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Trips Article 31(b) and the HIV/AIDS Epidemic

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TRIPS ARTICLE 31(B) AND THE HIV/AIDS EPIDEMIC

I. INTRODUCTION

In recent years, members of the international community have debated whether World Trade Organization (WTO) Members can fulfill their obligations under the international Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement)[1] while using provisions of the Agreement to address the HIV/AIDS epidemic. One provision is TRIPS Article 31(b), the subject of this Note.

TRIPS Article 31 covers compulsory licenses which, when used, remove a WTO Member from its general obligation to recognize exclusive patent rights before a patent period has expired.[2] Article 31 contains a number of requirements a Member must still meet, including the Article 31(b) requirement that "prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time."[3] Article 31(b) also provides, however, "[t]his requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency . . . ."[4]

The issue is whether the provision, "national emergency or other circumstances of extreme urgency," encompasses a public health emergency such as the HIV/AIDS epidemic. If so, then a WTO Member, through legislation, could set up a mechanism for producing pharmaceuticals and distributing them at a lower cost, without having to undergo difficult negotiations with pharmaceutical companies for a "reasonable" period of time.

This issue is likely to come before a WTO panel. The purpose of this Note is to provide some background information about the following: the HIV/AIDS epidemic—including some of the security and economic concerns it raises; the evolution of the debate—including some discussion of the relationship between free trade and intellectual property protection; and the World Trade Organization—its dispute settlement mechanism, objectives, and potential impact on the global community. In addition, the Note will address how a WTO panel could

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[1] 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 vol. 31, 33 I.L.M. 81 (1994) [hereinafter TRIPS].

[2] TRIPS, *supra* note 1, 33 I.L.M. at 95-96.

[3] *Id.* at 95.

[4] *Id.*

eventually interpret Article 31(b)'s waiver provision to conclude it does not encompass a public health emergency such as the HIV/AIDS epidemic.

II. BACKGROUND

A. HIV/AIDS

The incidence of disease, particularly in developing countries, is either unreported or under-reported due in part to stigmas attached to many diseases.[5] Countries are reluctant to reveal the information for fear it will reduce profit generated from trade, tourism, etc.[6] Nonetheless, the figures are astounding.

At the end of 2000, approximately 31.6 million people worldwide were infected with HIV, 90% of whom live in developing countries.[7] Seventy-five percent of infected individuals are in sub-Saharan Africa.[8] Seventy percent of the four million new infections worldwide in 1998 occurred in this region.[9] Eastern and southern African countries have been affected the most, with 10% to 26% of adults infected with HIV.[10] The disease, however, is also rapidly spreading through India, Russia, China, and other parts of Asia.[11] By 2010, projections indicate Asia and the Pacific region could exceed Africa in the number of infections.[12] Latin America is the third hardest hit region.[13]

Four-fifths of all HIV-related deaths (1.8-2 million out of 2.3 million) in 1998 were in sub-Saharan Africa.[14] These figures exceed the 1996 joint World Bank/World Health Organization (WHO) model's projections that deaths would peak at 1.7 million in 2006.[15] 11.5 million out of 13.9 million cumulative AIDS deaths have occurred in sub-Saharan Africa, even though the region contains only about a tenth of the world population.[16]

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[5] NAT'L INTELLIGENCE COUNCIL, CENTRAL INTELLIGENCE AGENCY, THE GLOBAL INFECTIOUS DISEASE THREAT AND ITS IMPLICATIONS FOR THE UNITED STATES 18 (2000), *at* http://www.cia.gov/nic/graphics/infectiousdiseases.pdf.

[6] *Id.*

[7] G.A. Res. 5-26/2, U.N. GAOR, 26th Special Sess., 8th plen. Mtg., at 1, U.N. Doc. A/Res/5-26/2 (2001), *available at* http://www.un.org/ga/aids/docs/aress262.pdf.

[8] *Id.*

[9] NAT'L INTELLIGENCE COUNCIL, *supra* note 5, at 27.

[10] *Id.*

[11] *Id.* at 15.

[12] *Id.* at 7.

[13] *Id.* at 30.

[14] NAT'L INTELLIGENCE COUNCIL, *supra* note 5, at 27.

[15] *Id.* at 43.

[16] *Id.* at 27.

The National Intelligence Council (NIC) projects 41.6 million children in twenty-seven countries (nineteen of which are in sub-Saharan Africa) will lose one or both parents to AIDS by 2010.[17] Some of these countries "will face a demographic upheaval as HIV/AIDS and associated diseases reduce human life expectancy by as much as 30 years and kill as many as a quarter of their populations over a decade or less, producing a huge orphan cohort."[18]

In June of 2001, the United Nations (UN) General Assembly recognized in its Declaration of Commitment on HIV/AIDS that the HIV/AIDS crisis in sub-Saharan Africa threatens, among other things, development and political stability.[19]

HIV/AIDS threatens development in part because the economic burden is so substantial. According to the Global AIDS Policy Coalition at Harvard University, the total direct and indirect costs of AIDS are estimated to have exceeded $500 billion by 2000.[20] Infectious diseases, particularly HIV/AIDS and malaria, impact productivity, profitability, and foreign investment.[21]

According to recent studies, this impact could be reflected in a 20% or more reduction in GDP by 2010 in some sub-Saharan countries.[22] The NIC reports "[a] senior World Bank official considers AIDS to be the single biggest threat to economic development in sub-Saharan Africa."[23] In Zimbabwe, more than half the health budget is already spent on treating AIDS.[24] In Kenya, 50% of health spending will go to AIDS by 2005.[25] In South Africa, the rate is projected to be 35% to 84% by 2005.[26]

AIDS-related costs to African firms may include absenteeism, productivity declines, health and insurance payments, and recruitment and training.[27] There is a high rate of loss to AIDS of middle and upper-level managers and their replacements.[28] In addition, a large number of skilled workers in mining and other important sectors are dying of AIDS.[29] According to the NIC, one study

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[17] *Id.* at 50.
[18] *Id.* at 9-10.
[19] G.A. Res. 5-26/2, *supra* note 7, at 2.
[20] NAT'L INTELLIGENCE COUNCIL, *supra* note 5, at 47-48.
[21] *Id.* at 9.
[22] *Id.*
[23] *Id.* at 46.
[24] *Id.* at 49.
[25] NAT'L INTELLIGENCE COUNCIL, *supra* note 5, at 49.
[26] *Id.*
[27] *Id.* at 47.
[28] *Id.*
[29] *Id.*

projects that in South Africa, benefit costs will nearly triple to 19% of salaries from 1995 to 2005, which will substantially affect corporate profits.[30]

Besides threatening development, HIV/AIDS could create political instability, even in democratic nations.[31] The large orphan population could contribute to this instability, considering various radical and/or political groups might find problematic regions to be good grounds for recruitment: "the pervasive child soldier phenomenon may be one example."[32] The UN Security Council, at its 4172nd meeting in July 2000, passed Resolution 1308, recognizing the growing impact of HIV/AIDS on social instability.[33] If it remains unchecked, the pandemic could pose a security risk.[34]

One study suggests infant mortality correlates strongly with political instability, which the study defined as: revolutionary wars, ethnic wars, genocides, and disruptive regime transitions.[35] Because HIV/AIDS not only affects the rural and lower income populations, but also the middle class and the political and military elite, tensions between the various groups could produce a struggle for control of limited state resources.[36]

HIV/AIDS is already prevalent in some militaries, predominantly in sub-Saharan Africa, with infection rates that range from 10% to 60%.[37] The NIC projects "[t]he greatest impact will be among hard-to-replace officers, noncommissioned officers, and enlisted soldiers with specialized skills."[38] A high rate of turnover in military leadership means international peacekeeping efforts could be negatively impacted and groups in military-dominated states could seize opportunities to launch military coups.[39]

The NIC also reports although sub-Saharan military capabilities will be impacted the most, particularly those with a modest level of modernization in weapons systems and platforms, in the future, HIV/AIDS could also severely impact the capabilities of more modernized militaries in former Soviet Union states, China, and certain rogue states with large armies and modern weapons arsenals.[40] The NIC even noted the relevance of intellectual property disputes:

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[30] NAT'L INTELLIGENCE COUNCIL, *supra* note 5, at 47.
[31] *Id.* at 50.
[32] *Id.*
[33] S.C. Res. 1308, U.N. SCOR, 55th Sess., 4172nd mtg. at 1, U.N. Doc. S/RES/1308 (2000).
[34] *Id.* at 2.
[35] NAT'L INTELLIGENCE COUNCIL, *supra* note 5, at 51-52.
[36] *Id.* at 50.
[37] *Id.* at 52.
[38] *Id.*
[39] *Id.*
[40] NAT'L INTELLIGENCE COUNCIL, *supra* note 5, at 52.

