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The Legal Status of the Doha Declaration on TRIPS and Public Health Under the Vienna Convention of the Law of Treaties

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I. INTRODUCTION

One of the most contentious issues before the World Trade Organization ("WTO") is the application of the Agreement on Trade-Related Aspects of Intellectual Property Rights ("the TRIPS Agreement", "TRIPS", or "the Agreement") to WTO members seeking to facilitate access to essential medicines. Members seek to use these medicines to combat ongoing epidemics such as HIV/AIDS or sudden threats such as the recent anthrax scares following the terrorist attacks on the United States on September 11, 2001.

Developing countries have argued that the TRIPS Agreement does not limit their sovereignty to address crises such as HIV/AIDS. They view compulsory and parallel licensing as permissible objectives that do not violate the TRIPS Agreement. Developed countries, particularly the United States and Switzerland, have argued that the only flexibility in the TRIPS Agreement is the staggered implementation periods developing countries enjoy under the Agreement. Under the staggered implementation schedule, developing countries have five years and least developed countries have ten years from January 1, 1996, to fully implement the Agreement.

The November 2001 Doha Declaration on TRIPS and Public Health ("the Doha Declaration") was in part necessitated by these divergent perspectives. The WTO's dispute settlement bodies have not directly addressed these divergent interpretations.[1] In addition, the legal effect of a unilateral interpretation of a treaty made by one of the contracting states is not binding upon other contracting states.[2] It is therefore useful to examine the extent to which the Doha Declaration resolves these divergent interpretations.

Under customary international law, treaty interpretation must be based on the text, context, object and purpose, and good faith. Where these methods do not result in a conclusive interpretation, supplementary bases of interpretation may be used. This Article argues that given the divergent interpretations of the TRIPS Agreement, the Doha Declaration should now be regarded as an interpretive element in the

1. WTO panel or appellate body reports "are not binding, except with respect to resolving the particular dispute between the parties to that dispute." WTO Appellate Body Report, *Japan–Taxes on Alcoholic Beverages*, WT/DS8/AB/R at 9 (Oct. 4, 1996). However, such reports could provide guidance to the WTO. *See* WTO Appellate Body Report, *United States–Tax Treatment For "Foreign Sales Corporations,"* WT/DS108/AB/R ¶ 115 at 31 (Feb. 24, 2000).

2. BARON ARNOLD DUNCAN MCNAIR, THE LAW OF TREATIES BY LORD MCNAIR 345–50 (1961).

interpretation of the TRIPS agreement under customary international law.

Part II outlines the rights of patent holders under the TRIPS Agreement and the challenges posed by the ongoing HIV/AIDS pandemic. Part III discusses the negotiations leading to the Doha Declaration. Part IV examines the extent to which the Doha Declaration can be construed as an element in the interpretation of the TRIPS Agreement.

II. PROTECTION OF PATENTS UNDER THE TRIPS AGREEMENT AND THE HIV/AIDS PANDEMIC

The TRIPS Agreement is a product of protracted negotiations at the Uruguay Round that ended in 1994. Like most General Agreement on Tariffs and Trade ("GATT") rules, the negotiations leading to its adoption were "long, unwieldy and exhausting . . . with substantive negotiations separated by several years."[3] The difficulty of amending GATT/WTO rules has resulted in an "additional complex of related instruments" whose legal status is uncertain.[4] The Doha Declaration was necessary in part due to the unwieldy legislative process surrounding the TRIPS Agreement.[5]

The TRIPS Agreement establishes patentability for product and process inventions in all fields of technology, provided they are new, involve an inventive step, and are capable of industrial application.[6] Patent rights must be available "without discrimination as to the place of invention, the field of technology or whether the products are imported or locally produced."[7] The Agreement also guarantees most favored nation treatment for intellectual property rights,[8] and requires members to "ensure that enforcement procedures...are available under their law so as to permit effective action against any act of infringe-

3. *See* Kenneth W. Abbot, *GATT as a Public Institution: The Uruguay Round and Beyond*, 18 BROOK. J. INT'L L. 31, 83 (1992).

4. JOHN H. JACKSON, RESTRUCTURING THE GATT SYSTEM 26–30 (1990).

5. As Abbot observes, "[t]his kind of legislative process cannot hope to keep pace with changes in practice and perception in the community at large, or to focus sufficient attention on the increasingly complex issues coming onto the international trade agenda." Abbott, *supra* note 3, at 83.

6. *See* Art. 27(1) of the Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, LEGAL INSTRUMENTS – RESULTS OF THE URUGUAY ROUND 33 I.L.M. 81, 108 (1994) [hereinafter TRIPS Agreement], *available at* http://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm.

7. Art. 27(1) of the TRIPS Agreement.

8. *See* Art. 4 (1) of the TRIPS Agreement provides that "[a]ny advantage, favour, privilege or immunity granted by a Member to the nationals of any other country shall be accorded immediately and unconditionally to the nationals of all other Members."

ment."[9] Members must ensure transparency by making their laws, regulations, judicial decisions, and administrative rulings available in a national language.[10] Disputes under the Agreement must be resolved through the WTO's Dispute Settlement Understanding.[11]

Under the earlier Paris Convention, each country was only obliged to extend intellectual property protection no worse than its own to its trading partners.[12] By requiring minimum levels of protection, the TRIPS Agreement therefore no longer allows countries to choose their level of intellectual property protection.

During the Uruguay negotiations on the TRIPS Agreement, a major goal of the United States, the European Union, Japan, Switzerland, and the Nordic countries was to establish a high level of intellectual property protection with a guarantee of enforcement.[13] Developing countries, particularly Brazil, argued that this position focused too much on the interests of owners of intellectual property rights and not enough on those of users. Brazil argued that the Agreement should reflect the needs of developing countries, such as access to technology.[14] During the Uruguay Round, the United States unilaterally pressured developing countries opposed to its negotiating position, such as Brazil, Thailand, and India, using the authority of the United States Trade Representative ("USTR") under super 301.[15] Therefore, the Agreement was negotiated within a coercive bargaining context, despite the fact that developing countries won some concessions in return for signing the TRIPS Agreement.[16]

The issue of access to essential medicines replays the original debate between developing and developed countries regarding the TRIPS Agreement. Developed countries continue to maintain that high levels of intellectual property protection provide the necessary incentive for investment in research and development, which is the best guarantee of access to essential medicines for all countries. In contrast, developing countries maintain that strict constructions of the TRIPS Agreement fail to recognize the legitimate interests of intellectual property rights users, especially in the context of crises such as HIV/AIDS.

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9. Art. 41(1). Under Articles 42 through 45, members must provide measures for the preservation of evidence, as well as preliminary and injunctive relief and civil damages.

10. *See* Art. 63(1) of the TRIPS Agreement.

11. *See* Art. 64 of the TRIPS Agreement.

12. *See* Paris Convention for the Protection of Industrial Property, Mar. 20, 1883, 21 U.S.T. 1583 (as revised on July 14, 1967 in Stockholm).

13. *See* THE GATT URUGUAY ROUND: A NEGOTIATING HISTORY (1986-1994), VOL. IV, PART I 478–79 (Terence P. Stewart, ed., 1999).

14. *See id.* at 481.

15. *See id.* at 495–514; *see also infra* note 114 and accompanying text.

16. *See* CHAKRAVARTHI RAGHAVAN, RECOLONIZATION: GATT, THE URUGUAY ROUND & THE THIRD WORLD 69–80 (1990).

