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ARTICLE: THE TRIPS AGREEMENT: IS IT BENEFICIAL TO THE DEVELOPING WORLD, OR SIMPLY A TOOL USED TO PROTECT PHARMACEUTICAL PROFITS FOR DEVELOPED WORLD MANUFACTURERS?

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SUMMARY:
... There is an ongoing struggle between the rights of pharmaceutical patent owners and those in desperate need of the drugs for whom they hold the patents. ... TRIPs allows a government member of the WTO to intentionally override a patent and use protected technology through two provisions: a "public health license" and a "compulsory license." ... Further, because India is a developing country, it is not required to achieve full compliance with the TRIPs Agreement until 2005. ... With the "pipeline" provision, pending pharmaceutical patents in Brazil receive protection only if the drug had been patented in another country and if no marketing or planned marketing for sale had taken place by the pharmaceutical companies or third parties. Basically, any drug that was being sold outside of Brazil did not receive patent protection in Brazil, and a Brazilian generic producer could freely manufacture the drug within Brazil. ... Relying on the "pipeline" provision, the government of Brazil began producing generic versions of the standard HIV/AIDS drugs in state-owned plants and the government began giving the generic drugs to infected Brazilians for free. ... Consequently, the possibility of a compulsory license to produce generic drugs, outlined within TRIPs, provides an immediate solution to the present problem of high pharmaceutical prices. ... The TRIPs requirement to "adequately remunerate" the patent holder provides additional tangible payment when a compulsory license has been granted. ...

TEXT:
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I. Introduction

There is an ongoing struggle between the rights of pharmaceutical patent owners and those in desperate need of the drugs for whom they hold the patents. Further technological innovation requires that there be sufficient incentive to research and develop (R&D) new drugs, but once these drugs are approved and protected by patent law, they should be made available to people who will suffer without them. n1 In this regard, a system [*244] of patent rights which is too protective will hinder availability by restricting widespread dissemination to the public. n2 On the other hand, a system of patent rights which is too weak will not encourage innovation and new technological research. n3 Thus, for the billions of the world's underprivileged, it is vital that a proper balance be achieved which benefits both sides. n4

In this Article, I will attempt to make sense of the current confusion surrounding pharmaceutical patent rights under the Agreement on Trade Related Aspects of Intellectual Property (TRIPs). n5 Section II of this Article will discuss the current restrictions enforced by the TRIPs Agreement. Section III will contain my analysis of TRIPs, the conflict between developed nations and developing nations, and conclude that, without a greater sense of global responsibility by rich nations, the TRIPs Agreement will act merely as a hindrance on the fight to eradicate disease in the developing world.

II. Background

A patent granted by a country essentially prevents others from making, using, or selling a particular invention for the limited period of twenty years in that particular country in exchange for complete publication of the technology protected by the patent. n6 Patent protection is allowed for any novel invention, whether a product or process. n7 In short, if a patent is obtained, only the patent owner has the right to use it in the country which granted the patent. However, with the growing importance of international trade, the simple idea of patent protection has become the subject of global economic and human rights initiatives.

When originally formed, the international economic organizations were envisioned to be closely related to the U.N. system and human rights. n8 In [*245] 1995 "the World Bank thus declared on the 50th Anniversary of the Universal Declaration of Human Rights: '"The world now accepts that sustainable development is impossible without human rights."' n9 Further, articles 25 and 27 of the U.N. Declaration of Human Rights conclude that both the right of an inventor to enjoy the profit from intellectual property (IP) rights and the right of humans to an adequate standard of living are important and complementary rights promoted by the United Nations. n10 In response to the underlying theme of the U.N. Declaration of Human Rights, the World Trade Organization (WTO) enacted TRIPs in 1994. n11 However, the TRIPs Agreement continues to incite defiance and confusion among the members of the WTO. Even though the requirements of TRIPs more closely resemble the current patent laws of developed nations, many argue that its objective is to provide a fair balance for all WTO member nations. n12

The TRIPs Agreement was established through negotiations between developed countries that have strong IP laws and less-developed countries that have weak, or no, IP laws. n13 The developed countries argued for increased IP protection in the less-developed countries while the less-developed countries desired more access to the open market. n14 Additionally, the less-developed countries wanted more access to life-saving medicines, which in many developing countries were not currently available.

