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**PARALLEL TRADE, UNPARALLEL LAWS: AN
EXAMINATION OF THE PHARMACEUTICAL
PARALLEL TRADE LAWS OF THE UNITED STATES,
THE EUROPEAN UNION AND THE WORLD
TRADE ORGANIZATION**

Julia A. Moore

I. INTRODUCTION

Intellectual property rights include patents: legal instruments by which the inventor of an innovative product is given the exclusive right to sell that product for a period of twenty years.¹ An inventor can receive a patent for a new product or process that involves an inventive step, if it has utility to some industry.²

As the world economy grows increasingly smaller, the laws of different nations that govern intellectual property are clashing on a global scale.³ While a product may be patented and protected in Country A, Country B may have no such laws governing patent rights. Accordingly, generic manufacturers in Country B produce the patented product and sell it at a significantly reduced rate. These conflicts create numerous problems between patent holder companies and countries with weak intellectual property laws and also between those nations and nations with strong intellectual property laws.⁴

Recently, conflict over patents has arisen in the pharmaceutical field. Patents are particularly important in pharmaceutical research because of the high cost of developing medications and the ease with which generic companies can replicate the chemical compound of the drug. Once obtained, patents protect the innovator in the market, and although patents appear anti-competitive and monopolistic, they actually help the market because the innovator is free to create knowing he will be recompensed for his efforts. This security allows inventors to create more drugs without worrying about recouping the

¹ Pharmaceuticals can have longer than twenty years of market exclusivity with laws such as the Orphan Drug Act, 21 U.S.C. §360cc, the Hatch-Waxman Act, 21 U.S.C. §355 and the FDA's provisions for pediatric testing.

² See 35 U.S.C. §§ 101-103; TERRENCE PRIME, EUROPEAN INTELLECTUAL PROPERTY LAW 178-89 (2000); Timothy A. Brisson & Victor Gallo, *Patent Law Basics*, 8 NEV. LAW. 10 (2000) (outlining intellectual property rights in a helpful chart).

³ Shanker A. Singham, *Competition Policy and the Stimulation of Innovation: TRIPS and the Interface Between Competition and Patent Protection in the Pharmaceutical Industry*, 26 BROOK. J. INT'L L. 363, 363 (2000).

⁴ *Id.*

expense of the creation process. Many governments in the developed world adhere to the principle that “[o]nly a strong intellectual property system can best serve the needs of the people around the world.”⁵

Both the United States and the European Union have strict patent regimes that protect the patent holder with no compulsory terms.⁶ However, not all of the patent policies of the United States and Europe are the same. One example of the different governments’ views is their approach to parallel importing. Parallel importing, which occurs between two or more nations, played a major role in the recent WTO discussions on free trade and intellectual property rights.

This note aims to prove that the economic policies of the United States and Europe with respect to parallel trade predict how they reacted to the problem of pharmaceutical parallel trading in the developing world. Part II will explain the importance of patents in the pharmaceutical field, Part III will define parallel trade and evaluate its economic strengths and weaknesses, Parts IV and V will examine the law surrounding parallel trade in the European Union and the United States, Part VI will examine parallel trade’s role in the World Trade Organization’s Trade-Related Aspects of Intellectual Property Rights Agreement and how the United States and the European Union behaved in that negotiation, and Part VII will conclude.

II. WHY PATENTS ARE IMPORTANT

The patent is essential to pharmaceutical research. Patents encourage pioneering drug companies to research and develop more drugs for the world’s diseases.⁷ A pharmaceutical company will only research drugs for which they can both obtain a patent and have data indicating a sizable population of consumers for that drug.⁸

⁵ Singham, *supra* note 3, at 364.

⁶ See 35 U.S.C. §101-103; PRIME, Note 2, at 181, *See generally*. Robert Weissman, *A Long Strange TRIPS: The Pharmaceutical Industry Drive to Harmonize Global Intellectual Property Rules, and the Remaining WTO Legal Alternatives Available to Third World Countries*, 17 U. PA. J. INT’L ECON. L. 1069, 1072 (1996).

⁷ Non-patent exclusivity can also keep a generic drug off the market, as market exclusivity law keeps the generic company from using the pioneer’s FDA marketing application data in its own application until the expiration of the non-patent exclusivity. Thus instead of generating their own data about the generic drug (which would be costly), the generic companies wait until the end of the pioneer’s market exclusivity. For more about non-patent exclusivity. See Valerie Junod, *Drug Marketing Exclusivity Under United States and European Union Law*, 59 FOOD & DRUG L.J. 479, 480 (2004).

