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The TRIPS Council's Solution to the Paragraph 6 Problem: Toward Compulsory Licensing Viability for Developing Countries

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INTRODUCTION

AIDS is a serious global health problem, affecting thirty-six million HIV-positive people worldwide.¹ Fortunately, lives can be saved and prolonged with proper treatment.² Although several drugs are on the market to treat AIDS,³ access to these pharmaceuticals is difficult for poor nations that cannot afford the high prices charged by pharmaceutical companies.⁴ Some critics argue that stronger patent laws lead to high drug prices.⁵

Drug prices increased after the Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS Agreement) took force in 1995.⁶ As a result, “[g]overnments in developing countries [were] concerned with bringing the price of these medicines

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1. Rosalyn S. Park, Note, *The International Drug Industry: What the Future Holds for South Africa's HIV/AIDS Patients*, 11 MINN. J. GLOBAL TRADE 125, 126 (2002).

2. *Id.* at 127.

3. Anti-retrovirals are currently the most successful type of AIDS drug, dramatically reducing the amount of virus in the blood and significantly decreasing mother-to-child transmission. *Id.* at 127-28.

4. See generally Zita Lazzarini, *Making Access to Pharmaceuticals a Reality: Legal Options Under TRIPS and the Case of Brazil*, 6 YALE HUM. RTS. & DEV. L.J. 103 (2003) (arguing that a full usage of exceptions to patents under the rules will increase access to drugs for middle-income countries).

5. See, e.g., Park, *supra* note 1, at 125-26 (“Stronger patent protection means higher drug prices . . .”). But see Lazzarini, *supra* note 4, at 108 (noting that “[t]he relationship between patent protection and price is [a] source of controversy”).

6. Park, *supra* note 1, at 125.

down, but in the process [came] under pressure from the developed world to comply with TRIPS in undertaking this process.”⁷ Developing countries continue to struggle with this, but may be aided by new developments that refine the TRIPS Agreement’s meaning regarding public health.

A practice known as compulsory licensing, allowed by the TRIPS Agreement, is one way for developing countries to obtain medicines more cheaply.⁸ However, Article 31(f) of the TRIPS Agreement limits the ability of developing countries to use compulsory licensing if they have little or no pharmaceutical manufacturing capabilities.⁹ The WTO Ministerial Conference had charged the TRIPS Council with fixing this problem, known as the Paragraph 6 Problem, before the end of 2002.¹⁰

This Note explains the TRIPS Council’s August 2003 Decision on the Paragraph 6 Problem in the context of past discussions and explores its implications for developing countries. Part I summarizes the origins of the TRIPS Agreement and explains the practice of compulsory licensing. Part II outlines the Paragraph 6 Problem and proposed solutions, while Part III explains the new TRIPS Council Decision that addresses the problem. Part IV analyzes the Decision’s solution and explores criticisms of the Decision. This Note concludes that the Decision is a positive step toward greater availability of medicine and will likely give developing countries bargaining power in negotiating cheaper drug prices.

7. Nabila Ansari, *International Patent Rights in a Post-Doha World*, 11 CURRENTS: INT’L TRADE L.J. 57, 61 (2002).

8. See Park, *supra* note 1, at 131-32.

9. See Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, art. 31(f), Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [hereinafter TRIPS Agreement]; Press Release, WTO NEWS 2003 Press Releases, Decision Removes Final Patent Obstacle to Cheap Drug Imports (Aug. 30, 2003), at http://www.wto.org/english/news_e/pres03_3/pr350_e.htm (last visited Jan. 5, 2004) [hereinafter Press Release].

10. WTO Ministerial Conference, Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)DEC/W/2 (Nov. 14, 2001), at http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.pdf (last visited Jan. 5, 2004) [hereinafter Doha Declaration]; see Press Release, *supra* note 9 (referring to the “Paragraph 6’ issue”).

I. THE TRIPS AGREEMENT AND COMPULSORY LICENSING

A. DEVELOPMENT OF INTERNATIONAL PATENT LAW AND THE TRIPS AGREEMENT

Protection for intellectual property rights has existed on the international level since as far back as the Paris Convention for the Protection of Industrial Property in 1883.¹¹ The Paris Convention established protection for trademarks and patents.¹² This treaty was criticized for failing to set substantive minimum standards and merely requiring that member countries treat foreign and domestic claimants equally.¹³

In 1967, the World Intellectual Property Organization (WIPO) was created to address global intellectual property protection issues.¹⁴ An agency of the United Nations, WIPO was faulted for its weak enforcement, inadequate protection of intellectual property, and ineffective dispute resolution system.¹⁵

The TRIPS Agreement emerged in 1994 from the Uruguay Round negotiations of the General Agreement on Tariffs and Trade (GATT).¹⁶ The inclusion of intellectual property on the agenda was the result of extensive lobbying by the United States and pharmaceutical companies.¹⁷ While WIPO may have

11. Paris Convention for the Protection of Industrial Property, Mar. 20, 1883, 21 U.S.T. 1583, 828 U.N.T.S. 305 (last revised July 14, 1967) [hereinafter Paris Convention]. The Berne Convention for the Protection of Literary and Artistic Works, adopted in 1887 and modified most recently in 1971, provides copyright protection. Berne Convention for the Protection of Literary and Artistic Works, Sept. 9, 1886, 828 U.N.T.S. 221 [hereinafter Berne Convention].

12. L. Danielle Tully, Note, *Prospects for Progress: The TRIPS Agreement and Developing Countries After the Doha Conference*, 26 B.C. INT'L & COMP. L. REV. 129, 132 (2003).

13. See Tully, *supra* note 12, at 131-32; Naomi A. Bass, Note, *Implications of the TRIPS Agreement for Developing Countries: Pharmaceutical Patent Laws in Brazil and South Africa in the 21st Century*, 34 GEO. WASH. INT'L L. REV. 191, 194-95 (2002). As a result, developing countries could sidestep intellectual property protections by refusing to recognize the protections domestically. The Berne Convention did provide standards, but did not provide sufficiently clear provisions for enforcement of rights. See Tully, *supra* note 12, at 132.

14. Bass, *supra* note 13, at 195.

15. See Tully, *supra* note 12, at 132 ("WIPO provided little in the way of coordination during the 1970s and early 1980s.").

16. The Uruguay Round lasted from 1986 to 1994. Robert Weissman, *A Long Strange TRIPS: The Pharmaceutical Industry Drive to Harmonize Global Intellectual Property Rules, and the Remaining WTO Legal Alternatives Available to Third World Countries*, 17 U. PA. J. INT'L ECON. L. 1069, 1077 (1996).

17. See *id.* at 1077 ("[T]he United States insisted that intellectual property pro-

seemed a logical choice, GATT was instead chosen as the vehicle for the international intellectual property agreement.¹⁸ For developed countries, GATT offered several advantages over WIPO, including stronger enforcement and the ability to bind Member countries to minimum standards.¹⁹ In contrast, developing countries such as India and Brazil opposed the inclusion of intellectual property protection in GATT on the grounds that intellectual property rights should not be joined with free trade.²⁰ The Uruguay Round also established the World Trade Organization (WTO) to oversee GATT and TRIPS.²¹ In addition, the Council for TRIPS (TRIPS Council) was created.²² It is responsible for managing the operation of the TRIPS Agreement, and is accountable to the General Council of the WTO.²³

The goal behind creating the TRIPS Agreement was to begin harmonizing global intellectual property laws.²⁴ WTO members are required to implement the TRIPS agreement into their own intellectual property laws.²⁵ Article 27 of the TRIPS Agreement sets out the definition of patents and patentable subject matter.²⁶ According to Article 28, a patent holder has the exclusive right of "making, using, offering for sale, selling, or importing" her product.²⁷ The patent holder also has the exclu-

tection be included in the Uruguay Round GATT negotiations . . ."). The pharmaceutical industry aggressively encouraged the United States to adopt its concerns about strict intellectual property protections as its own. *Id.* Tactics included frequent testimony before Congress and funding of academic studies that praised strict patent laws. *Id.* at 1076-77.

18. See Tully, *supra* note 12, at 133-34.

19. *Id.*; see also MICHAEL BLAKENEY, TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS: A CONCISE GUIDE TO THE TRIPS AGREEMENT 1-2 (1996) (discussing events leading up to the Uruguay Round).