In essence, the underlying themes promoted by TRIPs are: "(1) . . . minimum intellectual property rights protection through domestic laws; (2) . . . effective enforcement of those rights; and (3) . . . , submission of disputes to the WTO Dispute Settlement System." n15 Article 7 of the TRIPs Agreement reiterates these themes:

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and [*246] to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations. n16

TRIPs, however, provides flexibility in achieving these goals by allowing members to "adopt measures necessary to protect public health . . . and to promote . . . their socio-economic and technological development." n17 Under the language of article 8.1 members can organize their IP rules however they choose as long as they conform to the standards set under the TRIPs Agreement. n18 Simultaneously, article 8.2 allows a government to use appropriate measures to prevent a patent owner from improperly abusing their patent rights to "unreasonably restrain trade or adversely affect the international transfer of technology" within the marketplace. n19 Such provisions allow a developing country member to format its IP scheme to best match the particular needs of its country.

In some cases, a country's human rights needs arguably outweigh the importance of patent protection. TRIPs allows a government member of the WTO to intentionally override a patent and use protected technology through two provisions: a "public health license" and a "compulsory license." Article 30 of TRIPs allows a government to grant public health licenses to the extent that such action "does not unreasonably conflict with a normal exploitation of the patent and does not unreasonably prejudice the legitimate interests of the patent owner. . . ." n20

Alternatively, a compulsory license allows a party other than the patent owner to produce the patented invention without the owner's permission. n21 Even though TRIPs allows compulsory licensing, developing country members have been reluctant to implement such licensing because several mandatory preconditions must be met, which often prove difficult for the administrations of developing countries to satisfy. The granting state must first request voluntary permission of use from the patent holder, then restrict use of the compulsory license to predefined rationales, and then [*247] "adequately remunerate" the patent holder for such use. n22 The most problematic prerequisite, however, is the requirement that the compulsory licenses be used predominantly for the domestic market even if the nation has no domestic manufacturing capacity. n23 Yet, TRIPs provides that when a "national emergency or other extreme urgency" arises, a member is not required to obtain prior authorization in order to grant a compulsory license. n24 Under such an emergency, the member is, however, limited to non-commercial state-use and must notify the patent holder of such use. n25

Those in favor of compulsory licensing urge that it will reduce foreign dependence, encourage and establish domestic industry, increase competition in the marketplace, and provide more access to patented medicines. n26 The counter-argument presented by the critics of compulsory licenses is that the definition of "national emergency" will be broad and compulsory licenses will be granted for anything that can be categorized as such. n27 The reason that compulsory licensing is an issue of universal concern is that when governments issue compulsory licenses, the likely result is a sharp price reduction, similar to the introduction of other competitive forces like generic drugs. n28

A further alternative to compulsory licensing is the use of "parallel imports" n29 and avoiding liability to the patent owner through "exhaustion of rights." n30 TRIPs has declared that issues related to parallel imports or exhaustion of rights cannot be raised as a dispute in the WTO unless "fundamental principals of discrimination are involved." n31 Thus, these alternative government actions are seemingly available actions if they would be more effective than undertaking the process of acquiring a compulsory license.

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After the adoption of the TRIPs Agreement, however, there remained confusion about certain of its provisions.

Consequently, the Doha Ministerial Conference in November 2001 released a Declaration (Doha Declaration) in an attempt to clarify the confusion. n32 The Doha Declaration focused on the growing public health issues affecting the developing and least developed world, particularly with respect to HIV/AIDS, malaria, and other tropical diseases. n33 For example, an important decision issued through the Doha Declaration was the modification of the deadline for complete TRIPs compliance to 2005 for developing countries and 2006 for least-developed countries. Also, the Doha Declaration stated that the least-developed countries were not required to issue pharmaceutical patents until 2016. n34 This extra time period has allowed the least-developed countries to attack their public health issues without fear of WTO sanction and trade repercussions.