Though HIV/AIDS is incurable, drugs have made it treatable. For example, in the United States, retroviral drug treatment has quadrupled the median survival time for Americans diagnosed with HIV/AIDS from one to four years.[17] However, HIV/AIDS remains an intractable problem, particularly in developing countries. In sub-Saharan Africa, over five million people have contracted the virus, half of them between the ages of fifteen and twenty-four. Close to one million of those infected are children. In the former Soviet Union, there are over one million people infected with HIV/AIDS. In 2001, an estimated 30,000 people in Western Europe and another 45,000 in North America became infected. The economic and social impact of the virus has been staggering, particularly in sub-Saharan Africa. Countries, inter-governmental institutions, and non-governmental groups have designed and implemented programs to deliver a variety of services to address this pandemic.[18]

Rather than presenting the TRIPS Agreement with new challenges, the HIV/AIDS pandemic re-created tensions between developing and developed countries already apparent at the Uruguay Round. The tensions surrounding the Agreement are not merely between developing and developed countries. Tension also exists regarding the definition of an intellectual property right. If it is conceived in abstract terms as an exclusive power that provides incentives to invest in research, this definition ignores the social context of these rights.[19] The Doha Declaration on TRIPS and Public Health seeks to resolve this tension.

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17. *See U.S. Study Finds AIDS Patients Surviving Longer*, CNN.COM, Mar. 14, 2001.

18. *See* Peter Piot, UNAIDS Executive Director, Testimony to the Hearing of the Committee on Foreign Relations of the United States Senate on Halting the Global Spread of HIV/AIDS: The Future of U.S. Bilateral and Multilateral Responses (Feb. 13, 2002), *at* http://www.unaids.org/whatsnew/speeches/eng/2002/PiotSenate_130202.html.

19. Joseph Singer argues that property law is highly protective of the prerogatives of owners, but it also recognizes that ownership may impose vulnerabilities on others and limits the rights of owners when their actions impinge on the legitimate interests of others. *See* JOSEPH SINGER, THE EDGES OF THE FIELD: LESSONS ON THE OBLIGATIONS OF OWNERSHIP 20 (2000). *See generally* JAMES BOYLE, SHAMANS, SOFTWARE AND SPLEENS: LAW AND THE CONSTRUCTION OF THE INFORMATION SOCIETY (1996); Samuel K. Murumba, *Globalizing Intellectual Property: Linkage and the Challenge of a Justice Constituency*, 19 U. PA. J. INT'L ECON. L. 435 (1998); Ruth G. Okediji, *Toward an International Fair Use Doctrine*, 39 COLUM. J. TRANSNAT'L L. 75 (2000); GREGORY ALEXANDER, COMMODITY & PROPRIETY: COMPETING VISIONS OF PROPERTY IN AMERICAN LEGAL THOUGHT 1776–1970 (1997).

III. NEGOTIATING THE DOHA DECLARATION

A. Events Leading to the Declaration

The TRIPS Council held a special session in June 2001 to discuss the interpretation of the TRIPS Agreement. The goal of this special session was to define the relationship between intellectual property rights and access to essential medicines under the Agreement. The goal of the Africa Group and other developing countries was to clarify the extent to which the TRIPS Agreement allows members to promote and protect public health and "other overarching public policy objectives."[20]

The Special TRIPS Council heard over forty statements during the meeting on June 20, 2001. The United States argued that a strong patent regime would produce benefits for all countries, while acknowledging the interests of developing countries in access to essential medicines. The European Community's ("E.C.") delegation welcomed the discussion as laying the ground for a fruitful process towards the Doha Ministerial conference. Developing countries continued to emphasize that restrictive interpretations of TRIPS would unduly limit their ability to address public health emergencies such as AIDS.[21]

The joint developing country paper endorsed by the Africa Group, the Association of South-East Asian Nations, Brazil, and others presented a common legal interpretation of the TRIPS Agreement. The immediate challenge facing these countries is the need to lay a legal basis for steps to address the HIV/AIDS pandemic without fear of violating the TRIPS Agreement. This need for legal security is particularly urgent for countries of the Southern Africa region, where HIV/AIDS infection rates are near thirty percent of their populations. South Africa argued that challenges to its public health legislation by pharmaceutical companies necessitated legal certainty on the scope of the TRIPS Agreement.

By contrast, the United States adopted the position that the TRIPS Agreement strikes a balance between incentives for innovation and access to essential medicines. According to the United States, the developing countries were mistaken to argue that Articles 7 and 8 of the TRIPS Agreement are the backdrop against which the rest of the provisions of the Agreement should be read. Instead, the United States argued that the TRIPS Agreement accommodated developing coun-

20 *TRIPS and Public Health*, submission of the Africa Group and other developing countries to the Special TRIPS Council Meeting of June 2001, ¶ 5, *at* http://www.twnside.org.sg/title/twr131e.htm.

21. *See* Cecilia Oh, *Developing Countries Call for Action on TRIPS at Doha WTO Ministerial Conference*, *at* http://www.twnside.org.sg/title/twr131d.htm.

tries by allowing them longer transition periods for compliance. The United States also argued that compulsory licensing under Article 31 should be read together with Article 27.1, which would prevent member countries from taking steps to protect public health and to ensure their citizens' access to essential medicines.

In a follow-up informal meeting of the TRIPS Council on July 25, 2001, the United States and Switzerland declared that they would not endorse any proposal at the WTO Ministerial Conference in Doha that affirmed that the TRIPS Agreement permits countries to take measures to ensure access to essential medicines.[22] Developing countries, led by the Africa Group, proposed six elements to be included in a declaration to be issued at the Doha meeting:

> (1) the use of Articles 7 and 8 in the interpretation of all provisions in the TRIPS Agreement; (2) the right of countries to determine the grounds on which compulsory licences may be issued; (3) recognition of compulsory licences issued to a foreign manufacturer; (4) the right to parallel import; (5) a moratorium on all dispute actions aimed at preventing or limiting access to medicines or protection of public health; and (6) extension of transition periods for developing and least developed countries.[23]

The United States objected to a separate declaration, arguing that developing and least developed countries had not proven that the TRIPS Agreement limited access to essential medicines.

The United States, E.C., and Switzerland further objected to any discussions at the TRIPS Council of a moratorium on filing dispute settlement actions. They argued that only the General Council had the necessary mandate to discuss this "'political' issue."[24] At a General Council meeting on July 26, 2001, the United States sought to limit any link between TRIPS and public health to AIDS.[25] The United States also argued at the June 2001 TRIPS Council meeting that serious health problems like HIV/AIDS needed a "comprehensive approach," including medical infrastructure, doctors, nurses, and initiatives by multilateral institutions such as the World Health Organization.[26] Developing countries replied that the TRIPS Council did not

22. *See* Cecilia Oh, *US Opposed to Moves to Address Public-Health Concerns About TRIPS*, *at* http://www.twnside.org.sg/title/twr131f.htm.

23. *Id.*

24. *Id.*

25. *See id.*

26. *The Africa Group's Proposals*, *at* http://www.twnside.org.sg/title/twr131g.htm.

have the mandate to consider domestic responses to AIDS or other public health issues.[27]

When the TRIPS Council met on September 19, 2001, it discussed two drafts of a proposed ministerial declaration. The developing country draft[28] asserted that the TRIPS Agreement does not prevent members from taking measures to protect public health. Thus TRIPS does not remove a member's sovereign power to address public health emergencies within its own borders. The developed country draft argued that the most effective strategy for addressing public health emergencies is a combination of economic, social and health policies.[29] These policies require a strong patent regime to encourage the development of new drugs.

Notwithstanding these divergent positions, a Declaration on TRIPS and Public Health was issued by a consensus of all WTO members at the Doha Ministerial meeting in Qatar in November 2001. The Declaration provides in part:

> We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all.[30]

The Declaration acknowledges that HIV/AIDS, tuberculosis, malaria, and other epidemics are grave public health problems afflicting developing countries. It also reaffirms "the right of the WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose."[31]

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27. *See id.*

28. The group of developing countries included the African Group, Bangladesh, Barbados, Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, Haiti, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka, Thailand, and Venezuela. Draft Ministerial Declaration, *Proposal from a Group of Developing Countries*, IP/C/W/312 (Oct. 4, 2001), *available at* http://www.wto.org/english/ tratop_e/trips_e/mindecdraft_w312_e.htm.

29. The group of developed countries included Australia, Canada, Japan, Switzerland, and the United States. *See* Draft Ministerial Declaration, *Proposal from a Group of Developed Countries*, IP/C/W/313 (Oct. 4, 2001), *available at* http://www.wto.org/english/tratop_e/trips_e/mindecdraft_w313_e.htm.

30. Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/Dec/2 ¶ 4 (Nov. 14, 2001) [hereinafter Doha Declaration], *available at* http://www.wto.org/ english/thewto_e/minist_e/min01_e/mindecl_trips_e.pdf.

31. *Id.*

IV. THE LEGAL STATUS OF THE DOHA DECLARATION

The Doha Declaration was necessary because interpretation of TRIPS based on the text, context, object and purpose, and good faith did not settle divergent interpretations. My analysis of the legal status of the Doha Declaration under international law discloses at least three possibilities:

(1) As a subsequent agreement under Article 31 § 3(a) of the Vienna Convention on the Law of Treaties regarding the interpretation of the TRIPS agreement.[32]

(2) As evidence of subsequent practice establishing the understanding of WTO members regarding interpretation of the TRIPS Agreement.[33]

(3) As a declaration of commitment and intent that does not constitute an enforceable legal obligation.

A treaty should be interpreted in good faith using the ordinary meaning of its terms in context and in light of the treaty's object and purpose.[34] Text, context, object and purpose, and good faith are used "as one holistic rule of interpretation rather than a sequence of separate tests to be applied in a hierarchical order."[35] Article 3.2 of the WTO's Dispute Settlement Understanding incorporates this rule by requiring the dispute settlement panels to clarify WTO provisions "in accordance with customary rules of interpretation of public international law."[36] Only where application of this rule results in ambiguity can supplementary means of interpretation be used. Subsequent agreements and practice are recognized supplementary means of treaty interpretation under customary international law.[37]

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32. *See* Vienna Convention on the Law of Treaties, May 23, 1969, art. 31, § 3(a), 8 I.L.M. 679, 691–92 [hereinafter Vienna Convention].

33. *See* Vienna Convention art. 31, § 3(b) at 692.

34. Vienna Convention art. 31, § 1 at 691–92; *see also* Territorial Dispute (Libyan Arab Jamahiriya/Chad), 1994 I.C.J. 6, 21–2 (Feb. 3); Oil Platforms (Islamic Republic of Iran v United States of America), 1996 I.C.J. 803, 812 (Dec. 12).

35. World Trade Organization Report of the Panel, *United States–Sections 301-310 of the Trade Act of 1974*, WT/DS152/R ¶ 7.22 (Dec. 22, 1999).

36. Art. 3(2) of the Understanding on Rules and Procedures Governing the Settlement of Disputes, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 2, LEGAL INSTRUMENTS — RESULTS OF THE URUGUAY ROUND vol. 31, 33 I.L.M. 112, 115 (1994). The Appellate Body has noted that it does "not consider that Article 3.2 of the DSU is meant to encourage either panels or the Appellate Body to 'make law' by clarifying existing provisions of WTO Agreement outside the context of resolving a particular dispute." WTO Appellate Body Report, *United States–Shirts and Blouses*, WT/DS33/AB/R at 14 (May 23, 1997).

37. The International Court of Justice has recently treated Article 31 of the Vienna Convention as customary international law. *See* Kasikili/Sedudu Island (Botswana/Namibia), 1999 WL 1693057 ¶ 18 (Dec. 13). Neither Botswana nor Namibia

A. The Doha Declaration as a Subsequent Agreement Under Article 31 § 3(a) of the Vienna Convention on the Law of Treaties

Article 31 § 3(a) of the Vienna Convention on the Law of Treaties states that "any subsequent agreement between the parties regarding the interpretation of the treaty or the application of its provisions" shall be considered together with its context in the interpretation of a treaty.[38] The International Law Commission has stated: "an agreement as to the interpretation of a provision reached after the conclusion of the treaty represents an authentic interpretation by the parties which must be read into the treaty for purposes of its interpretation."[39]

Article 31 § 3(a) is useful to establish the intent of the parties to a treaty where the text, context, object and purpose, and good faith are incapable of resolving ambiguities.[40] Subsequent agreements reflect the intent of the parties and can be used to interpret the actual terms of the treaty.[41] Under recent WTO Appellate Body jurisprudence, there is precedent for giving a subsequent agreement between parties to a WTO treaty the same legal status as the WTO treaty.[42]

As described in Part III, the Doha Declaration was negotiated over several months by all members of the WTO initially through the TRIPS Council, which in turn made recommendations to the General Council. The General Council then reported to the Ministerial Conference at Doha, which issued the Doha Declaration. The Ministerial Conference has "the authority to take on decisions on all matters under any of the Multilateral Trade Agreements."[43] The Doha Declaration emerged from the WTO decision-making framework and was issued by the Ministerial Conference at Doha. This is consistent with

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were parties to the Vienna Convention but both of them considered Article 31 applicable "inasmuch as it reflects customary international law." *Id.* at ¶ 18. Similarly and directly relevant, a WTO panel has also held that Article 31 has "attained the status of rules of customary international law." *United States–Sections 301-310 of the Trade Act of 1974*, *supra* note 33, at ¶ 7.21.

38. Vienna Convention, art. 31, § 3(a) at 692.

39. Corfu Channel (Merits), 1949 I.C.J. 4, 25 (Apr. 9); Certain Expenses of the United Nations (Article 17, Paragraph 2 of the Charter), 1962 I.C.J. 151, 157, 160–61, 172–75; Territorial Dispute (Libyan Arab Jamahiriya/Chad), *supra* note 34, at 34–37.

40. Vienna Convention, *supra* note 36 and accompanying text.

41. Section 27 of Vice-President Weeramantry's dissenting opinion in Kasikili/Sedudu Island, *supra* note 37. The Appellate Body decision in *Japanese Alcohol* could be construed as an attempt to frame the disputed article as an agreement between the parties relating to the treaty, and thus part of the context rather than of the treaty. 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: TOWARDS A COMMON LAW OF INTERNATIONAL TRADE 59 (J.H.H. Weiler ed., 2000).

42. *Japan–Taxes on Alcoholic Beverages*, *supra* note 1, at 24; *see also* Howse, *supra* note 41.

43. Art. IV(1) of the Agreement Establishing the World Trade Organization.

the WTO's established practice of decision-making by consensus.[44] The various bodies of the WTO that negotiated the Doha Declaration possessed institutional competence, and therefore the Declaration was the result of the lawful process of negotiation and agreement that characterizes the GATT/WTO.

Declarations negotiated through the legislative process of the GATT/WTO have been used to interpret substantive provisions of GATT/WTO treaties. Paragraph 16 of the *Singapore Ministerial Declaration*, which summarized the 1996 Report of the Committee on the Trade and the Environment,[45] was issued at the conclusion of the 1996 WTO Ministerial Meeting in Singapore. The Appellate Body used the Report in its *Shrimp-Turtle* decision to support its findings, referring in particular to the Report's emphasis on "multilateral solutions."[46] This indicates that the Appellate Body viewed the Report as a relevant interpretive tool.

1. The Declaration Proposes a Balancing Approach to Interpretation of the TRIPS Agreement

The Doha Declaration captures the middle ground between the positions adopted by developing and developed countries. It embodies commitment to patent protection for the development of new drugs and to availability of these drugs for indigent populations. The third paragraph in the preamble to the Doha Declaration declares that "[w]e recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices."[47] The fourth paragraph of the Declaration fortifies this middle ground by affirming that the "TRIPS Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all."[48] This language cast in terms of members' rights to protect public health introduces an interpretation not expressly provided in the TRIPS Agreement. Hence these rights are not expressly derived from the TRIPS Agreement, but are exercis-

44. Art. IX(1) of the Agreement Establishing the World Trade Organization, 1994. Art. IX(2) provides that the "Ministerial Conference and the General Council shall have the exclusive authority to adopt interpretations of ...[WTO] Agreements." It further provides that interpretations of WTO Agreements such as TRIPS would be made on the recommendation of the Council overseeing the implementation of that Agreement.

45. Committee on Trade and the Environment, Report (1996) of the Committee on Trade and Environment, WT/CTE/1 (November 12, 1996).

