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**Will the August 20, 2003 Decision of the WTO Provide Adequate  
Protection for Patent Holders Rights and is Diversion Still a  
Threat to the Pharmaceutical Industry?**

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On August 20, 2003 World Trade Organization (WTO) member governments broke their deadlock<sup>1</sup> over intellectual property protection and public health, resulting in an international agreement.<sup>2</sup> The new agreement, titled “Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health,” allows any member country producing pharmaceuticals under compulsory licenses<sup>3</sup> to export to other member countries;<sup>4</sup> a

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1. WTO Members could not come to an agreement regarding specific instruction of the Ministerial Conference to the Council for TRIPS, contained in paragraph 6 of the Declaration, to find an expeditious solution to the problem of the difficulties that WTO Members with insufficient or no manufacturing capacity in the pharmaceutical sector could face in making effective use of compulsory licensing under the TRIPS Agreement. See Haochen Sun, *A Wider Access to Patented Drugs Under the TRIPS Agreement*, 21 B.U. INT’L L.J. 101, 108 (2003).

2. See Press Release, WTO, Decision Removes Final Patent Obstacle to Cheap Drug Imports, at [http://www.wto.org/english/news\\_e/pres03\\_e/pr350\\_e.htm](http://www.wto.org/english/news_e/pres03_e/pr350_e.htm) (last visited March 8, 2005) [hereinafter Patent Obstacle].

3. Compulsory licensing permits a Member state to legally license a party, other than the patent holder, rights to produce and distribute the patented pharmaceutical, subject to certain conditions in times of public health crises. See Kelly A. Friedgen, Comment, *Rethinking The Struggle Between Health & Intellectual Property: A Proposed Framework for Dynamic, Rather than Absolute, Patent Protection of Essential Medicines*, 16 EMORY INT’L L. REV. 689, 699 (2002). Article 31 of the TRIPS Agreement requires issuance based upon individual case consideration, limited scope and duration, failed attempts to negotiate a voluntary license over a reasonable period of time, non-exclusive and non-assignable use, meeting the demand of predominately the domestic market, the

privilege expected to be used only in good faith in order to deal with public health crises such as HIV/AIDS, tuberculosis and malaria.<sup>5</sup> Developed countries, however, remain fearful that the decision might be abused by developing countries and that patent protection may be undermined.<sup>6</sup> Many pharmaceutical companies are particularly concerned with a potential increase in diversion<sup>7</sup> of pharmaceuticals produced in response to public health crises.<sup>8</sup> Diversion not only defeats the purpose of the WTO decision,<sup>9</sup> but threatens research and development into new therapies for AIDS and other diseases.<sup>10</sup> Paragraph 2(b)(ii) of the Paragraph 6 Decision attempts to address these valid concerns by requiring exporting countries to clearly identify pharmaceuticals being produced under compulsory license through special packaging, coloring and shaping of products.<sup>11</sup>

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payment of adequate remuneration to the patent holder, and subject to judicial review within the Member state. Agreement of Trade-Related Aspects of Intellectual Property Rights, Dec. 15, 1993, 33 I.L.M. 86-87 [hereinafter TRIPS].

4. See Patent Obstacle, *supra* note 2; See also Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, WT/L/540 (Aug. 30, 2003), available at <http://www.wto.org/> (last visited March 8, 2005) [hereinafter Paragraph 6 Decision].

5. See Patent Obstacle, *supra* note 2.

6. See *HIV Drugs for Africa Diverted to Europe*, WASH. POST, Oct. 3, 2002 at A10; See also Naomi Klein, *Bush's AIDS Test*, The Nation, October 27, 2003, available at <http://www.thenation.com/docprint.mhtml?i=20031027&s=klein> (quoting Harvey Bale as saying that the Agreement weakens patents, will hurt corporate profits and will destroy the incentive for new research).

7. Diversion, also called "parallel trading" and "gray goods", is the exploitation of pricing differentials between different wholesale levels. See International Coalition Against Diversion, *Protecting Your Assets in the New Global Economy*, at <http://home.pipline.com/~pytete/> (last visited Jan. 18, 2004); see also Donald E. deKieffer, *Diversion*, available at [http://www.dhlaw.de/eng/04\\_publi/documents/diversion.2000.PDF](http://www.dhlaw.de/eng/04_publi/documents/diversion.2000.PDF) (explaining that diversion of IP protected goods is not grey market, but is actually theft or other criminal activity) (last visited March 8, 2005) [hereinafter deKieffer Diversion]. "Parallel imports, also called gray-market imports, are goods produced genuinely under protection of a trademark, patent, or copyright, placed into circulation in one market, and then imported into a second market without the authorization of the local owner of the intellectual property right." Keith E. Maskus, *Parallel Imports In Pharmaceuticals: Implications For Competition And Prices In Developing Countries*, available at [http://www.wipo.int/about-ip/en/studies/pdf/ssa\\_maskus\\_pi.pdf](http://www.wipo.int/about-ip/en/studies/pdf/ssa_maskus_pi.pdf) (last visited March 25, 2005).

8. *Id.*

9. See WTO News, The General Council Chairperson's Statement, at [http://www.wto.org/english/news\\_e/news03\\_e/trips\\_stat\\_28aug03\\_e.htm](http://www.wto.org/english/news_e/news03_e/trips_stat_28aug03_e.htm) (last visited March 8, 2005) [hereinafter Chairperson's Statement].

10. See Klein, *supra* note 6.

11. TRIPS: Council for TRIPS Decision of 30 August 2003 WT/L/540, Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health, at [http://www.wto.org/english/tratop\\_e/trips\\_e/implem\\_para6\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm) (last visited

This article examines the effectiveness of the requirements of importing and exporting member countries under the Paragraph 6 Decision and the “Best Practices” guidelines suggested by the WTO in order to prevent diversion of pharmaceuticals. Additionally, remedies available to patent holders that are victims of diversion under United States and International law are discussed. Finally, the article proposes other programs and mechanisms available to government entities and private pharmaceutical companies that would ensure shipments make it to the intended recipients.