> A growing controversy . . . will be over drug-related intellectual property rights, in which developing countries will press for more and cheaper drugs from developed country pharmaceutical firms and resort to producing their own generic brands if they are rebuffed. States will remain concerned, as well, about the growing biological warfare threat from rogue states and terrorist groups.[41]

As these comments indicate, developing countries are concerned about HIV-infected individuals not getting adequate medical treatment. In sub-Saharan Africa and China, "80 percent of the rural population no longer has subsidized health care .... Under this scenario access to essential drugs and basic medical care in these regions will remain poor or deteriorate ...."[42] Even in South Africa, a relatively prosperous country, only about 1 percent of HIV/AIDS-infected individuals are receiving the multi-drug treatment.[43]

According to the organization, Médecins Sans Frontières, 95% of HIV-infected individuals worldwide cannot afford the multi-drug regimines now believed to be essential to the treatment of the disease.[44] The current average price of the "cocktail" treatment in the United States is approximately $10,000 to $15,000 per patient per year.[45] In many developing nations, the prices are significantly less, but even prices that have been negotiated are still too costly for the average infected individual.[46]

As mentioned before, the UN General Assembly recently adopted a Declaration of Commitment on HIV/AIDS.[47] Many groups, including Médecins Sans Frontières, were optimistic about the Declaration.[48] There are several provisions that foreshadow further discussions relating to treatment access and

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[41] *Id.* at 53.

[42] *Id.* at 42.

[43] *Id.* at 49.

[44] Médecins Sans Frontières, *Background Information on HIV/AIDS* (Sept. 2001), *at* http://www.accessmed-msf.org/upload/ReportsandPublications/19920011113473/Aids%20BG(1).pdf.

[45] *Id.*

[46] Kaisernetwork.org, *Daily HIV/AIDS Report: Drug Access—Few HIV-Positive Africans Receiving Treatment Two Years After U.N. Push to Improve Access* (Mar. 29, 2002), *available at* http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=1&DR_ID=10323 ("Although some of the drugs' prices are only one-sixteenth the cost of the same drugs in the United States, they are still too expensive for many Africans, who on average have incomes of less than one dollar per day.") (citation omitted).

[47] G.A. Res. 5-26/2, *supra* note 7.

[48] Médecins Sans Frontières, *MSF Welcomes UN's Clear Commitment to AIDS Treatment* (June 27, 2001), *at* http://www.msf.org/content/page.cfm?articleid=7A83C8D6-20A5-459E-936D754AF8492FCF.

intellectual property rights.[49] The resolution reinforces the importance of finding effective solutions consistent with international law.[50]

B. EVOLUTION OF THE DEBATE

After a 1988 study by the United States International Trade Commission concluded U.S. companies were losing billions in international sales due to foreign competitors copying/stealing intellectual property, the research pharmaceutical industry took the lead in promoting strong international intellectual property protection.[51] The Pharmaceutical Manufacturers Association (PMA) led this effort as " 'one of the best organized, sufficiently funded, and powerful associations . . . .' "[52] PMA was and has been successful in its lobbying efforts in part because its members include former government officials from Commerce and the Office of the United States Trade Representative (USTR).[53]

The pharmaceutical industry began to frame the issue of the lack of intellectual property protection in certain countries as criminal, using the term "piracy" to gain support in Congress and from the public.[54] The media and government criticized foreign governments for their lack of protection.[55] President Reagan, convinced that the intellectual property of U.S. corporations was vulnerable, "pledged new efforts to protect intellectual property rights, stating that '[w]hen governments permit counterfeiting or copying of American products, it is stealing our future and it is no longer free trade.' "[56]

To elaborate on this point, in countries that offer only limited or no intellectual property protection and have the infrastructure to produce pharmaceuticals, manufacturers have the advantage of avoiding research and development costs.[57] They can then sell these "pirated" products for less money

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[49] *See generally id.*

[50] *Id.*

[51] Christopher S. Harrison, *Protection of Pharmaceuticals as Foreign Policy: The Canada-U.S. Trade Agreement and Bill C-22 Versus the North American Free Trade Agreement and Bill C-91*, 26 N.C. J. INT'L LAW & COM. REG. 457, 498 (2001).

[52] *Id.* at 499 (quoting Paul C.B. Liu, *Taiwan: U.S. Industry's Influence of Intellectual Property Negotiations and Special 301 Actions*, 13 UCLA PAC. BASIN L.J. 87, 106-07 (1994)).

[53] *Id.* at 500. PMA hired Gerald Mossinghoff, former Assistant Commerce Secretary and Commissioner of Patents and Trademarks, as its President, and Harvey E. Bale, Jr., who worked for twelve years for the USTR office.

[54] *Id.* at 495-96.

[55] *Id.* at 496.

[56] Harrison, *supra* note 51, at 496-97 (quoting Bruce Stokes, *Intellectual Piracy Captures the Attention of the President and Congress*, NAT'L J., Feb. 22, 1986, at 443).

[57] *See id.* at 466-67 (stating that in countries that do not protect intellectual property, manufacturers can produce patented pharmaceuticals without additional research and development

than the creators of the pharmaceutical.[58] Without adequate protection, "creators can no longer recover the cost of their investment in research and development, resulting in lower production, fewer trading opportunities, and higher costs to the consumer."[59] One argument is that permitting "piracy" distorts trade like affirmative governmental regulation:

> As exporters or investors are reluctant to introduce products or transfer technology containing key intellectual property for fear that such property will be pirated, piracy becomes a barrier to trade. To the extent that such a trade barrier discourages free trade, it contributes to a decline in competitiveness in the affected countries.[60]

In light of this view, the 1984 revisions to section 301 of the Trade Act of 1974 (section 301)[61] and the Omnibus Trade and Competitiveness Act of 1988 (Omnibus Trade Act)[62] were huge successes for the pharmaceutical industry. Initially, the 1974 legislation was enacted to enforce GATT and treaty conferred trade rights.[63] Section 301 expanded the scope of "unreasonable trade practices" and it "authorized the USTR to demand unrequited trade concessions from America's trading partners."[64] The Omnibus Trade Act amended section 301 and defined "as unreasonable, '[a]n act, policy, or practice . . . while not necessarily in violation of, or inconsistent with, the international legal rights of the United States, is otherwise unfair and inequitable.' "[65]

Within the Omnibus Trade Act is Special 301, an intellectual property-specific measure aimed at addressing inadequate or ineffective intellectual property protection.[66] Special 301 is "based on the assumption that the United States could use threats and negotiation to obtain meaningful changes in the intellectual property regimes of its trading partners.' "[67]

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costs).

[58] *Id.* at 467.

[59] Marshall A. Leaffer, *Protecting United States Intellectual Property Abroad: Toward a New Multilateralism*, 76 IOWA L. REV. 273, 277 (1991).

[60] Harrison, *supra* note 51, at 481.

[61] *Id.* at 500. Section 301 was called the "H-bomb of trade policy" by one USTR ambassador. *Id.*

[62] *Id.* at 501. Harrison calls the Omnibus Trade Act the "thermonuclear bomb" of foreign economic policy. *Id.*

[63] *Id.* at 500.

[64] *Id.*

[65] *Id.* at 502 (quoting Omnibus Trade Act, § 1301, 102 Stat. 1164, 1167 (1988)).

