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The Spirit of TRIPS and the Importation of Medicines Made under Compulsory License after the August 2003 TRIPS Council Agreement

*Jessica J. Fayerman**

I. INTRODUCTION

There has been a heated debate among developed and developing countries concerning the harmonization of pharmaceutical patent laws¹ since the drafting of the Agreement on Trade-Related Aspects of Intellectual Property Rights (“TRIPS”).² Some developing countries argue that bringing their domestic patent protection laws in line with patent law regimes in the developed world would cause necessary medicines to become too expensive for most citizens to afford.³ Some developed countries, however, argue that uniform world intellectual property laws are essential for the promotion of free and balanced trade and the maintenance of a healthy economy.⁴ They also argue that without intellectual property protection in the developing world, the drugs necessary to treat tropical diseases would never be developed in the first place.

In response to the assertions of the developed countries concerning a strong international intellectual property regime, some developing countries, particularly those in sub-Saharan Africa, advocate the use of

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¹ Susan K. Sell, *TRIPS and the Access to Medicines Campaign*, 20 WIS. INT’L L.J. 481, 514 (2002) [hereinafter Sell 2002 Article #1].

² Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, LEGAL INSTRUMENTS – RESULTS OF THE URUGUAY ROUND, vol. 31, 33 I.L.M. 81 (1994) [hereinafter TRIPS Agreement].

³ Sell 2002 Article #1, *supra* note 1, at 515.

⁴ Michelle M. Nerozzi, Note: *The Battle Over Life-Saving Pharmaceuticals: Are Developing Countries being “TRIPped” by Developed Countries?*, 47 VILL. L. REV. 605, 615 (2002).

compulsory licensing to ensure an adequate drug supply during epidemics and other periods of national emergency.⁵ When a government issues a compulsory license, it allows use or manufacture of a patented invention without the patent-holder's permission.⁶ Such a license would then enable the residents of that particular country to obtain drugs at prices lower than the pharmaceutical company charges elsewhere.⁷

Indeed, during the drafting of TRIPS, one of the concessions the developed countries made was to leave open the possibility of using compulsory licenses, embodied in Article 31.⁸ While Article 31 does not specifically allude to compulsory licensing, it does detail the circumstances in which a user may not have to grant a patent-holder all of the rights to which he would ordinarily be entitled under TRIPS.⁹ One scholar believes that compulsory licensing is the solution to the problem posed by high drug prices in developing countries and has argued for its expansion.¹⁰ As a result of pressure from the developing world, the criteria for issuing a compulsory license were clarified and expanded in the 2001 Doha Declaration¹¹ and again at a 2003 TRIPS Council meeting held prior to the World Trade Organization ("WTO") ministerial meeting.¹²

For the first time in 2003, the TRIPS Council agreed to allow developing countries to import drugs made under compulsory license in the form of a waiver of TRIPS Article 31(f).¹³ Prior to this, both TRIPS and

⁵ Keith E. Maskus, *Ensuring Access to Essential Medicines: Some Economic Considerations*, 20 WIS. INT'L L.J. 563, 571 (2002).

⁶ Nabila Ansari, *International Patent Rights in a Post-Doha World*, 11 CURRENTS: INT'L TRADE L.J. 57, 62 (2002).

⁷ *Id.* at 63.

⁸ DANIEL GERVAIS, *THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS* 159 (1st ed. 1998).

⁹ TRIPS Agreement, *supra* note 2, at art. 31. Article 31 is reproduced in the appendix at the end of this comment.

¹⁰ Arnaldo Lacayo, Comment: *Seeking a Balance: International Pharmaceutical Patent Protection, Public Health Crises, and the Emerging Threat of Bio-Terrorism*, 33 U. MIAMI INTER-AM. L. REV. 295, 297 (2002).

¹¹ Declaration on the TRIPS Agreement and Public Health, Adopted on 14 November 2001, WT/MIN(01)DEC/2 [hereinafter Doha Declaration], at <http://docsonline.wto.org/DDFDocuments/t/WT/min01/DEC2.doc> (Nov. 20, 2001).

¹² Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, Decision of 30 August 2003, WT/L/540, [hereinafter Implementation Decision], <http://docsonline.wto.org/DDFDocuments/t/WT/L/540.doc> (Sept. 2, 2003). The waiver embodied in the decision is to only be in effect until an amendment to the TRIPS Agreement is completed, with a scheduled date of the end of June 2004. *Id.* See also Jennifer May Rogers, Note, *The TRIPS Council's Solution to the Paragraph 6 Problem: Toward Compulsory Licensing Viability for Developing Countries*, 13 MINN. J. GLOBAL TRADE 443 (2004).

¹³ Implementation Decision, at <http://docsonline.wto.org/DDFDocuments/t/WT/L/540.doc> (Sept. 2, 2003).

Paragraph 6 of the Doha Declaration¹⁴ prohibited this practice, which rendered compulsory licensing rights useless for countries with no manufacturing capacity of their own.¹⁵ This comment examines this increasingly permissive use of international trading policies regarding the use of compulsory licensing. I argue that such a large expansion of licensing power dilutes the original purposes for which TRIPS was drafted and that there may be other mechanisms for protecting public health in the developing world that do not compromise intellectual property protection.

Part II of this comment tracks the history of Article 31 and other relevant articles of TRIPS, as well as their changing status after Doha and particularly after the latest agreement made in August 2003. More specifically, I will discuss the 2003 TRIPS Council interpretive agreement—the clarification of the Doha Declaration—in great detail since this has only been sparingly done in two law journal articles thus far¹⁶ due to its recent passage. Part III compares the original intent of TRIPS with the current state of compulsory licensing usage and makes the argument that the two are not in sync. Part IV suggests several solutions that will allow patent protection to remain unharmed in the developing world but will still help to alleviate the international public health crisis. These suggestions include: voluntary medicine donation programs, voluntary price discrimination plans, pooled procurement procedures, and public-funded developments. Finally, I propose a unique solution consisting of a worldwide Orphan Drug Program combined with price discrimination, similar to that in effect in the United States.

