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Pharmaceutical Price Controls in the European Union, Their Impact, and Potential Remedies

“If we do not find better ways to share the burden of developing new drugs and biologics, all of us will suffer.”¹

Introduction

In nearly every developed country in the world, with the exception of the United States, pharmaceutical prices are artificially set at a low level. This price controlling directly results in inflated prices in the United States (US), fewer pharmaceuticals coming to the market, and reduced availability worldwide. Reduced pharmaceutical availability particularly impacts developing and least developed countries. This shortsighted practice fails to consider social and economic implications, and is structured to circumvent domestic patent laws and international treaties.

Controlling the price of pharmaceuticals has the short-term local effect of lowering drug prices in a particular country. This may be a reasonable practice on a small scale in developing countries where low-income levels make full price payment nearly impossible. This paper takes issue with price controls in developed countries, where full price payment is possible, yet a government imposes pricing restrictions to allow citizens to pay less than their fair share.

¹ Mark B. McClellan, Comm’r, U.S. Food and Drug Admin., Speech before the First International Colloquium on Generic Medicine (September 25, 2003), *available at* <http://www.fda.gov/NewsEvents/Speeches/ucm053614.htm> (last visited Nov. 24, 2009) (discussing the issue of pharmaceutical price controls).

At a time when the health care issues in US politics are reaching a boiling point, it is important to understand a root cause of the high drug prices in the US: namely that US consumers are forced to subsidize the rest of the world's drugs, even in countries with income levels comparable to those in the US. Further it is important to address possible solutions to this inequitable situation. This paper will discuss price controls, particularly in the European Union (EU), additional practices that deflate the price of pharmaceuticals in the EU, and the effect of these controls. Finally this paper will analyze how these practices violate the spirit and letter of international patent law, and propose avenues available to remedy the situation.

1. Pharmaceutical Market Basics

Pharmaceutical products (drugs) are unique in two ways: first, they are generally just chemical compounds that have special effects on the human body, and second, they cost a tremendous amount of money to develop. Since drugs are chemical compounds, they are very easy to copy using fairly basic laboratory equipment. One could easily copy a drug, manufacture it, and charge a lower price without having to invest money to research and develop the drug. Drug development costs are enormous because it is difficult to predict drug efficacy and safety. Thousands, even millions of compounds are developed that are found to be ineffective or unsafe for every one drug that goes to market. To further increase this cost, there is a long and arduous path a compound must take through the FDA or other government testing programs to ensure safety.² As of

² Neal Masia, The Cost of Developing a New Drug (Apr. 23, 2008) *in* Focus on Intellectual Property, 82-83 (U.S. Department of State, Bureau of International Information Programs) *available at* <http://www.america.gov/st/econ-english/2008/April/20080429230904myleen0.5233981.html> (last visited Feb. 11, 2010).

2008, for each drug that was brought to market, the amount spent on research and development (R&D) and testing ranged from \$800 million to \$2 billion.³

Patent protection is essential to the pharmaceutical industry because of the huge cost of drug development, coupled with the ease with which they can be copied. Patents provide vital protection by temporarily allowing the drug patent holder to be the only one who can sell the patented drug so that they can charge enough for the product to recover their cost. The pharmaceutical industry, perhaps more than any other industry, relies on the full protection of patents to recover their R&D investment, to stay in business and to continue making life-saving products. This heavy reliance on patent protection means that patent-limiting regulations, or any other regulations that may circumvent patent protection have a substantial negative impact on drug developers. Price controls on pharmaceuticals are an example of a program that actively circumvents patent protection.