⁸ Diseases that only affect a small population or a poor population are not as profitable as others and therefore might pharmaceutical company’s interest. The United States passed the Orphan Drug Act in 1983, giving the pioneer company

Creating a new drug is highly expensive. Research-based drug companies outlay at least \$110 million and up to \$880 million to create and test one new drug.⁹ In the United States, the development and clinical testing of the drug often takes as long as ten years to complete.¹⁰ This only accounts for drugs that germinate past the initial stages; research and development money also goes towards “dry holes” potential drugs that are investigated but prove not to be viable medications. Only one in 4,000 chemical compounds created is ever marketed to the general public.¹¹ Thus, those drugs must generate enough money to cover the research and development of the other pharmaceuticals that never made it to the market and an additional profit beyond that for the company as an incentive to continue.

Two types of companies manufacture pharmaceuticals: pioneer producers and the generic producers.¹² The pioneering companies research and develop new drugs while the generic companies duplicate those drugs and sell them at reduced prices after the pioneers’ patent and market exclusivity has ended.¹³

Without patents and market exclusivity, a generic company could replicate the approved drug and sell it at a significantly reduced price in direct competition with the pioneer company. This would prevent the researching company from recouping the money it spent on development. In such a system, there would be little incentive for pharmaceutical companies to develop new medications. Pharmaceutical research in India proves this theory. India provides little to no pharmaceutical patent protection; accordingly, little to no research and development in pharmaceuticals occurs in India.¹⁴

Patents may seem like a trade hindrance, but they maintain the long-term economy by encouraging innovation and the development of new products. A patent creates efficiency and promotes the creation of other drugs, which counteracts the restriction of output required by exclusive property right.¹⁵ While patents appear to be anti-competitive and yet help the market economy, certain practices involving patented products are competitive and actually hurt the market economy. One of these anti-patent behaviors is parallel trade.

seven more years of market exclusivity, and the number of orphan drugs rose dramatically, including the anti-AIDS treatment AZT.

⁹ Junod, *supra* note 7, at 481.

¹⁰ *Id.*

¹¹ Singham, *supra* note 3, at 373.

¹² Junod, *supra* note 7, at 479

¹³ *Id.* at 479

¹⁴ Jean O. Lajuow & Iain Cockburn, *Do Patents Matter?: Empirical Evidence After GATT*, 7495 Nat’l Bureau Econ. Res. Working Paper 5, 7 (January 2000).

¹⁵ Singham, *supra* note 3, at 366

III. WHAT IS PARALLEL TRADE?¹⁶

Parallel trade poses an international problem in the pharmaceutical industry. Differences in economic, social, legal or regulatory regimes of countries create varying prices around the world for the same drug. This discrepancy often leads to parallel trade. A distributor in a country with a low price for drug A ships drug A to an unauthorized dealer in a country with higher price. The unauthorized dealer then sells the low priced drugs in the new country, competing directly with the drug A patent holder or authorized dealer in that country.¹⁷ If the country where the pharmaceutical is first patented has no patent rights, the patent owner has no protection against parallel imports.¹⁸

While such a system seems like it would bolster economic efficiency, the exact opposite occurs. By undercutting pricy and inefficient producers, the singular nature of the pharmaceutical industry makes parallel importing a pernicious phenomenon. Four market characteristics cause parallel trading to reduce economic welfare in the pharmaceutical world:

- (1) In high-technology industries, particularly those with a high ratio of sunk joint R&D costs, where parallel imports will inhibit the ability of firms to recoup R&D and other fixed costs and ultimately reduce their ability to innovate;
- (2) In situations where price discrimination (differential pricing) will enhance welfare by facilitating entry into new, low-priced markets and thus expanding output;
- (3) In cases where monopsony power by public authorities creates price distortions and drives price down below average fixed costs; and
- (4) In countries where free rider problems exist because parallel imports can freeze out authorized distributors through lower prices, thus undercutting information and service activities.¹⁹

Parallel importing is an anathema to the brand-name pharmaceutical company because of these factors. Pharmaceutical firms charge different prices in different geographic markets. The pharma-

¹⁶ In this note, parallel trade/trading and parallel imports/importing are used interchangeably.

¹⁷ Claude E. Barfield and Mark A Groombridge, *Parallel Trade in the Pharmaceutical Industry: Implications for Innovation, Consumer Welfare, and Health Policy*, 10 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 185, 185 (1999).

¹⁸ PRIME, *supra* note 2, at 13.