The Doha Declaration additionally provided clarification on issues pertaining to compulsory licenses. Each member nation of the WTO has been granted the freedom to determine the grounds upon which a compulsory license will be granted. n35 Further, confusion over the definition of "national emergency" or "extreme urgency" was dispelled by allowing each WTO member to determine what constituted such a situation but stipulating that "public health crises" are such situations. n36

The Doha Declaration, unfortunately, failed to address the controversy surrounding article 31(f) of the TRIPs Agreement, which restricts the use of compulsory licenses to "predominantly the domestic market." n37 As a result, on August 30, 2003, the General Council of the WTO released a statement which attempted to clarify the confusion. n38 In particular, part 2 of the statement provided the requirements a nation must meet before being granted a waiver of the customary obligations for compulsory licensing. n39

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This statement afforded many countries previously unable to manufacture pharmaceuticals with the ability to rely on a regional trade partner to produce the necessary medicine once production rights had been granted by a compulsory license. The problem with the Doha Declaration and the statement by the General Council is that they have no legally binding weight in Dispute Settlement within the WTO and will merely be used interpretively in cases involving TRIPs. n40 Thus, without firmly established principles within the WTO, members who choose to grant compulsory licenses still risk violating TRIPs.

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III. Analysis

The TRIPs Agreement provides a sufficient foundation through which to respect the wants and needs of both developed and underdeveloped nations. However, pharmaceutical manufacturers remain adamant about further increasing the strength of patent rights. Section A discusses why the pharmaceutical industry should, but does not, focus its assets on drugs vital to millions in the developing world. Section B presents an analysis of how TRIPs and related IP treaties have been successful in resolving disputes as well as protecting the vital interest of human rights. Examples of particular conflicts show that the agenda of developed nations extends beyond fair trade and public health. Section C argues that compulsory licensing is essential for the effective fight against the spread of disease and does not significantly harm patent holders' profit margins. Section D argues that while patent protection is vital to the furtherance of technological development, sufficient profits can be achieved without foregoing global health concerns.

A. The Focus of the Pharmaceutical Industry

Article 31 of the Vienna Convention states that particular terms in a treaty must be "interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object

and purpose." n41 As such, article 7 of the TRIPs Agreement unambiguously requires the use of technological knowledge in a manner conducive to social and economic welfare and to a balance of rights and obligations. n42

Pharmaceutical companies argue that in order to produce new drugs through R&D, they must make a substantial return of profit on drugs already being sold. Therefore, with patent protection for twenty years, the pharmaceutical company gains the necessary market exclusivity from which they are able to reap a huge return. However, this exclusivity also may tend to afford them the ability to set the price they desire; often this price is very high. Frequently, however, more than half of the R&D expenditure for new pharmaceuticals is funded by American tax dollars or private philanthropy, thus relieving the pharmaceutical manufacturers of [*251] a significant cost burden. n43 Consequently, the pharmaceutical industry appears to have an ideal market situation providing it with a significant opportunity to develop lifesaving drugs.

However, for pharmaceutical manufacturers, the recent trend has been to develop "lifestyle" drugs, which produce a large profit in developed countries, instead of drugs which may cure chronic diseases found mostly in poor regions, but which lack a potential for large profit. n44 For instance, between 1975-1997, only one percent of newly patented medicines were for arguably easily curable tropical diseases. n45 At the close of 1996, "only eight drugs on the WHO's 7th Model List of Essential Drugs were still under patent protection in Europe and five of these were classified as 'complementary' rather than 'essential.'" n46 Further, "the World Health Organization claims that of the $ 56 billion spent globally on R&D in 1994, only 0.2% was aimed at pneumonia, diarrheal maladies, and tuberculosis, which together account for 18% of global illness." n47 Due to a lack of access or production of vital medicines, nearly ten million people die in the developing world each year from infectious diseases. n48 Most of these people die from just six conditions: HIV/AIDS, malaria, measles, pneumonia, tuberculosis, and various forms of dysentery. n49 However, of these six conditions, only HIV/AIDS is a relatively new condition. n50 Therefore, it is entirely possible that if attention had been focused towards the other five conditions, a cure for them would be presently available for use.