[66] *Id.*

[67] *Id.* (quoting John Gero & Kathleen Lannan, *Trade and Innovation: Unilateralism v. Multilateralism*,

Special 301 surfaces in the HIV/AIDS context when U.S. officials believe countries have inadequate intellectual property protection of pharmaceuticals (regardless of whether the legislation of certain countries is TRIPS-consistent).[68] Special 301 requires the USTR to prepare a list of "priority" trading partners considered to be the worst offenders of intellectual property rights, then negotiate with these "priority" countries under the threat of sanctions.[69] There are other lists for countries whose violations are not as severe.[70]

One contributing factor for why Special 301 is so effective is that it delegates the monitoring responsibility to the industry.[71] Special 301 allows private interests (including intellectual property industry members) to monitor trading partners' intellectual property regimes and submit complaints to the USTR if there are any potential violations.[72] Private industry then continues to supplement further information to the USTR during the review process.[73] The USTR, using this information, then determines whether action should be taken.[74]

Section 301 and Special 301 have been effective in pressuring countries to adopt stronger intellectual property regimes. The U.S. has threatened unilateral trade sanctions under section 301 against Brazil for its inadequate pharmaceutical intellectual property protection.[75] In addition, using Special 301, the USTR has placed several countries on "watch lists," again using trade sanctions as a threat for compliance. Countries with a substantial percentage of exports going to the United States have little room to negotiate.[76] They may also find it problematic to bring the issue before the WTO.[77] Two examples are South Africa and Thailand.

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21 CAN.-U.S. L.J. 81, 84 (1995)).

[68] *See infra* notes 78-82 and accompanying text (referring to South Africa and Thailand).

[69] Judy Rein, *International Governance Through Trade Agreements: Patent Protection for Essential Medicines*, 21 NW. J. INT'L L. & BUS. 379, 399 (2001).

[70] Harrison, *supra* note 51, at 503. There are four lists on which countries can be classified. *Id.* For a more detailed description of the procedure for classifying countries for placement on different watch lists, see *id.* at 503-04.

[71] *See id.* at 504 (describing how private interests can to submit complaints to the USTR).

[72] *Id.*

[73] *Id.* at 505.

[74] *Id.*

[75] Rein, *supra* note 69, at 393.

[76] *Id.*

[77] A WTO panel has already heard a case involving Sections 301 to 310 and found them to be consistent with WTO obligations. United States—Sections 301 to 310 of the Trade Act of 1974-Report of the Panel, Symbol WT/DS152/R, *at* http://docsonline.wto.org/gen-search.usp (Dec. 22, 1999). In addition, developing countries are not on equal footing in the WTO. *See infra* notes 151-53 and accompanying text (discussing the differences between developed and developing countries).

In 1998 and 1999, the USTR placed South Africa on a watch list in response to the enactment of South Africa's Medicines and Related Substances Control Act (Medicines Act).[78] The USTR was concerned with "the Medicines Act's 'ill defined authority to issue compulsory licenses, authorize parallel imports and potentially otherwise abrogate patent rights.'"[79] Focusing on the parallel imports provision in the Medicines Act as being inconsistent with TRIPS, the United States negotiated with South Africa in hopes it would achieve the " 'repeal, termination or withdrawal' of Article 15C of the Medicines Act."[80] The United States suspended four items from receiving preferential tariff treatment under the Generalized System of Preferences (GSP).[81]

In addition, Thailand has been on the "priority" watch list for its limited protection of intellectual property rights.[82] AIDS activists tried to persuade the Thai Public Health Minister to grant a compulsory license for the drug didanosine (ddi), which would have been the first one issued under Article 31 of TRIPS, but pressure from the United States was too great.[83] Thailand's exports to the United States make up about one fourth of its total exports.[84]

Consumer rights groups[85] and organized members of the medical profession[86] have covered the compulsory licensing debate extensively in an effort to educate the general public. HIV/AIDS and human rights activists have directed criticism

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[78] Rein, *supra* note 69, at 401. For a detailed description of the Medicines Act and the resulting United States pressure on South Africa to change this legislation, see Duane Nash, *South Africa's Medicines and Related Substances Control Amendment Act of 1997*, 15 BERKELEY TECH. L.J. 485 (2000).

[79] Rein, *supra* note 69, at 401 (quoting Office of the United States Trade Representative, *USTR Announces Results of Special 301 Annual Review* (Apr. 30, 1999), *at* http://www.ustr.gov/releases/1999/04/99-41.html).

[80] Rein, *supra* note 69, at 401. *See* U.S. Government Efforts to Negotiate the Repeal, Termination or Withdrawal of Article 15(C) of the South African Medicines and Related Substances Act of 1965 (Feb. 5, 1999), *available at* http://www.cptech.org/ip/health/sa/stdept-feb51999.html. *See also* § 15C of Medicines and Related Substances Control Act [Medicines Act] of 1965 (as amended in 1997), JRSA 1997 vol. 3 at 1-63, *available at* http://www.polity.org.22/govdocs/legislation/1997/act90.pdf.

[81] Rein, *supra* note 69, at 401.

[82] *Id.* at 402-03.

[83] *Id.* at 402.

[84] *Id.*

[85] *See generally* Consumer Project on Technology, *About the Consumer Project on Technology*, *at* http://www.cptech.org/about.html (last revised on Feb. 22, 2001) (the Consumer Project on Technology (CPTech) was started by Ralph Nader in 1995). "[CPTech's] work is documented extensively on the CPT web page. Currently [CPTech] is focusing on intellectual property rights, and health care, electronic commerce (very broadly defined) and competition policy . . . James Love is the Director. Mike Palmedo works mostly on access to medicines." *Id.*

[86] *See* Médecins sans Frontièrs, *Campaign for Access to Essential Medecines*, *at* http://www.accessmed-msf.org/upload/reportsandpublications19920011113473/Aids%20BG(1).pdf (last visited Aug. 25, 2001).

predominantly at the office of the USTR, the pharmaceutical industry, and the WTO, in part because they believe strong international intellectual protection policies have prevented WTO Members from enacting or utilizing legislation that might give infected individuals better access to the costly but effective multi-drug regimens.

After South Africa made the USTR watch list in 1998 and 1999,

> [a]n explosion of publicity generated by AIDS activists in the United States ensued, and the U.S. government backed off its more aggressive stance.[87] ... The United States recognized South Africa's urgent need for more affordable health care in the context of the AIDS epidemic, and it pledged an end to the issue and restoration of GSP privileges in exchange for assurances that in implementing its health policy, South Africa would comply with TRIPS.[88]

In addition, in May 2000, President Clinton signed an executive order declaring that the United States would not seek changes in patent laws in sub-Saharan African countries that promote access to HIV/AIDS drugs.[89] President Bush could overturn this executive order without Congressional approval, but he has said he will not do it.[90] Though the executive order is limited to sub-Saharan African countries, Thailand received similar assurances from the United States with regard to its compulsory licensing laws.[91] And even more recently, the USTR announced the Administration's flexible approach in its dealings with Brazil.[92] The Brazil press release suggests the policy is not limited to sub-Saharan African countries.[93]

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[87] Rein, *supra* note 69, at 402 (citing Charles R. Babcock, *AIDS Activists Dog Gore a 2nd Day*, WASH. POST, June 18, 1999, at A12. "Activists targeted campaigning Vice President Gore, who was involved in negotiations through leadership of the U.S.—South Africa Binational Commission." *Id.* at n.130).

[88] Rein, *supra* note 69, at 402. *See also* Press Release, Office of the United States Trade Representative, U.S.—South Africa Understanding on Intellectual Property (Sept. 17, 1999), *at* http://www.ustr.gov/releases/1999/09/99-76.html.

[89] Anne-Marie Tabor, Recent Developments, *AIDS Crisis*, 38 HARV. J. ON LEGIS. 515, 527 (2001) (referring to Exec. Order No. 13, 155, 65 Fed. Reg. 30,521 (May 12, 2000)).

[90] *Id.*

[91] James T. Gathii, *Construing Intellectual Property Rights and Competition Policy Consistently with Facilitating Access to Affordable AIDS Drugs to Low-End Consumers*, 53 FLA. L. REV. 727, 766 (2001).

[92] Press Release, Office of the United States Trade Representative, *United States and Brazil Agree to Use Newly Created Consultative Mechanism to Promote Cooperation on HIV/AIDS and Address WTO Patent Dispute* (June 25, 2001), *at* http://www.ustr.gov/releases/2001/06/01-46.htm.

