_Announces_Interim_Plan_to_Help_Poor_Countries_fight_HIV-AIDS_other_Health_Crises.html?ht).

<sup>138</sup> The Motta text was named after Perez Motta, the chairman of TRIPS Council at the time, 16 December 2002.

<sup>139</sup> See, e.g., *id.*; Mary Moran, Médecins Sans Frontières, *Reneging on Doha: A MSF Analysis of Recent Attempts to Restrict Developing Countries Use of Compulsory Licensing to a Set List of Diseases* (May 13, 2003); Médecins Sans Frontières, Oxfam, HAI, TWN, CPT – Joint Press Release, *US Seeks Further Restrictions on Generic Medicines for DGC* (Aug 25, 2003); Médecins Sans Frontières Open Letter to Members of WTO (June 26, 2003); Letter from CPT, Oxfam, MSF, HAI to WTO Delegates Regarding December 16, 2002, Chairman’s Text for Solution to Paragraph 6 of Doha Declaration on TRIPS and Public Health (Dec. 19, 2002); CPT, MSF, Oxfam, TWN webpost, *NGOs: Say No to Poisonous Proposals on Paragraph 6*, available at <http://www.cptech.org/ip/wto/p6/ngos11252002.html> (Nov 25, 2002); Médecins Sans Frontières, Health GAP Sign on Letter to USTR Zoellick, available at [www.healthgap.org/press/press\\_releases.html](http://www.healthgap.org/press/press_releases.html).

<sup>140</sup> TRIPS Council, Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, WT/L/540, ¶ 1(a) (Sept. 2, 2003).

## 2. ELIGIBLE COUNTRIES

U.S. negotiating strategy sought to restrict the eligibility of members, primarily to avoid trade-diversion and price erosion in developed country markets. Initial proposals on the basis of income level and other pre-determined criteria were resisted by the developing negotiating bloc.<sup>141</sup> In the end, freedom to determine the sufficiency of manufacturing capacity for specific pharmaceutical products was left to the countries seeking imports. Specific labeling requirements and obligations on importing states to ensure that generic medicines were not re-exported were agreed upon to this end.

## 3. RELEVANT ARTICLES OF TRIPS AGREEMENTS

Paragraph 6 of the Doha Declaration did not specify the articles of TRIPS on which countries with little or no manufacturing capacities to issue compulsory licenses would rely. The limited exceptions in Article 30 and a waiver of Article 31(f) requirement of pre-dominant domestic supply were two candidates, however the U.S. and EU united in favor of Article 31(f) so that other Article 31 safeguards would remain as conditions for the grant of compulsory licenses, to which developing countries acceded.<sup>142</sup>

### **F. *Implementation of Paragraph 6 of the Doha Declaration***

Agreement on Paragraph 6 was reached on August 30, 2003. At the center of the decision was a waiver of Article 31(f), conditional on a satisfaction of a scheme of notifications and specifications by the importing and exporting countries. Paragraph 3 reiterates the requirement of Article 31(h) that the exporting country to pay adequate remuneration to the patent holder in that country, “taking into account the economic value to the importing Member.”<sup>143</sup> Guidelines on remuneration have been discussed at subsequent TRIPS Council meetings, however the extent to which this will affect prices is not yet known.<sup>144</sup> Participating Members are required to take measures to avoid trade diversion, while least-developed country members are exempt from notification requirements. Paragraph 11 tasks the TRIPS Council to convert the waiver into an amendment of the Agreement, but no consensus has yet been reached.<sup>145</sup>

This decision has been criticized by NGOs as being bureaucratic and vulnerable to delay, while Abbott argues that the generic pharmaceutical industry is accustomed to operating in a dense regulatory framework and that the scheme is workable. To date, no notifications to the WTO have been made,<sup>146</sup> but this does not necessarily mean that the availability of compulsory licensing has not been used as leverage against patent holders

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<sup>141</sup> Sun, *The Road to Doha and Beyond*, 15 EURO J. INT’L L. 1, 142 (2004).

<sup>142</sup> *Id.*

<sup>143</sup> TRIPS Council, *supra* note 142, ¶ 3.

<sup>144</sup> See TRIPS Council Annual Report, ¶ VIII, IP/C/32 (Dec. 8, 2004). Canada has adopted a sliding scale for calculation of royalties, based on the Human Development Index, ranging from 0.2% for the poorest countries and 4-5% for the richest countries.

<sup>145</sup> TRIPS Council Annual Report, ¶ VIII, IP/C/38 (Nov. 21, 2005).