One reason presented for this disparity has purely to do with the assumed inadequacy of profit potential within the developing world. Because of the claimed lack of purchasing power of those in the least developed countries, the pharmaceutical companies claim they cannot [*252] make enough money by selling their drugs. Thus, the pharmaceutical companies do not produce drugs needed in these regions. Pharmaceutical manufacturers argue that because the Gross Domestic Product of the developing world is only one-fifth of the world total, the developing world represents only one-fifth of the potential global market. n51 This argument is based entirely on purchasing power, rather than demand for product. n52 A recent World Health Organization estimate stated that nearly ninety-five percent of the world's HIV/AIDS victims reside in developing countries; thus, the demand for vaccines and medication is great. n53

B. Success of TRIPs in Dispute Resolution

Countries of the developed world generally have strong patent regimes. However, few developing countries have such patent regimes. TRIPs attempts to reconcile this situation by providing a level of patent protection desired by pharmaceutical manufacturers, which will also increase the availability and advancement of medicines within countries previously lacking such patent regimes.

Effectively, the members of the WTO have a set period of time to establish and enforce the requirements of TRIPs before they are sanctioned. The larger developing countries (India, Brazil, and China) must comply with TRIPs by 2005. n54 Least-developed countries (those of Sub-Saharan Africa) must comply by 2006 in general and have an extended compliance deadline of 2016 for pharmaceutical patents. n55 Additionally, article 67 of TRIPs requires developed countries to assist developing countries in creating and modifying their IP schemes, including assistance in

prevention of abuse of such schemes. n56 Ideally, such assistance should be carried out with solely the interests of the developing country in mind.

However, some critics claim that TRIPs, in fact, reduces a developing country's access to technology and discourages new technology needed for economic growth. n57 Assuming this assumption is valid, the balance of [*253] power must not be leveraged solely by the pharmaceutical companies and developed nations. In exchange for the strong patent rights manufacturers receive they must provide a sufficient benefit to society. n58 In fact, it would violate the objectives of the WTO to threaten a needy country with trade sanctions restricting access to vital drugs simply for the purpose of maintaining profitability. n59 This is because all WTO members must comply with TRIPs article 30 which generally articulates a policy interest in promoting public health. n60 Additionally, treatments for widespread conditions are valuable to society as a whole and will provide significant profits if focus is provided through R&D. n61

Recently, several developing countries have simultaneously felt the enforcement powers of TRIPs and the criticism of the developed world as a result of their actions. In some of these cases the developing countries' actions were, in fact, found to be in violation of TRIPs. However, in other instances, the speculation and attempted enforcement by developed nations was defeated by worldwide pressure.

1. India

India's 1970 patent law did not include patent protection for pharmaceuticals and thus did not issue patents for such products. n62 Additionally, in India, changes in a drug's production process do not require re-approval for marketing, thus allowing manufacturers to begin production and sale without revisiting the lengthy approval process previously completed for the same product. n63 Further, because India is a developing country, it is not required to achieve full compliance with the TRIPs Agreement until 2005. n64

This situation has allowed India to become the location of numerous independent drug manufacturers of generic equivalents of drugs originally patented and produced by Western pharmaceutical companies. There are [*254] an estimated 9000 registered small drug firms, 250 registered large drug firms, and possibly another 7000 unregistered small drug-producing firms in India. n65 In addition, these generic manufacturers utilize the publicly available research information from the Western patents to make further improvements on the drugs which have profited the patent holders. n66

As a result of the lack of R&D cost, the generic drugs produced by Indian manufacturers are significantly cheaper than those produced by the pharmaceutical companies who obtained a patent for their research. For example, "a UN study showed that 150mg of the HIV drug Fluconazole costs $ 55 in India, where it does not enjoy patent protection. However in countries that do provide patent protection the cost for an equivalent amount is much higher: $ 697 in Malaysia, $ 703 in Indonesia, and $ 817 in the Philippines." n67 Such a disparity in price has caused many countries in need of these drugs to rely on imports from Indian generics.

As a result of the Indian generic industry, the Indian government has come under scrutiny from industrialized nations for violating the TRIPs Agreement. The United States and the European Community brought action against India in 1997 for failing to meet the requisite steps for full TRIPs compliance. n68 The WTO panel agreed with the developed nations and sanctioned India until it achieved the level deemed necessary to satisfy the 2005 deadline for complete TRIPs compliance. n69 When fully compliant, the ability of Indian generic firms to freely produce patented pharmaceuticals at mere fractions of the price will no longer be available. The likely result will be that the price for such

drugs will significantly increase and the availability of such drugs to the Indian population "as well as other nations who imported from Indian manufacturers" will significantly decrease.