[93] *Id.*

An important point to note about this flexible approach is that most of these official announcements include the condition that developing countries be TRIPS-consistent in their legislation involving intellectual property rights.[94] Defining what is TRIPS-consistent legislation falls within the WTO's jurisdiction.[95]

A WTO panel has not yet issued a report on the precise meaning of Article 31(b), but the opportunity to do so may come in the future. The United States has already petitioned (though it eventually withdrew the petition) the WTO's Dispute Settlement Body (DSB) against Brazil on a compulsory licensing dispute.[96] In addition, the recent Declaration on the TRIPS Agreement and Public Health,[97] though not legally binding,[98] issued at the Doha Ministerial Conference in November 2001, may influence or compel some Members to test the waters by enacting or utilizing controversial public health legislation. Until the flexibility of the Declaration is solidified in an amendment to the TRIPS Agreement, there is room for dispute among Members.

United States officials may currently be hesitant to bring another compulsory licensing dispute before the WTO, either because the issue is too politically controversial or because they are fearful of an unfavorable outcome. An unfavorable outcome in this specific dispute would mean that TRIPS Article

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[94] *Id.*

> In February, the Bush Administration stated the commitment of the United States to a flexible approach that is sensitive to health crises and also protective of intellectual property rights. Under this policy, the Administration has informed WTO Members that as they take steps to address major health crises, such as the HIV/AIDS crisis in sub-Saharan Africa and elsewhere, the United States would raise no objection if Members availed themselves of the flexibility afforded by the WTO TRIPS Agreement.

Id. *See also* Gathii, *supra* note 91, at 766 (dealing with Thailand's health crisis).

[95] *See generally* World Trade Organization, TRIPS Material on the WTO Website, *at* http://www.wto.org/english/tratop_e/trips_e/trips_e.htm (last visited Aug. 25, 2002) (discussing various aspects of the TRIPS agreement).

[96] Press Release, Office of the United States Trade Representative, *supra* note 92.

[97] Doha WTO Ministerial 2001, Declaration on the TRIPS Agreement and Public Health, adopted on Nov. 14, 2001, WT/MIN(01)/DEC/2 (Nov. 20, 2001), *at* http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm (providing in part: "Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency"). *Id.*

[98] "Basically there are five different techniques for making decisions or formulating new or amended rules of trade policy in the WTO Charter: decisions on various matters, 'interpretations,' waivers, amendments to the agreements, and finally, negotiation of new agreements." John Jackson et al., LEGAL PROBLEMS OF INTERNATIONAL ECONOMIC RELATIONS, CASES, MATERIALS AND TEXT (3d ed. 1995).

31(b) language encompasses the HIV/AIDS public health emergency as a national emergency. Other trading partners of the United States could enact similar legislation and use the unfavorable ruling as persuasive authority in future disputes. Nevertheless, the fear of an unfavorable ruling is not likely to last if patent-holders see intellectual property protection weakening and pressure the government to take action before the WTO.

C. DISPUTE SETTLEMENT UNDER THE WORLD TRADE ORGANIZATION

The Uruguay Round Understanding on Rules and Procedures Governing the Settlement of Disputes (the Understanding on Dispute Settlement or DSU) established "an integrated, rules-based dispute settlement process with a right of appellate review."[99] Only Member states can initiate complaints and intervene in proceedings[100] and the DSU is the only mechanism available for resolving disputes unless parties agree otherwise.[101] The DSU assures "that all panel or Appellate Body reports will be adopted expeditiously and without modification."[102]

The DSU also prohibits Members from acting unilaterally on the following issues: "(1) whether an Uruguay Round agreement has been violated, (2) whether another member has failed to implement a DSB recommendation within a reasonable period of time, or (3) whether the level of suspension of concessions is appropriate."[103] The purpose of this commitment is to ensure that government-sanctioned barriers do not impede trade.[104]

After a country petitions the WTO to settle a dispute, the Member states involved in the dispute undergo negotiations.[105] If these discussions are not fruitful, the parties decide the composition of the panel of experts to consider the case.[106]

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[99] Kennedy, *infra* note 101, at 45.

[100] Jacqueline Peel, *Giving the Public a Voice in the Protection of the Global Environment: Avenues for Participation by NGOs in Dispute Resolution at the European Court of Justice and World Trade Organization*, 12 COLO. J. INT'L ENVTL. L. & POL'Y 47, 62 (2001).

[101] Kevin C. Kennedy, *Trade and the Environment: Implications for Global Governance: Why Multilateralism Matters in Resolving Trade-Environment Disputes*, 7 WIDENER L. SYMP. J. 31, 47 (2001); *see also* World Trade Organization, Trading into the Future—Disputes–Overview, *at* http://www.wto.org/english/thewto_e/whatis_e/tif_e/disp1_e.htm (stating that "[t]he Dispute Settlement Body has the sole authority to establish 'panels' of experts to consider the case, and to accept or reject the panels' findings or the results of an appeal").

[102] *Id.* at 45.

[103] Kennedy, *supra* note 101, at 47.

[104] *Id.* at 47.

[105] World Trade Organization, *supra* note 101.

[106] Kim Van der Borght, Critical Essay, *The Review of the WTO Understanding on Dispute Settlement, Some Reflections on the Current Debate*, 14 AM. U. INT'L L. REV. 1223, 1238 (1999).

Panels only base findings on cited agreements,[107] and they only address claims and issues necessary to reach a decision.[108] They can accept amicus briefs, though they are not required to do so.[109] One writer suggests that when amicus briefs are attached to a party's submission, the information appears to be "treated as part of the government's materials for purposes of accepting the information and having the opportunity to respond to it."[110] The WTO's General Council, acting as the Dispute Settlement Body (DSB) under the DSU,[111] then accepts or rejects a panel's conclusion.[112] Rejection, however, must be by consensus, making panel decisions virtually impossible to overturn.[113] After a ruling of the DSB, both sides can appeal.[114]

Three members of a permanent seven-member Appellate Body hear the appeal.[115] Members of the Appellate Body, like panels, can only base findings on cited agreements,[116] but can substitute a panel decision with a de novo decision of their own.[117] After the Appellate Body gives a report, the DSB again decides whether to accept or reject it.[118] Like panel reports, Appellate Body reports can only be rejected by a consensus of the DSB.[119]

In this system, panel and Appellate Body reports are not judgments; they are legal advice given to the DSB, which makes the actual decision.[120] The adoption of reports, however, is "quasi-automatic," due to DSB's voting system.[121] Therefore, WTO dispute settlement "in practice . . . functions as a judicial system of settling international disputes. . . . The direction taken by the WTO system has

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[107] World Trade Organization, *supra* note 101.

[108] Van der Borght, *supra* note 106, at 1243.

[109] Andrea Kupfer Schneider, *III. Institutional Concerns of an Expanded Trade Regime: Where Should Global Social and Regulatory Policy Be Made? Unfriendly Actions: The Amicus Brief Battle at the WTO*, 7 WIDENER L. SYMP. J. 87, 98 (2001).

[110] *Id.* at 98.

[111] Kennedy, *supra* note 101, at 45.

[112] World Trade Organization, *supra* note 101.

[113] *Id.* The winning party is unlikely to reject a favorable report, thus making consensus impossible.

[114] *Id.*

[115] *Id.* Each Appellate Body member has a four-year term.

[116] *Id.*

[117] Van der Borght, *supra* note 106, at 1243.

[118] World Trade Organization, *supra* note 101.

[119] Peel, *supra* note 100, at 63.

[120] Kim Van der Borght, *The Hague, Boston: Kluwer Law International 1999*, 94 AM. J. INT'L L. 427, 429-30 (2000) (reviewing DAVID PALMETER & PETROS C. MARVROIDIS, DISPUTE SETTLEMENT IN THE WORLD TRADE ORGANIZATION (1999)). The Hague, *Boston: Kluwer Law International, 1999*, 94 AM. J. INT'L L. 427, 429-30 (2000).

[121] *Id.*

set it firmly on route to becoming recognized de facto as an international court . . . ."[122]

D. COMMENTS ON THE WTO

Many people characterize the WTO as a secretive and powerful organization, which is isolated from non-governmental influence, and which limits state sovereignty. To some extent, these descriptions are accurate. Hearings are private; governments that petition the DSB do not have to make public their full submissions;[123] and the WTO only recently began publishing certain materials.[124] Its panels and Appellate Body are not required to consider amicus briefs presented by non-governmental organizations.[125] And finally, the organization has a highly effective, enforceable dispute settlement mechanism that prohibits states from acting unilaterally.[126]

Probably the most important characteristic of the WTO, however, is that its primary aim is to facilitate trade liberalization.[127] The DSU was primarily designed to promote that goal, not other social policies such as development, environment, security, and labor standards.[128] Though many critics argue the WTO is an isolated organization that acts against the important policy objectives of its Member states, the fact that the WTO favors free trade objectives over other social policy objectives may be a *reflection* of the national interests of its Member states.[129] For example, the United States has imposed import bans on certain products based on environmental concerns, actions other countries then challenged in the WTO.[130]

> When it came to calls for amending intellectual property rules, however, the United States and Europe switched stances on the issue of WTO competence. Defending U.S. biotechnology,

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[122] *Id.* at 430. *See also* Schneider, *supra* note 109, at 87 (suggesting that this "judicialization of the WTO and the growing importance of the dispute resolution mechanism mirror the worldwide trend toward a more binding international dispute resolution").