46. WTO Appellate Body Report, *United States–Import Prohibition of Certain Shrimp and Shrimp Products*, WT/DS58/AB/R at 50 (Oct. 12, 1998).

47. Doha Declaration ¶ 3.

48. Doha Declaration ¶ 4.

able in light of contemporary international concern regarding the HIV/AIDS pandemic, as discussed below.[49]

The second part of the fourth paragraph further provides that in "this connection, we affirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose."[50] This statement is consistent with Appellate Body jurisprudence construing exceptions to WTO commitments. The balancing test embodied in the Doha Declaration was embraced by the Appellate Body in *United States–Shrimp Products*.[51] In interpreting the chapeau of GATT's Article XX, the Appellate Body held that "the measures falling within the particular exceptions must be applied reasonably, with due regard to both parties...concerned."[52] In *Hormones*, this balancing approach was adopted by the Appellate Body to reverse a Panel decision on the burden of proof with regard to exceptions.[53] The Appellate Body held that "merely characterizing a treaty provision as an 'exception' does not by itself justify a 'stricter' or 'narrower' interpretation of that provision than would be warranted by examination of the ordinary meaning of the actual treaty words, viewed in context and in light of the treaty's object and purpose."[54] The Doha Declaration borrows its balancing approach from the jurisprudence on exceptions that has emerged from other WTO Agreements.

The chapeau of paragraph 5 of the Doha Declaration embraces this balancing approach because the members recognize a number of flexibilities contained therein "while maintaining [their] commitments in the TRIPS Agreement." These flexibilities include: reading each provision of the TRIPS Agreement in light of the object and purpose as expressed in its objectives and principles;[55] the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted;[56] the right to determine what constitutes a national emergency or other circumstances of extreme urgency;[57] the freedom to establish their regimes of exhaustion without

49. *See infra* note 62 and accompanying text.

50. *Id.*

51. *United States–Import Prohibition of Certain Shrimp and Shrimp Products*, *supra* note 46, at 42.

52. *Id.*, quoting WTO Appellate Body Report, *United States–Gasoline*, WT/DS2/AB/R at 22 (May 20, 1996).

53. WTO Appellate Body Report, *EC Measures Concerning Meat and Meat Products (Hormones)*, WT/DS26/AB/R at 28 (Jan. 16, 1998). Notably, the Doha Declaration also shifts the burden on those countries that challenge another country's action taken to address the HIV/AIDS pandemic in accordance with the Doha Declaration.

54. *Id.*

55. Doha Declaration ¶ 5(a).

56. Doha Declaration ¶ 5(b).

57. Doha Declaration ¶ 5(c).

challenge but subject to the MFN and national treatment provisions;[58] and extension of compliance periods for least developed countries.[59]

2. Interpreting Specific Provisions of the TRIPS Agreement

The chapeau of Paragraph 5 presupposes that the four flexibilities exist simultaneously with the rights and responsibilities embodied in the TRIPS Agreement. Previous decisions have read the analogous chapeau to Article XX of GATT to restrict exceptions to GATT.[60] Recently, however, the Appellate Body has held that the object and purpose of such a chapeau is to prevent abuse of the exceptions rather than to restrict them.[61] Hence, to that extent, Paragraph 5 fortifies the availability of the exceptions listed there to members pursuing public health goals in the context of pandemics like AIDS. Furthermore, the Appellate Body's dicta in *United States–Shrimp Products* supports reading the TRIPS Agreement "in light of contemporary concerns of the community of nations" when dealing with AIDS and similar health pandemics such as tuberculosis and malaria.[62]

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58. Doha Declaration ¶ 5(d).

59. Doha Declaration ¶ 7.

60. *See, e.g., Thailand–Restrictions on Importation of and Internal Taxes on Cigarettes*, Report of the Panel (1990) 37 B.I.S.D. 200, *available at* http://www.cptech.org/ip/health/country/gatt-thai.html.

61. *See United States–Import Prohibition of Certain Shrimp and Shrimp Products*, *supra* note 46, at 33. Further, the Appellate Body has held that given two plausible interpretations of the obligations of a member, the less onerous or constraining obligation should be adopted. *See EC Measures Concerning Meat and Meat Products (Hormones)*, *supra* note 53 at ¶ 165.

62. *United States – Import Prohibition of Certain Shrimp and Shrimp Products*, *supra* note 46, at 36. The Appellate Body referred to the protection and conservation of the environment as contemporary concerns of the international community that must be taken into account in interpreting the chapeau of Article XX of GATT. Furthermore, Sir Gerald Fitzmaurice has argued that:

> It is difficult to deny that the meaning of a treaty, or some part of it (particularly in the case of certain kinds of treaties and conventions), may undergo a process of change or development in the course of time. Where this occurs, it is the practice of the parties in relation to the treaty that effects, and indeed *is* that change or development.

GERALD FITZMAURICE, 1 THE LAW AND PROCEDURE OF THE INTERNATIONAL COURT OF JUSTICE 359 (1986). However, the recent Appellate Body Report of the WTO in *Shrimp II* indicates that an international consensus such as the one on preserving turtles as exhaustive resources can be used to legitimize unilateral sanctions. *See* B.S. Chimni, *WTO and Environment: Legitimisation of Unilateral Trade Santions*, ECON. & POL. WKLY., Jan. 12, 2002, at 133–39.

3. Interpreting the TRIPS Agreement in Light of Its Objectives and Principles

The Doha Declaration supports reading all the provisions of the TRIPS Agreement in light of Articles 7 and 8.[63] This reading is further supported by the Appellate Body's reference to Articles 7 and 8 in *Canada – Term of Patent Protection*, even though neither party specifically referred to these articles in establishing the panel and its jurisdiction. The Appellate Body noted that its ruling did not in any way prejudge "the applicability of Article 7 or Article 8 of the TRIPS Agreement in possible future cases with respect to measures to promote the policy objectives of the WTO members that are set out in those Articles. Those Articles still await appropriate interpretation...."[64]

This reading presupposes that the TRIPS Agreement balances patent protection with access to pharmaceutical products in the context of WTO members facing public health emergencies. Access to pharmaceutical products, however, is only one possible basis for such an interpretation. Other bases could arguably include technology transfers, preventing restraints of trade by patent owners, and linking

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63. Articles 7 and 8 are, respectively, the objectives and principles clauses of the TRIPS Agreement. Article 7 notes that:

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

TRIPS Agreement, *supra* note 6, at art. 7. Article 8(1) provides that:

> Members may, in formulating their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this agreement.

TRIPS Agreement, *supra* note 6, at art. 8. Article 8(2) provides that:

> Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

Id.

64. WTO Appellate Body Report, *Canada – Term of Patent Protection*, AB-2000-7, WT/DS170/AB/R, at ¶ 101 (Sept. 18, 2000). This observation is consistent with *Patent Protection for Pharmaceutical and Agricultural Products*, where the Appellate Body noted that if a party does not introduce a claim in its terms of reference, the claim cannot be adjudicated. *See* WTO Appellate Body Report, *Patent Protection for Pharmaceutical and Agricultural Products*, WT/DS50/AB/R, at ¶¶ 86, 88, 90, 92 and 96 (Dec. 19, 1997).

working requirements to the grant of patent rights under Article 8(2) of the TRIPS Agreement.[65]

Interpreting the TRIPS Agreement in light of its principles and objectives does not dictate any particular legal outcome. For example, Articles 7 and 8 do not determine the balance between protection of patent rights under Article 27.1 and the right to compulsory licensing in pursuit of a public health program:

> [W]hen one is dealing with the object and purpose of a treaty, which is the most important part of the treaty's context, the object and purpose does not constitute an element independent of that context. The object and purpose is not to be considered in isolation from the terms of the treaty; it is intrinsic to its text. It follows that, under Article 31 of the Vienna Convention, a treaty's object and purpose is to be used only to clarify the text, not to provide independent sources of meaning that contradict the clear text.[66]

What the Doha Declaration, however, does as a matter of law is not insignificant.[67] It mandates reading the TRIPS Agreement in light of its objectives and principles, thereby giving countries a legal basis in the Agreement itself to argue in favor of public policies. For example, in the Arbitration Proceedings pursuant to *Canada – Patent Protection of Pharmaceutical Products (Generic Medicines)*,[68] Canada argued that that it should have more time to comply with the repeal of the stockpiling provisions in its Patent Act because of the political sensitivity of reversing its "long standing policy of providing relatively low cost medication to consumers as soon as possible."[69] The Panel decision had required Canada to repeal statutory provisions that

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65. The United States filed, but later withdrew, a WTO complaint against Brazil asserting that the working requirement in Brazilian law was illegal under TRIPS. *See* Peter Capella, *Brazil Wins HIV Drug Concession From US: Complaint to WTO on Patent Law Withdrawn*, THE GUARDIAN, June 26, 2001, at 18.