2. Price Controls

A. What are Pharmaceutical Price Controls?

Pharmaceutical price controls are government controlled pricing schemes on drugs that lower the price from what a patent holding drug manufacturer would normally charge. In other words, price controls on drugs allow the government to circumvent a patented drug developer's right to charge a price that allows it to recover its R&D expenditures and make a profit. The implementation of price control schemes may be done in different ways in different countries.⁴ Typically these schemes involve a number

³ *Id.*

⁴ Margaret K. Kyle, Pharmaceutical Price Controls and Entry Strategies, 89 Rev. of Econ. & Stat. 88 at 92-93 Feb. 7 2007.

of different control regulations, however all of the EU countries have a regime that significantly restricts the pricing of pharmaceuticals.⁵

Some countries use a reference pricing system, where they set their price based on the price paid in other countries.⁶ In other countries the price of a drug may be negotiated between the government and a drug company- resulting in lengthy, inefficient and tense discussions.⁷ Profit, volume, and margin controls are also commonly regulated.⁸ Demand-side controls such as capping the total cost of drugs a doctor can prescribe, or a pharmacist can sell, may result in lower prices for consumers, but may also result in less drug access.⁹ Finally, many countries set a price floor on generic drugs (drugs that replicate off-patent drugs). This price floor supposedly promotes generic drug production, but results in much higher generic drug prices than in an uncontrolled (i.e. “US”) market.¹⁰

B. Who Implements these Price Controls?

Pharmaceutical price control schemes are not only implemented by developing nations who may require lower priced drugs for the wellbeing of their citizens, but also in developed countries with income levels near US levels. These countries include those of the European Union, Australia, Japan, and Canada, among others.¹¹ The extent of price control does not correspond to the average income of a country.¹² For example wealthy

⁵ *Id.*

⁶ *Id.*

⁷ *Id.*

⁸ *Id.*

⁹ *Id.*

¹⁰ US Dept. of Commerce. International Trade Administration, Pharmaceutical Price Controls in OECD Countries, 2004, at x, 23-24.

¹¹ *Id.* at viii.

¹² McClellan, *Supra* note 1.

countries such as France and Germany implement more restrictive pricing schemes than low-income Poland.¹³ This paper will focus on the European Union because of its widespread price control schemes, because many countries are fully developed- having income levels similar to the US, and because it comprises a number of countries at different development levels.

C. Why are these price controls implemented?

Generally, price control schemes are government responses to government created problems over the last thirty years.¹⁴ They are, by and large, implemented to curb the rising costs of pharmaceutical products. However, these increased costs are primarily a consequence of government regulations relating to drug approval, rather than any sort of corporate greed. Additionally, as socialized medicine has become more pervasive throughout Europe, the need to limit the tax burden and government spending emerged. One solution chosen to curb this spending was for government sponsored health care to pay less for pharmaceuticals. When a healthcare system has the power to pay whatever it wants, it is no surprise that price controls have been so uniformly implemented in the EU.

Supporters of price controls may claim that a patent holder has strong monopoly power and therefore price controls on drugs are justified.¹⁵ This monopoly, however, is not as absolute as these supporters would lead one to believe.¹⁶ There appears to be a misconception that because a drug is patented, it has an absolute monopoly on its

¹³ *Id.*

¹⁴ Kyle, *Supra* note 4.

¹⁵ Frank R. Lichtenberg & Tomas J. Philipson, The Dual Effects of Intellectual Property Regulations: Within- and Between- Patent Competition in the US Pharmaceutical Industry, 45 J. Law & Econ. 643, 644-45, 667 (Oct. 2002). (Suggesting in the concluding remarks that “a patent does not always confer great monopoly power in the usual sense of being able to raise price without substantial substitution.”).

¹⁶ *Id.* at 644-45

market.¹⁷ A patent does limit who can sell a particular product. However, in the case of drugs, there are often multiple compounds that can treat the same ailment.¹⁸ In practice there is a large amount of between-patent competition because competitors design around the patented drugs.¹⁹ In other words, once a drug is patented, it is published, allowing others to understand how the drug works. With this knowledge it is often possible to create a drug that is even more effective yet does not infringe the existing patent. Designing around patents results in competition even with patented drugs; competition causes prices to fall, and increases innovation.²⁰ Therefore, the concept of absolute monopoly for patented drugs is a misunderstanding, and does not provide support for price controls.