20. See Tully, *supra* note 12, at 133-34.

21. See Marrakesh Agreement Establishing the World Trade Organization (Apr. 15, 1994), Annex 1C, 1867 U.N.T.S. 154, 33 I.L.M. 1144 (1994), available at http://www.wto.org/english/docs_e/legal_e/04-wto.pdf (last visited Jan. 5, 2004) [hereinafter WTO Agreement].

22. See WTO Agreement, *supra* note 21, art. iv, para. 5.

23. BLAKENEY, *supra* note 19, at 8.

24. Ansari, *supra* note 7, at 60. The TRIPS Agreement supplements the Paris Convention. Article 2.1 of the TRIPS Agreement states: "In respect of Parts II, III and IV of this Agreement, Members shall comply with Articles 1-2 and Article 19, of the Paris Convention (1967)." TRIPS Agreement, *supra* note 9, art. 2.1. See also Carlos M. Correa, *Patent Rights, in* INTELLECTUAL PROPERTY AND INTERNATIONAL TRADE 189 (Carlos M. Correa & Abdulqawi A. Yusuf eds., 1998).

25. See Tully, *supra* note 12, at 134.

26. Article 27.1 says that "patents shall be available for any inventions, whether products or processes . . ." TRIPS Agreement, *supra* note 9, art. 27.1. The provision requires novelty, an inventive step, and industrial applicability. *Id.*

27. *Id.* art. 28.1(a).

sive right to license her product.²⁸

B. THE PRACTICE OF COMPULSORY LICENSING

Compulsory licensing allows a government to license a patent to a third party without the permission of the patentee, though the patentee is still paid royalties.²⁹ Developing nations are interested in compulsory licensing as a way to increase access to drugs by lowering their price.³⁰ The TRIPS Agreement allows for compulsory licensing as one way for developing nations to gain access to patented drugs.³¹ Article 31 is the provision on compulsory licensing, although it does not specifically use the term.³² Under Article 31, Member nations may determine the reasons for which they will grant compulsory licenses.³³ This is in contrast to the compulsory licensing rules in the Paris Convention, under which the primary reason for granting compulsory licenses was a failure to manufacture the patented item in the country in which the patent was held.³⁴ Article 31 makes no such requirement.³⁵ The TRIPS Agreement outlines several conditions that must be met before granting a compulsory license.³⁶

28. *Id.* art. 28.2.

29. See Haochen Sun, *A Wider Access to Patented Drugs Under the TRIPS Agreement*, 21 B.U. INT'L L.J. 101, 107 (2003).

30. See generally *id.* at 106-08 (stating that use of compulsory licensing promotes lower prices for pharmaceuticals). However, developed countries often oppose compulsory licensing, saying it "undermines intellectual property rights" and deters developing countries from advancing their own pharmaceutical industries. Bass, *supra* note 13, at 199.

31. See TRIPS Agreement, *supra* note 9, art. 31; Divya Murthy, Comment, *The Future of Compulsory Licensing: Deciphering the Doha Declaration on the TRIPS Agreement and Public Health*, 17 AM. U. INT'L L. REV. 1299, 1319-20 (2002).

32. Article 31 states that "[w]here the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder . . . the following provisions shall be respected . . ." TRIPS Agreement, *supra* note 9, art. 31. The "other use" is understood to refer to uses other than those allowed under Article 30; that is, compulsory licensing. BLAKENEY, *supra* note 19, at 90.

33. See TRIPS Agreement, *supra* note 9, art. 31; BLAKENEY, *supra* note 19, at 90; JAYASHREE WATAL, INTELLECTUAL PROPERTY RIGHTS IN THE WTO AND DEVELOPING COUNTRIES 318 (2001).

34. BLAKENEY, *supra* note 19, at 90. Manufacturing a patented product in a country where it is patented is known as "working" the patent. WATAL, *supra* note 33, at 318.

35. TRIPS Agreement, *supra* note 9, art. 31. It is debated, however, whether Article 27.1 forbids or allows countries from including the requirement of working the patent in their own laws as a ground for compulsory licensing. See WATAL, *supra* note 33, at 318 & n.64; Correa, *supra* note 24, at 203.

36. See TRIPS Agreement, *supra* note 9, art. 31; BLAKENEY, *supra* note 19, at

Articles 8 and 27 of the TRIPS Agreement provide further guidance on compulsory licensing. Article 8.1 states that in developing post-TRIPS legislation, Members may “adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic . . . development, provided that such measures are consistent with the provisions of this Agreement.”³⁷ This provision gives policy guidance to Articles 30, 31, and 40, and implies that a Member country cannot be punished for implementing patent laws to protect the public interest.³⁸ Article 27.2 states, “Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public*³⁹ or morality, including to protect human . . . life or health”⁴⁰ The scope of this seemingly broad public health exception is narrowed by two requirements: necessity and the absence of commercial exploitation.⁴¹ It has been argued, however, that a country could get around the commercial exploitation ban by distributing the drugs non-commercially, through a state-owned or non-profit group.⁴² Despite its promise, compulsory licensing has never been used under the TRIPS Agreement, although countries have threatened to use it.⁴³

91-92. For example, these conditions include making an effort to get permission from the rights holder before issuing a compulsory license and paying “adequate remuneration” to the rights holder. See TRIPS Agreement, *supra* note 9, arts. 31(b), 31(h).

37. TRIPS Agreement, *supra* note 9, art. 8.1.

38. J. H. Reichman, *Universal Minimum Standards of Intellectual Property Protection under the TRIPs Component of the WTO Agreement*, in INTELLECTUAL PROPERTY AND INTERNATIONAL TRADE: THE TRIPS AGREEMENT 36 (Carlos M. Correa & Abdulqawi A. Yusuf eds., 1998).

39. The term *ordre public* does not have a generally accepted definition, but is understood as being narrower than public order and related to security and prevention of riot and public disorder. Reichman, *supra* note 38, at 62.

40. TRIPS Agreement, *supra* note 9, art. 27.2.

41. *Id.*; Weissman, *supra* note 16, at 1100.

42. Weissman, *supra* note 16, at 1100.

43. See Amir Attaran, *The Doha Declaration on the TRIPS Agreement and Public Health, Access to Pharmaceuticals, and Options Under WTO Law*, 12 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 859, 870 & n.21 (2002) (“For something that has never been used, compulsory licensing excites a surprising amount of confrontation, pitting activists who tirelessly advocate it, against the pharmaceutical industry that lives in fear of it.”).

II. THE PARAGRAPH 6 PROBLEM AND POTENTIAL SOLUTIONS

A. THE PARAGRAPH 6 PROBLEM AND THE DOHA DECLARATION

The Doha Ministerial Declaration on the TRIPS Agreement and Public Health (Doha Declaration) emerged from the Ministerial Conference (the Conference) of the WTO of November 2001 in Doha, Qatar.⁴⁴ The Conference unfolded in an atmosphere of increased awareness of the concerns of developing countries in combating health problems.⁴⁵ The United States, for example, became more receptive to public health or national emergency exceptions to patent-holders' exclusive rights after the September 2001 terrorist attacks and anthrax scares.⁴⁶ The main purpose of the Conference was to begin a new set of economic negotiations to increase world trade flows;⁴⁷ nonetheless, the Doha Declaration addressed several issues related to the interpretation of TRIPS in light of current public health problems in developing countries.⁴⁸

In particular, the sixth paragraph of the Doha Declaration addressed the problem with compulsory licensing and developing countries:

We recognize that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to

44. See Murthy, *supra* note 31, at 1304-05.

45. See Alan O. Sykes, *TRIPS, Pharmaceuticals, Developing Countries, and the Doha "Solution,"* 3 CHI. J. INT'L L. 47, 54 (2002) (noting "the political climate prior to the Doha meeting was favorable to the objectives of the developing countries . . .").

46. See Jose Marcos Nogueira Viana, *Intellectual Property Rights, the World Trade Organization and Public Health: The Brazilian Perspective,* 17 CONN. J. INT'L L. 311, 313 (2002).

47. *Id.* at 311.

48. Doha Declaration, *supra* note 10. The Doha Declaration stated,

We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. . . . [W]e 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.