2. South Africa

South Africa has more people infected with HIV/AIDS than any other country on Earth. The current number is above 4.7 million and continues [*255] to rise. n70 South Africa also had some of the highest prices of pharmaceuticals in the world despite its status as a developing country. n71

In response, South African President Nelson Mandela passed the Medicines and Related Substances Control Amendment Act (Act) in an attempt to make drugs cheaper and more available. n72 Specifically, the Act allowed the South African Minister of Health to grant compulsory licenses for pharmaceuticals as long as the product was already being marketed by the patent owner. n73 The Act did not restrict the use of compulsory licensing to the degree that TRIPs requires and it neglected to mention the specific conditions TRIPs requires to grant a compulsory license. n74 The Act also encouraged the practice of parallel importation in order to further provide medication to South Africans. n75

Compulsory licensing is ideal for such a situation because it would allow South Africa to produce generic drugs in a state laboratory and control the distribution, at a potential discount of ninety percent over private pharmaceutical costs. n76 Additionally, the potential for parallel importation of drugs would allow South Africa to purchase a drug such as Fluconazole from a generic producer in Thailand for $ 0.60 per dose when the same drug cost $ 4.10 per dose from the patent holder. n77

However, in response to the Act, the South African Pharmaceutical Manufacturers Association and forty multinational manufacturers brought a law suit against South Africa. n78 They claimed the Act violated TRIPs through lax treatment of patent rights. n79 The United States and the European Commission also supported their respective pharmaceutical manufacturers in the suit against the South African government. n80 Further, the United States withheld trade benefits and threatened further trade sanctions if South Africa failed to repeal the Act. n81 The pharmaceutical [*256] companies eventually dropped the case in 2001, but only in response to the worldwide public outcry against the action. n82 Subsequent to this decision, the WTO released the Doha Declaration and clarified the flexibilities of TRIPs and a country's ability to decide whether to grant a compulsory license in response to public health and emergency needs.

3. Brazil

Brazil is an example to the rest of the developing world as to how HIV/AIDS can be controlled. In the mid 1990s Brazil had an estimated population of 536,000 people infected with HIV/AIDS. n83 Attempting to curb the outbreak, the Brazilian government used a loophole in its patent laws called the "pipeline" provision. n84 With the "pipeline" provision, pending pharmaceutical patents in Brazil receive protection only if the drug had been patented in another country and if no marketing or planned marketing for sale had taken place by the pharmaceutical companies or third parties. n85 Basically, any drug that was being sold outside of Brazil did not receive patent protection in Brazil, and a Brazilian generic producer could freely manufacture the drug within Brazil.

Relying on the "pipeline" provision, the government of Brazil began producing generic versions of the standard HIV/AIDS drugs in state-owned plants and the government began giving the generic drugs to infected Brazilians for

free. n86 The results speak for themselves. Because of the competition generated by the generic producers, the brand-name versions of the AIDS drugs reduced their price by seventy-nine percent, while the price of drugs which did not have a generic competitor fell by only nine percent during the same three years. n87 Further, because of the effectiveness of the drugs, hospitalization costs of HIV/AIDS patients in Brazil fell by $ 472 million over a two year period and HIV/AIDS mortality rates in Brazil were reduced by fifty percent during the 1996-1999 period. n88 The action by the Brazilian government is proof of what an effective generic market for drugs could accomplish in the fight against disease.

Alternatively, Brazil has threatened to use compulsory licensing in negotiations simply to lower prices of other patented drugs. Such leverage [*257] was provided by article 68 of the new Brazilian Industrial Property Code, which required that Brazilian patent holders manufacture the patented product in Brazil. n89 If the patent holder failed to comply with this provision for a three year period, the Brazilian government would grant a compulsory license, unless it had been financially impossible for the patent holder to comply with this regulation. n90 Such a provision allowed the Brazilian government to grant compulsory licenses under a much less stringent standard than that under TRIPs.