II. THE HISTORY AND CURRENT STATUS OF COMPULSORY LICENSING

A. Pertinent Provisions of the TRIPS Agreement

The TRIPS agreement came into force in 1994 as a means of harmonizing widely divergent world intellectual property laws.¹⁷ There are

¹⁴ Doha Declaration, *supra* note 11, para. 6 reads:

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.

¹⁵ Lacayo, *supra* note 10, at 300.

¹⁶ Amir Attaran, *Assessing and Answering Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: The Case for Greater Flexibility and a Non-Justiciability Solution*, 17 EMORY INT'L L. REV. 743 (2003) [hereinafter Attaran 2003 Article]. See also Rogers, *supra* note 12.

¹⁷ See Understanding the WTO: The Agreements: Intellectual Property: Protection and

several TRIPS Articles pertinent to the intellectual property and public health debates which have led some developing countries to call for compulsory licensing. First, Article 27(2) recognizes the conflict between intellectual property and public health when it ambiguously states that a patent is not required for an invention, product, or process which is necessary to protect public health.¹⁸ While it has been argued that under this Article such medicines as AIDS drugs should not be subject to TRIPS at all since these products are necessary to protect public health, rejoinders have been voiced arguing that 27(2) simply means that dangerous products should be excluded from patentability.¹⁹

More importantly, TRIPS Article 31 implicitly provides for compulsory licensing.²⁰ As mentioned above, it is interesting to note that the text of TRIPS itself never actually refers to “compulsory licensing” per se.²¹ Rather, it is possible to infer a provision for such licensing when it is read in conjunction with the earlier intellectual property agreements on which TRIPS was based.²² A compulsory license allows a government to manufacture a product without the patent holder’s permission. The subsections of Article 31 further clarify the conditions under which such a license can be granted. First, manufacturing can only begin once the government seeking the compulsory license has made reasonable efforts to get the permission of the patent owner.²³ Article 31(b), however, waives this provision in cases of “national emergency.”²⁴ In addition, export of

Enforcement [hereinafter TRIPS Explanation], at http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm (last visited Oct. 30, 2003).

¹⁸ TRIPS Agreement, *supra* note 2, art. 27(2). The text of this article reads:

Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

Article 27(2) has so far not constituted a major element of the international intellectual property/world health debate, but it is possible that developing countries could try to exploit its potential if the amendment to TRIPS envisioned by the 2003 Implementation Decision does not lead to desirable results.

¹⁹ 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, 871 (2002) [hereinafter Attaran 2002 Article].

²⁰ TRIPS Agreement, *supra* note 2, at art. 31.

²¹ *Id.*

²² Sara Ford, Comment, *Compulsory Licensing Under the TRIPS Agreement: Balancing Pills and Patents*, 15 AM. U. INT’L L. REV. 941, 953 (2000).

²³ TRIPS Agreement, *supra* note 2, at art. 31(b).

²⁴ *Id.*

compulsorily licensed products is forbidden.²⁵ Finally, the patent holder must be adequately compensated.²⁶

After the process of implementation for TRIPS began, the two Articles mentioned above led to confusion and even some international disputes.²⁷ For example, when South Africa amended its constitution to include provisions for compulsory licensing, a large number of drug companies in developed countries filed suit, arguing that Article 31 of TRIPS does not actually allow for compulsory licensing to be included in domestic legislation. While the suits were ultimately dropped after international outcry in support of a remedy for the public health crisis, the confusion still remained.²⁸

B. The Doha Declaration

In order to remedy the confusion that was produced by the tension between Article 27, which allows exclusion from patentability due to public health concerns, and Article 31, which implicitly provides for compulsory licensing, delegates made it a point to put clarification of some of the more contentious aspects of TRIPS on the agenda for the 2001 WTO meeting in Doha, Qatar.²⁹ While the resulting Declaration is merely an interpretative statement issued by the WTO and thus does not actually change any of the legal provisions of TRIPS, it is regarded as persuasive authority to be used in the event of a trade dispute.³⁰ The international pharmaceutical industry, including lobbyists on behalf of the Pharmaceutical Researchers and Manufacturers of America ("PhRMA"), believes that the resulting Doha Declaration made too many concessions to developing countries and undermined the original policy rationales underlying TRIPS.³¹ On the other

²⁵ *Id.* at art. 31(f).

²⁶ *Id.* at art. 31(h).

²⁷ Aditi Bagchi, *Compulsory Licensing and the Duty of Good Faith in TRIPS*, 55 STAN. L. REV. 1529, 1530 (2003).

²⁸ Alan O. Sykes, *TRIPS, Pharmaceuticals, Developing Countries, and the Doha "Solution,"* 3 CHI. J. INT'L L. 47, 53 (2002). The public outcry concerning the South African suit resulted from increasingly bad publicity of American pharmaceutical companies and consciousness-raising actions of a number of non-governmental organizations. The companies bringing suit were eventually forced to give in.

²⁹ *Id.* at 55.

³⁰ TRIPS Explanation, *supra* note 17.