[123] Peel, *supra* note 100, at 62.

[124] Kennedy, *supra* note 101, at 33, 54 (describing environmentalists' misgivings about the WTO and free trade). *See also generally* Schneider, *supra* note 109 (explaining the need for increased transparency).

[125] Peel, *supra* note 100, at 62.

[126] Kennedy, *supra* note 101, at 48.

[127] Gregory Shaffer, *The World Trade Organization Under Challenge: Democracy and the Law and Politics of the WTO's Treatment of Trade and Environment Matters*, 25 HARV. ENVTL. L. REV. 1, 12 (2001).

[128] Van der Borght, *supra* note 120, at 427.

[129] *See generally* Shaffer, *supra* note 127 (demonstrating Member states' positions on various issues).

[130] Shaffer, *supra* note 127, at 19-22.

> agribusiness and pharmaceutical interests, the United States responded, "the WTO [is] not an environmental organization and it lacked the competence to insert MEA [multilateral environmental agreement] goals in WTO Agreements."[131]

Regardless of who is responsible, the fact is panel and Appellate Body reports can impact other important social policy goals. Environmental groups are accurate when they assert panel and Appellate Body decisions have prohibited unilateral measures aimed at curbing environmental degradation.[132] It is unlikely, however, the DSB will start rejecting petitions that involve significant non-trade issues.[133] And "[i]t is more likely that the Appellate Body will increasingly use language demonstrating its ability to properly balance these issues . . . ."[134]

In contrast to groups who hope for a less powerful WTO, some people see the WTO regime as a mechanism for social change.[135] Because the system imposes obligations on nation states and issues judgments that are binding, these people see the WTO as an organization that could also enforce other social policy objectives.[136]

Other people hoping just for better representation of a variety of interests push for more non-governmental organization (NGO) involvement in the system.[137] To some extent, it is already taking place. Panels and Appellate Body members consider NGO briefs attached to government materials and can consider them even if they are not attached.[138]

People who favor more NGO involvement believe these organizations will ensure that "a broader set of values will be included in the WTO balancing act."[139] The assumption, however, is that the objectives of NGOs vary from those objectives of their respective governments.[140] One writer reported:

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[131] *Id.* at 34.

[132] Kennedy, *supra* note 101, at 33-35.

[133] Schneider, *supra* note 109, at 93.

[134] *Id.*

[135] *See, e.g.*, Patricia Stirling, *The Use of Trade Sanctions as an Enforcement Mechanism for Basic Human Rights: A Proposal for Addition to the World Trade Organization*, 11 AM. U. J. INT'L L. & POL'Y 1, 4 (1996) (proposing "the formation of an international human rights body within the WTO, charged with overseeing the administration of a system for multilateral enforcement of human rights through trade sanctions").

[136] *Id.* at 33-46.

[137] Van der Borght, *supra* note 106, at 1227.

[138] *See* Van der Borght, *supra* note 108, at 1243 and accompanying text; *see* Schneider, *supra* notes 109-10, at 98 and accompanying text.

[139] Schneider, *supra* note 109, at 93.

[140] *Id.*

> [A] recent study of NGO involvement in rule-making found that NGOs were far more likely to reflect their respective government's position, rather than form alliances with other NGOs in order to pressure governments. In other words, the idea that NGOs will actually counterbalance their governments is not true and, therefore, we might conclude that the presence of NGOs really does not add anything of substance to decision-making in the WTO.[141]

The other thing to consider in deciding whether to favor more NGO involvement in the WTO dispute settlement system is that more involvement of NGOs means more involvement of private industry actors, groups that are not necessarily in favor of the social objectives of certain NGOs.[142] As one writer put it, "[i]t is one thing to imagine that an environmental group might participate, it is another thing to see well-funded industry groups and law firms participating in the WTO dispute resolution process."[143] Already in one case, the Appellate Body allowed in amicus briefs from industry groups not attached to a government's filings.[144] Though the Appellate Body members did not use the briefs, they might do so in the future.[145]

The same concerns expressed above are equally applicable in the HIV/AIDS compulsory licensing dispute and could contribute to an unfavorable ruling for developing countries. Like environmental objectives, social objectives aimed at realizing human rights (right to health) need more recognition by Member states before WTO panels and the Appellate Body will consider them.[146] There is an "enduring gap between human rights principles and the practice of states. . . . [D]espite the lip service paid to the notion of human rights, those rights are routinely violated by governments all over the world."[147] Significantly, one writer suggests, "[s]o far the WTO dispute settlement scheme has been acceptable to members because WTO panels have not dared to suggest that trade is a human as opposed to a governmental right. . . . If the past is prologue, the WTO will need to build a political consensus (at both national and international levels)

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[141] *Id.*

[142] *Id.* at 100.

[143] *Id.*

[144] Schneider, *supra* note 109, at 98 (discussing the British Steel case).

[145] *Id.*

[146] Jose E. Alvarez, *How Not to Link: Institutional Conundrums of an Expanded Trade Regime*, 7-SPG WIDENER L. SYMP. J. 1, 14-15 (2001).

[147] Richard B. Bilder & David P. Stewart, Book Review and Note Review Essay, *U.S. Department of State, Human Rights at the Millennium*, 95 AM. J. INT'L L. 227, 227-28 (Jan. 2001).

before it tries to build a viable trade constitution that fully encompasses issues like human rights and the environment."[148]

Even if a WTO panel believes a human right to health exists and should be considered in the balance, many people believe strong intellectual property protection accomplishes public health objectives. Not only is there "broad recognition of the role that patents and [Intellectual Property Rights] can play in stimulating health-related research and development ('R&D')" but "the level of protection conferred to inventions may influence foreign investment, technology transfer, and research (especially joint research programs and research to address local needs)."[149] This predominant view will also make panel members unwilling or unable to call the right to have access to HIV/AIDS medications a human right that trumps intellectual property rights.

In addition, it is unlikely the WTO will refrain from hearing the HIV/AIDS compulsory licensing dispute. Though it is a politically controversial issue, the fact is WTO Members must fulfill their obligations under TRIPS and resolve disputes over its implementation in the WTO dispute settlement system.

Finally, a developing nation will not be on equal footing with the United States in dispute settlement. Developing countries often do not have the financial capabilities or expertise to effectively participate in the process; they cannot effectively enforce WTO recommendations; and the process is likely to hurt them more than an opposing developed nation.[150] In addition, at this point, WTO panels are not required to consider amicus briefs. Therefore, assistance in the form of amicus briefs from specialized non-governmental health organizations could have little impact.

Though some developing nations fared well in the environmental disputes,[151] in those disputes, unilateral actions by the United States were found inconsistent with trade liberalization.[152] In contrast, United States officials will maintain that the strongest intellectual property protection is necessary to facilitate trade liberalization in a TRIPS Article 31(b) dispute before a WTO panel. A developing nation, without the financial resources and comparative expertise of trade specialists, will be in the less favorable position of arguing for weaker intellectual property protection. Given the WTO's primary goal to facilitate trade liberalization, a WTO panel is likely to find in favor of the United States, and conclude that TRIPS Article 31(b) does not encompass public health emergencies.

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[148] Alvarez, *supra* note 146, at 18-19.

[149] Carlos Correa, *Public Health and Patent Legislation in Developing Countries*, 3 TUL. J. TECH. & INTELL. PROP. 1, 3 (2001).

[150] Van der Borght, *supra* note 106, at 1226.

[151] Kennedy, *supra* note 101, at 63.

[152] *See* Shaffer, *supra* note 127, 19-22.