¹⁹ Barfield, *supra* note 17, at 187.

ceutical companies reason that they base their prices on the average income in the area; however, it leads to gross price differences.²⁰ For instance, in 1995, the same amount of the antibiotic Amoxil cost \$8 in Pakistan, \$14 in Canada, \$36 in the United States, \$40 in Indonesia and \$60 in Germany.²¹ Parallel trading would allow a person in Germany who would ordinarily spend \$60 on Amoxcil to buy the \$8 Amoxcil from Pakistan, depriving the company of the profit from German consumers, which pays for the research and development costs. This essentially creates generic-like competition before patent protection and market exclusivity expire. Accordingly, the legislative purpose of patents disappears.

In some countries, such as those with socialized medicine or a poor population that cannot purchase drugs for themselves, the only purchaser of drugs is the government. In these cases, the patent holder only has one customer for its product, and will be forced to change its price to induce the monopsonic buyer to buy.²² In these countries, parallel trade could undercut the patent holder even further, as the buyer would have more than one supplier from which to choose.

Drug companies point to parallel trade and compulsory licensing to explain the decline in stock value and profits in recent years.²³ Glaxo-Wellcome claims parallel imports cost the company "tens of millions a year."²⁴ Without parallel trade, Glaxo-Wellcome predicts its profits would increase and would have more money for research and development.²⁵

Advocates of parallel trading assert that it does not differ from the doctrine of exhaustion of rights. Exhaustion of rights occurs when the patent holder has sold his product and then cannot prevent it from entering into a different market because his rights have been exhausted by the selling.²⁶ However, parallel trading differs through geography. Exhaustion of rights only applies to a certain geographic area. For instance, if a product enters the United States market, it is exhausted everywhere else in the United States market. Parallel trad-

²⁰ Barfield, *supra* note 17.

²¹ Editorial, *Blood and Gore: Office of the US Trade Representative Goes Too Far in Promoting Interests of US Drug Companies Abroad*, THE NATION, July 19, 1999, at 16. [hereinafter *Blood and Gore*].

²² *Id.*

²³ Bess-Carolina Dolmo, *Examining Global Access to Essential Pharmaceuticals in the Face of Patent Protection Rights: The South African Example*, 7 BUFF. HUM. RTS. L. REV. 137, 155 (2001).

²⁴ *Id.*

²⁵ *Id.*

²⁶ PRIME, *supra* note 2, at 9.

ing would be an international exhaustion of rights and would negatively impact the consumer.

Under the current system of intellectual property rights, the consumer is assured of the quality and safety standards of a drug, as he is able to identify the producer.²⁷ Doctors Without Borders notes that counterfeit and poor quality medicines are only aggravated in areas with parallel trading.²⁸ Despite these economic arguments against parallel trading, Europe has a bifurcated system that allows parallel importing in some parts of the market, but not in others.

IV. PARALLEL TRADE IN THE EUROPEAN UNION

Due to the nature of the European Union, parallel importing is not strictly prohibited. The European Union (EU) was formed in 1950 in part as an effort to allow the countries that signed the Maastricht Treaty (the Member States) to compete in the international market. Creating a single market within the EU has been a gradual and difficult process. One of the main goals of EU legislation has been the harmonization of laws and the creation of a single market so the EU can compete at a global level comparable to the United States.²⁹ In the EU, the drive towards the single market outweighs the negative effects of parallel trade within the Community.³⁰

As the result of the EU's push towards a single unified market, Articles 30 to 36 ban all qualitative restrictions on trade between Member States allowing for the free movement of goods and services in the European Market.³¹ Article 30 also prohibits "all measures having an equivalent effect" of a qualitative restriction.³² However, Article 36 made it clear that this does not threaten the protection of patents provided that the limitations were not actually arbitrary discrimination or disguised restrictions on trade between Member States.³³

To allow for the free movement of goods and services, EU law tolerates parallel trade.³⁴ In *De Peijer*, the European Court of Justice interpreted Articles 30 through 36, establishing the legality of parallel

²⁷ Singham, *supra* note 3, at 409 (citing National Economic Research Associates, *The Economic Consequences of the Choice of Regime in the Area of Trademarks*, (Feb. 8, 1999) Executive Summary at 6-7).

²⁸ *Id.*

²⁹ PRIME, *supra* note 2, at 88.

³⁰ Singham, *supra* note 3, at 410.

³¹ Article 30-36, 2002 O.J. (C 325)

³² *Id.*

³³ PRIME, *supra* note 2, at 5.