Doha Declaration, *supra* note 10, para. 4. WTO Ministerial Declarations, however, are not legally binding in the dispute resolution process; treaty language would trump any contradictory Ministerial Declaration. Sykes, *supra* note 45, at 54. Nonetheless, the Declaration is likely to be persuasive authority, should a dispute arise. *Id.*

this problem and to report to the General Council before the end of 2002.⁴⁹

As the WTO Ministerial points out, the Paragraph 6 Problem affects nations with little or no ability to manufacture pharmaceuticals.⁵⁰ The Paragraph 6 Problem arises from one of the conditions a Member country must meet to issue a compulsory license under Article 31 of the TRIPS Agreement:⁵¹ according to Article 31(f), any use of compulsory licensing “shall be authorized *predominately for the supply of the domestic market* of the Member authorizing such use.”⁵² This has been interpreted to mean that most of the products produced under a compulsory license must be intended for the licensing Member’s domestic market and not exported for commercial reasons.⁵³

The requirement of Article 31(f) causes the Paragraph 6 Problem to have two interconnected aspects.⁵⁴ First, Article 31(f) restricts the availability of export drugs made under compulsory licenses, causing problems for poor nations who, lacking sufficient domestic manufacturing capability, want to *import* generic copies of the drugs that another country has manufactured under compulsory licensing.⁵⁵ Second, the requirement that compulsory licensees supply mostly to the domestic market makes economies of scale unavailable to countries that could otherwise export.⁵⁶ Essentially, Article 31(f) does not account for countries that may need to import or export products in order to be able to use compulsory licensing at all. The result is the Paragraph 6 Problem: compulsory licensing fails to enable medicine-deprived developing countries that lack the capability to manufacture drugs domestically to purchase drugs produced abroad.

Rather than encouraging a literal reading, commentator

49. Doha Declaration, *supra* note 10, para. 6.

50. *Id.*

51. See TRIPS Agreement, *supra* note 9, art. 31(f); see also *supra* note 36 and accompanying text.

52. TRIPS Agreement, *supra* note 9, art. 31(f) (emphasis added).

53. It has been suggested that the word “predominately” indicates that greater than fifty percent of the products produced under compulsory licensing must be intended for the domestic market of the licensee Member. See Sun, *supra* note 29, at 110 (citing Frederick M. Abbott, *The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO*, 5 J. INT’L ECON. L. 469, 499 (2002)).

54. See Sun, *supra* note 29, at 110 (describing the nature of the problem in Paragraph 6 of the Doha Declaration).

55. *Id.*

56. *Id.*

Amir Attaran⁵⁷ urges that Paragraph 6 must be interpreted with reference to the Doha Declaration as a whole, and the surrounding political atmosphere.⁵⁸ Paragraph 1 of the Doha Declaration addresses the “public health problems afflicting many developing and least-developed countries,” and paragraph 4 refers to “WTO members’ right to protect public health, and in particular, to promote access to medicines for all.”⁵⁹ In light of these provisions, Attaran interprets Paragraph 6 as a charge to solve the problem of lack of access to pharmaceuticals suffered by developing countries with public health needs.⁶⁰

The TRIPS Council held numerous meetings in 2002 to discuss options for an “expeditious solution.”⁶¹ WTO Trade Ministers discussed the problem at a Mini-Ministerial meeting in November 2002, but did not reach a consensus.⁶² The TRIPS Council did not produce a final solution to the Paragraph 6 Problem by the 2002 deadline.⁶³ Nevertheless, it was predicted that the Doha Declaration would embolden developing countries to pass legislation to allow for compulsory licensing.⁶⁴

57. Amir Attaran is employed by the Kennedy School of Government at Harvard University. Attaran coauthored a controversial study asserting that patents do not impede access to AIDS drugs in Africa. Amir Attaran & Lee Gillespie-White, *Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa?*, 286 J. AM. MED. ASS’N 1886 (2001); see *Expanding Global Treatment Access: An Overview of the Issues*, amfAR AIDS Research, at <http://www.amfar.org/cgi-bin/iowa/news/feat/record.html?record=19> (last visited Jan. 5, 2004) (describing the study as controversial).

58. Attaran, *supra* note 43, at 864 (explaining that to be properly understood, Paragraph 6 must be read in conjunction with the Doha Declaration as a whole, and with an understanding of the surrounding political context).

59. Doha Declaration, *supra* note 10, paras. 1, 4.

60. Attaran, *supra* note 43, at 865. Attaran goes even further, concluding that the Paragraph 6 mandate is not limited to TRIPS, but extends also to other non-TRIPS areas of WTO jurisdiction, including pharmaceutical taxes and tariffs. *Id.* at 865-67. Attaran argues that under Paragraph 6, the TRIPS Council is also obligated to put pressure on the WTO to make changes in these other areas, because the problem extends beyond the TRIPS Agreement. *Id.* at 867.

61. Sun, *supra* note 29, at 112.

62. *Id.* The Mini-Ministerial meeting took place in Sydney on November 14-15, 2002. *Id.*

63. See Press Release, WTO NEWS 2002 Press Releases, Supachai Disappointed Over Governments’ Failure to Agree on Health and Development Issues (Dec. 20, 2002), at http://www.wto.org/english/news_e/pres02_e/pr329_e.htm (last visited Jan. 5, 2004).

64. Sykes, *supra* note 45, at 48.

B. CRITERIA FOR EVALUATING POTENTIAL SOLUTIONS TO THE PARAGRAPH 6 PROBLEM

Haochen Sun⁶⁵ proposes four criteria with which to evaluate potential solutions to the Paragraph 6 Problem: accessibility, sustainability, economic feasibility, and transparency.⁶⁶ Sun asserts that these are important considerations for evaluating whether a proposed solution will help developing country Members implement their public health policies.⁶⁷

Sun describes the accessibility feature as having three “overlapping dimensions.”⁶⁸ The solution to the Paragraph 6 Problem should be accessible to all without discrimination, actually physically and safely accessible, and affordable for all.⁶⁹ In discussing the sustainability feature, Sun notes that although the Doha Declaration charges the TRIPS Council with finding an “expeditious” solution, this does not mean that the solution ought to be a temporary or transitional solution.⁷⁰ Rather, Sun argues that the solution should have a long-term vision of setting up “a stable international legal framework that will help the least-developed country Members to gradually build a sound technological base to address their public health and public policy concerns,” as well as provide incentives to stimulate companies in developing countries to manufacture generic drugs.⁷¹ Sun also argues that for a proposed solution to be economically feasible, it should bring needed drugs to the market as quickly, easily, and inexpensively as possible, and should create incentives for the production and exportation of the drugs that developing country Members need.⁷² As Sun puts it, “[a] solution under paragraph 6 may be illusory if it does not benefit countries where manufacturing is technically feasible but not economically viable.”⁷³

65. Mr. Haochen Sun is the Assistant to the Secretary of the Center for WTO Studies at Zhejiang University College of Law in China. See Forum on Science and Technology for Sustainability, <http://ksgnotes1.harvard.edu/BCSIA/forum.nsf/people/SunHaochen> (last visited Jan. 5, 2004). Mr. Sun has published several articles on international intellectual property law, and has focused on the TRIPS Agreement and its impact on human rights. *Id.*

66. Sun, *supra* note 29, at 112-15.

67. *Id.* at 112.

68. *Id.* at 113.

69. *Id.*

70. *Id.* at 113-14.

71. *Id.* at 114.

72. See Sun, *supra* note 29, at 114-15.

73. *Id.* at 115.

Finally, Sun asserts that the proposed solution should require Members to report actions taken under the system to the TRIPS Council, thereby providing transparency in the process and helping to prevent exported products from being diverted from their intended destination.⁷⁴ Reporting of actions should be required of both the exporting and importing members, with the hope that the private sector will actually use the system that is established.⁷⁵

C. PROPOSED SOLUTIONS TO THE PARAGRAPH 6 PROBLEM

Commentators have offered several solutions in response to the Paragraph 6 Problem.⁷⁶ These solutions fit into four main types: an amendment to Article 31(f) of the TRIPS Agreement, a waiver of a Member's responsibilities under 31(f), a dispute settlement-based solution, and an authoritative interpretation of Article 30 of TRIPS.