## I. BACKGROUND

### A. *International Intellectual Property Protection*

As a result of a comprehensive debate in the 1995 Uruguay Rounds of the Negotiations on the General Agreement on Tariffs and Trade (GATT), the World Trade Organization (WTO) was created.<sup>12</sup> Another result of this “package deal” was the Agreement on Trade Related Aspects of Intellectual Property Rights (“TRIPS”), which is the most controversial component, subject to both praise and blame.<sup>13</sup> The goal of TRIPS was to harmonize world intellectual property (IP) laws.<sup>14</sup> TRIPS sets out minimum standards for the protection and enforcement of international IP rights, including copyrights, patents and trademarks.<sup>15</sup> TRIPS also established minimum standards to which each nation must adhere concerning the enforcement of domestic intellectual property rights.<sup>16</sup> Specific provisions cover civil and administrative procedures and remedies, provisional measures, border enforcement procedures, and criminal procedures.<sup>17</sup>

Although some see TRIPS as accomplishing the goal of harmonization with a fair balancing among differing interests, others,

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March 8, 2005) [hereinafter Implementation].

12. See Ronald J. T. Corbett, *Protecting and Enforcing Intellectual Property Rights in Developing Countries*, 35 INT’L LAW 1083, 1088 (2000).

13. See Sun, *supra* note 1, at 102.

14. See Nabila Ansari, *International Patent Rights in a Post-Doha World*, 11 CURRENTS: INT’L TRADE L.J. 57, 60 (2002).

15. See William Davis, *The Medicine Equity and Drug Safety Act of 2000: Releasing Gray Market Pharmaceuticals*, 9 TUL. J. INT’L & COMP. L. 483 (2001).

16. See TRIPS, *supra* note 3; See also Overview: the TRIPS Agreement, available at [www.wto.org/english/tratop\\_e/trips\\_e/intel2\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/intel2_e.htm) (last visited March 8, 2005); James Thuo Gathii, *The Legal Status of the Doha Declaration on TRIPS and Public Health Under the Vienna Convention on the Law of Treaties*, 15 HARV. J.L. & TECH. 291 (2002).

17. See TRIPS, *supra* note 3.

mainly developing nations, refute this claim.<sup>18</sup> Some developing country Members of the WTO believe that implementation of their domestic public health policies are adversely affected by the limitation of access to essential medicines<sup>19</sup> needed during public health crises due to TRIPS provisions.<sup>20</sup> While it is true that other factors such as infrastructure and professional support play an important role in determining access to drugs, it is also true that the prices that result from the existence of patents ultimately determine how many people suffering from AIDS and other diseases may go untreated.<sup>21</sup>

The WTO attempted to address these concerns by writing flexibilities, such as compulsory licensing, into the TRIPS Agreement.<sup>22</sup> Article 30 of the Agreement allows governments to issue compulsory licenses to companies to make patented products or use patented processes under license without the consent of the patent owner, but only under certain conditions aimed at safeguarding the legitimate interests of the patent holder.<sup>23</sup> Some governments, including the African Group,<sup>24</sup> sought clarification of how these flexibilities would be interpreted, and how far their right to use them would be respected.<sup>25</sup>

The Doha Declaration on TRIPS and Public Health (“the Doha Declaration”) addressed these divergent perspectives.<sup>26</sup> Members reached an agreement in principle, which acknowledged the need to assist developing countries in combating the three fatal pandemics of AIDS, malaria and tuberculosis.<sup>27</sup> While promoting both access to

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18. See Ansari, *supra* note 14.

19. The World Health Organization defines essential drugs and medicines as “those drugs that satisfy the health care needs of the majority of the population; they should therefore be available at all times in adequate amounts and in the appropriate dosage forms, and at a price that individuals and the community can afford.” See Friedgen, *supra* note 3, at 693 (citing World Health Organization, Expert Committee of Essential Drugs, at <http://www.who.int/medicines/organization/par/edi/trs/trs895.shtml>).

20. See Sun, *supra* note 1, at 103.

21. Carlos M. Correa, *TRIPS and Access to Drugs: Toward a Solution for Developing Countries without Manufacturing Capacity*, 17 EMORY INT’L L. REV. 389, 390-391 (2003).

22. See Patent Obstacle, *supra* note 2. See also Friedgen, *supra* note 3 (explaining compulsory licensing under TRIPS).

23. See Patent Obstacle, *supra* note 2.

24. The African Group is comprised of all the African members of the WTO. *Id.*

25. *Id.*

26. See Gathii, *supra* note 16 at 292.

27. Jean Bizet (France), *The Trips Agreement and Public Health*, Presented at Cancun Session of The Parliamentary Conference on The WTO (Sept. 9-12, 2003), at <http://www.ipu.org/splz-e/cancun/5b.pdf> (last visited March 8, 2005) [hereinafter

existing medicines and the creation of new medicines, ministers at the Doha Ministerial Conference focused on the importance of implementation and interpretation of the TRIPS Agreement in favor of public health.<sup>28</sup> The declaration provided that the TRIPS Agreement does not and should not prevent WTO members from taking measures to protect public health, and that it should be interpreted accordingly:

We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all. In this connection, we reaffirm the right of WTO members to use, to the full, the provisions, in the TRIPS Agreement, which provide flexibility for this purpose.<sup>29</sup>

This declaration gave developing country Members the autonomy to make and implement domestic public health policies with respect to intellectual property protection.<sup>30</sup> It also clarified members' right to adopt an international principle of exhaustion of rights, including parallel importation.<sup>31</sup> And similarly, it confirmed the members' rights to grant compulsory licenses on the grounds determined by each member.<sup>32</sup> Furthermore, these countries were granted the power to determine what constitutes a national emergency.<sup>33</sup>

Known as the Paragraph 6 Problem, Ministers at Doha recognized, but failed to resolve one critical issue with compulsory licensing.<sup>34</sup>

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Cancun Session].

28. See Patent Obstacle, *supra* note 2.

29. WTO Ministerial Conference, Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/21 (Nov. 14, 2001) at para. 4, available at [http://www.wto.org/english/thewto\\_e/minist\\_e/min01\\_e/mindecl\\_e.htm](http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.htm) (last visited March 8, 2005) [hereinafter Doha Declaration].

30. See Sun, *supra* note 1, at 102.

31. Correa, *supra* note 21 at 392. See also Bizet, *supra* note 27 (explaining that the declaration emphasizes the importance of public health by allowing the "flexibilities" such as compulsory licensing). Bizet also points out that the declaration text is very similar to prevailing Western laws, such as French and American, which will grant such licenses where a genuine reason exists for circumventing patent protection. *Id.*

32. Correa, *supra* note 21, at 392.

33. See Ansari, *supra* note 14, at 64.

34. Doha Declaration, *supra* note 29 at paragraph 6 ("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 this problem and to report to the General Council before the end of 2002."). See also Patent Obstacle, *supra* note 22.