66. United States v. Iran, No. 130-A28-FT, ¶ 58 (Iran-U.S. Cl. Trib. Rep. 2000). In the TRIPs context, see Abbott Frederick M., *The TRIPS Agreement, Access to Medicines and the WTO Ministerial Declaration*, 5 J. WORLD INTELL. PROP. 15 (2002).

67. *See* HENRY G. SCHERMERS, INTERNATIONAL INSTITUTIONAL LAW 610–12 (2d ed. 1980). Schermers discusses the legal effect of United Nations decisions, arguing that a decision does not have different legal effects when it is expressed as a 'declaration' rather than a 'resolution'.

68. Report of the Panel, *Canada — Patent Protection of Pharmaceutical Products*, WT/DS114/R (Mar. 17, 2000)

69. Robert L. Howse, *The Canadian Generic Medicines Panel – A Dangerous Precedent in Dangerous Times*, 3 J. WORLD. INTELL. PROP. 495 (July 2000).

allowed generic drug manufacturers to stockpile patent products prior to the expiration of their patent term in readiness for marketing upon the expiration of the patents. If the Panel had read this provision in light of the TRIPS Agreement's objectives and principles, it might have found in favor of Canada. Indeed, as Robert Howse has observed, the panel implausibly found the stockpiling provisions inconsistent with the TRIPS agreement while upholding the rights of competing generic manufacturers to test patented products prior to the expiration of the period of protection.[70] The Doha Declaration's exhortation that each provision of the TRIPS agreement be read in light of the object and purpose as expressed in its objectives and principles is therefore not inutile for countries in Canada's position. Similarly, the United States[71] was pursuing public health security goals when it considered, but did not invoke, domestic legislation to override Cipro patents during the anthrax scare.[72] The consideration of these goals by a developed country in the context of anthrax lends legitimacy to other countries' consideration of similar goals in the context of public health emergencies such as AIDS.[73] In this context, therefore, the Declaration would preclude interpreting the obligations of the TRIPS Agreement solely from the perspective of how the government's policies curtail right holders' interests and would permit consideration of

70. *See id.* at 498.

71. In the United States, compulsory licensing is not subject to exceptions as those that encumber it in Article 31 of TRIPS. The U.S. government does not have to seek a license or negotiate for use of a patent or copyright. Any federal employee can use or authorize the use of a patent or a copyright under 28 U.S.C § 1498(a). The right owner is entitled to compensation, but cannot enjoin the government or a third party authorized by the government to prevent use. Use by any contractor, subcontractor, person, firm, or corporation who receives authorization from the federal government to use patents or copyrights is construed as use by the federal government, and cannot be sued for infringement. Compensation is not based on lost profits or royalties, but rather on reasonable royalty or, as one court has put it, since compensation is based on eminent domain, the proper measure is "what the owner has lost, not what the taker has gained." Leesona Corp. v United States, 599 F.2d. 958, 969 (Ct. Cl. 1979). This section explicitly provides that it shall not have extra-territorial effect.

72. *See* Paul Zielbauer, *A Nation Challenged: The Latest Case; Connecticut Woman, 94, Is Fifth From Inhalation Anthrax*, N.Y. TIMES, Nov. 22, 2001, at A1; Timothy J. Burger, *Feds Push Bayer to Boost Cipro Stockpile*, DAILY NEWS (New York), Oct. 20, 2001, at 8; Geoff Dyer, et al., *Canada Climbs Down on Anthrax Drug*, FIN. TIMES, Oct. 24, 2001, at 4. The Bush administration has been criticized for failing to invoke its authority to override the Cipro patent to facilitate stockpiling and affordable access. The government instead decided to negotiate a price cut. *See* Russell Mokhiber & Robert Weissman, *The Cipro Rip-Off and the Public Health* (Nov. 8, 2001), *at* http://www.counterpunch.org/mokhiber3.html.

73. According to the Executive-Director of UNAIDS, twenty million of the sixty million people infected with HIV/AIDS in the first ten years of the epidemic are dead. *See* Peter Piot, Testimony to the hearing of the Committee on Foreign Relations of the United States Senate on Halting the Global Spread of HIV/AIDS: the Future of U.S. Bilateral and Multilateral Responses (Feb. 13, 2002) *available at* http://www.unaids.org/whatsnew/speeches/eng/2002/PiotSenate_130202.html.

how the policy safeguards consumers' interests in the provision of low-cost essentials medicine during public health emergencies.

4. National Emergencies

The TRIPS Agreement does not define what constitutes a national emergency or other circumstance of extreme urgency. The Doha Declaration does specify that HIV/AIDS, tuberculosis, malaria, and other epidemics are all instances of public health crises that can represent national emergencies or other circumstances of extreme urgency. This is a significant elaboration of Article 31, particularly in view of the fact that at the pre-Doha negotiations, the United States had reluctantly indicated that only HIV/AIDS should qualify under the emergency criteria.[74] At the very least, for purposes of public health emergencies, the United States' pre-Declaration position (to the effect that Article 31(b) rights are subject to Article 27.1 patent rights and adequate remuneration) can now safely be said to have been overcome. Pursuant to the Declaration's exhortation that all provisions of the TRIPS Agreement be read in light of its objectives and principles, it is untenable to suggest that the invocation of compulsory licensing under Article 31 to address a public health emergency would necessarily be overridden by the provisions of Article 27.1 on patent rights or even the rights to normal exploitation and legitimate interests of patent owners referred to in Article 30.

According to the Kenya National AIDS HIV/AIDS Strategic Plan 2000–2005:

> HIV/AIDS is a great threat to our nation. It has caused deaths of over a million Kenyans since 1984. There is yet no known cure, and we estimate that over two million out of our total population of 29 million are living with HIV/AIDS. The rate of infection is rising and it is unlikely that an effective affordable cure or vaccine will be developed in the near future. It is for these reasons that my Government declared HIV/AIDS a national disaster on 25 November 1999.[75]

The report details the impact of HIV/AIDS on education, agriculture, health, social services, the industrial sector, and the armed forces.

74. *See supra* note 25 and accompanying text.

75. Daniel Arap Moi, *Foreword* to KENYA NATIONAL HIV/AIDS STRATEGIC PLAN, 2000-2005, at ix (2000).

The Kenya Industrial Property Act of 2001 waives the preconditions for providing compulsory licenses "in the case of a national emergency or other circumstances of extreme urgency, provided the owner of the patent shall be so notified as soon as is reasonably practicable."[76] Issuing these compulsory licenses, then, would not violate the TRIPS Agreement in light of the national AIDS emergency.

5. The Freedom to Establish Their Regimes of Exhaustion Without Challenge but Subject to the MFN and National Treatment Provisions

Paragraph 5(d) of the Declaration provides that "the effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment of Articles 3 and 4."

To what extent does the Doha Declaration clarify Article 6 of the TRIPS Agreement regarding exhaustion of rights?[77] Article 6 provides that none of its provisions, except those dealing with nondiscrimination, national treatment, and most favored nation, can be used to address the issue of exhaustion of intellectual property rights in a WTO dispute. Exhaustion means that once a patent holder has sold a patented invention, the patent holder has no further right to exclude others from subsequent use, including offering to sell or distribute the patented invention. In essence, exhaustion presupposes that the patent owner, unless there is an agreement to the contrary, implicitly licenses the subsequent use and resale of a patented product upon first sale.