1. *Solution #1: Amendment to Article 31(f) of the TRIPS Agreement*

One solution to the Paragraph 6 Problem is to amend or delete Article 31(f) of the TRIPS Agreement. Because such an amendment is "of a nature that would alter the rights and obligations of the Members,"⁷⁷ it would only "take effect for the Members that have accepted them upon acceptance by two-thirds of the Members and thereafter for each other Member upon acceptance by it."⁷⁸ In order to accept an amendment, a Member delivers an instrument of acceptance to the WTO Secretariat, but only after fulfilling the necessary requirements under its domestic legal system.⁷⁹ The practical effect is that before a Member country accepts an amendment, it must ratify it at the national level.⁸⁰ While Sun does not suggest how Article 31 should be amended, he seems to suggest deleting the arti-

74. *Id.*

75. *Id.*

76. *See, e.g.,* Attaran, *supra* note 43, at 868-78; Murthy, *supra* note 31, at 1338-45; Sun, *supra* note 29, at 132-36.

77. WTO Agreement, *supra* note 21, art. x, para. 3.

78. *Id.* In the case of an amendment that would *not* alter the rights and obligations of the Members, *all* Members can be bound by the vote of two-thirds of the Members. *Id.* para. 4.

79. *See* Sun, *supra* note 29, at 117-18.

80. *See id.* at 118.

cle's "predominately" requirement.⁸¹ Attaran and Divya Murthy,⁸² on the other hand, propose amending TRIPS to create an exception to Article 31(f) for Members to issue compulsory licenses to export to another Member that lacks the ability to manufacture its own pharmaceuticals.⁸³ Murthy also suggests amending the definition of "third party" to include foreign entities when a Member does not have sufficient manufacturing ability.⁸⁴

Although an Article 31 amendment has the benefit of permanence, Attaran and Sun do not consider this the best option.⁸⁵ Sun describes the national ratification requirements as "legally insecure and time consuming."⁸⁶ Bureaucratic problems also arise when a product is patented in the importing country, because Article 31 requires two compulsory licenses: one for the exporting country and one for the importing country.⁸⁷ In addition, Article 31(h) calls for the patentee to be adequately remunerated when a compulsory license is issued.⁸⁸ With two compulsory licenses, this would result in the patentholder being paid twice for the same product.⁸⁹ Due to these problems, none of the commentators have recommended the Article 31(f) amendment as the best option.⁹⁰

2. *Solution #2: Waiver of Responsibilities Under Article 31(f) of the TRIPS Agreement*

Sun and Attaran both address the potential solution of a waiver of a Member's obligations under Article 31(f) of the TRIPS Agreement.⁹¹ The Ministerial Conference has the authority to waive obligations imposed on a Member by the TRIPS

81. See *id.* at 116.

82. Divya Murthy received his JD in 2003 from American University, Washington College of Law. Murthy, *supra* note 31, at 1299 n.1.

83. See Attaran, *supra* note 43, at 868-70; Murthy, *supra* note 31, at 1341-44.

84. See Murthy, *supra* note 31, at 1341.

85. See Attaran, *supra* note 43, at 869-70; Sun, *supra* note 29, at 122-27.

86. See Sun, *supra* note 29, at 124.

87. See Attaran, *supra* note 43, at 869. Attaran's article includes a table that is helpful in understanding the differences between an Article 31 amendment and an Article 30 based solution. *Id.*

88. TRIPS Agreement, *supra* note 9, art. 31(h).

89. Attaran refers to this as "double compensation." Attaran, *supra* note 43, at 873 n.28.

90. See generally *id.*; Murthy, *supra* note 31; Sun, *supra* note 29.

91. See Attaran, *supra* note 43, at 874-75; Sun, *supra* note 29, at 118-19.

Agreement.⁹² Attaran frames his discussion in terms of Member countries requesting waivers on an individual basis, dismissing this option as “slow and cumbersome,” because the Ministerial meets only every two years and because a waiver must be reviewed yearly after being granted.⁹³ On the other hand, Sun points to cases where the relevant Council recognized the need for a waiver to apply to several Members, resulting in a “collective waiver.”⁹⁴ Thus, under the collective waiver situation, individual countries would not each have to request a waiver.⁹⁵ The requirement of yearly Ministerial review would still apply, however, and Sun cites this as a negative aspect of the waiver, along with its temporary nature.⁹⁶ Because of the annual review, Members might challenge the waiver yearly, perhaps arguing that the exceptional circumstances justifying the waiver are no longer present.⁹⁷ Due to its temporary and potentially legally unstable nature, the waiver is similarly not considered one of the best options.⁹⁸

3. *Solution #3: Dispute Settlement Solutions*

A third category of potential solutions relates to an agreement not to bring dispute settlement proceedings against Members who produce and export generic pharmaceuticals intended for poor countries without the manufacturing capacity in violation of Article 31(f). The first form this could take is a moratorium on dispute settlement, as discussed by Sun.⁹⁹ In this situation, WTO Members would agree not to bring a WTO complaint against countries that produce patented pharmaceuticals in the situation described above.¹⁰⁰ Although the WTO Agreement does not specifically address moratoria, the Ministerial Conference has the authority to decide on a moratorium on dis-

92. See WTO Agreement, *supra* note 21, art. ix, para. 3. The waiver process would begin with a request for a waiver submitted to the TRIPS Council. Sun, *supra* note 29, at 118. The Council would create a draft of the waiver, and send it to the Ministerial Conference, which could then grant the waiver upon approval by three-fourths of its Members. *Id.* at 118-19.

93. Attaran, *supra* note 43, at 874-75.

94. Sun, *supra* note 29, at 118.

95. See *id.* at 118-19.

96. See *id.* at 122-23.

97. See *id.* at 123.

98. See *id.* at 122-23; Attaran, *supra* note 43, at 869-70; Murthy, *supra* note 31, at 1343-44.

99. See Sun, *supra* note 29, at 120-21.

100. See *id.* at 120.

putes arising under Article 31(f) of the TRIPS Agreement.¹⁰¹ A related version of this solution is a rule of non-justiciability, as discussed by Attaran.¹⁰² This would involve the Ministerial Conference amending Appendix Two of the Dispute Settlement Understanding (DSU), the codification of special WTO dispute settlement rules.¹⁰³

The difference between a moratorium and a rule of non-justiciability is that a moratorium is an agreement decided on by the Ministerial Conference,¹⁰⁴ while a rule of non-justiciability actually becomes a part of the DSU by amendment.¹⁰⁵ The United States argued in favor of a moratorium in March 2002, because it would not require an amendment to TRIPS and could be overseen by the TRIPS Council.¹⁰⁶ Sun dismisses the moratorium option because, like a waiver, it would be a temporary solution.¹⁰⁷ In contrast, Attaran presents the rule of non-justiciability as the best solution, arguing that it is more consistent with the legal design of TRIPS and there are precedents in WTO law for using a rule of non-justiciability.¹⁰⁸

4. Solution #4: Article 30-based Solutions

Another solution that has been suggested is an authoritative interpretation of Article 30 under Article IX, Paragraph 2 of the WTO Agreement.¹⁰⁹ This solution has the benefit of permanence.¹¹⁰ An interpretation can be adopted if three-fourths of Members vote for it.¹¹¹ Unlike the Article 31 solution, here only one compulsory license would be required.¹¹² This solution also avoids the double compensation problem found in the Article 31

101. See *id.*

102. See Attaran, *supra* note 43, at 871-77.

103. See *id.* at 875-76; Sun, *supra* note 29, at 120-21.

104. See Sun, *supra* note 29, at 120.

105. See Attaran, *supra* note 43, at 875-76.

106. See Richard Elliot, *U.S. Offers Moratorium on Compulsory Licensing Disputes, Rejects Amending TRIPS*, at <http://lists.essential.org/pipermail/ip-health/2002-March/002760.html> (Mar. 7, 2002) (last visited Jan. 5, 2004). At that time the United States also opposed an amendment of Article 31 and an authoritative interpretation of Article 30, two potential solutions the European Union had presented. See *id.*

107. See Sun, *supra* note 29, at 122-23.

108. See Attaran, *supra* note 43, at 872-73.

109. See Attaran, *supra* note 43, at 868-70; Murthy, *supra* note 31, at 1344-45; Sun, *supra* note 29, at 121-22.

110. See Sun, *supra* note 29, at 125.

111. See WTO Agreement, *supra* note 21, art. ix, para. 2.

112. Attaran, *supra* note 43, at 869; Murthy, *supra* note 31, at 1344.

solution.¹¹³ In spite of this, Attaran argues that “an interpretation cannot achieve by the back door what would otherwise require an amendment.”¹¹⁴ Although Attaran prefers the rule of non-justiciability to this solution, both Sun and Murthy argue that the Article 30 interpretation is the best solution.