Price control supporters may also note that drug developers are not *forced* to sell a product in a given market, but for many life-saving drugs, it is unlikely that a drug producer could refuse sale without facing serious consequences. Threats of non-sale may be effective during price negotiations, but if a major drug developer were to refuse to sell its drugs in a particular country, while maintaining patent protection, the potential public outcry could be enormous.²¹ The press would no doubt vilify the company as heartless and evil. The Cipro controversy following the anthrax scare after 9/11 is an example of one such response.²² Moreover, there is a potential that a country could respond to the

¹⁷ *Id.* at 667

¹⁸ *Id.*

¹⁹ *Id.*

²⁰ *Id.*

²¹ Kyle, *Supra* note 4.

²² For a discussion of the CIPRO controversy, see IPFrontline.com , Bayer-CIPRO® - A Case For Overriding Patent Owner Rights?, <http://www.ipfrontline.com/depts/article.asp?id=1346&deptid=6> (last visited Feb. 11, 2010).

non-sale of a life-saving drug with a compulsory license. Compulsory licenses are licenses granted on patented articles, issued by the government without the patent holder's permission.²³ These compulsory licenses are permissible, yet are rarely used.²⁴ Were a drug company to refuse to sell an important drug, it is certainly possible that the conditions for a compulsory license could be met.²⁵ Finally, it is possible that not making a drug available could be seen to be an abuse of IP rights and an unreasonable restraint of trade. This could allow member countries to take appropriate measures to combat the non-sale of a patented drug.²⁶ Thus, in reality, the ability of a patent holder to refuse to sell certain drugs in a given market is quite limited.

Finally, though drug companies are profitable businesses, their profits are not staggering, and they are certainly not gouging consumers to reap windfall profits. Drug companies typically make equal to less profit than other comparable large corporations, like those in the communications industry for example. 2008 operating incomes (Operating Income = Operating Revenue minus Operating Expenses; a simple measure of profit excluding interest and taxes) of Pfizer, GlaxoSmithKline, Verizon, and AT&T

²³ See Agreement on Trade-Related Aspects of Intellectual Property Rights, [hereinafter TRIPS], Article 31 Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, THE LEGAL TEXTS: THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS 320 (1999), 33 I.L.M. 1197, 1209 (1994). (TRIPS is an international minimum standards agreement on IP rights).

²⁴ *Id.*

²⁵ TRIPS Article 31, 33 I.L.M. 1197, 1209 (TRIPS Article 31 sets forth a series of requirements that must be met before a compulsory license can be granted. Some noteworthy requirements include efforts to obtain authorization, unless there is a national emergency or other circumstance of extreme urgency, at part (b); a non-exclusivity requirement at part (d); and the right holder must be paid "adequate remuneration in the circumstances of each case" in part (h)); For a more thorough discussion of compulsory licensing of pharmaceuticals See generally Sara M. Ford, Compulsory Licensing Provisions Under the TRIPS Agreement: Balancing Pills and Patents, 15 Am. U. Int'l L. Rev. 941 (2000).

²⁶ TRIPS Article 8, at 33 I.L.M. 1197, 1201.

demonstrate this. In 2008 Pfizer and GlaxoSmithKline had operating incomes of \$9.7 Billion and \$7.1 Billion, respectively.²⁷ Meanwhile Verizon and AT&T reaped operating incomes of \$16.9 Billion and \$23 Billion, respectively.²⁸ Thus it is clear that the profits of major drug companies, while high, are near, or less than the profits other large corporations.

3. Other Schemes Implemented by the EU to Reduce Pharmaceutical Prices

As if controlling the price of drugs in a country were insufficient, EU members engage in other practices that further erode and circumvent patent protection on drugs. For the purpose of this paper, these practices will be included in the “price control” term. One of these practices is called parallel importing: the sale of drugs bought in one country and sold in another country.