Since January 1, 1996, U.S. patent owners have had the right to exclude others from offering to sell a patented invention in the United States and from importing the invention into the United States.[78] Hence under U.S. law, if a firm in a second country makes and sells a U.S. patent owner's product and imports it into the United States, the importation would constitute a violation of U.S. law.[79] If the product

76. Kenya Industrial Property Bill of 2001, § 74(2).

77. Article 6 provides that "[f]or purposes of dispute settlement under this agreement, subject to the provisions of Articles 3 and 4, nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights."

78. *See* 35 USC § 154(a)(1) (1999) & 35 U.S.C. § 271(a) (1994). For an early case, see Dunlop Co., Ltd. v. Kelsey-Hayes Co., 484 F.2d 407 (6th Cir. 1973). *See also* United States v. Univis Lens Co., 316 U.S. 241, 249 (1942).

79. *See* Boesch v. Graff, 133 U.S. 697 (1890). It is unclear though what the scope of the national exhaustion as a norm under U.S. law is after the 1996 amendments. However, prior to 1996, the law on exhaustion for United States patent rights

> [m]ay occur if a sale in a foreign country is unrestricted and the seller holds the patent rights to sell in the United States as well as in the foreign country, but exhaustion will not occur if the person owning or possessing license rights under the United States pat-

was under patent protection in the second country, that firm would be in violation of the TRIPS Agreement. In the European Union ("EU"), the sale of a patent license by the consent of the patent holder exhausts the patent holder's right to the good and the patent holder cannot oppose the use of it by others in subsequent transactions. However, the EU, like the United States, does not recognize international exhaustion. Hence, if the sale is made outside of the EU and is subsequently distributed in the EU, the patent holders rights to control the price or permit the licensee to sell it still exist.[80] Both the EU and the United States therefore have protectionist regimes that forestall competition from cheaper foreign manufacturers.

In contrast, developing countries maintain that they have a right to determine whether or not to allow parallel imports. Unlike the United States and the EU, they argue that patent holders should not have the right to allow parallel imports. The Declaration is supportive of every member of the WTO establishing their own regime of exhaustion as long as it complies with the non-discriminatory obligations of the TRIPS Agreement. This is a significant legal clarification in view of pre-Doha controversies regarding the scope of a WTO member's right to define its own regime of exhaustion. This clarification might result in a bifurcated regime of exhaustion among WTO members. Countries seeking to promote public health programs such as affordable medicines or access to essential drugs during a health crisis might adopt an international exhaustion regime under which right holders cannot take action against parallel imports. The right established by the Declaration for countries to determine what constitutes a national emergency increases and strengthens sovereignty to establish international exhaustion regimes. Once a country determines that it faces a health emergency, it can then seek to import drugs from another country where the right holder has licensed the drug. By contrast, countries with big pharmaceutical industries such as the United States might seek to maintain their present regimes of exhaustion under which right holders can take action against parallel importers.

6. Extension of Compliance Periods for Least Developed Countries

Paragraph 7 of the Declaration provides a major concession to least developed countries. Prior to Doha, the Agreement required

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ent is not the same person who has made or authorized the sale abroad.

5 DONALD S. CHISUM, CHISUM ON PATENTS § 16.05[3][a][ii] (1999); *see also* Shubha Ghosh, *Pills, Patents and Power: State Creation of Gray Markets As a Limit on Patent Rights*, 53 FLA. L. REV. 789 (2001).

80. *See* Silhouette International Schmied GmbH & Co. KG v. Hartlauer Handelsgesellschaft mbH, 1998 E.C.R. I-4799 (1998).

compliance from January 1, 2006.[81] Now the least developed countries have until 2016 to come into compliance with the TRIPS Agreement. This ten year extension, without prejudice to these countries to seek further extensions, only applies to pharmaceutical products, and as such only delays implementation of Sections 5 and 7 of Part II of the TRIPS Agreement.

B. The Doha Declaration as Evidence of Subsequent Practice Under the TRIPS Agreement

Article 31 § 3(b) of the Vienna Convention on the Law of Treaties describes the role of subsequent practice in treaty interpretation: "subsequent practice . . . establishes the agreement of the parties regarding its interpretation."[82] The word "agreement" was included in the final draft of the Vienna Convention on the Law of Treaties as a replacement for the word "understanding" as a way of conforming the English version of the treaty with the Spanish, Russian, and French versions.[83] Hence, the word "agreement" in the English text has the same meaning as the French *accord* or the Spanish *acuerdo*; "agreement" includes both agreement in writing, such as the Doha Declaration, as well as agreement manifested by conduct, such as subsequent practice.[84]

Sir Gerald Fitzmaurice has argued:

> [T]he way in which the parties have actually conducted themselves in relation to the treaty affords legitimate evidence as to its correct interpretation....

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81. Art. 66(1) of the Trips Agreement.

82. Vienna Convention on the Law of Treaties, May 23, 1969, art. 31, § 3(b), 8 I.L.M. 679, 691–2 (1969).

83. United Nations Conference on the Law of Treaties, First Session, Vienna 26 March–24 May, at 442.

¶ 29, U.N. Doc A/CONF.39/11 (1968).

84. Sir Humphrey Waldock observed that the "word 'understanding' was chosen by the Commission instead of 'agreement' expressly in order to indicate that the assent of a party to the interpretation may be inferred from its reaction or absence of reaction to the practice." Humphrey Waldock, *Sixth Report on the Law of Treaties*, U.N. Doc. A/CN.4/186 and Add. 1–7, 2 INT'L LAW COMM'N 51, 99 (1966). Similarly, the Court of Arbitration in the Beagle Channel Arbitration observed:

> [T]he court cannot accept the contention that no subsequent conduct, including acts of jurisdiction, can have probative value as a subsidiary method of interpretation unless representing a formally stated or acknowledged "agreement" between the Parties. The terms of the Vienna Convention do not specify the ways in which "agreement" may be manifested.

Case Concerning a Dispute Between Argentina and Chile Concerning the Beagle Channel, 21 R.I.A.A. 55, 187 (1977).

> [C]onduct usually forms a more reliable guide to intention and purpose than anything to be found for instance in the preparatory work of the treaty, simply because it has taken concrete and active, and not merely verbal or paper, form.[85]

For example, in a 1963 arbitration decision between the United States and France, subsequent practice of the two parties was held relevant to the interpretation of the governing 1946 treaty. Subsequent practice was interpreted as tacit consent to modify the treaty "not by virtue of the Agreement of 1946 but rather by virtue of an agreement that implicitly came into force at a later date."[86] U.S. courts have also relied on subsequent practice to interpret ambiguous treaty provisions. For example, the Second Circuit has relied on subsequent conduct to find that the term "accident" as used in the Warsaw Convention in the context of liability for aviation accidents includes hijackings.[87] Therefore consensus or common understanding between WTO members manifested by conduct can provide important guidelines on the interpretation and implementation of the words of the TRIPS Agreement.

The Doha Declaration evidences the embryonic stages of subsequent practice, which can therefore establish agreement of WTO members regarding interpretation of specific provisions of the TRIPS Agreement. As elucidated in Part III(a), the Doha Declaration allows nations additional flexibility under TRIPS with regard to interpreting TRIPS in light of its objectives and principles, granting compulsory licenses, defining national emergencies, and establishing regimes of exhaustion. To the extent these options under the Doha Declaration are utilized by WTO members, they help constitute subsequent practice that can be used in interpreting the TRIPS Agreement.

Other decisions and policies adopted by WTO members may constitute subsequent practice under TRIPS. For example, the United States withdrew a trade dispute filed under the WTO's Dispute Settlement Understanding against Brazil in 2000.[88] The complaint involved a Brazilian law that empowered the Brazilian government to

85. GERALD FITZMAURICE, 1 THE LAW AND PROCEDURE OF THE INTERNATIONAL COURT OF JUSTICE 357 (1986).

86. Decision of Arbitration Dispute Concerning International Air Transport Services Agreement (U.S. v. Fr.), 58 AM. J. INT'L L. 1016, 1023–1027 (1964).