³⁴ Joseph Darbra & Joan Rovira, *Parallel Imports of Pharmaceuticals in the European Union*, 14 PHARMACOECONOMICS 129, 131-36 (1998).

imports within the EU.³⁵ The Court held that patients can import cheaper medicines for their own use from a pharmacy in another member state, provided that the product was available for sale in their own country.³⁶

As a result of the *De Peijer* ruling, the European Commission created a guideline for national authorities within the EU. Parallel imports are allowed if the importing countries verify that the medicinal imports are authorized within their borders and comply with the EU guidelines.³⁷ This creates price equalization across the European Community, promoting a greater sense of one market across Europe.³⁸

The EU justifies parallel importing with the doctrine of exhaustion of rights. In *Centrafarm*, a UK dealer imported goods from Holland and sold them in the UK for less than the original patent holder.³⁹ The plaintiffs argued that this parallel import threatened their profits and asserted their patent rights. However, the Court ruled that the original dealer, by selling the product in the UK, exhausted his patent rights for the entire EU. The court decided that exercising patent rights to prevent parallel importation created an unreasonable interference on the free movement of goods as the profits from the first market should recompense the patent owner sufficiently.⁴⁰

The EU also favors parallel importing because of socialized medicine. In countries where the government pays for most of the medical needs of the people, cheaper drugs result in lower cost for governments.⁴¹ Thus, EU Member States prefer to reduce their national medical costs by using parallel trade.⁴² However, the EU Council has declared that parallel trade can only exist within the borders of the European Community.⁴³ While the European Community opposes parallel trade involving a Member state and a non-member state, it allows

³⁵ Case 104/75, *Offieeve van Justice vs. de Peijer*, E.C.R. 613, 1976 C.M.L.R. 271 (1976).

³⁶ *Id.*

³⁷ Commission Communication: Parallel Importation of Medicinal Products, May 6, 1982.

³⁸ Dolmo, *supra* note 23, at 156. There are significant levels of pharmaceutical parallel trade in four of the European States: Denmark, Germany, the Netherlands and the United Kingdom, with Sweden and Norway increasing their parallel importing as well.

³⁹ Case 15/74, *Centrafarm B.V. v. Sterling Drug Inc.*, ECR 1147 (1974).

⁴⁰ *Id.*

⁴¹ See Barfield, *supra* note 17.

⁴² See Barfield, *supra* note 17, at 199.

⁴³ See *id.*

parallel importing within the European Community to promote the larger goal of one European market.⁴⁴

When it comes to parallel imports, the EU views the harmonization of community laws as more important than intellectual property rights.⁴⁵ Outside of the European Community, the free movement of goods and services no longer trump the intellectual property rights of the patent holder, and, thus, parallel importing loses its privileged status.⁴⁶

While the EU considers its goal of market harmonization more important than the intellectual property rights of the patent holder, this has not affected the number of pharmaceutical companies that settle within its borders.⁴⁷ Along with the United States and Japan, the EU leads the world in pharmaceutical development.⁴⁸ However, this lax view towards the rights of pharmaceutical companies makes the EU more likely to be in favor of parallel trading to alleviate the global AIDS crisis.

V. PARALLEL TRADE IN THE UNITED STATES

The strong pharmaceutical drug lobby pressured the government to forbid parallel trade in the United States. The United States spends 2.8% of its gross domestic product on research and development, as opposed to the 2% the rest of the developed world spends.⁴⁹ Pioneering pharmaceutical firms spend approximately 20% of their total profit on research and development, or 30% of the total costs of the company.⁵⁰ Due to their prominence in the national market, the interests of the research/development pharmaceutical firms are strongly protected by both the laws of the United States and the U.S. Trade Representative in his dealings abroad.

Under United States patent law, patent owners have the right to exclude others from making, using, offering for sale, selling or importing a patented invention.⁵¹ It is a priority of the lawmaker to en-

⁴⁴ See *id.*

⁴⁵ See *id.*

⁴⁶ See *id.*

⁴⁷ See *id.*

⁴⁸ This may be because Europeans have the money necessary to buy medicine and along with the United States and Japan, make up 80% of the world drug market.

⁴⁹ Singham, *supra* note 3, at 372.

⁵⁰ Patricia M. Danzon, *The Economics of Parallel Trade*, 13 PHARMAECONOMICS 301 (1998).

⁵¹ See 35 U.S.C. § 271 (1995).

sure that adequate incentives for investment in the development of new drugs exist.⁵²

Restrictions on trade were not always viewed as positive, pro-competitive measures. Until 1977, vertical trade restrictions, where a company at one stage of production imposes a contractual limit on a firm at another stage of production, were *per se* illegal.⁵³ However, in the *Sylvania* case, the Supreme Court ruled that restrictions such as vertical trade are widely used and have not proved to be harmful to competition, and therefore should be analyzed under the rule of reason to determine their legality.⁵⁴

The rule of reason analysis asks whether the challenged trade limitation is likely to harm competition and take from the consumer the advantages of a competitive system.⁵⁵ Parallel trade clearly passes the rule of reason. Parallel trade restricts others from importing lower priced goods to the disadvantage of the patent holder, which seems to damage the consumer in the short term, but benefits competition in the long term as the patent holder is not discouraged from creating new products. In this way, parallel trading escapes being monopolistic, and, therefore, the Sherman Antitrust Act does not deem it illegal.⁵⁶

The patent holder can impose and enforce territorial restrictions on sales in the United States. In 1994, Congress amended patent law to strengthen the patent holder's rights against the parallel importer. "[W]hoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefore, infringes the patent."⁵⁷ The U.S. courts continue to support patent holders in international exhaustion claims by defendants and ban parallel trade in pharmaceuticals.