Parallel importing is an outgrowth of the EU policy of having a free movement of goods across borders²⁹, but it raises serious patent and fairness issues. There is a large

²⁷ Moneycentral.msn.com, Pfizer Inc – MSN Money, <http://moneycentral.msn.com/investor/invsb/results/statemnt.aspx?Symbol=pfe> (last visited Feb. 10, 2010); Moneycentral.msn.com, GlaxoSmithKline PLC– MSN Money, <http://moneycentral.msn.com/investor/invsb/results/statemnt.aspx?Symbol=GLAXF> (last visited Feb. 10, 2010).

²⁸ Moneycentral.msn.com, Verizon Communications Inc – MSN Money, <http://moneycentral.msn.com/investor/invsb/results/statemnt.aspx?Symbol=US%3aVZ> (last visited Feb. 10, 2010); Moneycentral.msn.com, AT&T Inc – MSN Money, <http://moneycentral.msn.com/investor/invsb/results/statemnt.aspx?Symbol=US%3AT> (last visited Feb. 10, 2010).

²⁹ Mattias Ganslandt & Keith E. Maskus, Parallel Imports of Pharmaceutical Products in the European Union, 3 (Research Institute of Industrial Economics Working Paper No. 546) (2001) available at <http://swopec.hhs.se/iuiwop/papers/iuiwop0546.pdf> (last visited Feb. 16, 2010); See also Tim Volkheimer, Note, Patents and the Free Movement of Goods: A Shift Towards European Arbitrariness?, 15 Colum. J. Eur. L. 495, 499-500 (2009) (Discussing a court’s reasoning that “to curtail the intra-Community trade on the

disparity in the development levels of the EU member countries, with some being fully developed and some being impoverished nations.³⁰ In lower income countries such as Greece or Poland, low cost drugs may be needed because of a limited ability to pay.³¹ However, because of parallel importing, it is legal to sell drugs produced and sold at lower prices in Greece or Poland in any other country in the EU regardless of ability to pay.

Parallel importing appears to interfere with patent protection, but has been found not to by EU case law.³² EU courts instead encourage this practice, favoring free flow of goods over patent and IP protection.³³ Currently, patents are issued separately in each country in the EU. In other words there is no single EU-wide patent. By widely accepted international treaty, a patent gives a patent holder the right to control the first sale of a product exclusively.³⁴ It follows therefore, that a patent owner who has a patent in high-income Switzerland should be able to control the first sale of its drug *in Switzerland*, regardless of whether it has been produced in Switzerland, or imported from elsewhere, because the Swiss patent gives the patent holder rights *in Switzerland*. However EU case law holds otherwise, and in so doing encourages practices that conflict with patent protections and patent policies.

basis of IPRs would lead to an isolation of markets within the common market, contrary to the essential purpose of the Treaty.”).

³⁰ US Dept. of Commerce. International Trade Administration, *Supra* note 10 at 17, Figure 4 (Note GDP Per Capita row, with Gre (Greece) and Pol (Poland) having substantially lower values compared to the US, and the remainder having GDP nearer to the US number, with Switzerland in particular having GDP higher than the US).

³¹ *Id.*

³² See Volkheimer, *Supra* note 29 at 501-506 (discussing a series of EU court rulings on the issue of patent rights, free movement of goods in the EU, and patent exhaustion).

³³ *Id.*

³⁴ TRIPS Article 28, 33 I.L.M. 1197, 1208.

Under the current EU system, parallel importing is permitted based on what is called the exhaustion doctrine. This doctrine holds that if a drug has been sold in one country, the patent holder has already profited by the sale of their product, and the export and resale of the drug in another country is permissible.³⁵

At first glance the practice of parallel imports violates patent rights exclusively granted under the Trade Related Aspects of Intellectual Property Rights Agreement (TRIPS) Article 28: the right of a patent holder to control the imports and sales of their patented products.³⁶ However, the footnote immediately after these rights conferred, footnote 6, indicates that these rights are subject to TRIPS Article 6. Article 6 deals with the exhaustion doctrine, and unfortunately, allows countries to craft laws to circumvent the exclusive patent rights granted in Article 28, if the law can be squeezed into the exhaustion doctrine framework.