Such authorizations benefited developing countries which were further advanced, such as India, Thailand, Brazil and South Africa, who have laboratories and the scientific capabilities to produce the pharmaceuticals.<sup>35</sup> The Agreement, however, overlooked the poorest developing countries which do not possess the technical production ability, although they are often the countries most affected by the diseases targeted in the declaration.<sup>36</sup> Specifically, the Agreement did not directly address whether countries, which were unable to produce pharmaceuticals domestically, could import patented drugs made under compulsory licensing.<sup>37</sup> Article 31(f) of the TRIPS Agreement in fact required that products under compulsory licensing would be “predominately for the supply of the domestic market.”<sup>38</sup>

Failing to define the term “predominately” in this provision left the WTO members, who lacked the requisite manufacturing infrastructure, with the unmet need of generic drugs.<sup>39</sup> Ironically, these countries, which were suffering the most severely due to public health crises, found it complicated to contract with a more developed country that was willing to supply them with drugs made under compulsory licensing.<sup>40</sup> This difficulty was due to the fact that developing countries producing pharmaceuticals under compulsory licenses were aware that the WTO accepted the manufacture of medicines for local use, but it was against the marketing of generic medicines and by extension, its export outside the domestic market mainly because of opposition from the big pharmaceutical groups.<sup>41</sup>

There were, however, a few countries, such as India, that were willing to export pharmaceuticals to developing countries lacking infrastructure. Indian law does not provide patent protections for pharmaceutical products, therefore manufacturers are able to produce generic versions of US and EU patented pharmaceuticals at a fraction of the price without violating local patent law.<sup>42</sup> After 2005, however, when the TRIPS Agreement has become fully operative, exporting countries must fully comply with the Agreement and will no longer be able to produce and export cheap generic copies of patented medicines.<sup>43</sup> Consequently, the limited source of affordable drugs will be lost and developing countries suffering from emergency

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35. Cancun Session, *supra* note 27.

36. *Id.*

37. *See* Sun, *supra* note 1, at 103.

38. *See* Patent Obstacle, *supra* note 2.

39. *Id.*

40. *Id.* *See also* Sun, *supra* note 1, at 103.

41. *See* Cancun Session, *supra* note 27.

42. Correa, *supra* note 21, at 393.

43. *Id.*

public health crises and unable to benefit from compulsory licensing will become entirely dependant upon expensive patented pharmaceuticals.<sup>44</sup>

WTO Members entrusted the TRIPS Council with the task of finding a legal solution to this problem.<sup>45</sup> The council's challenge was to reach an agreement that, in theory, would grant certain countries the authority to manufacture and export to "countries which need them the most" the generic medicines used for "diseases of an epidemic proportion" on a case by case basis.<sup>46</sup> According to the Doha Declaration, the TRIPS council should have found a solution and reported it to the General Council before the end of 2002.<sup>47</sup> Unfortunately, determination of which medicines were covered by the agreement and which countries could benefit remained unresolved and the deadline was not met.<sup>48</sup>

In the meantime, while a solution was still being negotiated, the licensed medicine-manufacturing countries such as the European Union, the United States, Switzerland and Canada, ended the moratorium and pledged unilaterally to refrain from taking the matter to court.<sup>49</sup> In light of the fact that developing countries are not bound to uphold the TRIPS Agreement until 2005, continuing to supply them developing countries with generic medicines at the present time did not constitute a violation of international law.<sup>50</sup>

#### *B. Why is the WTO deadlocked? Intellectual Property Rights vs. Human Rights*

It is generally undisputed that the developing world is suffering from multiple infectious diseases that are responsible for over 300

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44. *Id.*

45. Cancun Session, *supra* note 27.

46. Although the guidance was stated in vague terms laden with flexibility, the Council was advised that it should, at a minimum, guarantee the poorest countries access to generic products at an acceptable price and avert the risk of re-export to other countries. *Id.* at II (b) 14.

47. Doha Declaration, *supra* note 29, at paragraph 6. *See also* Sun, *supra* note 1, at 102.

48. Cancun Session, *supra* note 27. *See also* Sun, *supra* note 1, at 102. The TRIPS Council and the WTO General Council met on December 20, 2002, and noted the obvious opposition of the United States and the absence of a consensus on the text which had been proposed four days earlier by the Ambassador of Mexico who is Chairman of the TRIPS Council. No headway has been made since, despite a second attempt, albeit unsuccessful, at a compromise at the Mini-Ministerial in Tokyo in mid February 2003. Cancun Session, *supra* note 27 at, II (b) 14.

49. Cancun Session, *supra* note 27.

50. *Id.*

million illnesses and almost six million deaths per year.<sup>51</sup> The stakes involved are very high indeed. According to the World Health Organization (WHO), a third of the world population, approximately two billion people, do not have access to essential medicines.<sup>52</sup> The critical health situation of developing countries is due mainly to the AIDS epidemic which affects 42 million persons throughout the world, the majority of whom are in Africa, and 90% of whom have no medicines.<sup>53</sup> Although treatment for these diseases exists and would likely have a profound effect on the morbidity and mortality rates, access to these essential medicines for combating HIV/AIDS, malaria and tuberculosis is greatly hindered by the existence of patents.<sup>54</sup> The magnitude of this problem justifies making available to those persons affected the pharmaceutical products which are currently out of their reach because of their market price.

This problem of access has therefore emerged as a global priority.<sup>55</sup> Human rights activists advocate easing or eliminating patent protections for certain drugs, on the basis that such protections violate international human rights to health.<sup>56</sup> It is estimated that some 6.8 million persons are affected by the AIDS virus in West Africa.<sup>57</sup> At the price set on the European market, treating these populations would cost €6 billion a year, a far cry from the €500 million which the developing countries are able to allocate each year to their health budgets.<sup>58</sup>

On the other side, representatives of the pharmaceutical industry vigorously defend and lobby for the international application of intellectual property rights.<sup>59</sup> The United States often stresses the importance of IP protection for research and development, arguing that intellectual property contributes to public health objectives globally.<sup>60</sup> The patent system embodies a compromise between competing short-term and long-term economic and social interests.<sup>61</sup>

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51. Friedgen, *supra* note 3, at 690.

52. Cancun Session, *supra* note 27.

53. *Id.*

54. Correa, *supra* note 21, at 390.

55. Friedgen, *supra* note 3, at 690. See also Ellen 't Hoen, *TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way From Seattle to Doha*, 3 CHI. J. INT'L L. 27, 38 (2002).