Consequently, the United States initiated action against Brazil in 2001 at the WTO Dispute Settlement Body, claiming that article 68 violated TRIPs. n91 The United States argued that article 68 discriminated against American owners of Brazilian patents and violated article 27.1 and article 28.1 of the TRIPs Agreement. n92 In response, the Brazilian government claimed that their compulsory licensing provision was compliant with TRIPs, as well as article 5 of the Paris Convention, which is incorporated into TRIPs through article 2.1. n93 Article 5 of the Paris Convention stated that "[e]ach country . . . shall have the right to take legislative measures providing for the grant of compulsory licenses . . . ." n94

In response, the United States received criticism from nongovernmental organizations throughout the world, who felt the U.S. action would halt the positive impact Brazil was making in their fight against HIV/AIDS. n95 Responding to this pressure, the United States withdrew its action against Brazil on June 25, 2001. n96 Eventually a compromise was reached between the two nations. Brazil agreed to consult and negotiate with the United States and the pharmaceutical manufacturers before granting any future compulsory licenses. n97

Although the point of disagreement between the United States and Brazil stemmed from a provision of the Brazilian Code, the TRIPs Agreement in fact specifically provided for the granting of such compulsory licenses. Brazil could have produced the same drugs under the "public non-commercial use" exception in article 31 of TRIPs because [*258] Brazil produced the pills in state-owned labs and distributed them to the public for free. n98

4. The United States

The United States is the world's leader in the R&D of new pharmaceuticals. n99 This is likely a result of the strict American patent scheme, which provides the incentive of strong patent rights to inventors. In addition, the United States is one of the only developed nations without national pharmaceutical pricing controls. n100 As a result, drug prices within the United States are far greater than similarly situated nations such as Canada. Many critics blame these high prices on the U.S. lawmaker's susceptibility to the persuasiveness of lobbyists, who have received $ 236 million from the U.S. Pharmaceutical Association over a two year period. n101

This influence on the government from the private sector may explain the consistent pressure the United States applies on developing nations who stray even slightly from the requirements of the TRIPs Agreement. The power to exert such pressure arises from § 301 of the 1974 U.S. Trade Act, which allows private parties to force the U.S.

Government to act any time foreign trade practices have the potential to unfairly limit U.S. commerce. n102 Further, the United States declared in the 1984 Trade and Tariff Act that "intellectual property protection [is] explicitly actionable under § 301." n103 This language provides the wherewithal for private pharmaceutical companies to use the U.S. government any time they feel threatened.

Additionally, the U.S. Trade Representative is required to compose a "watch list" of trading partners who fail to provide adequate IP rights to U.S. companies even if the allowed rights are fully compliant with TRIPs. n104 When a country is placed on this list, the United States uses § 301 to revoke or threaten to revoke the "Most Favored Nation" status of a nation until the desired changes are made to the identified nation's IP [*259] laws. n105 This exertion of power seems to extend far beyond the scope of TRIPs. The idea of TRIPs is to create a standard of "minimum" rights in each nation, not to require rights equivalent to, or in excess of, the rights established in industrialized nations with centuries of practice.

Recognizing such a disparity, the European Union initiated a WTO Dispute Settlement action against the United States challenging the validity of § 301. n106 In such disputes within the WTO, the general council also functions as the Dispute Settlement Body. n107 The argument presented by the European Union claimed that article 23 of the Uruguay Round of the Understanding on Rules and Procedures Governing the Settlement of Disputes prohibits the use of unilateral actions by WTO members. n108 Therefore, just as the United Nations requires of its members, WTO members must also submit claims to the general body of the WTO, or, in this case, the panel for Dispute Settlement, before initiating action against another member nation. n109 In fact, § 301(E) specifically requires an investigation pursuant to an alleged violation of a trade agreement, such as the WTO, and requires the U.S. Trade Representative to abide by the dispute settlement provisions established by such a trade agreement. n110 Thus, unilateral action undertaken by the United States pursuant to § 301 is not only in violation of the WTO, but also the language of the U.S. Trade Act.

The irony of the position taken by the United States is that the United States often permits the practices for which it holds others accountable. In particular, the United States uses threats of compulsory licenses within its own borders. n111 However, in contrast to the reasons for granting compulsory licenses that developing countries rely on, the United States is not as stringent when operating domestically. For example, in the period following the September 11, 2001 attacks, there was a panic in response to threats of Anthrax poisoning. From the Anthrax scare, five fatalities occurred. n112 German pharmaceutical giant Bayer AG had a patent for and produced an antibiotic called Ciprofloxacin Hydrochloride (Cipro) widely [*260] believed to fight Anthrax poisoning. n113 The United States understandably felt a need to stockpile a large amount of Cipro in case of future attacks.