United States policy firmly opposes pharmaceutical parallel trading because of the large number of pioneer drug companies in the United States. In the past, industries, such as the pharmaceutical industry, would go directly to the country in question to negotiate their intellectual property rights, leaving the United States government out

⁵² See Alfred B. Engelberg, *Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness?*, 39 IDEA 389 (1999). This is one of the main thrusts of the Hatch-Waxman Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

⁵³ Sergio Baches Opi, *The Approaches of the European Commission and the U.S. Antitrust Agencies Towards Exclusivity Clauses in Licensing Agreements*, 24 B.C. INT'L & COMP. L. REV. 85, 133 (2000).

⁵⁴ *Continental T.V. v. GTE Sylvania*, 433 U.S. 36, 57-58 (1977).

⁵⁵ Opi, *supra* note 47, at 91.

⁵⁶ See 15 U.S.C. § 1 (2005).

⁵⁷ 35 U.S.C. § 271(a) (1994).

of the negotiations.⁵⁸ However, as the economy became more internationalized, “firms saw government as a potential ally against foreign companies.”⁵⁹ The Pharmaceutical Research and Manufacturers of America (PhRMA) became a powerful lobbying group and had a significant influence over the United States’ involvement in TRIPS.⁶⁰

The U.S. Trade Representative, whose goal is to promote American commercial business abroad, is an influential and tenacious ally of the pharmaceutical company. For example, the U.S. Trade Representative used threats of trade sanctions to reduce the amount of illegal generic production in at least seven other countries.⁶¹

However, the United States government appears to practice parallel importing and compulsory licensing in other areas, such as in pollution control devices, pesticides, and computer processing chips.⁶² This hypocrisy stems from the close relationship of the United States to the drug companies, resulting in contradictory trade policy.⁶³ In most cases, the United States is a constant supporter of freer market economies, but, in the case of pharmaceutical industries, the policy becomes the protection of the patent-holding companies at the expense of competitive markets.

Because, by definition, parallel trading concerns at least two countries, it is an international concern, and the laws of the United States do not govern the way other countries act. This led to the TRIPS conference of 1994 and the ensuing battle over whether parallel trading would be allowed in the case of world medical crises.

VI. TRIPS, DOHA AND THE WTO NEGOTIATIONS

Trade Related Aspects of Intellectual Property Agreement (TRIPS) is a minimum intellectual property rights agreement; it encompasses both developed and developing countries, so its rules are more flexible than those of countries with strong patent protection.

⁵⁸ Susan K. Sell, *Proceedings of the 2002 Conference Access to Medicines in the Developing World: International Facilitation or Hindrance?: Panel #2: TRIPS and Access to Medicines: TRIPS and the Access to Medicines Campaign*, 20 WIS. INT’L L.J. 481, 484-85 (2002).

⁵⁹ *Id.* at 485.

⁶⁰ For more evidence of PhRMA’s influence over the U.S. Trade Representative, see Sell, *supra* note 52, at 494 (explaining the Argentinean patent problem); Weissman, *supra* note 6, at 1075-78 (discussing political maneuvering).

⁶¹ *Blood and Gore*, *supra* note 21, at 16. (“The Office of the USTR . . . has become a virtual appendage of the drug industry.”)

⁶² Dolmo, *supra* note 23, at 144.

⁶³ *Id.* at 152.

A. *Why Developing Countries Approve Parallel Trade*

Parallel trade in the context of developing nations is both a humanitarian and economic concern. In developed nations, parallel imports enable other distributors to undercut the patent holder's price and outsell him in the market. In developing nations, parallel trade allows the population to get the medication it needs.

While patent rights are essential for the developed country, a developing country must weigh the rights of the patent holder with the public health and find the rights of the patent holder wanting. In Thailand and South Africa, the governments believe that the AIDS crisis prevails over patent rights. A developing nation can override a drug company's patent rights by obtaining a compulsory license under the 1994 TRIPS agreement.