In the end, these four potential methods of solving the Paragraph 6 Problem each have their benefits and drawbacks. As noted by Sun, although these features would be considered in crafting the solution, the TRIPS Council’s exact solution would be the result of political negotiations.¹¹⁵

III. THE TRIPS COUNCIL’S DECISION ON THE PARAGRAPH 6 PROBLEM

After much discussion by commentators of what form the solution should take, and prolonged negotiations by developed and developing countries, on August 30, 2003, the Council for TRIPS finally set forth its Decision in answer to the Paragraph 6 charge of the Doha Declaration.¹¹⁶ Lauded as a “landmark deal”¹¹⁷ and an “historic agreement for the WTO,”¹¹⁸ the Decision takes the form of a waiver of countries’ obligations under Article 31(f) of the TRIPS Agreement, with respect to pharmaceutical products.¹¹⁹ It is intended as an interim waiver that will expire when an amendment to the TRIPS Agreement takes effect, with such amendment to be based upon and to replace the Decision.¹²⁰ In the Decision, the Council charged that work should begin on such an amendment before the end of 2003, to

113. See Attaran, *supra* note 43, at 873 n.28; Sun, *supra* note 29, at 126.

114. Attaran, *supra* note 43, at 874 (highlighting Article IX, paragraph 2 of the WTO Agreement).

115. See Sun, *supra* note 29, at 116.

116. Press Release, *supra* note 9; see Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, WTL/540 (Aug. 30, 2003), available at http://www.wto.org/english/tratop_e/TRIPS_e/implem_para6_e.htm (last visited Jan. 5, 2004) [hereinafter Paragraph 6 Decision].

117. Scott Miller, *WTO Drug Pact Lifts Trade Talks*, WALL ST. J., Sept. 2, 2003, at A2.

118. Press Release, *supra* note 9.

119. Paragraph 6 Decision, *supra* note 116, para. 2. The Decision was also welcomed by the head of the World Health Organization (WHO) as a “good step forward.” InteliHealth: HIV/AIDS, *WHO Head Welcomes Decision to Let Poor Countries Import Cheap Drugs to Fight Killer Diseases* (Sept. 2, 2003), at <http://www.intelihealth.com/IH/ih/WSIH000/333/8013/368847.html> (last visited Jan. 5, 2004) [hereinafter *WHO Head Welcomes*].

120. Paragraph 6 Decision, *supra* note 116, para. 11.

be completed within six months.¹²¹ A statement by General Council Chairperson Carlos Pérez del Castillo, Uruguay's ambassador, accompanied the Decision.¹²²

The Decision, formally titled "Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health," sets out a system under which the requirements of Article 31(f) are waived in certain situations.¹²³ The heart of the Decision is found in paragraph 2, which states that "[t]he obligations of an exporting Member under Article 31(f) of the TRIPS Agreement shall be waived with respect to the grant by it of a compulsory license to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s) . . ."¹²⁴

The waiver is a "collective waiver," designed to apply to a number of Member countries.¹²⁵ Paragraph 1(b) outlines which countries are eligible to import under the system.¹²⁶ Least-developed country Members are by definition considered "eligible importing Member[s]."¹²⁷ A Member can also become eligible to import by notifying the TRIPS Council that it intends to use the system.¹²⁸ Although under this provision all WTO Member countries are technically eligible to import pharmaceuticals,¹²⁹ the Decision lists twenty-three developed country Members that have agreed not to use the system at all.¹³⁰ In addition, several other Member countries have stated that they will use the system only in extreme emergency situations.¹³¹

121. *Id.*

122. *The General Council Chairperson's Statement*, WTO 2003 News Items, Aug. 30, 2003, at http://www.wto.org/english/news_e/news03_e/trips_stat_28aug03_e.htm (last visited Jan. 5, 2004) [hereinafter *Chairperson's Statement*]; see Press Release, *supra* note 9. The Chairperson's Statement focused on the issue of diversion of drugs from their target market, a concern of pharmaceutical companies. See *Chairperson's Statement*.

123. Paragraph 6 Decision, *supra* note 116.

124. *Id.* para. 2.

125. See *supra* note 94 and accompanying text.

126. Paragraph 6 Decision, *supra* note 116, para. 1(b).

127. *Id.*

128. *Id.*

129. See Press Release, *supra* note 9.

130. See Paragraph 6 Decision, *supra* note 116, para. 1(b) & n.3. These countries are Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom and United States of America. *Id.* at n.3.

131. Paragraph 6 Decision, *supra* note 116, para. 1(b). These countries include Hong Kong China, Israel, Korea, Kuwait, Macao China, Mexico, Qatar, Singapore, Chinese Taipei, Turkey and United Arab Emirates. Press Release, *supra* note 9.

The waiver covers only pharmaceutical products, which are defined in paragraph 1(a) as “any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the [Doha] Declaration.”¹³²

The Decision sets out several requirements that must be met for a country to use the system.¹³³ These requirements are broken down into requirements for the eligible importing member,¹³⁴ requirements for the exporting Member’s compulsory license,¹³⁵ safeguards against trade diversion,¹³⁶ and notification requirements for the exporting Member.¹³⁷

First, the eligible importing Member must notify the TRIPS Council of the names and quantities of the products it is importing.¹³⁸ If the Member is not a least-developed country, the Decision requires it to confirm that the Member has “established that it has insufficient or no manufacturing capacities in the pharmaceutical sector” for the particular products it plans to import.¹³⁹ The Member must confirm that it has granted or will grant a compulsory license if the product is patented in its territory.¹⁴⁰

Second, the Decision calls for the exporting member to take steps to ensure that the products produced under the system will not be diverted from their intended market.¹⁴¹ It requires that the exporting Member’s compulsory license be for only the amount needed by the eligible importing Member, and that all of the production be sent to that Member.¹⁴² In addition, the

132. Paragraph 6 Decision, *supra* note 116, para. 1(a). This includes active ingredients and diagnostic kits. *Id.* “Vaccines” had been mentioned in earlier definitions of pharmaceutical products, but were omitted in the final version. See Chakravarthi Raghavan, *Differences Unresolved On Implementing TRIPS and Public Health* (Third World Network), Nov. 25, 2002, at <http://www.twinside.org.sg/title/5243a.htm> (last visited Jan. 5, 2004).

133. Paragraph 6 Decision, *supra* note 116, para. 2.

134. *Id.* para. 2(a).

135. *Id.* para. 2(b).

136. *Id.* paras. 4, 5.

137. *Id.* para. 2(c).

138. Paragraph 6 Decision, *supra* note 116, para. 2(a)(i).

139. *Id.* para. 2(a)(ii). According to the Annex to the Decision, “[l]east-developed country Members are deemed to have insufficient or no manufacturing capacities in the pharmaceutical sector.” *Id.* at Annex. If at one time an eligible importing Member found that its manufacturing capacity was insufficient to meet its needs, but it later becomes sufficient, then the system would no longer apply. *Id.*

140. *Id.* para. 2(a)(iii); see *supra* note 87 and accompanying text.

141. Paragraph 6 Decision, *supra* note 116, para. 2(b).

142. See *id.* para. 2(b)(i).

products must be “clearly identified as being produced under the system . . . through specific labelling or marking,” which may include special packaging, coloring or shaping of the products.¹⁴³ This information must also be posted by the licensee on a website.¹⁴⁴ Several of the Decision’s other provisions also address preventing trade diversion.¹⁴⁵ Paragraph 5 orders Members to prevent the diversion into their countries of products produced under the system, and provides for the TRIPS Council to review the matter if any Member thinks another Member’s measures are insufficient in this regard.¹⁴⁶ Paragraph 4 directs eligible importing Members to take “reasonable measures within their means [and] proportionate to their administrative capacities” to prevent trade diversion, and instructs developed country Members to help with this upon request.¹⁴⁷ Finally, the exporting Member must notify the TRIPS Council of the license and provide it with information regarding the license and licensee.¹⁴⁸

The Decision avoids the double remuneration problem of the patentee being paid twice¹⁴⁹ by waiving the requirement that the importing Member pay the patent holder when the exporting member has already paid in accordance with Article 31(h) of the TRIPS Agreement.¹⁵⁰ The Decision also encourages Members to overcome the problem outlined in the Doha Declaration’s Paragraph 6 by building up pharmaceutical sector capacity in developing country Members.¹⁵¹

The final paragraph outlines the lifespan of the waiver and

143. *Id.* para. 2(b)(ii). This is required only where use of these distinguishing features is “feasible” and does not raise the price significantly. *Id.*

144. *See id.* para. 2(b)(iii).