Consequently, the U.S. government threatened to issue a compulsory license to produce Cipro generically unless Bayer reduced the price. n114 However, this threat never materialized, most likely because of the unwillingness of the United States to retreat from its consistently hard-line stance on international patent rights. n115 The United States eventually entered into an agreement to purchase one hundred million pills of Cipro from Bayer AG at a discounted price. n116 The threat of granting a compulsory license for this situation left many WTO members skeptical of the motives of the United States.

The "public health" exception articulated in article 30 of TRIPs is arguably a more valid excuse for compulsory licensing than stockpiling. n117 Stockpiling aims merely to protect the patented product's competitive value, rather than correct an emergency. n118 This situation clearly outlined the position of the United States when trade is concerned. The United States seems to interpret TRIPs however it desires, so long as it benefits the United States. Many in the developing world are left understandably displeased when the United States maintains a policy under which it simultaneously threatens to grant a compulsory license for itself in response to five deaths, while maintaining a hard

line position against poor countries wishing to grant the same rights in response to spreading diseases afflicting millions. n119

Additionally, the acts undertaken by the United States in issuing and threatening to issue compulsory licenses after signing the TRIPs Agreement is considered evidence of a "customary international law norm" against which it may not later argue in similar cases involving other WTO member nations. n120 The International Court of Justice declared that "behavior after conclusion of the treaty may evince state practice out of a sense of legal obligation." n121 The United States should abide by the customs it has helped to establish and allow developing nations in need, to utilize compulsory licensing when it is deemed necessary. Such cooperation from a powerful and developed nation, such as the United [*261] States, would undoubtedly help solidify the foundation of TRIPs, from which new technologies in developing nations will possibly emerge.

C. Compulsory Licensing is Essential to Combat the Spread of Disease

Although the United States and other industrialized nations actively participate in the TRIPs discussions, they also consistently attempt to further strengthen the rights granted to patent holders seemingly without regard for prevalent human rights interests. n122 The main arguments presented by these developed countries for maintaining strong patent regimes are: "(1) strong patent protection stimulates future innovations of medical products; (2) patents encourage capital investment in pharmaceutical companies; and (3) strong patent regimes attract direct foreign investment, thereby benefiting developing nations in the long term." n123 In response, developing countries claim that any long term benefits stemming from strong patent rights cannot help curb the current public health crises. n124 Consequently, the possibility of a compulsory license to produce generic drugs, outlined within TRIPs, provides an immediate solution to the present problem of high pharmaceutical prices.

First of all, generic drugs can be produced for a fraction of the cost because generic producers do not require research and development; instead they obtain their knowledge from the patent once its contents are made publicly available. n125 Therefore, if the developed nations were to relax their policies on compulsory licensing with respect to disease control in, at a minimum, less developed countries, producers of generic drugs would potentially be able to increase quality through practice and stringent standards.

However, the argument is valid that the infrastructure required to effectively distribute these drugs is simply not present in the countries most in need. n126 The generic or donated drug programs can be subject to corruption by the leaders of developing nations. n127 There is also the possibility that these drugs may be smuggled back into developed [*262] countries and sold at a lower cost than what the patent holders charge. However, this has been happening for years within the United States when Americans purchase drugs in Canada. n128

Secondly, TRIPs requires manufacturers to separate their drugs issued through compulsory license by identifiable markings. n129 With the help of the many international NGOs and Aid Organizations, such as The International Dispensary Association and UNICEF, quality assurance in distribution can be secured. n130

Parallel importing is clearly a dilemma. However, the world community has chosen to remain neutral on this issue by removing concrete rules from the TRIPs Agreement. n131 Thus, the individual nations have the ability to decide whether parallel importing is feasible. n132

D. Balancing Profits with Global Health Concerns

Many pharmaceutical companies have taken action to aid poor nations in their fight against disease. Several have donated large quantities of their drugs. One group of large manufacturers has pledged over $ 275 million towards the fight against HIV/AIDS in Africa. n133 This is a number which is larger than the amounts actually provided by many developed nations. n134