56. Friedgen, *supra* note 3 at 690.

57. Cancun Session, *supra* note 27.

58. *Id.*

59. Friedgen, *supra* note 3, at 690.

60. 't Hoen, *supra* note 55, at 38.

61. See ASEAN Workshop on the TRIPS Agreement and its Impact on Pharmaceuticals, at

<http://www.who.int/medicines/library/dap/aseantripsagreement.pdf> (last visited

Along with a well-functioning regulatory structure and marketing system, it allows the private pharmaceutical industry to contribute to a socially driven public health sector by providing it with cost-effective new technologies, including pharmaceuticals.<sup>62</sup>

The commercial sector discovers and develops nearly all new drugs and vaccines, but this is expensive and risky.<sup>63</sup> The purpose of the US patent system is to encourage technological innovation by providing economic incentives to inventors.<sup>64</sup> Such incentives are necessary to investigate thousands of new compounds and to invest an average of several hundred million dollars in research and development.<sup>65</sup>

Incentives for innovation are lost when the patent monopoly is disturbed, thereby threatening the profit scheme.<sup>66</sup> The pharmaceutical industry is not particularly concerned with this threat in regards to developing countries, which lack infrastructure, because they hold no such patent monopoly in these countries and the critical need is recognized.<sup>67</sup> This is evident in the industries willingness to lead initiatives, which seek to respond to the needs of the poor and suffering.<sup>68</sup> Such pharmaceutical industry-based ventures include drug donation and give-aways, drug discounting, and voluntary licensing of technology related to various diseases.<sup>69</sup>

Diversion of the product into higher-priced markets capable of bearing the high costs, which is sought by the pharmaceutical companies, is the focal concern of the pharmaceutical industry.<sup>70</sup> This position is understandable in light of basic economic theory.<sup>71</sup>

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March 8, 2005) [hereinafter ASEAN].

62. *Id.*

63. *Id.*

64. Lawrence M. Sung, Ph.D., *Intellectual Property Protection or Protectionism? Declaratory Judgment Used by Patent Owners Against Prospective Infringers*, 42 AM. U.L. REV. 239, 244 (Fall, 1992) (explaining the American patent system with historical perspectives of IP protection). *See also*, John Miller, Comment, *A Call to Legal Arms: Bringing Embryonic Stem Cell Therapies to Market*, 13 ALB. L.J. SCI. & TECH. 555, 566-567 (2003) (explaining that the “monopoly-profit-incentive” thesis has become the dominant rationale for justification of the patent system).

65. *See* ASEAN, *supra* note 61.

66. *See* Miller, *supra* note 64, at 566-567 (citing Study of the Subcommittee on Patents, Trademarks, and Copyrights of the Senate Comm. on the Judiciary, 85<sup>th</sup> Cong., An Economic Review of the Patent System 21 (Comm. Print 1958) (Fritz Machlup), in 1 Research Studies in Patent Law (1956-63)).

67. Friedgen, *supra* note 3, at 707.

68. *Id.* at 690.

69. *Id.* (providing an in-depth discussion of efforts of various international actors).

70. *Id.* at 707.

71. *Id.*

Introducing a diverted product into a market where the product is already patent protected effectively destroys the patent holder's monopoly,<sup>72</sup> ultimately affecting the amount of research funds available and in turn the availability of essential medicines.<sup>73</sup>

### C. What is Diversion?

Product diversion refers to products sold by a manufacturer that are distributed, in violation of a contract, law or regulation, into markets other than those originally intended.<sup>74</sup> With product diversion, third parties can undercut a company's price and reap huge profits.<sup>75</sup> This international scheme hinges on an industry practice in which U.S. manufacturers set up different pricing for the same products in accordance with each region's particular economic status.<sup>76</sup>

Diversion of pharmaceuticals produced under compulsory licenses could theoretically occur when drugs produced by country A<sup>77</sup> are exported to country B<sup>78</sup> under the Paragraph 6 Decision. The medicines intended for country B could be diverted in one of three ways; first, country A could break the contract and export the drugs directly to country C<sup>79</sup> at prices substantially lower than the local market; second, in route to country B diverters could steal the pharmaceuticals and sell them in country C at a great profit; and finally, after the importation, country B, could decide that the financial income brought in from selling the drugs would be more essential to the greater public than the drugs and could choose to export into country C at a large profit.

The origin of diverted goods is not exclusive to pharmaceuticals produced under compulsory licenses. Diversion has long been a problem after the sale of goods directly from the patent holder into a foreign market or via donation of the pharmaceuticals into a

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72. Friedgen, *supra* note 3, at 707.

73. See ASEAN, *supra* note 61.

74. Product Diversion Investigations, at <http://www.njinvestigator.com/Product%20Diversion.htm> (last visited March 8, 2005) [hereinafter *Diversion*].

75. *Id.*

76. *Id.*

77. Typically a developing country, which has been granted a compulsory license in order to combat a local public health crisis, also called the "exporting member." See *infra*, section II (a), defining "eligible exporting member" under the Paragraph 6 Decision.

78. A developing country that does not have the capability or infrastructure to produce the drug, also called the importing member. See *infra*, section II (a), defining "eligible importing member" under the Paragraph 6 Decision.

79. A country where the drug is already in the market, including the patent holder's country.

developing country in a public health crisis.<sup>80</sup>

## II. THE PARAGRAPH 6 DECISION

On August 30, 2003 at the Ministerial Conference in Cancun, with public health and intellectual property rights in mind, ministers settled the unanswered question of exportation/importation of products produced under compulsory licenses.<sup>81</sup> Although the United States initially aimed at limiting the availability of compulsory licenses to countries affected by HIV/AIDS, malaria and tuberculosis, the diplomatic battle came to an agreement, when the United States accepted text covering all diseases, as was originally mandated by the Declaration.<sup>82</sup>

The final agreement waives countries' obligations under Article 31<sup>83</sup> of the TRIPS agreement, by allowing any WTO member country to export pharmaceutical products made under compulsory licenses within the terms set out in the decision.<sup>84</sup> This solution was based on a compromise developed by the Chair of the TRIPS Council and on a "Statement by the Chair" proposed by the United States as a condition to accept the deal and satisfy the U.S. pharmaceutical companies.<sup>85</sup> The Decision takes the form of an interim waiver that would last until the TRIPS Agreement is amended.<sup>86</sup>

In his statement, General Council Chairperson Carlos Perez del Castillo, Uruguay's ambassador, provided comfort for those who feared that the decision might be abused.<sup>87</sup> He first stated that, "Members recognize that the system that will be established by the Decision should be used in good faith to protect public health and, without prejudice to paragraph 6 of the Decision, not be an instrument to pursue industrial or commercial policy objectives."<sup>88</sup> Secondly, he emphasized that "the purpose of the Decision would be defeated if products supplied under this Decision are diverted from the markets for which they are intended. Therefore, all reasonable measures should be taken to prevent such diversion in accordance

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80. International Coalition Against Diversion, *Protecting Your Assets in the New Global Economy*, available at <http://home.pipline.com/~pvteye/> (last visited March 8, 2005).