The EU case law fails to appreciate that price controls prevent a fair profit from being realized; therefore the policy behind the exhaustion doctrine does not fully apply to products in a price controlled market. This lack of understanding has led the courts to come to a questionable conclusion regarding the legality of parallel importing. The policy supporting exhaustion is that it is unfair for a company to profit twice from the sale of a good (once in each country).³⁷ This is a fair and reasonable policy *assuming* that a company was able to fairly profit from the first sale. In a price controlled market, since profits are limited, the patent holder does not fairly or fully benefit from the first sale of

³⁵ See Volkheimer, *Supra* note 29 at 504-06, (discussing Case C-187/80, *Merck v. Stephar*, 1981 E.C.R. I-2063, which held that a patent was exhausted when sold in Italy was being imported into the Netherlands).

³⁶ TRIPS Article 28 33 I.L.M. 1197, 1208.

³⁷ *Id.*

their product. Since a pharmaceutical patent holder does not fully benefit from the first sale of their product in the EU, the exhaustion doctrine should not apply. Patent holders should have the right to control the import and sale of their products as explicitly granted in TRIPS in each country that it holds a patent in, without interference of the exhaustion doctrine.³⁸

To combat parallel importing and ensure that further R&D is possible, pharmaceutical companies must limit production volume to increase the probability that the drugs produced in one country will stay there. EU courts have upheld this practice.³⁹ In the *Glaxo* case an EU court held that a drug manufacturer cannot refuse ordinary orders for drugs, but can limit a drug supply based on past business dealings, and the size of orders in relation to the requirements of the market.⁴⁰ The downside to limiting production volume is that there is a very real potential that those in need in the supply-limited country would be unable to get drugs, because they would have been sent elsewhere to sell for a greater profit.

4. The Result of EU Price Controls

Price controls circumvent the economic incentive provided by patent protection and therefore substantially limit the value of a patent and the benefits it provides. The results of weakened EU drug patents are inflated US prices, and decreased pharmaceutical innovation. Price controls limit a drug developer's ability to recover

³⁸ TRIPS Article 28.1, 33 I.L.M. 1197, 1208.

³⁹ Joined Cases C-468/06 to C-478/06, *Sot.Lélos kai Sai EE and others v. GlaxoSmithKline AEVE Farmakeftikon Proionton*, 2008 E.C.R. I-7139 (hereinafter “the Glaxo case”).

⁴⁰ *Id.*

costs, there is a decreased incentive to invest \$1 billion to develop a drug, resulting in fewer health enhancing drugs being developed, and a lower quality of life worldwide. Why would an investor want to risk such an enormous sum of money if it is unlikely to be returned with a profit? The answer is that no sane investor would. This is why unadulterated patent protection is so essential.

The practice of controlling the price of drugs is admittedly very attractive at first glance: why pay more when the government can keep your prices low? The practice becomes less attractive however, to anyone who would consider the consequences of restricting an industry: shifted costs to the unrestricted US market, stifled medical progress worldwide, and a furtherance of the AIDS crisis. In addition, price controls result in a circumvention of patent protection, heavily de-valuing pharmaceutical patents.

One direct consequence of pharmaceutical price controls is price shifting to the US consumer.⁴¹ If a price is artificially lowered in one market, a manufacturer will raise prices as much as possible in another market to cover its losses.⁴² This results in drug manufacturers raising prices in the US market to make up for losses they suffer in the EU, and the impact in the US is striking.⁴³ A worldwide drug price de-regulation would save US consumers between 4.9 and 7 billion dollars annually.⁴⁴ As of 2003, US consumers paid for approximately half of the pharmaceutical spending worldwide, while only consuming a small fraction of the prescription drugs consumed.⁴⁵ Currently in the

⁴¹ Staff of S. Comm. Of Republican Policy, 108th Cong., Pharmaceutical Price Controls Abroad: An Unfair Trade Policy (2003); *See also* US Dept. of Commerce. International Trade Administration, *Supra* note 10, at x.