145. *See id.* paras. 4-5.

146. *See* Paragraph 6 Decision, *supra* note 116, para. 5.

147. *Id.* para. 4.

148. *See id.* para. 2(c). This information includes the “name and address of the licensee, the product(s) for which the licence has been granted, the quantity(ies) for which it has been granted, the country(ies) to which the product(s) is (are) to be supplied and the duration of the licence,” along with the address of the website required in paragraph (2)(b)(iii). *Id.* para. 2(c).

149. *See supra* notes 36, 88-89 and accompanying text.

150. Paragraph 6 Decision, *supra* note 116, para. 3.

151. *See id.* para. 7. Paragraph 7 encourages Members to pay special attention to the pharmaceutical sector when working towards technology transfer to developing country Members pursuant to Article 66.2 of TRIPS and paragraph 7 of the Doha Declaration. *Id.* Article 66.2 of TRIPS says, “[d]eveloped country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base.” TRIPS Agreement, *supra* note 9, art. 66.2.

what is to happen when the waiver ends.¹⁵² It provides that the waiver will be in effect until an amendment to the TRIPS Agreement replaces it.¹⁵³ The proposed amendment to TRIPS shall be rooted in the Decision.¹⁵⁴ This provision also charges the TRIPS Council to start work on the amendment before the end of 2003, with the goal of completing the amendment six months later.¹⁵⁵ This timeline makes the issue of yearly Ministerial review of the waiver (and possible challenges by Members) less pressing, assuming the deadlines are met.¹⁵⁶

IV. UNDERSTANDING THE PARAGRAPH 6 DECISION AND ITS IMPLICATIONS

The TRIPS Council's solution appears to be a combination of an interim waiver and a command to amend TRIPS.¹⁵⁷ The Decision calls for an amendment to the TRIPS Agreement to create an exception for the particular circumstances required by the Decision; the waiver is to be effective in the meantime.¹⁵⁸

A. EXAMINATION OF THE DECISION UNDER THE FOUR SUN CRITERIA

This section analyzes the TRIPS Council's recent Decision, using the four criteria Sun employed to examine a solution's efficacy in solving the Paragraph 6 problem and helping developing country Members implement their public health policies.¹⁵⁹ The Decision's strengths and shortcomings are discussed within the framework of these criteria, which include accessibility, sustainability, economic feasibility, and transparency.¹⁶⁰

1. Accessibility

Sun's first criterion is the accessibility of the solution on

152. Paragraph 6 Decision, *supra* note 116, para. 11.

153. *Id.*

154. *Id.*

155. *Id.*

156. See *supra* notes 96-97 and accompanying text.

157. See generally Paragraph 6 Decision, *supra* note 116.

158. See *id.* para. 11.

159. See *supra* notes 68-75 and accompanying text (explaining how Sun uses his criteria to analyze a potential Paragraph 6 solution).

160. See *supra* notes 69-75 and accompanying text.

various levels.¹⁶¹ One question is whether the Decision results in a scheme that is accessible to all people without discrimination.¹⁶²

The Decision is accessible in the sense that all Member countries are theoretically eligible to issue a compulsory license under the system set out in the Decision.¹⁶³ The issue of how health-related pharmaceuticals will in fact become safely and actually available to the people in developing countries who need it, however, is not addressed by the Decision. Some leaders of developing countries seem optimistic that this Decision should help developing countries gain access to more affordable generic versions of needed drugs.¹⁶⁴ In the end, the Decision's impact on this aspect of accessibility will not be known until the Decision is used over time.

2. Sustainability

The second criterion for examining the Decision is sustainability.¹⁶⁵ Sun had concluded that because of its temporary or transitional nature, waiver is not a sustainable solution,¹⁶⁶ but perhaps, when coupled with the charge to amend Article 31 of TRIPS within a certain time limit, the Decision passes the sustainability test.

At the same time, the Article 31 amendment poses its own problems on the sustainability question, especially with the hurdle of national ratification.¹⁶⁷ It could certainly not be a long-term solution for the Paragraph 6 Problem to be fixed by a temporary waiver, only to have it unravel when it came to national ratification of an Article 31 amendment. This could present a problem for the Decision's sustainability. On the other hand, the fact that nations have already agreed to this Decision may mean national ratification will not prove too large a hurdle.

161. See *supra* notes 68-69 and accompanying text.

162. See *supra* note 69 and accompanying text.

163. See *supra* notes 127-31 and accompanying text.

164. For example, Kenyan Ambassador Amina Chawahir Mohamed praised the Decision, saying, "This is good news for Africa. It is especially good news for the people of Africa who so desperately need access to affordable medicine." Naomi Koppel, *WTO to Let Poor Nations Import Generic Drugs*, PHILA. INQUIRER, Aug. 31, 2003, at A14. See also *WHO Head Welcomes*, *supra* note 119 (reporting that South Africa's health minister Manto Tshabalala-Msimang "welcomed the WTO announcement").

165. See *supra* notes 70-71 and accompanying text.

166. See *supra* notes 96-98 and accompanying text.

167. See *supra* notes 77-80, 86 and accompanying text.

As noted, however, an Article 31 amendment is of a nature that would affect the rights of Members.¹⁶⁸ An amendment of this type would not take effect for any country that did not ratify or had not yet ratified the amendment.¹⁶⁹

This aspect of the national ratification requirement leads to a potential uncertainty in the operation of the Decision. Paragraph 11 states: "This Decision, including the waivers granted in it, shall terminate for each Member on the date on which an amendment to the TRIPS Agreement replacing its provisions takes effect for that Member."¹⁷⁰ The effect of this provision is unclear, since it *could* mean that if Article 31 of TRIPS were amended, but a Member had yet to ratify it, the waiver would still be effective for the Member not yet ratified even though the waiver has expired for other Member countries that ratified the amendment. If this is so, it may or may not present a problem when an exporting Member country grants a compulsory license under the waiver to an importing Member that operates under the amendment. If the amendment really will be drafted to mirror the Decision, then perhaps there will be no problem since the two would operate the same way. If, however, during political wrangling the amendment comes to differ significantly from the Decision, different requirements might create problems. The possibility that the amendment will differ from the waiver seems to be allowed by the language of the Decision, which says the "amendment will be based, *where appropriate*, on this Decision . . ."¹⁷¹ If the TRIPS Council became convinced during preparation of the amendment that the waiver was lacking in some way, it might decide not to include that aspect in the amendment. There is evidence, however, that several Member countries want to keep the amendment purely technical, and simply incorporate the waiver into TRIPS without reviving discussion of its merits.¹⁷² In sum, the sustainability of the Decision will depend heavily on the way TRIPS is amended and the success of the ensuing national ratification process.

168. See *supra* note 77 and accompanying text.

169. See *supra* note 78 and accompanying text.

170. Paragraph 6 Decision, *supra* note 116, para. 11 (emphasis added).

171. *Id.* (emphasis added).

172. See *TRIPS Council Shows Little Progress on Health and Biodiversity*, BRIDGES WKLY TRADE NEWS DIG., Nov. 26, 2003, at <http://www.ictsd.org/weekly/03-11-26/story4.htm> (last visited Jan. 6, 2004) [hereinafter *TRIPS Council Shows Little Progress*] ("Most Members stressed that this work should be a "technical" effort, without re-opening the substance of the Decision.").

3. *Economic feasibility*

Another benchmark for gauging the usefulness of a solution to the Paragraph 6 Problem is its economic feasibility; that is, whether the Decision creates a system that will make access to needed medicines quick, easy, and inexpensive.¹⁷³ A related issue is whether the Decision creates sufficient incentive for generic pharmaceutical manufacturers to produce and export low-priced drugs to developing country Members who lack the capacity to make their own.¹⁷⁴ Paragraph 6 of the Decision instructs developed country Members to “provide technical cooperation” under Article 67 of TRIPS to develop a system of regional patents for developing and least-developed Members.¹⁷⁵ This is a good step because it addresses the problem, but it does not set up any formal mechanisms that will actually help developing countries make use of compulsory licensing.