<sup>146</sup> See WTO Notifications Website, Notifications by Importing WTO Members, [http://www.wto.org/english/tratop\\_e/trips\\_e/public\\_health\\_notif\\_import\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/public_health_notif_import_e.htm); Notifications by Exporting WTO Members, [http://www.wto.org/english/tratop\\_e/trips\\_e/public\\_health\\_notif\\_export\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/public_health_notif_export_e.htm).

for the grant of voluntary licensing.<sup>147</sup> To date, Canada, Korea, Norway, and Sweden have implemented domestic legislation enabling them to export under compulsory licensing, but no requests have yet been received.<sup>148</sup>

## V. CONCLUSIONS

The flexibilities confirmed by the Doha Declaration have not been subject to any disputes in the WTO, consistent with commitments to avoid litigating this issue. Developing countries have implemented in national law the legislative flexibility to take advantage of compulsory licensing and parallel importation, while a number of countries have resumed or instituted generic medicine based public health programs, to the salvation of thousands of victims of diseases, such as Brazil, India, and a number of sub-Saharan African countries.<sup>149</sup> For developing countries, however, transitional periods came to an end in January 2005, enlivening obligations to implement TRIPS across the board. A number of developing countries have applied for extensions, defied these obligations, or have fulfilled these obligations only on paper, with weak enforcement.<sup>150</sup>

In this regard, it is arguable that the WTO has been weakened as forum for the enforcement and expansion of intellectual property, but this situation has caused other fora to be re-opened for the projection of intellectual property interests by their sponsor states.

At the multilateral level, Abbott reports that substantive patent harmonization has been the subject of renewed negotiations at WIPO and that “[t]here is a fairly widely held perception that the U.S. and EU industry interest groups will attempt to achieve in WIPO what cannot be achieved at the WTO... These rules may be used as benchmarks by OECD patent offices, and effectively filter into developing country patent system.”<sup>151</sup>

Bilaterally, Drahos identifies a ‘global intellectual property ratchet’, operated by the U.S. and EU, which takes TRIPS as a floor, and seeks to raise the ceiling of standards through a strategy of Free Trade Agreements (FTA), Bilateral Investment and Intellectual Property Treaties (BIT/BIP), that coordinate bilateral and multilateral strategies through a process of forum shifting which incorporate TRIPS-plus provisions such as:

- Early implementation of TRIPS for developing and least developed countries;<sup>152</sup>
- Widening the standards for patentability, i.e. excluding 27.3(b) of TRIPS on non-patentability of biological processes, i.e. Article 16 of the U.S.-Jordan BIT;
- Limiting the grounds for grants of compulsory licenses to anti-competitive practices, public non-commercial use, national emergency and circumstances of

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<sup>147</sup> Hogerzeil, *supra* note 37 at 305-11.

<sup>148</sup> TRIPS Council Annual Reports, *supra* note 144.

<sup>149</sup> Report on the Workshop on the WTO Decision on Access to Medicines, organized by the Commonwealth and ACP Secretariat, IP/C/W/439 (Oct. 12-14, 2004).

<sup>150</sup> Pharmaceutical Research and Manufacturers of America, National Trade Estimate Report on Foreign Trade Barriers, Dec, 12, 2003.

<sup>151</sup> Abbott, *supra* note 95 at 433.

<sup>152</sup> U.S. Bilateral Investment Treaty Program: Fact Sheet, Released by the Office of Investment Affairs, Bureau of Economic and Business Affairs, Jan. 10, 2006, <http://www.state.gov/e/eb/rls/fs/2006/22422.htm>.

extreme urgency, failure to meet working requirements, which directly limit the flexibilities won at Doha;<sup>153</sup>

- Extensions of patent terms and test data exclusivity;
- Obligation to join intellectual property associations and ratify other multilateral conventions; and
- Non-exhaustion of international intellectual property rights, by way of remedy to patent holders, for example Article 16.7.2 of the U.S.-Singapore FTA.<sup>154</sup>

The Most-Favored Nation (MFN) principle is the mechanism by which this ratchet will work to continuously raise the bar of intellectual property protection, while the forum-shifting strategies of developed country states will proliferate the institutional and legal possibilities by which this will occur. In this view, the success of co-existence of norms of human rights and intellectual property in imposing a ceiling on global intellectual property standards, as suggested by Helfer, seems questionable. Drahos and Braithwaite propose that

Developing countries should consider forming a veto coalition against the further ratcheting up of intellectual property standards. The alliance between NGOS and developing countries on the access-to-medicines issue and the fact that this alliance has managed to obtain Special Sessions of the TRIPS Council on this issue suggests that this coalition is a realistic possibility. The position of such a veto coalition should be converting the Council for TRIPS from a body that secures a platform to one that polices a ceiling.<sup>155</sup>

This proposal presupposes the possibility of strengthening the WTO multilateral system and the TRIPS Agreement to mediate the inter-state bargaining over intellectual property. The mass subscription of the developing countries to the WTO was primarily motivated by the desire to avoid the arbitrariness of bilateralism, and by the promise of multilateralism whereby the strong seek to secure compliance from the weak, and the weak desire to discipline the strong. The proliferation of bilateral and regional free trade and investment agreements and widespread dissatisfaction with the slow progress of WTO negotiations, now suspended as of July 28, 2006, does not advance these prospects.