⁴² *Id.*

⁴³ *Id.*

⁴⁴ US Dept. of Commerce. International Trade Administration, *Supra* note 10.

⁴⁵ McClellan, *Supra* note 1.

US, patented drug prices are almost prohibitively high, especially for those who do not have insurance. This high cost is due in large part to the fact that EU citizens do not pay fair prices for their drugs.

Another direct result of price controls is a limitation of innovation via substantially decreased R&D funding.⁴⁶ Innovative pharmaceutical companies (and any other company that does business by selling innovative products) reinvest the vast majority of their profits into research and development. This money goes to hire more people to work to find the next big thing: cancer drugs, AIDS vaccine, diabetes treatments, and so on. Price controls are estimated to reduce drug industry R&D investment by \$5-8 billion annually as of 2004.⁴⁷ Without these controls, the industry could introduce at least three to four new drugs annually.⁴⁸ Currently there are approximately 30 new drugs approved each year, meaning that there could be a 10%-13.3% increase in drug innovation per year.⁴⁹ Fewer new drugs results in a lowered quality of life on a worldwide scale.⁵⁰

Perhaps the most tragic result of price controls is that with less profits, and fewer drugs, pharmaceutical manufacturers are less able to be charitable when choosing how to manage their money. Drug companies have less monetary freedom and must put a higher percentage of profits into R&D, instead of providing low cost drugs and aid to under-

⁴⁶ *Id.*

⁴⁷ US Dept. of Commerce. International Trade Administration, *Supra* note 10.

⁴⁸ *Id.*

⁴⁹ *Id.*

⁵⁰ *Id.*

developed countries. Often those in developing countries cannot afford even the manufacturing cost of a complex new drug, and rely on aid from others.⁵¹

This lack of freedom may slow progress fighting the international HIV/AIDS crisis. HIV/AIDS is overwhelmingly a disease of the poor, and is at epidemic levels in parts of the world where it is impossible for citizens to pay for the high cost of manufacture of the newest treatments. Pharmaceutical companies would have far more freedom to provide HIV/AIDS treatments were they receiving a fair price for their pharmaceuticals in countries that could afford them, such as those of the EU.

Were pharmaceutical companies making the appropriate profits from drugs sold in the EU, they would have more money to donate to these developing countries, providing them with important drugs. However, because the EU and others do not pay fair prices for their drugs, profits to pharmaceutical companies are limited, and they do not have the freedom to support drug distribution in developing countries.

5. Price Controls Violate The Spirit and Letter of International Law

Price controls violate the spirit of TRIPS as stated in Article 7, fail to meet the minimum standards of TRIPS under Articles 28, and 66.2, and find no justification in Article 8.⁵² TRIPS is an international agreement organized by World Trade Organization (WTO), and a country must sign on to the agreement before they can be part of the WTO. All of the countries at issue in this paper (US, and EU countries) are members of the

⁵¹ Gavin Yarney, [Drug Companies Cut HIV Drug Prices in the Developing World](http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1118035/), 320 BMJ 1357. 2000 May 20, *available at* <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1118035/> (last visited Feb. 15, 2010).

⁵² *See generally* TRIPS Agreement, 33 I.L.M. 1197

WTO and TRIPS signatories. TRIPS is a minimum standards agreement, meaning that it sets the minimum amount of IP protection, though countries are free to provide more protection, they cannot provide less. Based on the plain language of the TRIPS agreement, pharmaceutical price controls violate the spirit and letter of the TRIPS agreement.

Pharmaceutical price controls implemented by EU countries violate the spirit of the TRIPS agreement as set forth in the objectives: Article 7.⁵³ Article 7 of TRIPS states:

“The protection and enforcement of intellectual property rights should *contribute to the promotion of technological innovation* and 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...*”
(Emphasis added).⁵⁴

Price controls fail to conform with the TRIPS objectives in three aspects: they do not promote technological innovation⁵⁵; they do not provide mutual advantages to producers and the users⁵⁶; and they are not implemented to be conducive to social or economic welfare, even for the countries who implement the controls.⁵⁷

EU countries are not contributing to the promotion of innovation when they circumvent patent protections by imposing of price controls; therefore they are in violation of TRIPS Article 7. Price controls do not contribute to the promotion of technological innovation because they limit profit and thus limit R&D investment for innovative drug companies. These newly created drugs could be life-saving cancer, heart

⁵³ TRIPS Article 7, 33 I.L.M. 1197, 1200.