Paragraph 7 of the Decision encourages Members to use the system set forth in the Decision to promote investment and technology transfer by the pharmaceutical sector to fix the problem of countries not having sufficient manufacturing capacities.¹⁷⁶ Although Paragraph 7 focuses specifically on the pharmaceutical sector, it seems to merely reiterate what was already set forth in Article 66.2 of the TRIPS Agreement and the Doha Declaration.¹⁷⁷ It would have been more effective for the Decision to propose a concrete system for helping developing country Members build up their technology base.

It is not clear whether developing and least-developed country Members will make use of compulsory licensing under the system. Nor is it clear whether the waiver-plus-Article 31-amendment solution will prove economically feasible. The very existence of this Decision may potentially increase competition between generic drug manufacturers and the companies with the patents, thereby decreasing drug prices.¹⁷⁸

173. See *supra* notes 72-73 and accompanying text.

174. See *supra* note 72 and accompanying text.

175. See Paragraph 6 Decision, *supra* note 116, para. 6.

176. See *id.* note 116, para. 7; see *supra* note 151 and accompanying text.

177. See Paragraph 6 Decision, *supra* note 116, para. 7; see *supra* note 151 and accompanying text.

178. See *WTO OKs Deal on Cheaper Generic Drugs*, REUTERS HEALTH, Sept. 1, 2003, at <http://12.42.224.152/HealthNews/reuters/NewsStory0901200318.htm> (last visited Jan. 6, 2004) [hereinafter *WTO OKs Deal*]; *supra* note 30 and accompanying text (noting that compulsory licenses may reduce drug prices).

4. Transparency

The final criterion is the level of transparency achieved by the solution.¹⁷⁹ Under this factor, the Decision seems to do fairly well. The main concern of transparency is whether the private sector will actually act within the system the solution establishes.¹⁸⁰ Paragraph 2 of the Decision sets out detailed notification requirements for the exporting and importing Members.¹⁸¹ Because the Members who use the system are required to make the notifications, including posting information on a website, this will help increase transparency of the use of the system.¹⁸² It will also help countries to guard against exported products being diverted from their intended markets. The process will hopefully be more efficient and accessible due to the fact that WTO approval is not among the notification requirements for eligibility of Member countries to import under the system.¹⁸³

In sum, the Decision will probably increase accessibility to needed medicines, and though it is yet unclear how well the Decision fares under the sustainability and economic feasibility criteria, the Decision provides a sufficiently transparent process to genuinely help developing countries.

B. EXAMINING CRITICISMS OF THE DECISION

The Decision has been criticized for focusing too narrowly on the concerns of developed country Members.¹⁸⁴ Developed countries and pharmaceutical companies have worried that if countries are allowed to import generic copies of drugs, these drugs will be diverted from their destination and end up back in developed country markets,¹⁸⁵ where the availability of cheap drugs would undercut pharmaceutical company profits.¹⁸⁶ As a

179. See *supra* notes 74-75 and accompanying text.

180. See *supra* note 75 and accompanying text.

181. See *supra* notes 138-48 and accompanying text.

182. Paragraph 6 Decision, *supra* note 116, para. 2.

183. *Id.* at n.2; see *supra* notes 127-28 and accompanying text.

184. See, e.g., Médecins Sans Frontières, *Chairman's Text Brings New Difficulties to WTO "Paragraph 6"* (Aug. 27, 2003), at <http://www.msf.org/content/page.cfm?articleid=77830ACA-8EC5-419A-82AB7D7ED6A2E1ED> (last visited Jan. 5, 2004) [hereinafter *Chairman's Text*].

185. See Miller, *supra* note 117, at A2.

186. See Hugh McCullum, *Drug Companies Use Their Muscle Against the Poor* (Southern African Research and Documentation Centre), Feb. 28, 2001, at <http://www.sardc.net/editorial/sanf/2001/iss4/SpecialReport.html> (last visited Jan. 5, 2004).

result of these concerns, the Decision includes a number of provisions designed to provide safeguards against drug diversion.¹⁸⁷ With all the attention the Decision devotes to this aspect,¹⁸⁸ together with the Chairperson's Statement,¹⁸⁹ these safeguards will likely be effective against drug diversion. Ultimately, this may be a positive result for developing countries, because if pharmaceutical companies are satisfied that the waiver protects their interests, there may be less opposition when the Article 31 amendment is drafted and ratified.¹⁹⁰

Debate rages as to the impact of the Decision on developing countries, and whether it will actually help them at all. Critics assert that the Decision's provisions create too many procedural "hoops" for developing country Members to jump through in order to use compulsory licensing.¹⁹¹ On the other hand, most of these provisions are designed to prevent drug diversion, a phenomenon that also harms developing countries by further depriving patients in developing countries for which the medications were intended.¹⁹²

Critics have also focused on the General Council Chairperson's statement that accompanied the Decision.¹⁹³ In this statement, the Chairperson declares "the system . . . established by the Decision should be used in good faith to protect public health and . . . *not be an instrument to pursue industrial or*

187. See *supra* notes 138, 141-48, and accompanying text.

188. Three of the Decision's eleven paragraphs address protection against trade diversion. See Paragraph 6 Decision, *supra* note 116, paras. 2, 4-5.

189. See *Chairperson's Statement*, *supra* note 122.

190. See Paragraph 6 Decision, *supra* note 116, para. 11 (charging the TRIPS Council to begin drafting an amendment to the TRIPS Agreement by the end of 2003, to be based on the Decision).

191. Shapi Shacinda, *WTO Rules Mean Life, Death to Africa*, HOUSTON CHRON., Sept. 7, 2003, at 5, available at 2003 WL 57440840. The organization Médecins Sans Frontières (a/k/a MSF or Doctors Without Borders) has also criticized the Decision and the accompanying Chairperson's Statement, saying:

The sum total of the Chairman's Statement and the [Decision] is a system in which countries must jump through a multi-layered tangle of hoops to get access to a few medicines. Any one of these hoops can easily be closed off by political pressure or economic infeasibility, rendering the system extremely vulnerable.

Chairman's Text, *supra* note 184. The organization called upon WTO Members to reject the Decision. See *id.*

192. See *Put Fighting Disease First*, STAR LEDGER, Sept. 10, 2003, at 14, available at 2003 WL 18727632.

193. See *Chairman's Text*, *supra* note 184; see also *supra* note 122 and accompanying text.

commercial policy objectives."¹⁹⁴ Critics worry that this statement is ambiguous and may make developing countries reluctant to use compulsory licensing under the system.¹⁹⁵ One editorial expressed the concern shared by developing countries that if the statement "means no for-profit manufacturer or distributor can be involved at any level, the provision is a poison pill. It is not reasonable to believe that any charitable operation can gear up to make and supply what the global AIDS fight needs."¹⁹⁶ Nonetheless, it seems generally understood that the Decision will help developing countries in more than one way, since developing country Members with the ability to manufacture generic drugs will be able to supply those drugs to other countries, thereby boosting their own economies.¹⁹⁷ Whether the Chairperson's statement will negatively limit the Decision's scope will depend on its interpretation by Member countries and also on whether it becomes part of TRIPS via the amendment.¹⁹⁸

Attaran and others suggest further WTO ministerial action for changes outside the TRIPS Council's jurisdiction.¹⁹⁹ If nothing else, recommendations should have been made in the Chairperson's Statement that accompanied the Decision.²⁰⁰ Such recommendations would have been a step towards addressing the broader concerns set out in the Doha Declaration,²⁰¹ which Attaran argues necessarily color the Paragraph 6 call to action.²⁰² Other areas of the access-to-medicines problem should have been addressed in addition to the Paragraph 6 Problem of TRIPS. For example, Attaran suggests "rolling back pharmaceutical access barriers such as taxes and tariffs" under GATT.²⁰³

194. See *Chairperson's Statement*, *supra* note 122 (emphasis added).

195. See Press Release, MSF, Flawed WTO Drugs Deal Will Do Little to Secure Future Access to Medicines in Developing Countries (Aug. 30, 2003), at <http://www.msf.org/content/page.cfm?articleid=C1540425-7F56-4D60-A6CB9D7ABA6D627F> (last visited Jan. 5, 2004) ("The statement . . . adds another layer of uncertainty that leaves developing countries vulnerable to pressure not to use the system.").