³¹ See Peter N. Fowler & Alice T. Zalik, *A U.S. Government Perspective Concerning the Agreement on the Trade-Related Aspects of Intellectual Property: Past, Present and Near Future*, 17 ST. JOHN'S J. LEGAL COMMENT. 401 (2003). With regards to the purpose of TRIPS and its importance for U.S. policy, the authors write that, "[t]he TRIPS Agreement ensures that our national creativity and innovation are as protected abroad as they are at home, and perhaps even more importantly, that other nations are encouraged to develop their own national spirit and economy based on creativity and innovation." *Id.* at 402. See also Attaran 2002 Article, *supra* note 19.

hand, some world leaders and lobbying groups, including Action Aid, Doctors Without Borders, and Oxfam, argued that the Declaration provided just the right balance of maintaining the integrity of international intellectual property while allowing developing countries to make exceptions for clear public health reasons.³²

The Doha Declaration specifically recognizes that Article 31 grants national governments the power to issue compulsory licenses and to take action in situations in which they believe public health concerns outweigh the urgency of international intellectual property protection.³³ The Declaration also further clarifies 31(b), which sets out parameters for the use of compulsory licensing, stating that developing countries have discretion in determining what constitutes a national emergency.³⁴ The Declaration itself states that epidemics such as AIDS and malaria would indeed be adequate grounds to declare a national emergency.³⁵

However, Paragraph 6 of the Declaration contains a problem that was unresolved even after Doha. TRIPS Article 31 specifically states that medicines under compulsory license cannot be exported outside of the country that issued the license.³⁶ Paragraph 6 of the Declaration recognizes that this element of the Agreement cannot be changed by interpretative statement. It also acknowledges that prohibiting the importation of drugs made under compulsory license means countries with no manufacturing capacity cannot take advantage of this method of obtaining access to medicines.³⁷ In order to rectify this problem, it set a deadline for the end of 2002 for the delegates to meet and resolve this particular issue.³⁸ While the WTO delegates failed to meet the deadline, they did convene prior to the September 2003 WTO meeting in Cancun.³⁹ There they issued a statement outlining a compromise regarding the problems in Paragraph 6 of the Declaration.⁴⁰

C. The TRIPS Council Agreement

This Agreement temporarily waives the provision of Article 31(f)

³² See Sara DeForge, Comment, *A Tough Pill to Swallow: The United States' Passive Efforts in Curtailing Intellectual Property Rights in Favor of Humanity*, 4 LOY. L. & TECH. ANN. 75, 79 (2004). See generally Susan K. Sell, *Post-TRIPS Developments: The Tension Between Commercial and Social Agendas in the Context of Intellectual Property*, 14 FLA. J. INT'L L. 193 (2002) [hereinafter Sell 2002 Article #2].

³³ Doha Declaration, *supra* note 11.

³⁴ *Id.*

³⁵ *Id.*

³⁶ TRIPS Agreement, *supra* note 2, art. 31(b).

³⁷ Doha Declaration, *supra* note 11, ¶ 6.

³⁸ *Id.*

³⁹ TRIPS Explanation, *supra* note 17.

⁴⁰ Implementation Decision, *supra* note 12.

which prohibits the export of compulsory licensed products outside of the domestic market.⁴¹ This waiver is scheduled to last until member governments choose to amend TRIPS Article 31(f).⁴² Thus, under the terms of the Agreement, countries can now export medicines made under compulsory license to other countries that need them, subject to certain conditions.⁴³ First, the Agreement defines an “eligible importing member” as a least-developed country that first notifies the TRIPS Council of its intent to import medicines made under compulsory license only in a “limited” way.⁴⁴ Acceptable means of importation would be for use only in “situations of national emergency or other circumstances of extreme urgency,” the exact meaning of which seems unclear.⁴⁵ The Agreement therefore is structured to ensure that a country will not import products made under compulsory license merely to avoid high pharmaceutical prices in its domestic market.

Paragraph 2 of the Agreement specifies what information a potential importing country must produce in order to meet the legal standards of TRIPS.⁴⁶ The country must state the name and the expected quantity of the drug it wishes to import.⁴⁷ It must then present evidence to the TRIPS Council that it does not currently have the manufacturing capacity to produce the medicine on its own without having to resort to importing it from elsewhere.⁴⁸ Finally, the importing country must promise that the compulsory license it grants for the drug is in compliance with Article 31 of TRIPS.⁴⁹

Exporting countries are also subject to a number of conditions under the Agreement. They are required to limit the amount of the drug they export to the importing country and must clearly identify the medicine earmarked for export with special labeling or special colors and shapes for the product itself.⁵⁰ This provision helps to prevent “grey market” importation of pharmaceuticals into markets other than the one originally intended by allowing consumers and distributors to differentiate from quantities of the drug being sold in that market legally. Finally, in another effort designed to combat the grey market problem, exporting countries must publicize on the internet the names and quantities of medicines they

⁴¹ *Id.*

⁴² *Id.*

⁴³ Attaran 2003 Article, *supra* note 16, at 765.

⁴⁴ Implementation Decision, *supra* at note 12, at ¶ 1(b).

⁴⁵ *Id.*

⁴⁶ *Id.* at ¶ 2(a).

⁴⁷ *Id.* at ¶ 2(a)(i).

⁴⁸ *Id.* at ¶ 2(a)(ii).

⁴⁹ *Id.* at ¶ 2(a)(iii).

⁵⁰ Implementation Decision, *supra* note 12, at ¶ 2(b)(i)-(ii).

have exported under compulsory license.⁵¹

The Agreement also contains a number of other provisions designed to ensure that importation of medicines manufactured under compulsory license is not undertaken capriciously. Paragraph 3 calls for adequate remuneration to the exporting country by the importing one "taking into account the economic value to the importing Member of the use that has been authorized in the exporting Member."⁵² This requirement guarantees that each potential importing country takes some kind of economic responsibility for its incursion into the international intellectual property regime.

More importantly, Paragraph 4 requires importing countries to take "reasonable measures" according to their individual administrative capacities to make sure that medicines that are imported into their borders are not re-exported to wealthier countries.⁵³ This Paragraph also calls for developed countries to fill in the financial and administrative gaps to ensure parallel importation of imported drug products doesn't become too much of a problem.⁵⁴ Similarly, Paragraph 5 requires all WTO Members to provide legal means to guarantee that products which have crept over their borders through parallel importation are not sold domestically.⁵⁵

Finally, the Agreement contains a number of forward-thinking provisions aimed at eliminating the need to import products made under compulsory license in the future. Paragraph 7 generally exhorts members to encourage the transfer of needed technology across the borders of LDCs so that in the future they will have the capacity to produce the medicines they need for themselves.⁵⁶ Paragraphs 8-11 discuss annual reporting procedures and contemplate a TRIPS Council meeting by the end of 2003 to suggest a more permanent solution to the problem of compulsory licensing.⁵⁷

The discussion of the various provisions of the Agreement above reveals the detail in which the WTO delegates attempted to solve the problems of Paragraph six of the Doha Declaration prior to Cancun. Part III below asserts that despite all this careful detail, the Agreement fails on a number of counts to meet the concerns of industry in the developed world, including that the Agreement is simply not in sync with the original purposes of TRIPS.