81. See Patent Obstacle, *supra* note 22.

82. Correa, *supra* note 21 at 393.

83. See TRIPS, *supra* footnote 3.

84. See Patent Obstacle, *supra* note 22. See also Implementation, *supra* note 11.

85. Correa, *supra* note 21, at 393-94.

86. *Id.* at 397.

87. See Chairperson's Statement, *supra* note 9.

88. *Id.*

with the relevant paragraphs of the Decision.”<sup>89</sup> Details in the decision explain exactly how compulsory licensing should be used to protect public health and how diversion can be prevented.

*A. In Good Faith to Protect Public Health*

Paragraph 1 (b) addresses the United States concern that low-cost producers in places such as India would smuggle medicines into rich markets and use their technologies to boost profits rather than for humanitarian reasons.<sup>90</sup> The provision defines “eligible importing member” as any least-developed country Member, and any other Member that has made a notification to the Council for TRIPS of its intention to use the system as an importer.<sup>91</sup> In the latter case any WTO Member may at any time notify the council that it will use the compulsory licensing system as an importer.<sup>92</sup> In order to justify such use, the Member must show that importation is necessary due to national emergency or other circumstances of extreme urgency or in cases of public non-commercial use.<sup>93</sup> By limiting importing members to countries with justifiable humanitarian needs other than commercial needs, the Decision does not allow for exploitation of compulsory licenses.

Paragraph 2 further limits the possibilities of exploitation by waiving the responsibilities of Article 31 of the TRIPS agreement, but setting out obligations of both exporting and importing members with respect to granting compulsory licenses to the extent necessary for the purposes of production of pharmaceuticals and their export.<sup>94</sup>

Specifically, the importing member must notify the Council providing them with details of product need, establishing that the requesting member has insufficient or no manufacturing capacities in the pharmaceutical sector for the products, and confirming that,

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89. *Id.*

90. See Scott Miller, *WTO Drug Pact Lifts Trade Talks – Landmark Deal Provides Medicines to Poor Nations*, available at <http://www.usvtc.org/WTO/WTO%20Drug%20Pact%20Lifts%20Trade%20Talks.htm>; *EU’s Lamy Is Optimistic*, WALL ST. J., Sept. 2, 2003, at A2.

91. See Implementation, *supra* note 84.

92. *Id.*

93. *Id.* “Exporting member is defined as a Member using the system set out in this Decision to produce pharmaceutical products for, and export them to, an eligible importing member.” *Id.* Section (b) also notes that some Members will not use the system in the Decision as importing Members and that some other Members have stated that, if they use the system, it would be in no more than situations of national emergency or other circumstances of extreme urgency. *Id.*

94. See Implementation, *supra* note 84.

where a pharmaceutical product is patented in its territory, it has granted or intends to grant a compulsory license in accordance with Article 31 of the TRIPS Agreement and the provisions of the Decision.<sup>95</sup> The Decision goes on to require that exporting Members produce only the amount of pharmaceuticals necessary to meet the needs of the importing Member and that all such products will be shipped in their entirety to the cited importing Member.<sup>96</sup>

Restricting the amount of product that the exporting Member can produce and export to the actual need of the importing countries is another attempt by the Council to ensure that compulsory licensing will only be used in good faith in order to ensure public health.

### *B. Preventing Diversion*

The importing members under the Decision have the burden of ensuring that drugs imported into their country are not re-exported, or diverted, to other markets.<sup>97</sup> In order to make this feasible, exporting members are required to produce products that can be clearly identified as being produced under the system set out in the Decision.<sup>98</sup> The Decision does not lay out any specific requirements but identifies methods such as special packaging, coloring or shaping of the products. This provision is, however, only required if such distinction is feasible and does not have a significant impact on price.<sup>99</sup> Paragraph 2 also requires that the exporting Member post on a Web site the quantities of pharmaceuticals being supplied to each destination, listing the distinguishing features of the products.<sup>100</sup>

Paragraph 4 of the Decision requires that importing members must also “take reasonable measures within their means, proportionate to their administrative capacities and to the risk of trade diversion, to prevent re-exportation of the products that have actually been imported into their territories under the system.”<sup>101</sup>

With the new Decision laid out it seems that the WTO has finally come to a conclusion that satisfies both the pharmaceutical industry’s and the developing country’s desire for a more balanced set of regulations for the protection of international IP rights. It has yet to be seen, however, how the Decision will affect each side in practice.

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95. *Id.*

96. *Id.*

97. *Id.*

98. See Implementation, *supra* note 84.

99. *Id.*

100. *Id.*

101. *Id.*

### III. IMPLEMENTATION OF THE DECISION

With the Decision in place and paragraph 6 of the Doha Declaration now a reality the question remains, will developing countries have the capability to even take advantage of the new Decision? Multiple criticisms of the Decision quickly emerged after the agreement was reached.<sup>102</sup>

Some commentators believe that the United States, at the behest of the pharmaceutical lobby, was successful in pushing for so many conditions, that the deal has become far from workable.<sup>103</sup> A coalition of Non-Government Organizations declared that the new deal was in fact just “a gift bound in red tape.”<sup>104</sup> Even if countries wanted to import cheap generics they would first have to jump through multiple hoops to prove that they are truly in need, unable to afford patented drugs and incapable of producing the medicines domestically.<sup>105</sup> Furthermore, since the Agreement also puts up extensive requirements for the exporting member to comply with, there is no guarantee that there will be a sufficient supply of drugs for the importing members to buy.<sup>106</sup>

It has also been suggested that, because the Decision takes the form of an interim waiver,<sup>107</sup> national laws must be aligned with the waiver in order for its benefits to be realized.<sup>108</sup> If such alignment is not realized, patent holders may succeed in initiating a complaint invoked under the provision in the national laws.<sup>109</sup> Revision or amendment of national laws may impede, if not prevent, the waiver

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102. See Correa, *supra* note 21, at 398; Klein, *supra* note 6; Scott Miller, *supra* note 90.