This paper has argued that a human-rights-centered approach to intellectual property can be successful in terms of constraining state behavior in the WTO, but the WTO is only one forum of international contestation over the ownership and use of knowledge. The main thesis of this paper in terms of the cumulative processes and power of human rights norms is not limited to the WTO or to intellectual property rights. The potential of NGO activism through promoting human rights and influencing state policy at a national level, the operation of the UN human rights system at an international level can together accumulate a body of influential norms and soft law which elaborate and

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<sup>153</sup> Drahos, *Expanding Intellectual Property's Empire: the Role of FTAs, Regulatory Institutions Network*, Research School of Social Sciences, AUSTRALIAN NATIONAL UNIVERSITY (Nov. 2003).

<sup>154</sup> Drahos, *BITS and BIPS; Bilateralism in Intellectual Property*, 4 J. WORLD INTELL. PROP. 791 (2001).

<sup>155</sup> DRAHOS & BRAITHWAITE, *INFORMATION FEUDALISM* 12 (2002).

relate state obligations to respect, promote, and fulfill human rights to other fields of state obligation. Whether these normative sets seek to prevail or co-exist with competing norms will depend on the dimensions of the issue at hand, but this conceptual approach to the interaction of international legal regimes offers much in terms of strategies to evaluate and relate competing rights and obligations to advance human rights in global governance generally.

## VI. APPENDIX: WTO DISPUTE TABLE

Dispute	Defendant	Complainant	Third Parties	TRIPS Article	Subject of complaint	Request consult	Agreement	Panel Report	App Body Report	DSB Adoption	Outcome
DS36	Pakistan	US		Art 27 Art 70.8	No patents for pharmaceutical products No mailbox for filing patents	30/4/96	07/03/97				Mailbox created
DS37	Portugal	US		Art 33	Patent term less than 20 years	30/04/96	08/10/06				Extend patent term to 20 years
DS50	India	US	EC	Art 27 Art 70.8 Art 70.9	No patents for pharmaceutical products No mailbox for filing patents No exclusive marketing rights after mailbox filing	02/07/96		05/09/97	19/12/97	16/01/98	Mailbox created Exclusive marketing rights granted on patent application
DS79	India	EC	US	Art 27 Art 70.8 Art 70.9	No patents for pharmaceutical products No mailbox for filing patents No exclusive marketing rights after mailbox filing	28/04/97		24/08/98		22/09/98	Mailbox created Exclusive marketing rights granted
DS114	Canada	EC	Australia Brazil, Colombia, Cuba, India, Israel, Japan, Poland, Switz', Thailand, US	Art 27.1 28(1)(a) Art 30	Non-exclusive patent rights Regulatory review exception Stockpiling for sale on patent expiration	19/12/97		17/03/00		(07/04/00 18/08/00 - arbitration report)	Regulatory review maintained Stockpiling exception scrapped
DS153	EC	Canada		Art 27.1	Patent extensions for drugs and agro chemicals only as discriminatory on basis of technology	02/12/98					Retaliatory complaint against DS114, not pursued
DS170	Canada	US		Art 33 Art 70.2	Patent term only 17 years for patents filed before 1989 TRIPS not applied to patents in force 01/01/96	06/05/99		05/05/00	18/09/00	12/10/00 (28/02/01 Arbitration report)	
DS171	Argentina	US		Art 31(k) Art 70.9 Art 28.1 28.1(b) Art 50 Art 27.3 Art 70.4 Art 39.3	Automatic compulsory licensing for anti-competitive use of patent No exclusive marketing rights Non-exclusive right of importation No product by process patent protection Lack of preliminary injunctions for patent infringement Non-patentability of micro-organisms No transitional patents Lack of protection of test data from unfair commercial use	06/05/99	20/06/02				- Agreement on judicial determination of anti-competitive practice - EMR's for patents filed after 01/01/95 or subject to patent or marketing approval in other WTO members - Legislative interpretation - Legislative amendment - Legislative amendment - Legislative interpretation - Legislative amendment
DS196	Argentina	US			Implementation of DS171	30/05/00	20/06/02				Finalisation of implementation of DS171 outcomes
DS199	Brazil	US	Dom Rep, Honduras, India, Japan	Art 28.1 Art 31	Local working requirement for patent exclusivity, failure to work grounds for compulsory licence	30/05/00	19/07/01				Agreement to consult, withdrawal of DS224
DS224	US	Brazil		Art 27 Art 28	Discriminatory aspects of US patent code	31/01/01					Withdrawn on agreement on DS199