⁵¹ *Id.* ¶ 2(b)(iii).

⁵² *Id.* ¶ 3.

⁵³ *Id.* ¶ 4.

⁵⁴ *Id.*

⁵⁵ *Id.* ¶ 5.

⁵⁶ Implementation Decision, *supra* note 12, at ¶ 7.

⁵⁷ *Id.* ¶¶ 8-11.

III. THE INCONSISTENCY BETWEEN THE TRIPS COUNCIL DECISION AND THE ORIGINAL PURPOSES OF TRIPS

A. Criticisms of the Agreement

The first article to present in-depth criticism of the 2003 Agreement was written by Amir Attaran, an immunologist and lawyer.⁵⁸ His major argument is that it will be ineffective at promoting public health in the least-developed countries because countries so rarely issue compulsory licenses under any circumstances. Attaran reasons that this implies that compulsory licensing is simply not practical, and a developing country would not utilize it even if such use were legally available.⁵⁹ While Attaran finds reliance on compulsory licensing an ineffective and inappropriate method of improving public health in the developing world, this particular article presents several suggestions on how to ameliorate this latest effort at a compromise on international intellectual property. I shall incorporate these suggestions when I assess whether the Agreement, either as it stands or in Attaran's iteration, adheres to the original purposes of TRIPS.⁶⁰

Attaran first asserts that the ability to import drugs made under compulsory license may not be as valuable as anti-globalization activists believe it is, simply because of the rarity with which licenses have been issued in the years since the TRIPS Agreement was signed.⁶¹ For example, Canada stopped issuing compulsory licenses for pharmaceuticals in the early 1990s and there have been no compulsory licenses issued since that time.⁶² If governments have been so reluctant to issue compulsory licenses to alleviate public health crises within their own borders, they will surely not take the drastic political step of issuing a license to help the citizens of a foreign country.⁶³

Many developing countries wish to respect the international patent system as it currently stands in order to attract new investment and technology into their economies.⁶⁴ Indeed, the "velvet handcuffs of international custom and comity are [so] strong" as to prevent any action by

⁵⁸ Attaran 2003 Article, *supra* note 16.

⁵⁹ *Id.* at 747. Indeed, Attaran perceives the entire debate on compulsory licensing to be somewhat puzzling: "The total absence of pharmaceutical compulsory licenses is all the more striking when one recalls the lobbying of anti-globalization activists, whose primary goal is not public health, but compulsory licensing *per se*." *Id.* In addition, he points out that pharmaceutical companies need not fear the empty threat of compulsory licensing.

⁶⁰ *See infra* Part III.C.

⁶¹ Attaran 2003 Article, *supra* note 16, at 747.

⁶² *Id.* at 747 n.7.

⁶³ *Id.* at 748.

⁶⁴ *Id.* at 750.

these developing countries that may alienate potential investors.⁶⁵ Thus, while the provisions of the Agreement may “stretch” Article 31 far beyond the original limits foreseen by its drafters, it actually may not matter if no country ever resorts to the exportation of compulsory licensed medicine.

Second, Attaran criticizes the temporary nature of the 2003 Agreement.⁶⁶ He objects to the fact that the TRIPS Council is now beholden to yet another set of negotiations by the end of 2003, increasing the potential for inefficiency. As it was, delegates failed to meet their deadline to clarify Paragraph six of the Doha Declaration, and came to a striking impasse regarding the protection of public health during the negotiations rounds at Doha.⁶⁷ This inability to negotiate in an effective and timely manner will lead to uncertainty about the permanent status of TRIPS Article 31(f). If WTO delegates fail to permanently amend Article 31 and continue to advise the world that the Agreement is only a temporary solution, a country wishing to import a medicine made under compulsory licensing may not know whether such an action will be considered legal in the future.

Third, Attaran proposes a number of changes to the text that he claims will lend it much-needed clarity if compulsory licensing is indeed the policy the WTO adopts in promoting public health in the developing countries.⁶⁸ In order to establish certainty, the author would retool the definition of “eligible importing member.”⁶⁹ He suggests an alternative based on a default rule which declares any country below a certain level of income should be deemed to have no pharmaceutical manufacturing capacity of its own.⁷⁰ This rule is more inclusive than the current definition, which only allows the “least developing countries” to be eligible importing members.⁷¹ Such a change would ensure that countries like Côte d’Ivoire, Kenya, and others which are better off relative to those countries typically considered “least developed,” such as Botswana and Sierra Leone, but with no

⁶⁵ *Id.*

⁶⁶ *Id.* at 767. Attaran had also balked at the idea that Paragraph six of the Doha Declaration could even be limited at all: there is nothing in Paragraph six which ever expressly allows for the Doha Declaration to only be limited to specific diseases. Indeed, this is a potential reason why the Implementation Decision could be considered illegal *per se*. *Id.* at 752.

⁶⁷ Attaran 2003 Article, *supra* note 16, at 768. “Far from putting the current debate to rest, Paragraph 11 of the Motta Text mandates a new set of negotiations to amend the TRIPS Agreement, and despite suggesting a mid-2004 deadline to negotiate and adopt that amendment, past WTO history teaches that it will take much longer.” *Id.* (citation omitted)

⁶⁸ *Id.* at 766. The author, however, more fully believes that non-justiciability is a better alternative to the public health access crisis than endeavoring to perfect any kind of solution related to compulsory licensing. *Id.* at 770.