When a state grants a compulsory license, the grantee obtains the right to produce the patented medication without the permission of the patent holder.⁶⁴ Once the state issues a compulsory license, it can produce a generic drug providing the consumer a more affordable price.⁶⁵ The government then repays the patent holder what it believes is reasonable compensation.⁶⁶ These generic drugs must be used in the domestic market and cannot be exported to other markets.

Compulsory licensing hinders the market in developed companies. If the government ignored the patent rights of one company in favor of another, it would end innovation in the country. However, in developing countries, compulsory licensing may be the only way that medicines critical to people's survival get to the poorest citizens. Thus, in developing countries, it does not help the populace to have a strong intellectual property regime.

Compulsory licensing is primarily a humanitarian concept. The legislature's hope is that the compulsory license will result in an increase of life-saving medicines within his country.⁶⁷ However, the drug companies oppose such legislation because it leads to the dilution of intellectual property rights in developing countries and does not allow the innovator to be properly compensated for his drug. Pharmaceuticals are afraid that the developing countries will begin to see obtaining drugs through a compulsory license as the norm as opposed to an exception in the case of crisis.⁶⁸

⁶⁴ Sell, *supra* note 52, at 500.

⁶⁵ *Id.*

⁶⁶ Divya Murthy, Note, *The Future of Compulsory Licensing: Deciphering the Doha Declaration on the TRIPS Agreement and Public Health*, 17 AM. U. INT'L L. REV. 1299, 1307 (2002).

⁶⁷ Sara M. Ford, Note, *Compulsory Licensing Provisions Under the TRIPS Agreement: Balancing Pills and Patients*, 15 AM. U. INT'L L. REV. 941, 966 (2000).

⁶⁸ *Id.*

B. How

Article 31 of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement allows compulsory licensing.⁶⁹ There are five criteria for a compulsory license: (1) the licensee must have applied to the patent-holder for authorization, (2) but did not obtain it; (3) the license cannot be exclusive to one company; (4) the use of the license is limited to the original purpose and (5) during the time when such circumstances still exist; and the patent-holder receives proper compensation from the drug sales.⁷⁰ Article 31 requires the country be in the grip of a “national emergency” that the patented drug can alleviate.⁷¹ On the surface, compulsory licensing seems like a good way to alleviate crushing health crises in developing countries. However, often the countries do not have the production infrastructure to implement the compulsory license they have been granted; they are unable to exercise the compulsory license not because of right, but because of ability.

Section F of Article 31 requires production of the compulsorily licensed drug to occur mainly in the domestic market of the licensing country.⁷² The architects of TRIPS intended to block any country with a compulsory license from exporting the drugs to countries where the patent is protected with this section.⁷³ However, Section F has the indirect effect of preventing countries unable to make the generics from importing them from another country with the compulsory license. As a result, Section F blocked the poorest of developing nations from getting the medications they needed.

The WTO Ministerial Conference in Doha in November 2001 did not address parallel trade in pharmaceuticals for developing countries.⁷⁴ The WTO recognized this, and in their ministerial, urged the TRIPS Council to find a solution and “report back to the General

⁶⁹ Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakech Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments – Results of the Uruguay Round vol. 31, 33 I.L.M. 81, 93 (1994) [hereinafter TRIPS Agreement].

⁷⁰ *Id.*

⁷¹ See WTO Ministerial Conference, Declaration on the TRIPS Agreement and Public Health, Nov. 20, 2001, ¶ 5, available at http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm (last visited May 27, 2005) [hereinafter Doha Ministerial Declaration]. Paragraph 5 provides a description of a national emergency: health crises such as AIDS, tuberculosis, malaria and other diseases likely to spread broadly.

⁷² Press Release, World Trade Organization, Decision Removes Final Patent Obstacle to Cheap Drug Imports (Aug. 30, 2003), available at <http://docsonline.wto.org> [hereinafter Final Patent Obstacle].

⁷³ *Id.*

⁷⁴ Final Patent Obstacle, *supra* note 72.

Council before the end of 2002.”⁷⁵ Due to a deadlock between the members, the Council missed this original December 31st deadline.

The United States and EU took opposite sides in this debate. While the United States signed the TRIPS agreement, it claimed countries taking advantage of compulsory licensing under TRIPS in fact violated TRIPS. The EU was much more willing to allow parallel trade in the context of the developing world’s AIDS crisis.