III. ANALYSIS

The subject of this analysis is the compulsory license provision of TRIPS Article 31, more specifically, Article 31(b). A successful compulsory license under this provision would obligate a country to meet the other mandatory requirements of Article 31 (discussed below), but allow the country to waive the requirement of first attempting to obtain authorization from the patent right holder.[153] The issue is whether TRIPS Article 31(b) encompasses a public health emergency such as the HIV/AIDS epidemic.

A. WTO PANEL AND APPELLATE BODY REVIEW

Decisions of the WTO DSB are not precedent for future decisions, but they are binding on the parties involved, and are persuasive authority.[154] Subsequent panels often consider adopted panel reports under GATT 1947 and 1994.[155] The reports "create legitimate expectations among WTO Members, and, therefore, should be taken into account where they are relevant to any dispute."[156] The Appellate Body has even said a panel could find guidance in the reasoning of a relevant unadopted panel report.[157] Therefore, in a TRIPS Article 31(b) dispute, a WTO panel may consider past GATT decisions, its own recommendations, and Appellate Body recommendations, adopted or unadopted, if it finds such decisions to be relevant to the dispute.

Article 3.2 of the Dispute Settlement Understanding requires that panels and the Appellate Body " 'clarify' the WTO Agreements, including GATT 1994 . . ., 'in accordance with customary rules of interpretation of public international law.' "[158] According to the Appellate Body, this requirement first refers to Articles 31 and 32 of the Vienna Convention on the Law of Treaties (Vienna Convention).[159]

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[153] TRIPS, *supra* note 1, 33 I.L.M. at 95.

[154] Rein, *supra* note 69, at 398 n.113. Note that previous panel decisions under GATT 1947 and GATT 1994, as well as WTO panel and Appellate Body decisions, "do not constitute 'subsequent practice in the application of the treaty which establishes the agreement of the parties regarding its interpretation' in the sense of Article 31(3)(b) of the 1969 Vienna Convention." Hannes L. Schloemann & Stefan Ohlhoff, *"Constitutionalization" and Dispute Settlement in the WTO: National Security as an Issue of Competence*, 93 AM. J. INT'L L. 424, 431 n.38 (Apr. 1999).

[155] Schloemann & Ohlhoff, *supra* note 154, at 431 n.38.

[156] *Id.*

[157] *Id.*

[158] *Id.*

[159] *Id.*

According to Vienna Convention Article 31, a treaty is to be interpreted in accordance with the ordinary meaning of the terms of the treaty, in their context, and in light of the treaty's object and purpose.[160] Subsequent agreements between the parties regarding the treaty's interpretation or application, subsequent practice in the application of the treaty that establishes agreement regarding its interpretation, and any relevant rules of international law applicable in the relations between the parties are also to be taken into account.[161] According to Article 32, supplementary means of interpretation may be used to confirm the meaning resulting from application of Article 31 or to determine the meaning when interpretation yields ambiguous, obscure, absurd, or unreasonable results.[162]

B. TRIPS, GENERALLY

The TRIPS Agreement created an international structure for the protection of intellectual property rights.[163] It "sets forth detailed obligations in respect to the protection of inventions, including:

> (1) to recognize patents for inventions in all fields of technology, with limited exceptions; (2) not to discriminate with respect to the availability or enjoyment of patent rights; (3) to grant patents rights for at least twenty years from the date of application; (4) to limit the scope of exceptions to patent rights and to grant compulsory licenses only under certain conditions; and (5) to effectively enforce patent rights.[164]

Because the Agreement does not establish uniform international law or legal requirements, countries are permitted to design regulations that balance intellectual property protection with other public policy objectives.[165] How much room they have to balance and still be TRIPS-consistent, however, is central to TRIPS Article 31(b)'s construction.

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[160] Vienna Convention on the Law of Treaties, May 23, 1969, art. 31.1, 1155 U.N.T.S. 331, 341 [hereinafter Vienna Convention].

[161] *Id.*

[162] *Id.*

[163] Correa, *supra* note 149, at 3.

[164] *Id.* at 3-4.

[165] *Id.* at 4.

C. TRIPS ARTICLE 31

Under TRIPS, a term of patent protection is twenty years. The idea behind compulsory licenses is that they offer some protection against abuses of power that might occur during this time.[166] Most compulsory licenses in the United States have been issued under antitrust laws to remedy anticompetitive practices.[167]

TRIPS Article 31, though it does not use the term "compulsory license," sets forth the provisions that must be followed should countries decide to grant compulsory licenses. Provided are the most relevant provisions to this Note:

> Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected: . . .
> (b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a *national emergency or other circumstances of extreme urgency* or in cases public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable . . .
> (c) the scope and duration of such use shall be limited to the purpose for which it was authorized . . .
> (f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use . . .
> (g) authorization for such use shall be liable . . . to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur . . .
> (h) the right holder shall be paid adequate remuneration . . . .[168]

Though many states agree the HIV/AIDS crisis meets the definition of "national emergency,"[169] "there is no firmly entrenched concept of 'emergency'

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[166] *Id.* at 6.
[167] *Id.* at 44 n.177.
[168] TRIPS, *supra* note 1, 33 I.L.M. at 95 (emphasis added).
[169] *See* Doha Declaration, *supra* note 97.

in international law."[170] Therefore looking solely at the terms of Article 31(b) is inadequate in this case. In deciding whether the terms "national emergency" can be interpreted to include a public health emergency, and more specifically the HIV/AIDS crisis, one must consider all of the terms of TRIPS Article 31, in light of the object and purpose of the Agreement, and determine whether it accommodates this particular public health objective. The following sections will reveal the difficulties in concluding that TRIPS Article 31(b) can be used to address the HIV/AIDS public health emergency.

D. TRIPS ARTICLES 7 AND 8.1

In finding the object and purpose of Article 31's "national emergency provision," a compulsory licensing dispute could involve discussion of TRIPS Articles 7 and 8.1.

TRIPS Article 7 states the "Objectives" of the Agreement:

> The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.[171]

TRIPS Article 8 states the "Principles" of the Agreement. Article 8.1 provides:

> Members may, in formulating or amending 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.[172]

In the Canada-Patent Protection of Pharmaceutical Products dispute (Canada dispute), a WTO panel addressed the consistency of certain Canadian patent legislation with the TRIPS Agreement.[173] One disputed piece of legislation was

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[170] Schloemann & Ohlhoff, *supra* note 154, at 445.
[171] TRIPS, *supra* note 1, 33 I.L.M. at 86-87.
[172] *Id.* at 87.
[173] Canada–Patent Protection of Pharmaceutical Products, WT/DS114/R (Mar. 17, 2000)

the "regulatory review exception,"[174] which allowed use of a patented product for the development and submission of information required by Canadian law. Unlike compulsory licensing under TRIPS Article 31, the "regulatory review exception" falls under TRIPS Article 30.[175] Both Article 30 and 31, however, "permit exceptions to patent rights subject to certain mandatory conditions."[176]

In assessing the object and purpose of Article 30, the panel compared the views of Canada and the European Communities regarding Articles 7 and 8.1. According to Canada, Article 7 makes the "balance between the intellectual property rights created by the Agreement and other important socio-economic policies of WTO Member governments" one of the TRIPS Agreement's key goals.[177] Furthermore, "Article 8 elaborates the socio-economic policies in question, with particular attention to health and nutritional policies."[178] The European Communities, in comparison, viewed Articles 7 and 8 as "statements that describe the balancing of goals that had already taken place in negotiating the final texts of the TRIPS Agreement."[179]

Essentially, the panel found that the mere presence of Article 30 shows a recognition that the TRIPS Agreement's definition of patent rights would need to be adjusted, but Article 30's limited conditions "testify strongly that the negotiators of the Agreement did not intend Article 30 to bring about what would be equivalent to a renegotiation of the basic balance of the Agreement."[180]

Given that TRIPS Articles 30 and 31 both permit exceptions to patent rights, a similar analysis could be given to TRIPS Articles 7 and 8.1 in a HIV/AIDS-related compulsory licensing dispute. They will therefore be considered in determining the object and purpose of Article 31. Developing countries,

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[hereinafter Canada Dispute].

[174] Canadian Patent Act, section 55.2(1) provides:

> It is not an infringement of a patent for any person to make, construct, use or sell the patented invention solely for uses reasonably related to the development and submission of information required under any law of Canada, a province or a country other than Canada that regulates the manufacture, construction, use or sale of any product.