⁶⁹ *Id.*

⁷⁰ *Id.* at 760-61.

⁷¹ Implementation Decision, *supra* note 12, ¶ 1(b).

cognizable manufacturing capacities, would still be able to take advantage of compulsory licensing.⁷²

Attaran further suggests that his default rule should be extended such that any country with a certain percentage of its population infected with the HIV virus or which faced a bioterrorism disaster could be treated as if it had insufficient manufacturing capacity.⁷³ Countries besieged by major epidemics would thus be entitled to import medicines made under compulsory license even if they have manufacturing capacity, simply if they need some outside “help” to supplement their domestic pharmaceutical supplies. This rule would give the definition of “eligible importing member” the flexibility it needs to function in emergency situations, regardless of the requesting importing country’s manufacturing status.

Unfortunately, Attaran’s proposed modifications to the Text do very little to bring the concept of compulsory licensing closer to the original purposes of TRIPS. His rules for determining when a potential importer can be considered an “eligible importing member” only encourage the developing world’s reliance on outside assistance when the WTO should instead be encouraging domestic technological development. His first rule in particular promotes the opposite type of incentive. If a country below a certain level of income was deemed to have “no manufacturing capacity,”⁷⁴ those countries that do have the technology to become self-sufficient would be less inclined to utilize and develop this already existing technology. Thus, there is no effective way to reconcile the permissive importation of products made under compulsory license—even with Attaran’s proposed changes—that reconciles them with the original TRIPS purpose of technology transfer.

While Attaran’s suggestions for clarifying the scope of the Agreement are helpful, his analysis would benefit from an exploration of whether the Agreement is true to the original purposes of TRIPS. Thus, to supplement the analysis of Attaran’s article above, the discussion below compares the Agreement with the purposes of TRIPS, asserts that they are not in sync, and then goes on to propose solutions to the access problem that do not as heavily infringe upon international intellectual property protection.

B. The Purposes of TRIPS

Many authors agree that WTO delegates initially drafted the TRIPS Agreement in order to promote the increased research and development investment that occurs as a result of strong worldwide patent protection.⁷⁵

⁷² Attaran 2003 Article, *supra* note 16, at 761.

⁷³ *Id.* at 763.

⁷⁴ *Id.* at 766.

⁷⁵ Sykes, *supra* note 28, at 49.

Taking the pharmaceutical industry as an example, a company has very little incentive to invest the millions of dollars it takes to bring a product to market if generic companies might undercut its pricing structures upon the exportation of a medicine to a foreign country.⁷⁶ Incentives to develop drugs to treat afflictions abroad, such as tropical diseases, would be particularly low.⁷⁷

TRIPS also sought to achieve a number of other goals that were designed to promote industry in the developed world. At the top of this list was the maintenance of a healthy world trading system.⁷⁸ Indeed, Nabila Ansari asserts that the "fair and economic conduct of international trade is dependent on secure intellectual property rights."⁷⁹

Poor international intellectual property protection has been analogized to trade barriers, such as tariffs.⁸⁰ Such other types of intellectual property protection ensure that artists and inventors remain within their own countries where they can receive sufficient remuneration for their work.⁸¹ Furthermore, trade barriers limit technological growth and development in the developing world because they discourage investment. Similarly, a lack of intellectual property protection creates the same detrimental result that a trade barrier does for the less industrialized country. Inadequate patent protection will diminish the incentives for research and development of certain tropical diseases.⁸² In this context, therefore, intellectual property protection for some ultimately benefits all.

However, the drafters of the TRIPS Agreement recognized the importance of providing access to medicines in the era before full international intellectual property protections were available.⁸³ Indeed, one author argues that TRIPS "attempts to strike a delicate balance between the short-term objective of providing access to existing medicines and the long-term objective of developing new medicines through incentives for future Research and Development."⁸⁴ The TRIPS Council, a group of delegates assigned by the WTO to oversee the provisions of TRIPS, also recognized the need for "maximum flexibility in the domestic implementation of laws

⁷⁶ See SUSAN K. SELL, PRIVATE POWER, PUBLIC LAW: THE GLOBALIZATION OF INTELLECTUAL PROPERTY RIGHTS Ch. 6 (2003).

⁷⁷ CARLOS M. CORREA & ABDULQAWI A. YUSUF, INTELLECTUAL PROPERTY AND INTERNATIONAL TRADE: THE TRIPS AGREEMENT 10-15 (1998).

⁷⁸ TRIPS Explanation, *supra* note 17.

⁷⁹ Ansari, *supra* note 6, at 58.

⁸⁰ *Id.* at 59.

⁸¹ *Id.*

⁸² Ansari, *supra* note 6, at 58.

⁸³ Lacayo, *supra* note 10, at 312.

⁸⁴ Grace K. Avedissian, *Notes and Comments: Global Implications of a Potential U.S. Policy Shift Toward Compulsory Licensing of Medical Inventions in a New Era of "Super-Terrorism,"* 18 AM. U. INT'L L. REV. 237, 251 (2002).

and regulations in order to enable [the developing countries] to create a sound and viable technological base.”⁸⁵ Thus, not only was TRIPS designed to ensure that developing countries would be able to utilize the medicines needed to combat public health crises, it also asserted the goal of building technology in the least developed countries so that they would not have to resort to methods such as compulsory licensing in the future.

A number of TRIPS articles acknowledge the plight of people in need of access to medications, but as I argue below, these articles also embody solutions to the pharmaceutical access problem. Technology building provisions and other remedies for national health emergencies in the Agreement seek to promote international intellectual property rights rather than degrade them.⁸⁶ Article 7, for example, calls for international intellectual property protection to be instituted “in a manner conducive to social and economic welfare.”⁸⁷ Once again, this “social and economic welfare” may consist of much more than simply allowing a country to import medicines made under compulsory license whenever it has a public health emergency.