In December of 1997, three years after the TRIPS agreement, President Nelson Mandela of South Africa signed into law an act which allowed the Minister of Health to revoke the patents and issue compulsory licenses for several drugs that staved off the symptoms of HIV/AIDS.⁷⁶ National Institutes of Health created several of the drugs that South Africa marked for compulsory licensing, including AZT, DDI, and DDC. The NIH gave those patent rights to the pharmaceutical companies that manufactured them. The act also allowed for parallel importing so countries could take advantage of the discriminatory pricing policies and import the cheapest drugs.⁷⁷

The United States tried to stop both Thailand and South Africa from using compulsory licensing. PhRMA challenged the South African Medicines Act in South Africa’s high court with the full support of the Patent and Trademark Office, then-Vice President Gore, the U.S. Trade Representative and others.⁷⁸ The U.S. Trade Representative (USTR) also threatened Thailand with sanctions on their core imports if they did not stop plans to produce the generic version of the AIDS drug DDI.⁷⁹

The press became involved, and equated supporting strong patent regimes with preventing HIV/AIDS sufferers from getting critical medications.⁸⁰ The media portrayed PhRMA’s suit against South Africa and the USTR’s Thai sanctions as favoring patents over lives. Journalists pointed out that compulsory licensing under TRIPS “was

⁷⁵ Doha Ministerial Declaration, *supra* note 65. The parallel trade problem is often referred to as the “Paragraph 6” issue as it appears in paragraph six of the document.

⁷⁶ Patrick Bond, *Globalization, Pharmaceutical Pricing, and South African Health Policy: Managing Confrontation With U.S. Firms and Politicians*, 29 INT’L HEALTH SERVICES 768 (1999). The Act is the South African Medicines and Medical Devices Regulatory Authority Act of 1997.

⁷⁷ South African Medicines and Medical Devices Regulatory Authority Act, Article 15c (1998). Thailand also tried to take advantage of compulsory licensing to provide medication to their AIDS population.

⁷⁸ Sell, *supra* note 52, at 501.

⁷⁹ *Id.*

⁸⁰ Karl Vick, *African AIDS Victims Losers of a Drug War*, WASH. POST, Dec. 4, 1999 at A1.

intended as a lifeline. But, in practice, any country reaching for this lifeline has been handcuffed by United States trade negotiators.”⁸¹

The United States position against compulsory licensing was further undermined by the Health and Human Services’ reaction to the anthrax scare.⁸² U.S. Secretary of Health and Human Services threatened Bayer, the producers of Cipro, that the United States would issue a compulsory license unless Bayer reduced its price for the government.⁸³ This move garnered many critics, who pointed out that anthrax caused less than a dozen deaths, while AIDS is cutting a wide swath through the populations of both Thailand and South Africa. In 1999, PhRMA and the U.S. Trade Representative dropped their suit against South Africa under pressure from international rights groups and the press.⁸⁴

Despite this relaxed position on compulsory licenses, the United States was still reluctant to allow parallel trading in humanitarian cases. As stated before, compulsory licensing is not an option for countries without the infrastructure to create the generic drugs. In the case of these developing nations, parallel trading is the only way they can obtain the drugs necessary to alleviate their medical crises. But parallel trade was still prevented by Article 31(f).⁸⁵ Since the paragraph six problem was the only intellectual property issue still undecided after the Doha Ministerial Conference, it was necessary to find a compromise that all members of the WTO would agree to.

The EU was more open to parallel trade as a solution to the paragraph six problem and accepted the original proposal.⁸⁶ After the WTO missed the 2002 deadline, the EU proposed a tiered pricing system for AIDS drugs similar to that used already for vaccines and contraceptives.⁸⁷ Under this system, the drug producing companies submitted their bids to international agencies who handle the costs and burden of distribution. While the drugs sell at a fraction of their cost in developed countries, drug companies still make a small profit. This system allows poorer countries to ignore barriers on parallel trade and focus on their health problems.

The United States rejected this proposal. In a letter to the European trade representative, the U.S. Trade Representative Robert

⁸¹ *Id.*

⁸² Murthy, *supra* note 60, at 1314-15.

⁸³ *Id.*

⁸⁴ Dolmo, *supra* note 23, at 138.

⁸⁵ See TRIPS Agreement, *supra* note 63.

⁸⁶ Elizabeth Becker, *Poor Nations Can Purchase Cheap Drugs Under Accord*, N.Y. TIMES, Aug. 30, 2003, at A14.

⁸⁷ Donald G. McNeil, Jr., *U.S. at Odds With Europe Over Rules on World Drug Pricing*, N.Y. TIMES, July 20, 2001 at A1.

Zoellick claimed that a tiered pricing system would erode patent protections.⁸⁸ He reasoned that while there are only a few drugs that treat AIDS, the diseases that affect those with AIDS are numerous: malaria, tuberculosis, pneumonia, meningitis, fungal infections, and cancer.⁸⁹ The Bush administration and the pharmaceutical industry believe that if they discount AIDS drugs, Africa would begin to ask for discounts on drugs treating these secondary diseases. The domino effect would create compulsory licenses for many major drugs and the drug companies would lose much of their revenue.