103. Klein, *supra* note 6.

104. *Id.* See also, *supra* section II (a) discussing requirements of the Paragraph 6 Decision.

105. Klein, *supra* note 6. See also, *supra* section II (a) discussing requirements of the Paragraph 6 Decision.

106. *Id.* See also, *supra* section II (a) discussing requirements of the Paragraph 6 Decision.

107. According to paragraph 11 of the Decision: 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. The TRIPS council shall initiate by the end of 2003 work on the preparation of such an amendment with a view to its adoption within six months, on the understanding that the amendment will be based, where appropriate, on the Decision and on the further understanding that it will not be part of the negotiations referred to in paragraph 45 of the Doha Ministerial Declaration (WT/MIN(01)/DEC/1).

108. Correa, *supra* note 21, at 398.

109. *Id.* at 390.

from being used.

Others find the Decision favorable, but burdened with problems. The European Union's trade commissioner, Pascal Lamy, supports the decision but stated, "We all have to be very modest. We have solved about 10% of the problem of access to medicines by developing countries."<sup>110</sup> The problem that Lamy emphasizes is that even if life-saving drugs do become cheaper, they will remain too costly for many people. And furthermore, most developing nations do not have the distribution system or the trained staff to get the medicines to the people in need.<sup>111</sup>

If it in fact is true that the recent Decision will not help solve the public health crises, who will benefit from the compulsory licensing and exportation of generic pharmaceuticals? It has been suggested that the generic producers will be the only entity seeing benefits from the Decision.<sup>112</sup> There stands the possibility that generic firms may use the Decision as a way to reach new markets.<sup>113</sup> Many analysts in fact agree that the Indian generic industry stands to gain the most from such exploitation of the new Decision.<sup>114</sup> South Africa's local generic drug manufacturers will also benefit from the loopholes in the Decision.<sup>115</sup>

European Union trade commissioner Pascal Lamy stated that finally the WTO has reached an even balance between human rights and intellectual property rights, however criticism from both sides of the fence seems to indicate that implementation of paragraph 6 of the Doha Declaration does not solve the majority of the problems.<sup>116</sup> Patients in need of essential medicines may not receive any increased access and pharmaceutical companies relying on patent licensing may see the risk of diversion increase.

The pharmaceutical companies' hesitations about the Decision becomes more of a reality if in fact the Decision will only slightly affect public health issues and only benefit generic drug producers. If this proves to be the case, worries about the diversion of pharmaceuticals becomes a valid concern and forefront issue.

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110. Miller, *supra* note 90.

111. *Id.*

112. Brand, *Generics Reps Praise New WTO Drug Plan*, Washington Drug Letter (Vol. 35, No. 36) (Sept. 15, 2003).

113. *Id.*

114. *Id.*

115. All Africa, *WTO Deal Paves Way for Cheaper Drugs*, available at <http://www.cdcnpin.org/PrevNews/2003/sept03/update091103.txt> (last visited March 25, 2005).

116. *See* Miller, *supra* note 90.

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#### IV. WILL THE PREVENTION OF DIVERSION MEASURES BE EFFECTIVE?

##### A. “Best Practice Guidelines”

In his statement, the General council emphasized the importance of Members recognizing that the purpose of the Decision would be defeated if products supplied under the Paragraph 6 Decision are diverted from the markets for which they are intended.<sup>117</sup> He goes on to suggest that all reasonable measures, including special packaging and/or special coloring or shaping, should be taken to prevent diversion.”<sup>118</sup>

The Chairman further describes that in the past companies have developed procedures to prevent diversion of products and includes as an attachment to the decision “Best Practices” guidelines, which were developed upon the experiences of pharmaceutical companies.<sup>119</sup> Member countries and producers are encouraged by the Chairman to draw from and use these practices, and to share information on their experiences in preventing diversion.<sup>120</sup>

##### B. Case Example – GlaxoSmithKline

Listed as an example under the “Best Practice Guidelines,” was the pharmaceutical company GlaxoSmithKline (GSK), which recently

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117. See Chairperson’s Statement, *supra* note 9.

118. *Id.* [T]he provisions of paragraph 2(b)(ii) apply not only to formulated pharmaceuticals produced and supplied under the system but also to active ingredients produced and supplied under the system and to finished products produced using such active ingredients.” *Id.* “It is the understanding of Members that in general special packaging and/or special coloring or shaping should not have a significant impact on the price of pharmaceuticals.” *Id.*

119. See Chairperson’s Statement, *supra* note 9.

120. See Chairperson’s Statement, *supra* note 9. Companies have often used special labeling, coloring, shaping, sizing, etc. to differentiate products supplied through donor or discounted pricing programs from products supplied to other markets. Examples of such measures include the following: Bristol Myers Squibb used different markings/imprints on capsules supplied to sub Saharan Africa; Novartis has used different trademark names, one (Riamet®) for an anti-malarial drug provided to developed countries, the other (Coartem®) for the same product supplied to developing countries. Novartis further differentiated the products through distinctive packaging; Merck differentiated its HIV/AIDS antiretroviral medicine CRIVAN through special packaging and labeling, i.e., gold-ink printing on the capsule, dark green bottle cap and a bottle label with a light-green background; Pfizer used different coloring and shaping for Diflucan pills supplied to South Africa. *Id.*

used different outer packaging for its HIV/AIDS medication Combivir.<sup>121</sup> Unfortunately, it took a hard lesson for GSK to effectively make these changes in packaging.