E.g., *id.* at 2.1; *see also id.* at 7.2.

[175] Canada Dispute, *supra* note 173, at 7.39. TRIPS Article 30, Exceptions to Rights Conferred, provides: "Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties." TRIPS, *supra* note 1, 33 I.L.M. at 95.

[176] Canada Dispute, *supra* note 173, at 7.91.

[177] *Id.* at 7.24.

[178] *Id.*

[179] *Id.* at 7.25.

[180] *Id.* at 7.26.

however, are unlikely to find that these provisions unequivocally support involuntary licenses in a public health emergency context.

According to the plain terms of Article 8.1, public health measures adopted by Members must be "consistent with the provisions of this Agreement" (such as TRIPS Article 27.1 discussed below) and "necessary" to protect public health.[181] A panel will find that TRIPS Article 31(b) public health emergency legislation is not consistent with TRIPS Article 27.1, that it is not "necessary" under Article 8.1, and that when the other terms of Article 31 are applied in the HIV/AIDS context, it upsets the basic balance of the Agreement.

E. TRIPS ARTICLE 27.1

In the Canada dispute, though the debate revolved in part around whether TRIPS Article 30 was subject to TRIPS Article 27.1, the panel also briefly discussed TRIPS Article 31 and the relationship between these two provisions.[182] The panel report noted the "acknowledged fact that the Article 31 exception for compulsory licenses and government use is understood to be subject to the non-discrimination rule of 27.1."[183] TRIPS Article 27.1 provides in part, "patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced."[184]

Though the panel found TRIPS Article 30, like TRIPS Article 31, was subject to the non-discrimination requirement of TRIPS Article 27.1,[185] it did not find the evidence sufficient to prove Canada's "regulatory review exception" (section 55.2(1)) was discriminatory.[186] The panel deferred from giving a precise definition of discrimination, but concluded in this particular dispute:

> It was not proved that the legal scope of Section 55.2(1) was limited to pharmaceutical products, as would normally be required to raise a claim of *de jure* discrimination. Likewise, it was not proved that the adverse effects of Section 55.2(1) were limited to the pharmaceutical industry, or that the objective indications of purpose demonstrated a purpose to impose disadvantages on pharmaceutical patents in particular, as is often required to raise a claim of de facto

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[181] *Id.* at 4.30(a).
[182] *Id.* at 7.90-7.91.
[183] Canada Dispute, *supra* note 173, at 7.91.
[184] TRIPS, *supra* note 1, 33 I.L.M. at 93-94.
[185] Canada Dispute, *supra* note 173, at 7.93.
[186] *Id.* at 7.105. *See supra* note 174 for the text of section 55.2(1).

> discrimination. Having found that the record did not raise any of these basic elements of a discrimination claim, the Panel was able to find that Section 55.2(1) is not inconsistent with Canada's obligations under Article 27.1 of the TRIPS Agreement.[187]

In the Canada dispute, the legislation itself did not mention pharmaceuticals. It used the language, "any product."[188] Canada even cited a court decision in which a producer of a medical device invoked section 55.2(1).[189]

If a developing nation has legislation that attempts to utilize the TRIPS Article 31(b) "national emergency or other circumstances of extreme urgency"[190] exception in a public health emergency context such as HIV/AIDS, and its primary purpose is to ease the patent protection on certain pharmaceuticals, there could be an Article 27.1 discrimination problem. Though the Canada panel did not give a precise definition of the term "discriminatory," a WTO panel might find the language in the above Canada panel's conclusion persuasive. A developing nation would be unlikely to surpass challenges that the legal scope of such legislation is not limited to pharmaceuticals, and that adverse effects are not limited to the pharmaceutical industry. A panel would find the legislation discriminatory, and thus inconsistent with TRIPS Article 27.1.

In addition, though the Canada panel indicated at one point in its report that "Article 27 does not prohibit bona fide exceptions to deal with problems that may exist only in certain product areas,"[191] it offered no further explanation of "bona fide." There may be room for debate in the future over what exceptions a panel will consider to be bona fide under TRIPS Article 27.1. Nonetheless, even if a panel finds TRIPS Article 31(b) public health emergency legislation to be "consistent with the terms" of Article 27.1, it is not likely to find such legislation "necessary" within the meaning of TRIPS Article 8.1.

F. GATT ARTICLE XX

A WTO panel hearing the TRIPS compulsory licensing dispute could consider a prior panel's analysis of the term "necessary" in the GATT Article XX exceptions.[192] GATT, like TRIPS, is committed to the goal of liberal trade.[193]

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[187] *Id.*

[188] *Id.* at 2.1.

[189] *Id.* at 7.97.

[190] TRIPS, *supra* note 1, 33 I.L.M. at 95.

[191] Canada Dispute, *supra* note 173, at 7.92.

[192] *See* Schloemann & Ohlhoff, *supra* note 154, at 431 n.38; *but see* Correa, *supra* note 149, at 11 (arguing that it is "doubtful whether GATT Article XX(b) would apply in the TRIPS context").

[193] Kennedy, *supra* note 101, at 38.

GATT, however, also includes exceptions that can be invoked to restrict certain imports.[194] GATT Article XX provides in part: "nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures: . . . (b) *necessary* to protect human, animal or plant life or health . . . ."[195]

In Thailand-Restrictions on Importation of and Internal Taxes on Cigarettes (Thai Cigarettes), a 1990 GATT panel defined the term "necessary" in GATT Article XX(b).[196]

The United States claimed Thailand's imposition of import restrictions on tobacco was inconsistent with GATT Article XI.[197] Thailand, however, claimed it was trying to protect its public from the harmful ingredients in imported tobacco[198] and reduce the consumption of cigarettes,[199] thus falling within the scope of the Article XX(b) exception.

The panel agreed the issue fell within the scope of Article XX(b), and noted that it "clearly allowed contracting parties to give priority to human health over trade liberalization; [H]owever, for a measure to be covered by Article XX(b) it had to be 'necessary.' "[200] The panel determined that import restrictions "could be considered to be 'necessary' in terms of Article XX(b) only if there were no alternative measure consistent with the General Agreement, or less inconsistent with it, which Thailand could reasonably be expected to employ to achieve its health policy objectives."[201] The panel concluded there were other measures consistent with GATT available to Thailand to achieve this health policy goal, and therefore found that the import restrictions were not necessary within the meaning of Article XX(b).[202]

"This interpretation of 'necessary,' " according to one writer, "restates the minimum derogation principle. In other words, any measure taken under one of the Article XX exceptions must be the least trade restrictive measure available."[203]

In a more recent report, European Communities—Measures Affecting Asbestos and Asbestos-Containing Products, the Appellate Body discussed the necessity of a French measure that prohibits the manufacturing, importing, etc.

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[194] *Id.*

[195] General Agreement on Tariffs and Trade, Oct. 30, 1947, art. XX(b), 61 Stat. A-11, A-60, 55 U.N.T.S. 194, 262 (emphasis added) [hereinafter GATT].

[196] Thailand Restrictions on Importation of and Internal Taxes on Cigarettes, Nov. 7, 1990, GATT B.I.S.D. (37th Supp.) at 200 (1989-1990), DS10/R-375/200 (Oct. 5, 1990) [hereinafter Thai Cigarettes].

[197] *Id.* at 202.

[198] *Id.* at 223.

[199] *Id.* at 223-24.

[200] *Id.* at 223.

[201] Thai Cigarettes, *supra* note 196, at 223.

[202] *Id.* at 225-26.

[203] Kennedy, *supra* note 101, at 40.

of products containing asbestos fibers.[204] The Appellate Body said the object of the measure is the "preservation of human life and health through the elimination, or reduction, of the well-known, and life-threatening, health risks posed by asbestos fibres."[205] It emphasized the importance of this objective and even noted that the more important the value pursued, the easier it would be to see the necessity in measures designed to achieve such objectives.[206]

The Appellate Body, however, discussed and did not reject the Thai Cigarettes interpretation of "necessary."[207] In addition, it still asked if "there is an alternative measure that would achieve the same end and that is less restrictive of trade . . . ."[208] France's chosen level of health protection was a "halt in the spread of asbestos-related health risks."[209] The "controlled use" alternative proposed by Canada, according to the Appellate Body, was not reasonable because it "would involve the continuation of the very risk the Decree seeks to halt."[210] Thus, the French restriction was "necessary" under Article XX(b).[211]

TRIPS Article 31, like GATT Article XX, removes in particular instances a Member state from its obligations under other portions of the Agreement. And though unlike GATT Article XX, TRIPS Article 31 itself does not include the term "necessary,"[212] TRIPS Article 8.1 (discussed above) does include such language in reference to public health measures.[213] If a WTO panel decides to use similar reasoning as it did in Thai Cigarettes, it might find that for a public health measure to be covered by TRIPS Article 31(b), it must also be necessary, according to the "principles" addressed in TRIPS Article 8.1.