Most importantly, the drugs themselves would not be available to anyone if not for the pharmaceutical producers. Because of the small number of highly successful products, the twenty year market exclusivity provided by patent protection is necessary to generate enough profit to fund further research and development. n135 "[P]harmacueitcal companies invest on the order of 12- 19% of their sales revenue in research and development." n136 Today, the average drug requires 12 years and $ 500 million to research and develop. n137 One major reason for this is the huge sums spent on marketing and employee compensation packages. For [*263] example, in 2000, $ 2 billion was spent on media advertising by the pharmaceutical industry. n138 Even then, only 1 in 5,000 tested drugs will be approved for patient use, and of those approved, only 3 out of 10 will generate enough revenue to equal or exceed the cost of R&D. n139 After the expiration of the 20- year patent term, the generics significantly increase competition. "Industry experts say . . . 80% of profits are milked out of a drug in the first 18 months of its reincarnation as a generic." n140 Therefore, the revenue generated by those few blockbuster products is vital to innovation of new technology and possible new cures.

The potential for loss of revenue, however, by granting compulsory licenses to poor nations, who could not afford the drugs in the first place, would be minimal. Developing countries, which account for 75% of the world's population, only account for 10% of the global pharmaceutical market. n141 Additionally, with the assistance from NGOs and government, widespread and costly media advertising can be arguably reduced in the developing world, thus further lessening the cost to the pharmaceutical companies. The TRIPs requirement to "adequately remunerate" the patent holder provides additional tangible payment when a compulsory license has been granted. n142

The Dispute Settlement Panel at the WTO could also provide an adequate setting for unbiased negotiations between generic producers and the pharmaceutical manufacturers. n143 Such open negotiations could lead to proper pricing and production schemes so as to satisfy the needs of both parties. As such, while patent protection is necessary, the possibility of reduction of cost as well as payment for use are potentially mechanisms through which objectives of both sides could be achieved.

IV. Conclusion

Clearly, the battle between pharmaceutical patent rights and access to these drugs is also a battle between industrialized nations pursuing very strict patent rights and developing nations attempting to improve or establish a system of patent rights to comply with TRIPs. Both sides use the TRIPs Agreement for legal support. However, due to the ambiguous nature of the wording in the TRIPs Agreement, interpretations vary.

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The WTO negotiations and TRIPs have been criticized as methods for rich countries with established patent schemes to enforce unreasonable demands on poor countries who are trying to gain access to the world market. n144 As a result, it is arguable that the bilateral negotiations held when forming and enforcing TRIPs were merely protections of interests of the developed countries at the expense of those who are underdeveloped. n145 Due to this potentially unfair limitation on fair trade, the TRIPs Agreement, which attempts to introduce technology to poor regions, may eventually hinder innovation and access to the technology available in the developed world. n146

Recently, however, as a result of the Doha Declaration and the Statement by the General Council, several

industrialized nations, including the United States, have committed not to use the new rules to import pharmaceuticals and many other nations have agreed to use the new rules only in situations of national emergency. n147 However, it is clear that industrialized nations should also provide more assistance to developing nations through a "Fair Followers Mentality" to improve their intellectual property regimes. n148 This requirement to assist in the preparation of laws and regulations is already codified in article 67 of TRIPs. However, the industrialized nations should not provide assistance with the goal of merely protecting their own interests. n149 The objectives of both developed and developing countries must be equally respected and supported in order for TRIPs to be effective.

There is a significant necessity in the underdeveloped world for new technology and access to such technology, thus making it imperative for a proper balance to be obtained. n150 Upon the achievement of such an understanding by all WTO members, sufficient profit may be raised for future R&D and inexpensive drugs may be distributed to control the spread of disease.

Legal Topics:

For related research and practice materials, see the following legal topics:
International Trade LawDispute ResolutionArbitrationPatent LawInequitable ConductGeneral OverviewPatent LawOwnershipConveyancesLicenses

FOOTNOTES:

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following conditions: (i) only the amount necessary to meet the needs of the eligible importing Member[s] may be manufactured . . . ; (ii) products produced under the license shall be clearly identified as being produced under the system . . . ; and (iii) before shipment begins, the licensee shall post on a website the . . . quantities being supplied to each destination . . . and . . . the distinguishing features of the products . . . (3) Where a compulsory license is granted by an exporting Member under the system set out in this Decision, adequate remuneration . . . shall be paid . . . to the [patent holder] . . . (4) . . . eligible importing Members shall take reasonable measures . . . to prevent re-exportation of the products that have actually been imported into their territories under the system. Id.

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