Similarly, subsection b of Article 8(1) calls for national legislatures to “promote the public interest in sectors of vital importance to their socio-economic and technological development.”⁸⁸ While representatives of the developing countries have argued that this Article implies that the WTO should allow exceptions to strict patent enforcement in the developing world,⁸⁹ representatives of industrialized countries believe that it means all countries should strive to protect patents within their borders in order to maximize the transfer of needed technology.⁹⁰ In fact, the essential purpose of TRIPS is to build technological investment—both in the developed and the developing world—through uniform adherence to patent protection.⁹¹

C. The Objectives of the Motta Agreement do not Match the Purposes of TRIPS

Motta’s modification of the Doha Declaration will fail on several counts to bolster pharmaceutical research and development capacity in the least developed countries.

First, compulsory licensing alone represents a significant deviation from the goal of patent protection because it allows the privileges that an inventor worked diligently to obtain to be undermined without his or her

⁸⁵ CORREA & YUSUF, *supra* note 77, at 11.

⁸⁶ *Id.* at 12.

⁸⁷ TRIPS Agreement, *supra* note 2, at art. 7.

⁸⁸ *Id.* at art. 8(1).

⁸⁹ Sell 2002 Article #1, *supra* note 1, at 516.

⁹⁰ Lacayo, *supra* note 10, at 298.

⁹¹ Ansari, *supra* note 6, at 60.

consent. If the goal of patent protection is to provide for the transfer of technological investment, the existing public health crises in least developed countries will inevitably worsen.⁹²

The disjuncture between the purposes of TRIPS and importation of drugs made under compulsory license becomes even more obvious after an examination of the language comprising the TRIPS Agreement. For example, Article 7, which lays out TRIPS' objectives, calls for patent protection to be implemented through means "conducive to social and economic welfare."⁹³ Nabila Ansari argues, "countries that fail to implement [intellectual property] protection for the innovations from human capital will be left behind in their development."⁹⁴ Thus, the Motta Agreement's "solution" of broadening the Article 31 compulsory licensing exception may instead encourage further dependence by least developed countries on outside assistance to combat public health crises within their borders.

International intellectual property protection benefits the developing world in a number of ways that are more consistent with the original purposes of TRIPS, of promoting world technological development through strong intellectual property protection, than the compulsory licensing exception to Article 31.⁹⁵ First, pharmaceutical companies require adequate incentives to undertake research and development for certain tropical diseases that only affect individuals in the developing world.⁹⁶ Unlike medicines that already exist to treat diseases in countries that provide strong patent protection, research and development will never begin for medicines that treat tropical diseases because companies know that they will not receive adequate remuneration for their work in the countries to which they would sell these products.⁹⁷ Indeed, the first step in combating a public health crisis is to ensure that the essential medicines exist before the pricing of such drugs even becomes an issue.⁹⁸ Some authors in favor of compulsory licensing seem to forget that without intellectual property protection there would be no medicine there at all for the country to license.⁹⁹

Further, strong international intellectual property protection can help to combat the "brain drain" of engineers and inventors out of the least developed countries. The exodus of trained professionals is quickened by

⁹² Maskus, *supra* note 5, at 572.

⁹³ TRIPS Agreement, *supra* note 2, at art. 7.

⁹⁴ Ansari, *supra* note 6, at 58.

⁹⁵ *Id.*

⁹⁶ Maskus, *supra* note 5, at 568.

⁹⁷ Ansari, *supra* note 6, at 60.

⁹⁸ Maskus, *supra* note 5, at 568.

⁹⁹ See generally Sell 2002 Article #1, *supra* note 1.

inadequate protections that undermine financial reward to innovators.¹⁰⁰

Similarly, a lack of intellectual property protection causes research firms from the developed countries to leave the market just when their innovation is required the most.¹⁰¹

In addition, industry will be less likely to invest in the LDCs when the “piracy” that results from a loss of patent protection causes a loss in profits and resulting shareholder dissatisfaction.¹⁰²

IV. ALTERNATIVES TO COMPULSORY LICENSING AND A UNIQUE SOLUTION

In light of the inevitable failure of imported medicine made under compulsory licensing as a long-term solution to public health crises in the developing world, one must begin to explore alternatives that do not have the deleterious effect of anti-patent measures. The alternatives suggested in some of the literature have become even more relevant as the prohibition on importation embodied in TRIPS Article 31 has been lifted. As mentioned above, if a poverty-stricken country with neither pharmaceutical manufacturing capacity nor an adequate infrastructure to distribute health care to its population can rely on imports of compulsory licensed drugs, it will lack the incentives to promote technological growth of its own.¹⁰³ The alternatives in the literature avoid these types of disincentives.

A. Price Discrimination

Price discrimination is the process of varying the price charged for a product based on the country in which it is sold. Under such an arrangement, the price is keyed to what the citizens in each of the countries can afford.¹⁰⁴ Setting the price depends upon the local elasticity of demand, or the level to which the price can be raised without driving consumers out of the market.¹⁰⁵ Under a price discrimination regime, pharmaceutical companies can maintain their price and profit structures in wealthy countries while allowing the developing world access to needed medicines.¹⁰⁶ However, one hazard of a price discrimination plan is parallel importation, the “grey market” problem.¹⁰⁷ Parallel importation occurs when medicines sold at lower prices in less developed countries find their

¹⁰⁰ Ansari, *supra* note 6, at 58.

¹⁰¹ *Id.*

¹⁰² Ansari, *supra* note 6, at 59.

¹⁰³ Lacayo, *supra* note 10, at 301.

¹⁰⁴ Maskus, *supra* note 5, at 569.

¹⁰⁵ Sykes, *supra* note 28, at 63.