87. *See* Husserl v. Swiss Air Transport Co., Ltd., 351 F.Supp. 702 (D.C.N.Y. 1972); *see also* Day v. Trans World Airlines, Inc., 528 F.2d 31 (2d Cir. 1975); RESTATEMENT OF FOREIGN RELATIONS LAW OF THE UNITED STATES, § 325, Reporters' Note 5 (1987).

88. Press Release, Office of the United States Trade Representative, U.S. and Brazil to Cooperate on HIV/AIDS and WTO Patent Dispute, (June 25, 2001) *at* http://usinfo.state.gov/topical/econ/ipr/ipr-braziltrips.htm.

grant compulsory licenses for failure to work patents it had granted.[89] Brazil argued that the law was necessary to encourage patent holders to manufacture their drugs in Brazil at affordable prices and to facilitate technology transfer. The contemporaneous withdrawal of the complaint with the commencement of the United Nations General Assembly special session on HIV/AIDS and the TRIPS Council special session symbolized a movement towards balancing patent protection and health concerns.[90] Paragraph 7 of the Doha Declaration acknowledges this balance by affirming the "commitment of developed-country Members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country Members pursuant to Article 66.2 [of TRIPS]."[91]

A similar situation occurred with the South African Medicines and Related Substances Control Amendment Act 90 of 1997, which authorized the South African government to engage in compulsory licensing to address their HIV/AIDS epidemic.[92] Promulgation of the law concerned the United States Trade Representative ("USTR") about possible violations of U.S. intellectual property rights and led to the addition of South Africa to the USTR's watch list under the Omnibus Trade and Competitiveness Act of 1988.[93] In addition, thirty-

89. WTO Notification of Mutually Agreed Solution, *Brazil – Measures Affecting Patent Protection*, WT/DS199/3 (Jan. 9, 2001).

90. *See* Peter Capella, *Brazil Wins HIV Drug Concession From US: Complaint to WTO on Patent Law Withdrawn*, GUARDIAN, June 26, 2001, at 18. On August 17, 2000, the UN Subcommission for the Protection and Promotion of Human Rights adopted a resolution on "Intellectual Property and Human Rights" that asserted the primacy of human rights over intellectual property rights. *See Intellectual Property and Human Rights*, Sub-commission on Human Rights Resolution 2000/21, Aug. 16, 2001.

91. WTO Ministerial Conference, Fourth Session, Doha, 9–14 November 2001, *Declaration on the TRIPS Agreement and Public Health*, WT/MIN(01)/DEC2, at ¶ 7 (Nov. 20, 2001); *see also* TRIPS Agreement, *supra* note 6, art. 66.2, at 108.

92. Medicines and Related Substances Control Act 101 of 1965 After Amendment by the Medicines and Related Substances Control Amendment Act 90 of 1997 (S. Afr.); *see also* Zackie Achmat, We Can Use Compulsory Licensing and Parallel Imports: A South African Case Study, *at* http://www.hri.ca/partners/alp/tac/license.shtml; Anthony Stoppard, *Health-South Africa: Drug Companies Drop Lawsuit Against Government*, INTER PRESS SERVICE, Apr. 19, 2001, *available at* http://www.aegis.com/news/ips/2001/IP010413.html.

93. Omnibus Trade and Competitiveness Act of 1988 § 1303(b), 19 U.S.C. § 2242(a)–(b) (1999). Under this section, the United States Trade Representative ("USTR") is required within thirty days after the submission of the annual National Trade Estimates (foreign trade barriers) to report to Congress those foreign countries that (1) deny adequate and effective protection of U.S. intellectual property rights and (2) those countries under (1) that are determined by the USTR to be priority foreign countries. The USTR identifies as priorities only those countries that have the most onerous or egregious acts, policies, or practices that have the greatest adverse impact on the relevant United States products and that are not entering good faith negotiations or making significant progress in bilateral and multilateral negotiations to provide adequate and effective intellectual property rights protection. *Id.*

nine pharmaceutical companies filed suit in South Africa challenging the law as being inconsistent with South Africa's obligations under the TRIPS Agreement. [94] The United States eventually withdrew South Africa from the watch list, but noted that the withdrawal was not a recognition of the legitimacy of compulsory licensing.[95] Subsequently, the pharmaceutical companies withdrew their suits against the South African government.[96] Mike Moore, the WTO Director-General, noted upon settlement of the suits: "The settlement shows that the WTO's Agreements, such as TRIPS, contain the necessary flexibility to meet the health needs of developing countries and can be used as a basis for resolving difficult issues concerning access to essential drugs."[97] These bilateral negotiations and decisions have precedential value in establishing the understanding of states regarding the flexibility of the TRIPS Agreement.

Additional policy responses demonstrate an understanding of the need to balance patent protection with the access to essential medicines. For example, Executive Order 13,155, signed by President Clinton in May 2000 ordered the USTR not to impose trade sanctions as it had done with South Africa.[98] In December 2001, the House passed HR 2069, *Global Access HIV/AIDS Prevention, Awareness, Education, and Treatment Act of 2001*, which authorized appropriations of $750 million toward the *Global AIDS and Tuberculosis Relief Act of 2000* and $50 million for the procurement and distribution of HIV/AIDS pharmaceuticals for developing countries.[99]

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94. *See* Simon Barber, *US Remains Hostile to South Africa Drugs Act*, BUS. DAY, Sept. 27, 1999, at 4.

95. *See* Press Release, Department of Trade and Industry, Joint Understanding Between the Governments of South Africa and the United States of America (Sept. 17, 1999), *at* http://www.polity.org.za/povdocs/pr/1999/pro9176.html; *see also* Barber, *supra* note 94, at 4; Black Radical Congress, *Activists Lock Gore Out of His Office, Criticizing SA AIDS Drugs Deal*, AFR. NEWS SERVICE, Aug. 25, 1999.

96. *See* Stoppard, *supra* note 92.

97. Mike Moore, Moore Welcomes News of Settlement of South Africa Drug Lawsuit, (Apr. 19, 2001), *at* http://www.wto.org/english/news_e/spmm_e/spmm58_e.htm.

98. *See* Exec. Order No. 13,155, 65 Fed. Reg. 30,521, 30,522 (May 10, 2000). This Executive Order also required sub-Saharan African countries to provide adequate and effective intellectual property protection as a precondition for increasing access to HIV/AIDS drugs. In February 2001, Joseph Papovich, the U.S. Trade Representative for Intellectual Property Rights, stated that President Bush was "not considering a change in the present 'flexible policy' on compulsory licensing of drugs by AIDS-stricken countries." GRAEME DINWOODIE ET AL., INTERNATIONAL INTELLECTUAL PROPERTY LAW AND POLICY 436 (2001).

99. *See* Global Access to HIV/AIDS Prevention, Awareness, Education, and Treatment Act of 2001, H.R. 2069, 107th Cong., §§ 4(a)–(c), 7.

C. The Doha Declaration as a Legally Non-Binding Statement of Intent and Commitment

The Doha Declaration's legally binding status depends on the circumstances in which it was formulated, specific wording, subject matter, and the degree of support.[100] For example, although United Nations General Assembly decisions do not necessarily create law, they assist in the evolution and consolidation of the law.[101] Where a vast majority of states signify their acceptance to a declaration, this can be equivalent to codification of customary international law.[102] Sometimes, United Nations General Assembly decisions become customary law as a result of subsequent state practice.[103] Not a single WTO member dissented from or abstained from voting for the Doha Declaration. This stands in contrast to the responses of developed countries to the contentious attempts by developing countries in the 1960s and 1970s to use UN General Assembly declarations and resolutions to reform aspects of international law.[104] Even if a country concluded that the Doha Declaration is not legally binding, it still constitutes soft law with substantial hortatory authority that puts political pressure on governments and international institutions to comply.[105]

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100. *See* IAN BROWNLIE, PRINCIPLES OF PUBLIC INTERNATIONAL LAW 15 (4th ed. 1990); Bruno Simma & Philip Alston, *The Sources of Human Rights Law: Custom, Jus Cogens, and General Principles*, 12 AUSTL. Y.B. INT'L L. 82 (1992); OSCAR SCHACHTER, INTERNATIONAL LAW IN THEORY AND PRACTICE 85 (1991); ANTHONY AUST, MODERN TREATY LAW AND PRACTICE 26–46 (2000).