196. See *Put Fighting Disease First*, *supra* note 192.

197. See *WHO Head Welcomes*, *supra* note 119.

198. See *infra* note 225 and accompanying text.

199. See *supra* note 60 and accompanying text.

200. See *Chairperson's Statement*, *supra* note 122.

201. See *supra* note 59 and accompanying text (quoting the Doha Declaration's broad statements on the access-to-medicines and public health problems of developing countries).

202. See *supra* notes 58, 60 and accompanying text.

203. Attaran, *supra* note 43, at 867.

C. THE LEGACY OF THE DECISION

Despite its shortcomings, the Decision is likely to be effective for several reasons. Before the time comes for national ratification of an Article 31 amendment, the waiver will have been in place for almost one year.²⁰⁴ Countries with large pharmaceutical companies might see compulsory licenses in action under the waiver, and observe that with the safeguards in place, trade diversion poses little threat.²⁰⁵ Perhaps after this “trial period” provided by the waiver, national ratification would not present as big a hurdle as previously predicted.²⁰⁶ Then again, this will only work if Member countries actually grant compulsory licenses under the system, a prospect that is uncertain. To date, no countries have notified the TRIPS Council that they will import²⁰⁷ or export²⁰⁸ under the Decision.²⁰⁹

The Decision will probably be effective even if eligible Member countries do not actually issue compulsory licenses under its scheme, because it will likely act as a bargaining tool in obtaining lower drug prices from pharmaceutical companies’ prices.²¹⁰ For instance, just under a week after the TRIPS Council Decision was unveiled, Brazil’s President Luiz Inacio Lula da Silva signed a decree that authorized Brazil to import generic versions of AIDS pharmaceuticals.²¹¹ Brazil maintained that patented drugs are too expensive to continue buying them from multinational pharmaceutical companies.²¹² Brazil acknowledged that its new policy technically does not fall within the TRIPS Decision, but analysts saw the move as “taking advantage of a climate of flexibility sparked by the recent WTO ac-

204. See Paragraph 6 Decision, *supra* note 116, para. 11. The Decision came out on August 30, 2003, and calls for work on the amendment to be completed by June 2004.

205. See *supra* notes 138, 141-48 and accompanying text.

206. See *supra* notes 86, 167-69 and accompanying text.

207. *Notifications by Importing WTO Members* (WTO, Geneva, Switzerland), at http://www.wto.org/english/tratop_e/trips_e/public_health_notif_import_e.htm (last visited Feb. 16, 2004).

208. *Notifications by Exporting Members of the Grant of a Compulsory Licence Under the Decision* (WTO, Geneva, Switzerland), at http://www.wto.org/english/tratop_e/trips_e/public_health_notif_export_e.htm (last visited Feb. 16, 2004).

209. See *supra* notes 128, 148 and accompanying text (discussing the Decision’s notification requirements).

210. See *WTO OKs Deal*, *supra* note 178 (quoting the idea that the Decision may “act[] as a negotiating leverage to make medicines available more cheaply”).

211. See Miriam Jordan, *Brazil to Stir Up AIDS-Drug Battle*, WALL ST. J., Sept. 5, 2003, at A3.

212. See *id.*

cord.”²¹³ The decree came after negotiations with three pharmaceutical companies failed to advance to Brazil’s liking.²¹⁴

Changes like those in Brazil’s laws are only one step in making compulsory licensing a reality. The system’s effectiveness also hinges on Member countries changing their patent laws to allow the grant of compulsory licenses for *export* in accordance with the Decision’s conditions.²¹⁵ To date, Canada, Norway, and Switzerland have begun this process.²¹⁶ In early November 2003, Canada took the first step towards changing its laws as the Canadian Parliament approved a bill that would amend the Patent Act to allow generic pharmaceutical manufacturers to get compulsory licenses for producing and exporting generic drugs to developing countries unable to make their own.²¹⁷ The bill will next go through committee hearings.²¹⁸ Canadian civil society organizations, while supporting the initiative, argued that the bill in its current form is flawed.²¹⁹ In addition, for the system to work, generic drug companies must also decide to *manufacture* the generic drugs for export.

The Decision gave the end of 2003 as a deadline to start work on amending the TRIPS Agreement to replace the temporary waiver.²²⁰ In a communication circulated just before the TRIPS Council’s November 18, 2003 meeting, the European Communities (EC) urged the Council to stick to this schedule.²²¹ Still, a trade news digest reported that Members at the meeting “appeared to have given little thought to how to convert [the Decision] into an amendment of the TRIPS Agreement, as called

213. *See id.*

214. Brazil had negotiated with Abbott Laboratories, Merck & Co. and Roche Holding AG for several weeks before issuing the decree. *See* Associated Press, *Brazil Starts Patent Breaking AIDS Drugs* (Sept. 5, 2003), at <http://www.intelihealth.com/IH/ihtIH/WSIHW000/333/8013/368999.html> (last visited Jan. 5, 2004).

215. *See Communication from the European Communities on the Implementation of the General Council Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, IP/C/W/416 (Nov. 21, 2003), available at www.wto.org [hereinafter *Communication from the European Communities*].

216. *See TRIPS Council Shows Little Progress*, *supra* note 172.

217. *See UPDATE: Amendments to Canada’s Patent Act to Authorize Export of Generic Pharmaceuticals* (Canadian HIV/AIDS Legal Network, Montreal, Quebec), Nov. 10, 2003, at http://www.aidslaw.ca/Maincontent/issues/cts/patent-amend/PatentActAmendment_Update.pdf (last visited Jan. 6, 2004).

218. *See id.*

219. *Id.* at 2-4. Among these flaws are the ability of patent-holders to take over generic manufacturer contracts, limitations on which pharmaceutical products merit a compulsory license, and the exclusion of non-WTO member countries. *Id.*

220. Paragraph 6 Decision, *supra* note 116, para. 11.

221. *See Communication from the European Communities*, *supra* note 215.

for in the Decision.”²²² Members agreed to conduct informal consultations until the March 2004 TRIPS Council meeting.²²³

Various Members have suggested ideas on the form the amendment should take.²²⁴ The EC would like to see textual changes to the TRIPS Agreement that “faithfully reflect” the substance of the Decision, while the United States would rather not alter the language of the Agreement, but would instead add a footnote referring to the waiver and Chairperson’s Statement.²²⁵ Yet another option is to add an annex to the TRIPS Agreement that includes the text of the Decision.²²⁶

One item of business that *has* been completed is the creation of the webpage on the WTO website for posting the importing and exporting Member notifications.²²⁷ Now all that is needed is a bold country to step up and test compulsory licensing under the system laid out in the Paragraph 6 Decision.

CONCLUSION

The Decision presents a step in the right direction to increasing the availability of cheap drugs to developing countries suffering from health crises. The Decision does well as far as its transparency, although whether the Decision will result in an economically feasible, sustainable, and accessible system remains to be seen. It is possible that countries will make use of the Decision’s compulsory licensing provisions to import generic drugs. If nothing else, countries that previously could not import generic drugs may now threaten to do so under the system set out in the Decision. Thus, even if compulsory licensing remains unused, the Decision will likely function as a bargaining tool in favor of poor countries negotiating with pharmaceutical

222. See *TRIPS Council Shows Little Progress*, *supra* note 172. According to the Digest, “[v]ery little substantive discussion took place on TRIPs and health” at the meeting. *Id.*

223. *Id.*

224. *Id.*

225. *Communication from the European Communities*, *supra* note 215.

226. *See id.*

227. *TRIPS and Public Health: Dedicated Webpage for Notifications* (WTO, Geneva, Switzerland), at http://www.wto.org/english/tratop_e/trips_e/public_health_e.htm (last visited Jan. 5, 2004). The Decision outlines that these notifications “will be made available publicly by the WTO Secretariat through a page on the WTO website dedicated to this Decision.” See Paragraph 6 Decision, *supra* note 116, nn.5 & 9. As mentioned, the site currently lists no notifications. See *supra* notes 206-09 and accompanying text.

companies. The Decision may also increase awareness of the public health problems facing developing countries.