In response to the AIDS crises, GlaxoSmithKline, one of six international pharmaceutical companies participating in a drug discount program for developing countries, sent 40,000 packs of HIV/AIDS medications to countries in need in Africa.<sup>122</sup> The value of these medications was more than \$18 million, but sold to the African companies at a discount rate of up to 90%.<sup>123</sup> When these much needed medications finally reached Africa however, the shipments were diverted, relabeled and sent back to Europe for resale in the grey market.<sup>124</sup> Only 10% of the shipment made it to the intended recipients.<sup>125</sup>

Although in theory the Chairman's suggestions seem to be a workable solution to the problem of diversion, they may be impractical if the importing and exporting countries are incapable of monitoring and controlling their borders. The "Best Practices" guidelines suggest things such as; different markings/imprints on capsules, different trademark names, special packaging and labeling, and different shading of the bottle colors.<sup>126</sup> The diverters themselves, in the GSK case, did exactly what one of the guidelines suggests: they changed the labeling, originally written in German, to labels that were in Dutch.<sup>127</sup> According to the Chairman, this should have been an immediate indication that the imported pharmaceuticals were grey market goods. However if each and every customs agent in

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121. *Id.*

122. Washington Post Staff Writer, *HIV Drugs for Africa Diverted to Europe*, WASH. POST, Oct. 3, 2002, at A10.

123. *Id.*

124. *Id.*

125. *Id.* GSK officials believed that the diversion was accomplished in the following way: GSK used airfreight companies to transport the medicine to Africa. Once on the ground, the shipments were moved from one company that handles customs clearances on imports to another that performs the same task. They were then sent to an airfreight service employed by the profiteers and flown to Europe. Delivered to wholesalers there, the drugs made their way into the regular chain of commerce. *Id.* GlaxoSmithKline along with the European Federation of Pharmaceutical Industries and Associations expressed deep concern about this incident and pushed for a way to stop this illegal trade by methods such as stricter border controls and adherence to existing trade regulations. GSK stated that if a solution is not reached, many pharmaceutical companies have warned that they will reduce research into new therapies for AIDS and completely stop importation of these drugs into developing countries. See Washington Post Staff Writer, *HIV Drugs for Africa Diverted to Europe*, WASH. POST, Oct. 3, 2002, at A10.

126. See Implementation, *supra* note 11.

127. Washington Post Staff Writer, *HIV Drugs for Africa Diverted to Europe*, WASH. POST, Oct. 3, 2002, at A10.

every country were not trained to identify the slight differences outlined in the “Best Practices,” then it would be very difficult for them to even recognize the distinction. It took Dutch officials nearly a year to identify GSK’s diverted drugs.<sup>128</sup>

Furthermore, borders agents are faced with huge volumes of imports on a daily basis. Even in the United States only two percent of products that cross the border are inspected. In the event that these measures were employed and inspectors at the borders were able to identify diverted goods, would the slight possibility of being caught be an adequate deterrent to stop illegal importers from trying again?

## V. OTHER SOLUTIONS? A SPECTRUM OF OPTIONS

### A. Implementation of Civil and Criminal Penalties

Presently, diversion is a reality. Until, a more practical solution to the big issue is found, pharmaceutical companies may look to prosecution to tame the effects of diversion. Paragraph 5 of the Paragraph 6 Decision requires that “Members shall ensure the availability of effective legal means to prevent the importation into, and sale in, their territories of products produced under the system set out in this Decision and diverted to their markets inconsistently with its provisions, using the means already required to be available under the TRIPS Agreement.”<sup>129</sup> Article 61 of the TRIPS agreement provides in part that, “members may provide criminal procedures and penalties to be applied in... cases of infringement of intellectual property rights, in particular where they are committed willfully and on a commercial scale.”<sup>130</sup>

The difficulty with these provisions is that they require developing countries to employ strict border controls and criminal procedures and penalties. There are several reasons why developing countries will not incorporate criminal procedures set by the minimum standards of TRIPS, into their domestic laws. Most intellectual property belongs to foreigners; therefore enforcing TRIPS provisions leads to a transfer of wealth from developing countries to developed countries.<sup>131</sup> Also, enforcing TRIPS negatively impacts domestic

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128. *Id.*

129. See Implementation, *supra* note 84.

130. World Health Organization, *Globalization, TRIPS, and Access to Pharmaceuticals 4* (March 2001) at [http://www.who.int/medicines/library/edm\\_general/6paggers/PPMO3%ENG.pdf](http://www.who.int/medicines/library/edm_general/6paggers/PPMO3%ENG.pdf) (last visited March 8, 2005).

131. Frederick M. Abbott, *Symposium on Global Competition and Public Policy*

businesses and impinges on the sovereign rights of countries to develop independent of foreign influence. Furthermore, there is the practical problem of inadequate administrative personnel to ensure the timely and reasonable acquisition and registration of intellectual property rights.<sup>132</sup> And most importantly, imposition of strict product diversion rules would severely tax the impoverished enforcement regimes of poor countries.<sup>133</sup>

Pharmaceutical companies should not depend on developing Members to provide effective legal means to prevent the importation into their countries, because it is unlikely that they will be effective in accomplishing such a task, as their primary focus is to provide their people with food, water and essential medicines, not protect big industries' IP rights. Developed countries should focus their efforts of preventing diversion at the major borders, especially their own. Legal provisions are already in place to effectively prosecute diverters in the United States.

Although the sophisticated diversion scheme, such as the GlaxoSmithKline case, is a relatively new phenomenon, the concept of diversion is not. It has been addressed in Common Law and U.S. statutes for many years, generally under the rubric of fraud.<sup>134</sup> There are several criminal violations that may occur in a typical parallel trade diversion scheme. A few of the potential US remedies available are under the National Stolen Property Act<sup>135</sup> (interstate transportation of stolen goods), mail and wire fraud,<sup>136</sup> false and fraudulent statements to officers of the U.S. government,<sup>137</sup> and Federal Food, Drug, and Cosmetic Act.<sup>138</sup>

The receipt of diverted products may constitute violations under the National Stolen Property Act ("NSPA"). Section 2314 of the NSPA provides that it is illegal for anyone to "transport in interstate or foreign commerce any goods... knowing the same to have been

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*in an Era of Technological Integration, The New Global Technology Regime: The WTO TRIPS Agreement and Global Economic Development*, 72 CHI.- KENT L. REV. 385, 387 (1996). See also, J.H. Reichman, *Bargaining Around The Trips Agreement: The Case For Ongoing Public-PRIVATE INITIATIVES TO FACILITATE WORLDWIDE INTELLECTUAL PROPERTY TRANSACTIONS*, 9 DUKE J. COMP & INT'L L. 11 (1998).

132. Health GAP (Global Access Project), U.S. Breaks Promises and Undermines WTO Public Health Accord While AIDS Deaths Mount, 11/13/2002.

133. *Id.*

134. *Supra* note 5.

135. 18 U.S.C. §§ 2314, 2315.

136. 18 U.S.C. §§ 1341, 1343.