Panel members who believe that the strongest intellectual property protection promotes free trade will probably not consider compulsory licensing legislation that makes the HIV/AIDS crisis a "national emergency or other circumstance[] of extreme urgency,"[214] thus waiving the TRIPS Article 31(b) requirement, to be the least trade restrictive measure available. There will be arguments from the developed world that negotiating lower medication prices, donating medication,

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[204] European Communities—Measures Affecting Asbestos and Asbestos-Containing Products, WT/DS135/AB/R at 164-175 (Mar. 12, 2001) [hereinafter EC—Asbestos Dispute].

[205] *Id.* at 172.

[206] *Id.*

[207] *Id.* at 170.

[208] *Id.* at 172.

[209] EC-Asbestos Dispute, *supra* note 204, at 173.

[210] *Id.* at 174.

[211] *Id.* at 175.

[212] TRIPS, *supra* note 1, 33 I.L.M. at 95.

[213] *Id.* at 87.

[214] *Id.* at 95.

and further developing infrastructure in the most affected nations are alternatives to relaxing intellectual property rights.

In addition, though the Appellate Body report in the EC—Asbestos Dispute appears to reflect a more flexible approach to dealing with measures used to preserve human life and health, the factual circumstances in a HIV/AIDS compulsory licensing dispute will be significantly different. The alternatives mentioned above cannot be said to continue a risk a developing nation seeks to halt. Though they may not be as quick or effective, they do and will help developing nations deal with the epidemic, and are thus reasonable alternatives and less restrictive of trade than compulsory licenses under the national emergency exception. Therefore, a panel is likely to conclude that public health emergency legislation is not "necessary" within the meaning of TRIPS Article 8.1, and thus is not covered by TRIPS Article 31(b).

G. OTHER IMPLEMENTATION DIFFICULTIES INHERENT IN TRIPS ARTICLE 31

The national emergency provision only waives one requirement of TRIPS—that before a compulsory license is issued, the proposed user must first try to obtain a voluntary license from the right holder.[215] The other provisions of TRIPS Article 31 must still be met. Difficulties in implementing these measures or the potential for them to be used for extended periods of time may further persuade a panel that TRIPS Article 31 generally does not encompass public health emergencies.

According to TRIPS Article 31(c), the scope and duration of use is limited to the purpose for which it was authorized, and that authorization, according to TRIPS Article 31(g), is liable to be terminated "when the circumstances which led to it cease to exist and are unlikely to recur."[216]

If applied in the context of a HIV/AIDS public health emergency, this language could be interpreted to mean that as long as the HIV/AIDS crisis exists or is likely to recur, countries may use compulsory licenses without first attempting to gain voluntary approval from patent holders. Such an interpretation has the potential to make a twenty-year monopoly on a pharmaceutical worthless in developing nations hardest hit by the HIV/AIDS epidemic, considering it will likely take more than twenty years to address the problem. In addition to losing profits in countries manufacturing the drugs under Article 31(b), the patent holder could lose profits in countries lacking the infrastructure to manufacture the drugs, which import the drugs from those manufacturing countries. TRIPS Article 31(f) limits this practice to some extent, stating that

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[215] *Id.* at 95.

[216] *Id.* at 95; *see supra* note 168 and accompanying text.

compulsory licenses must be "predominantly for the supply of the domestic market of the Member authorizing such use,"[217] but the total loss of profit from widespread use of such measures could be significant in the eyes of patent holders.[218]

Finally, according to TRIPS Article 31(h), "the right holder shall be paid adequate remuneration."[219] One writer has noted that to determine compensation, "authorities may require the patent holder to disclose product-specific R&D investments, revenues and other relevant economic data, while ensuring adequate protection of any confidential commercial data."[220] Though developing countries may be willing to compensate pharmaceutical companies, these companies may be less than willing to turn over the information necessary to come up with compensation figures.

A powerful argument of the industry in the compulsory licensing debate is that in order to encourage innovation and development, it is imperative that companies retrieve research and development costs through exclusive patent ownership.[221] High prices and twenty-year monopolies recover these costs. Many companies, however, have substantial profit margins even when research and development costs are taken into account (with some companies making annual profits two to three times the amounts they put into research and development).[222] In addition, some of the research used in developing these drugs has been publicly funded.[223] There are many reasons for keeping commercial data on individual drugs confidential, but one of them is that as long as it is kept confidential, the general public's backing for the strongest intellectual property protection remains intact. Even if a company is assured that confidential commercial data will be protected, it is still possible that the public will draw

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[217] TRIPS, *supra* note 1, 33 I.L.M. at 95; *see supra* note 168 and accompanying text.

[218] Proponents of the strongest intellectual property protection could argue that like parallel imports, compulsory licensing schemes impact profits in such a way that it becomes difficult for the company to recoup research and development costs, thus in the end harming those nations in greatest need of innovative medicines. *See* A. Bryan Baer, *Price Controls Through the Back Door: The Parallel Importation of Pharmaceuticals*, 9 J. INTELL. PROP. L. 109, 134-35 (2001) (discussing the negative consequences of parallel imports).

[219] TRIPS, *supra* note 1, 33 I.L.M. at 95; *see supra* note 168 and accompanying text.

[220] Correa, *supra* note 149, at 51.

[221] *See id.* at 43.

[222] For details on profits and revenues allocated to research and development, marketing, etc., see Families USA, *Profiting from Pain: Where Prescription Drug Dollars Go*, Families USA Foundation, *available at* http://www. familiesusa.org/PPreport.pdf (July 2002).

[223] For details on government involvement in research and development, see Consumer Project on Technology, *Additional Notes on Government Role in the Development of HIV/AIDS Drugs*, *available at* http://www.cptech.org/ip/health/aids/gov-role.html (last modified Feb. 23, 2000).

negative inferences from what constitutes "adequate" compensation on a particular drug.

Because of these implementation difficulties, a panel may find Article 31 cannot realistically accommodate public health emergencies such as the HIV/AIDS epidemic. Like the GATT panel's analysis of the limitations of TRIPS Article 30 in the Canada case, a WTO panel may find that Article 31's limited conditions also "testify strongly" that negotiators of the TRIPS Agreement did not intend Article 31 "to bring about what would be equivalent to a renegotiation of the basic balance of the Agreement."[224] The risk that patents will be of less value in certain countries, and that compensation will be too difficult, may give a panel cause to believe that such an application of TRIPS Article 31 is upsetting the basic balance of the agreement, and is therefore unacceptable.

IV. CONCLUSION

A panel in the WTO as it exists today will likely find: that TRIPS Article 31(b) legislation directed at pharmaceuticals is discriminatory, and therefore inconsistent with TRIPS Article 27.1; that because there are less restrictive trade measures available to address the HIV/AIDS epidemic, it is not "necessary" under TRIPS Article 8.1; and that when the other terms of Article 31 are applied in the HIV/AIDS context, it upsets the basic balance of the Agreement—and thus conclude that TRIPS Article 31(b) does not encompass public health emergencies such as the HIV/AIDS epidemic.

Current political influences on the WTO and the WTO texts as they exist primarily promote the liberalization of trade. Panels and the Appellate Body issue reports and decisions that impact other important social policy goals. People who are dissatisfied with the current WTO, particularly in the context of HIV/AIDS, should work towards making the right to health a legal and enforceable human right in the international community, getting developing nations better WTO legal assistance and an effective enforcement mechanism,[225] and influencing WTO Members to amend the TRIPS Agreement to accommodate public health objectives aimed at addressing the HIV/AIDS epidemic. Accomplishing these goals could bring a more suitable balance of social policy objectives into the WTO dispute settlement process.

JOHANNA KIEHL

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[224] *See supra* note 180 and accompanying text.
[225] Van der Borght, *supra* note 106, at 1226.