Zoellick also asserted that the lack of cheap AIDS drugs in Africa is a function of the “enormous infrastructure problems plaguing this region, rather than drug prices.”⁹⁰ Zoellick believed the drug companies should be trusted to provide their products at the lowest possible price. He also opposed any system proposed by the EU that regulates world drug prices or creates a database to track varying drug cost in different markets.⁹¹ This resistance led Doctors Without Borders drug price specialist Ellen t’Hoen to claim the European Union does not want the \$10 billion dollar fund to “turn into a subsidy for Big Pharma, and the United States is saying the reverse.”⁹²

On August 30, 2003, the WTO developed a compromise that suited all members, and allowed for parallel trade to nations in medical crises.⁹³ Those countries may obtain a compulsory license to a patented drug; they cannot produce it, but may import it from another “eligible importing Member” that has a compulsory license to the drug.⁹⁴ The importing Member must take “reasonable measures” to make sure the drug imported into the country is not re-exported to another country.⁹⁵

In an effort to confine the parallel licensing only to the most needy countries, the United States convinced several countries not to take advantage of the parallel licensing provision. Those countries—China, Korea, Israel, Kuwait, Mexico, Qatar, Singapore, Turkey and the United Arab Emirates—announced separately that they would only use the system in “situations of national emergency or other cir-

⁸⁸ *Id.*

⁸⁹ *Id.*

⁹⁰ *Id.*

⁹¹ *Id.*

⁹² *Id.*

⁹³ Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, Decision of the General Council, Aug. 30, 2003, *available at* http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm (last visited May 27, 2005).

⁹⁴ *Id.*

⁹⁵ *Id.*

cumstances of extreme urgency.”⁹⁶ The Bush administration also stated it wanted the measure restricted to a certain number of diseases to prevent the domino effect with other compulsory licenses, but no such stipulation was made in the compromise.⁹⁷

Throughout the WTO negotiations, the United States maintained its anti-patent weakening position, forcing the rest of the WTO to adjust their policies to reflect this stance.⁹⁸ The EU proves itself more open to measures that would potentially damage the pharmaceutical industry, such as the pricing database, tiered pricing systems, and parallel trading for compulsorily licensed drugs.

In countries where the general population cannot afford the medication they need, parallel trade may benefit the patent holder. Often the sick in developing countries are priced out of buying medication altogether; the average yearly wage of South Africans barely covers the costs of buying AIDS medication for that year. Since Africa accounts for only 1.6% of the global market for pharmaceuticals, it seems unlikely that parallel trading in South Africa is affecting the ability of the pharmaceutical companies to conduct R&D.⁹⁹ Although the drug companies feared a domino effect of compulsory licensing, such a situation has not yet occurred, nor is it likely to constitute a “national emergency” under the August 30th compromise.¹⁰⁰

VI. CONCLUSION

During the last decade, the United States has acted as the agent of the pharmaceutical companies, protecting their patent rights and drug profits above public health concerns. This position garnered much criticism from the world at large. While the United States agreed to the August 30, 2003 declaration about parallel trade, the declaration is not legally binding.¹⁰¹ Perhaps the United States will adopt the same policy toward parallel trading that they had towards compulsory licensing after TRIPS. However, the criticism of the world at large and the press may stop any attempts to prevent the developing world’s access to AIDS medications.

Europe is much more open to the concept of parallel trade as a panacea for the medication crises in the developing world. Less wed-

⁹⁶ Press Release, World Trade Organization, Decision Removes Final Patent Obstacle to Cheap Drug Imports (Aug. 30, 2003), *available at* http://www.wto.org/english/news_e/pres03_e/pr350_e.htm (last visited May 27, 2005).

⁹⁷ Elizabeth Becker, *In Reversal, U.S. Nears Deal On Drugs for Poor Countries*, N.Y. TIMES, Aug. 28, 2003, at A1.

⁹⁸ Weissman, *supra* note 6, at 1084.

⁹⁹ Dolmo, *supra* note 23, at 155.

¹⁰⁰ Becker, *supra* note 80.

¹⁰¹ Final Patent Obstacle, *supra* note 72.

ded to the concerns of the pharmaceutical companies, the EU is quicker to place the health concerns of the developing world over the intellectual property rights of the drug patent holder. This seems to be the WTO's vision as well. Pascal Lamy, the European Trade Representative who negotiated with Robert Zoellick during the 2002 deadlock, recently became that organization's fifth Director-General. The economic results of the 2003 compromise will most likely determine how the WTO acts in future.