101. *See* Legal Consequences for States of the Continued Presence of South Africa in Namibia (South West Africa) Notwithstanding Security Council Resolution 276, 1971 I.C.J. 16, 31 (June 21) (referring to the UN General Assembly declarations on self-determination and independence of peoples in territories that have not yet attained independence as having legal effect); *see also* Western Sahara, Advisory Opinion, 1975 I.C.J. 12, 23-35 (Oct. 16); Louis B. Sohn, *The New International Law: Protection of the Rights of Individuals Rather than States*, 32 AM. U. L. REV. 1, 16 (1982).

102. *See* Schermers, *supra* note 66, at 612. Schermers also notes that "[n]o constitution of an international organization refers to declarations as a separate class of decision. No constitution expressly empowers an organization to issue declarations. But this does not necessarily prevent organs from doing so." *Id.* at 611.

103. *See* OBED ASAMOAH, THE LEGAL SIGNIFICANCE OF THE DECLARATIONS OF THE GENERAL ASSEMBLY OF THE UNITED NATIONS 47 (1966).

104. *See generally* International Arbitral Tribunal: Award on the Merits in Dispute Between Texaco Overseas Petroleum Company/California Asiatic Oil Company and the Government of the Libyan Arab Republic (Compensation for Nationalized Property), 17 I.L.M. 1 (1978).

105. U.S. practice under the Restatement of Foreign Relations Law dictates:

> International organizations generally have no authority to make law, and their determinations of law ordinarily have no special weight, but their declaratory pronouncements provide some evidence of what the states voting for it regard the law to be. The evidentiary value of such resolutions is variable. Resolutions of universal international organizations, if not controversial and if

The United States has maintained that Doha was a political declaration with no legal authority. The United States Trade Representative's Fact Sheet summarizing the results of the Doha meeting refers to the Doha Declaration on TRIPS and Public Health as a political declaration.[106] From this perspective, the Declaration is not a fait accompli for countries seeking to facilitate access to essential medicines. Rather, it is an implicit reciprocation by the West to developing country governments for their implementation of the TRIPS Agreement and their acquiescence to a new round of WTO talks.[107] The United States in particular would have been unwilling to sign the Declaration had it suspended the legal obligations of developing countries under TRIPS.

Distinguishing legal claims from non-legal or political claims, such as access to essential medicines, can deprive them of their status as rights and thereby serve to legitimize an unjust status quo. As Richard Bilder argued more than three decades ago, "[t]o assert that a particular social claim is a human right is to vest it emotionally and morally with an especially high order of legitimacy."[108] Asserting that a particular claim is not a right not only denies disempowered peoples the potentially transformative value of rights,[109] but also robs their claims of legitimacy in the moral currency of international relations.[110] This denial results from the conceptualization of certain claims as political, social, or public, so that as a result they fall outside and cannot disturb the private commercial or contractual character of trade, financial, or banking regimes.[111] For example, the Second Cir-

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adopted by consensus or virtual unanimity, are given substantial weight.

RESTATEMENT (THIRD) OF FOREIGN RELATIONS LAW OF THE UNITED STATES, § 103 cmt. c (1987; *see also* James T. Gathii, *Good Governance as a Counter Insurgency Agenda to Oppositional and Transformative Social Projects in International Law*, 5 BUFF. HUM. RTS. L. REV. 65, 117–20 (1999); Voting Procedure on Question Relating to Reports and Petitions Concerning the Territory of South-West Africa, Advisory Opinion, 1955 I.C.J. 67, 118–20 (June 7) (separate opinion of Judge Hersch Lauterpacht); FITZMAURICE, *supra* note 85, at 431–32.

106. *See* Text: USTR Fact Sheet Summarizing Results from WTO Doha Meeting, Nov. 15, 2001, *at* http://www.usembassy.it/file2001_11/alia/a1111516.htm.

107. *See* James T. Gathii, *WTO Spin Unconvincing*, AFRICAN BUS., Jan. 1, 2002, at 5.

108. Richard Bilder, *Rethinking International Human Rights: Some Basic Questions*, 1 WIS. L. R. 171, 174 (1969).

109. *See* KIMBERLÉ CRENSHAW ET AL., CRITICAL RACE THEORY: THE KEY WRITINGS THAT FORMED THE MOVEMENT xxxii (Kimberlé Crenshaw ed., 1995).

110. *See* Makau wa Mutua, *The Ideology of Human Rights*, 36 VA. J. INT'L L. 589 (1996).

111. *See generally* James T. Gathii, *Re-characterizing the Social in the Constitutionalization of the WTO: A Preliminary Analysis*, 7 WIDENER L. SYMP. J., 137, 164–73 (Spring 2001); James T. Gathii, *Neo-Liberalism, Colonialism and International Governance: Decentering the International Law of Governmental Legitimacy*, 98 MICH. L. REV. 1996, 2027–34 (2000); James T. Gathii, *Construing Intellectual Prop-*

cuit has held that debt restructuring plans between a country indebted to Western financial institutions do not override the underlying contractual obligations to repay the debt.[112] As a result, Costa Rica's commitment to a debt restructuring plan under the supervision of the International Monetary Fund was dubbed a political issue, rather than a legal issue, to give the country time to meet its commitments.[113] This outcome is typical where issues between developed and developing countries are examined through a commercial lens.

Not surprisingly, the Declaration does not override existing United States laws that precondition continuation of assistance on developing country protection of U.S. patents. This is because developing countries failed to win the guarantee that they could adopt measures such as compulsory and parallel licensing to address the AIDS pandemic without fear of bilateral pressures being applied against them. Under the notorious unilateral powers dubbed section 301[114] that were recently upheld by a WTO panel, the USTR is required to report measures taken to ensure protection of U.S. intellectual property rights through imposition of retaliatory tariffs. Under this decision, the respect of developing countries for U.S. patents can still be enforced outside the WTO's Doha Declaration and TRIPS Agreement.[115]

V. CONCLUSION

By exhorting WTO members to construe all provisions of the TRIPS Agreement in light of its objectives and principles clauses, the Doha Declaration sets an interpretive baseline that requires balancing the interests of producers and consumers of intellectual property rights. That baseline forestalls a construction of the TRIPS Agreement biased either in favor or against any of these contending positions, thereby laying down a framework for a more fair determination of the conflicting interests in the TRIPS Agreement. This framework does not guarantee a particular result in any case. However, if the Doha Declaration is taken as an element in the interpretation of the TRIPS Agreement, and WTO members choose to accommodate each other

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erty Rights and Competition Policy Consistently With Facilitating Access to Affordable Aids Drugs to Low-End Consumers, 53 FLA. L. REV. 728, 737–53 (2001).

112. *See* Allied Bank Int'l v. Banco Credito Agricola De Cartago, 757 F.2d. 516, *cert denied*, 473 U.S. 934 (1985)

113. *Id.*; *see also* Elliot Associates L.P. v. Banco de la Nacion, 194 F.3d 363 (2d Cir. 1999).

114. Trade Act of 1974, tit. III, ch. 1, § 301, 19 U.S.C. §2411(a)(1), *amended by* Omnibus Trade and Competitiveness Act of 1988, § 1303(b).

115. *See* James T. Gathii, *Re-characterizing the Social in the Constitutionalization of the WTO: A Preliminary Analysis*, 7 WIDENER L. SYMP. J. 137, 152–53, 163–64 (Spring 2001). For the recent Section 301 panel decision, see *supra* note 35.

on a case by case basis as they address public health crises, the declaration might build a more stable and perhaps fair legal framework.