¹⁰⁶ *Id.*

¹⁰⁷ *Id.* at 64.

way back into the stream of commerce in wealthier countries and are sold there at lower-than-market prices.¹⁰⁸

While this form of illegal activity may be difficult to curb completely, the Motta Agreement's provisions for stemming parallel importation of products made under compulsory license¹⁰⁹ may present a viable solution. As previously discussed above, Paragraph 5 of the Motta Agreement calls for drug products earmarked for export to other countries under compulsory license to be shaped and colored differently than their counterparts used for sale in the domestic market.¹¹⁰ While it may result in extra expense, pharmaceutical companies would perhaps engage in this type of differentiation when pursuing in voluntary price discrimination schemes. Alternatively, governments of wealthy countries could provide incentives to domestic industry to help ensure access to medicines in the developing world through price discrimination by funding the necessary changes to the appearance of the drugs as to avoid the parallel importation problem.

Under a system of price discrimination, pharmaceutical companies would maintain the freedom to license their products if and to whom they wish. They can still maintain their profit margins in industrialized countries where patients can afford to pay full price for their products. At the same time, in developing countries they can charge only what an economic analysis suggests citizens can afford. The other solutions mentioned below give the companies less control over pricing. Most importantly, under a price discrimination scheme the company would maintain full control over the patent they have spent millions of dollars in research and development costs to secure.

B. Voluntary Donation Schemes

Another method of securing access to medicines in the developing world is to encourage companies in wealthier countries to voluntarily donate surplus supplies of certain drugs.¹¹¹ Such a scheme would be based on the altruism of the wealthier countries, rather than the forced submission to compulsory licensing envisioned by the Doha Declaration and the Agreement. A company voluntarily undertaking a drug donation plan would generate favorable publicity, perhaps increasing shareholder investment and sales. This in turn would cause other companies to follow its example. Governments could encourage voluntary donation schemes by providing tax incentives for companies willing to participate.¹¹²

Critics of voluntary donation launch three primary attacks against the

¹⁰⁸ Nerozzi, *supra* note 4, at 618.

¹⁰⁹ See Implementation Decision, *supra* note 12, at ¶ 5.

¹¹⁰ *Id.*

¹¹¹ Maskus, *supra* note 5, at 573.

¹¹² *Id.*

plan. Susan Sell notes that such solutions are merely pretexts for companies who do not wish to be subjected to diminished patent protection through compulsory licensing.¹¹³ In addition, relying on voluntary drug donations risks large fluctuations in supply: a company would probably suspend donations if it encountered a drop in profits.¹¹⁴ Furthermore, the simple donation of drugs in times of national emergency would not further the TRIPS purpose of promoting technology transfer to the developing world.

Still, drug donation (and voluntary price reductions in the case of India to help serve that country's particularly large population) remains a popular current method of managing drug supplies to fight AIDS in countries such as Haiti and India.¹¹⁵ Indeed, both the Haitian and Indian cases serve as examples of efforts to ensure an adequate supply of essential medicines through methods other than diminished intellectual property protection.

C. Bulk Procurement Programs

Bulk procurement occurs when a group of developing countries pool their collective resources to obtain large quantities of needed drugs to help treat their populations in situations of national emergency.¹¹⁶ Non-governmental organizations, such as Doctors Without Borders, have also undertaken such schemes on a charitable basis.¹¹⁷ These organizations advocate that "global procurement guarantees high demand, reliable payment, and straightforward negotiation of lower prices."¹¹⁸ These advantages could make pooled procurement and bulk purchasing superior to voluntary donations if it means more consistent and reliable drug delivery that is not contingent upon a company's current profit situation. The high demand could also be advantageous to drug companies who typically do not expect to reap a very large profit in the developing world.

Pooled procurement also confers benefits beyond those of compulsory licensing because it requires regional blocs of countries to work together to solve a common problem, rather than negotiate individually with a distant exporter. This format would even out the differential in bargaining power between wealthy producer countries and the least developed countries.

¹¹³ Sell 2002 Article #1, *supra* note 1, at 516.

¹¹⁴ Maskus, *supra* note 5, at 573.

¹¹⁵ See Celia W. Dugger, *In the Vanguard Fighting AIDS, an Army of Haitian Villagers*, N.Y. Times, Nov. 29, 2003, available at <http://www.wehaitians.com/november%202003%20health%20news%20this%20month.html> (last visited Nov. 29, 2003); Amy Waldman, *India Announces Plans to Expand AIDS Therapy Programs*, N.Y. Times, Nov. 30, 2003, available at <http://www.nytimes.com/2003/11/30/international/asia/30CND-INDI.html?ex=1101099600&en=643cb4a6145239f0&ei=5070&intemail0>.

¹¹⁶ Nerozzi, *supra* note 4, at 629.

¹¹⁷ *Id.*

¹¹⁸ *Id.*

Following a national or regional health emergency, such a collective regional effort could lead to domestic technology investment and future beneficial patent protection as envisioned by TRIPS.

Critics of pooled procurement and bulk purchasing schemes focus on several shortcomings.¹¹⁹ The least developed countries may not be able to afford needed drugs even on a collective regional basis. The drugs obtained through bulk purchasing may be lower in quality, and the least-developed countries may lack the collective bargaining power to negotiate adequate prices for themselves.¹²⁰

As a solution, author Keith Maskus calls for the formation of a “global purchase fund” funded by wealthier countries to decrease transactions costs and reduce collective action problems.¹²¹ Like voluntary donation problems, this type of fund would function from the altruism and the desire for good publicity of governments and pharmaceutical companies in the developed world. Like the other alternatives mentioned above, these motivations are superior to compulsory licensing, which provides disincentives for development negotiations with countries that may later undermine profits by issuing a compulsory license.