137. 18 U.S.C. § 1001

138. US Food and Drug Administration, Federal Food, Drug and Cosmetic Act, at <http://www.fda.gov/opacom/laws/fdact/fdctoc.htm> (last visited March 8, 2005).

stolen, converted or taken by fraud.” Section 2315 provides that it is illegal for anyone to receive, sell, or dispose of any goods with a value of over \$5,000 if such goods have moved in interstate or foreign commerce if such person knows the goods have been stolen, unlawfully converted, or taken. In diversion cases, the manufacturer is wrongfully deprived of the possession and use of its property by the fraudulent misrepresentation of the destination of merchandise.<sup>139</sup>

Many parallel trade diversion schemes are carried out through the use of the mails and wires and may be a criminal violation of the mail and wire fraud statutes. Under sections 1341 and 1343, the use of the mails or wires in interstate or foreign commerce, to carry out any scheme to defraud is a criminal violation of U.S. law.<sup>140</sup> All that must be shown to establish a violation of either the mail or wire fraud statutes is that the diverters knowingly engaged in a scheme to defraud and that they used the mails or wires to further the scheme.<sup>141</sup> A charge of mail or wire fraud is punishable by up to 5 years imprisonment, fines, or both.<sup>142</sup>

Section 1001 of Title 18 of the U.S. Code proscribes making false and fraudulent statements to any U.S. department or agency.<sup>143</sup> Anyone violating this section shall be fined not more than \$10,000 or imprisoned not more than five years, or both.<sup>144</sup>

To perpetuate this fraudulent scheme, the U.S. importer, as a matter of necessity, will make false and fraudulent statements directly to the U.S. Customs Service. The U.S. importer, in filing of the entry documents, will claim title to the products as purchasers. However, the importer cannot claim title for several reasons: (1) the goods constitute stolen property under the National Stolen Property Act,<sup>45</sup> (2) title is voidable because the products were obtained by fraud,<sup>46</sup> and (3) title never passed to the foreign consignor pursuant to the language on the invoice.<sup>47</sup> Further, the U.S. importers may be misstating the value of the imported merchandise.<sup>48</sup> Accordingly, any statements or representations made by the U.S. importers violate 18 U.S.C. §1001 because such statements are false and fraudulent.<sup>145</sup>

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139. See deKieffer *Diversion*, *supra* note 7.

140. 18 U.S.C. §§ 1341, 1343

141. 18 U.S.C. §§ 1341, 1343

142. *Id.*

143. 18 U.S.C. § 1001.

144. *Id.*

145. See deKieffer *Diversion*, *supra* note 7.

It is extremely unlikely that grey market parallel traders are taking precautions to ensure compliance with Federal Food, Drug and Cosmetic Act (FDCA).<sup>146</sup> Even if the drug is approved in the United States, if the drug is also manufactured in the US, it is a violation of the Act for anyone other than the US manufacturer to import the drug into the United States.<sup>147</sup> Violations of the FDCA also occur when labeling is incorrect<sup>148</sup> or the medications are dispensed without a valid prescription.<sup>149</sup> A person who violates the act can be held criminally liable under 21 U.S.C. 333.<sup>150</sup> A violation that is committed with the intent to defraud, like most diversion schemes, is a felony. It is also a felony to knowingly import a drug in violation of the reimport prohibition.<sup>151</sup>

The United States recently brought an action against companies involved in the importation of pharmaceuticals from Canada for American patients under the FDCA.<sup>152</sup> The defendants, who assisted individuals in procuring prescription medications by accepting prescriptions and other medical documents in the United States and sending them to participating physicians and pharmacies in Canada, were held liable for violating §331(d) and were enjoined from operating any of their 85 stores in the United States.<sup>153</sup>

The importation scheme in this case is not a diversion scheme, but it illustrates how the United States or other entities could use US law to stop illegal importation of pharmaceuticals into the United States.<sup>154</sup> Other remedies are also available to pharmaceutical companies under European Union law<sup>155</sup> and international law.<sup>156</sup>

Pharmaceutical companies have several different options of legal remedies available to them in combating diversion and importation of pharmaceuticals. Unfortunately though, they are not the only group being adversely affected by diversion. No matter what the end result of a diversion scheme is, the originally intended recipients are not receiving their medications. Another solution to both sides of the

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146. 21 U.S.C. §§ 331 et seq.

147. 21 U.S.C. § 381(d)(1)

148. 21 USC §353 (b) (2)

149. *Id.*; *See also*, 21 USC § 381 (a).

150. *United States v. Dotterweich*, 320 US 277 (1943).

151. 21 U.S.C. 333 (b)(1)(a), 381(d)(1).

152. *United States v. Rx Depot, Inc*, 290 F.Supp. 2d 1238 (N.D. Ok., 2003).

153. *Id.* at 1245.

154. This scheme is actually a classic case of parallel importation. *See Maskus, supra* note 7.

155. *See* EU - Enforcement Directive, *available at* <http://www.fiapf.org/pdf/AdvocEuropeenforcement.pdf> (last visited March 8, 2005).

156. Article 61 of TRIPS.

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problem may also be available.

*B. Development of Dispersion Plans*

Compulsory licensing with allowed exportation does solve the solution of limited quantities of essential medicines available in the market.<sup>157</sup> As discussed above however, other variables such as the importing/exporting provisions of the new decision and lack of infrastructure in the importing country may limit the benefits, due simply to unwillingness to use the provisions or due to diversion of produced drugs.<sup>158</sup> It is evident then, that a mechanism needs to be in place that ensures medicines, produced under compulsory licenses or even donated by pharmaceutical companies, is taken from its production source, transported to the country in need and then completely dispersed to the intended patients. In order to accomplish this, a distribution policy must be developed and implemented.

## VI. CONCLUSION

Although it has taken several years and continual negotiation, the WTO has come to a temporary agreement on how to balance human rights and intellectual property rights. Although it is exactly what the developing countries were pushing for, allowing the exportation of pharmaceuticals manufactured under compulsory licenses may not be the best solution to the critical public health issues many developing countries are facing. This exportation also exposes pharmaceutical companies to an increased threat of diversion, which will in turn lead to decreased profits and potentially a reduction in research and development of essential medicines.

The WTO Paragraph 6 Decision could be effective if combined with a pharmaceutical dispersion scheme, which would ensure that the essential medicines reached the patients that are in desperate need. Implementation of a dispersion plan would also greatly reduce the chance that diverters could intercept the shipments, therefore solving both of the current problems. Unfortunately, implementation of such a plan will require large amounts of funding and personnel. Until this or another solution is realized the international community will have to make the best of the Decision.

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157. See generally Friedgen, *supra* note 3 at 690.

158. See *supra* section IV.