D. Publicly Funded Research and Development

One scholar argues that publicly funded research will lead to greater availability of medical supplies to treat tropical diseases which are otherwise neglected by pharmaceutical companies in the developed world.¹²² As an example, Maskus credits publicly funded agricultural research with improving nutrition in certain developing countries.¹²³ Using this model, governments of countries in the industrialized world could provide more funding for both universities and for-profit research institutions to study tropical diseases. However, a problem with publicly-funded research is that voters may not wish to see their tax dollars being spent on research for diseases that do not exist domestically. As a potential solution, Maskus calls for research donations to come from multinational organizations and NGOs, which are not accountable to voters, to supplement government funding.¹²⁴ This solution is unlikely to work well, however, since most NGO’s do not have adequate capital to fund such expensive projects as supplying expensive pharmaceuticals for large groups of people in developing countries.

¹¹⁹ See Sell 2002 Article #2, *supra* note 32.

¹²⁰ Maskus, *supra* note 5, at 570.

¹²¹ *Id.*

¹²² *Id.* at 574.

¹²³ *Id.*

¹²⁴ *Id.* at 576.

E. Orphan Drug Production

Another alternative to public-funded research would be a plan similar to the current Orphan Drug Program in the United States.¹²⁵ The Orphan Drug Act defines an orphan drug as one that treats a disease affecting less than 200,000 people in the United States or one that would not be profitable for other reasons.¹²⁶ The government thus provides a number of incentives, including market exclusivity, assistance with new drug applications, research grants and tax benefits to encourage the production of these drugs.¹²⁷

A group of international organizations and governments could form a world orphan drug program, pooling their resources to provide the same kinds of incentives as those in the U.S. Orphan Drug Act. When combined with price discrimination, perhaps among developing countries with varying levels of income and differing abilities to pay for drugs, this plan would both ensure the existence of drugs important to the developing world and the means for inhabitants to afford them.

The combination of a worldwide orphan drug program and price discrimination *within the developing world* is an ideal solution to the problem of access to medicines. The market exclusivity provision would give companies in the developed world an incentive to research and develop a drug needed in the developing world. At the same time, companies could charge higher prices for the drug if they were to find a market for it in the industrialized world. However, neither can function effectively without the other—if companies only utilize publicly funded research to provide incentives to find cures for tropical diseases, the least developed countries may still not be able to afford these drugs. Similarly, if companies only engage in price discrimination, they will still have no incentive to produce those drugs that only affect the developing world. Thus, companies must be able to engage in price discrimination for the medicines they develop for tropical diseases with public funding among different countries in the developing world.

For example, although India and Botswana may both be ravaged by AIDS,¹²⁸ the former can afford to pay more for life-saving pharmaceuticals than the latter. Drugs developed under the worldwide Orphan Drug Program will be sold in the developing countries with higher elasticity of demand. Thus, since India is a wealthier country in terms of *per capita*

¹²⁵ See Orphan Drug Act, 21 U.S.C. § 360 (aa – ee) (1994).

¹²⁶ *Id.*

¹²⁷ *Id.*

¹²⁸ The website <http://avert.org> estimates that in 2001, 38.8% of the population of Botswana was living with HIV or AIDS. While in India that number is only 0.7%, there were still nearly 6 million inhabitants living with HIV or AIDS in 2001. See <http://www.avert.org/statindx.htm> (last visited Feb. 1, 2004).

income, companies could charge a higher price for drugs there without having too many residents enter the market. At the same time, the lowest possible price would be charged in a country like Botswana where most residents would choose to go without medicine if the cost were prohibitively high.

The solution above is not perfect. Underfunding among governments and international organizations will cause the incentives in a worldwide Orphan Drug Program to be less than what many companies would hope. At the same time, parallel importation would limit the effectiveness of price discrimination. Nevertheless, this solution is still superior to the access program outlined by the Doha Declaration and the Motta modification. Alternatives such as the one mentioned above will still allow developing countries to overcome national emergencies while promoting technological transfer and research incentives for tropical diseases.

V. CONCLUSION

The problem of international access to pharmaceuticals is a real and pressing concern. Residents in countries like Botswana, where nearly forty percent of the population was living with HIV or AIDS in 2001, are in dire need of more affordable medications. The TRIPS Agreement seemingly foreclosed diminished international intellectual property protection as a means of ensuring drug access except in the most extreme circumstances. However, both the public health-minded Doha Declaration and Motta Agreement established compulsory licensing as a temporary access solution. Forcibly requiring a company to relinquish the patent protection it had spent millions of dollars in research and development costs to secure, however, is blatantly contrary to the intellectual property-protecting goals of TRIPS.

In the future, the WTO ought to avoid plans requiring compulsory licensing, and especially the newly legalized ability for developing countries to import medicines made under compulsory license, because they are both unsustainable solutions and contrary to the object and purpose of TRIPS. Possible solutions to the drug access problem that do not impinge upon international intellectual property rights include solutions such as voluntary price discrimination plans or a world-wide orphan-drug program funded by the governments of industrialized countries that will both provide residents in developing countries with the drugs they need and will keep intellectual control of pharmaceuticals in the hands of their inventors. Contrary to the assertions of anti-pharmaceutical industry groups, strong intellectual property protection is the most efficient way to ensure adequate research and development in the future. The WTO's asserted solution of compulsory licensing simply will not achieve this goal.

APPENDIX – ARTICLE 31 OF TRIPS¹²⁹

Article 31

Other Use Without Authorization of the Right Holder

Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

(a) authorization of such use shall be considered on its individual merits;

(b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;

(c) the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;

(d) such use shall be non-exclusive;

(e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;

(f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;

(g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;

the right holder shall be paid adequate remuneration in the

¹²⁹ TRIPS Agreement, *supra* note 2, at art. 31.

circumstances of each case, taking into account the economic value of the authorization;

(i) the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(j) any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur;

(l) where such use is authorized to permit the exploitation of a patent ("the second patent") which cannot be exploited without infringing another patent ("the first patent"), the following additional conditions shall apply:

(i) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;

(ii) the owner of the first patent shall be entitled to a cross-license on reasonable terms to use the invention claimed in the second patent; and

(iii) the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.