⁵⁴ *Id.*

⁵⁵ US Dept. of Commerce. International Trade Administration, *Supra* note 10, at 25-27.

⁵⁶ *Id.*

⁵⁷ Kyle, *Supra* at 4; *See also* Jean Lanjouw, Patents, Price Controls and Access to New Drugs: How Policy Affects Global Market Entry, WHO Commission on Intellectual Property Rights, Innovation and Public Health, April 2005 at 5-8.

disease, or HIV/AIDS drugs. Price controls stifle technological innovation and run contrary to the TRIPS objectives of Article 7.

Price controls further fail to follow the objectives of TRIPS by failing to provide mutual benefit to producers, i.e. the pharmaceutical companies, in relation to the consumers. Price controls limit profits and thus discourage new drug producers. The resulting lack of benefits to producers is evidenced by a substantial exodus of drug R&D from Europe to the US corresponding to the imposition of price controls.⁵⁸ In 1990, 49% of worldwide pharmaceutical R&D was performed in the European Union, though as price controls become more pervasive, this number dropped to 37% by 2000, with the balance mostly moving to the unregulated US.⁵⁹ Price controls fail to provide a mutual benefit to drug producers, and again run contrary to the TRIPS objectives of Article 7.

Price controls are not conducive to social or economic welfare in that they result in fewer jobs and a decreased access to medicine, and therefore violate TRIPS Article 7. The exodus of European drug R&D means less research jobs are available in the EU. Additionally, price controls result in fewer drugs being released in Europe, and cause drugs to be released an average of one full year later than in the US.⁶⁰ The slower drug introduction is caused by strategic release by drug companies to influence prices in countries that use reference pricing, lengthy price negotiations, and other regulatory difficulties caused by the extensive pricing regulations in the EU.⁶¹ Drugs that are held from introduction because of price controls could save or enhance many lives, but do not because EU countries refuse to pay a fair price for them.

⁵⁸ Peter Mitchell, Price Controls Seen as Key to Drug Lag, *Nature*, April 2007, at 257.

⁵⁹ Kyle, *Supra* note 4, at 95.

⁶⁰ *Id.*

⁶¹ *Id.*; *See also* Lanjouw, *Supra* note 57.

Price controls unreasonably prejudice and interfere with the patent holder's right to sell, granted in TRIPS Article 28.1, because a drug patent holder is forced to sell its product at a set price, and is limited to realizing a negligible profit.⁶² It is generally recognized that the pharmaceutical companies creating new drugs make the vast majority of their profits in the United States.⁶³ The corollary to this is that only a negligible profit is made by selling pharmaceuticals in the EU and elsewhere. One of the main purposes of a patent is to allow recovery of R&D cost through sale. While TRIPS Article 30 allows limited exceptions to the exclusive rights conferred by a patent under Article 28, these exceptions cannot "unreasonably prejudice the legitimate interests of the patent owner".⁶⁴ Price controls unreasonably prejudice a drug patent holder's legitimate interests of recovering its R&D costs and making a reasonable profit through its right to sell. Therefore price controls interfere with a right granted in TRIPS Article 28.1.

Price controls are in fact disincentives to enterprises and institutions and discourage technology transfer to least developed countries, in violation of TRIPS Article 66.2.⁶⁵

Article 66.2 states:

Developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country members in order to enable them to create a sound and viable technological base.⁶⁶

Price controls discourage technology transfer to least-developed country members by limiting profits, and thus limiting the freedom of drug companies to provide assistance to

⁶² TRIPS Article 28.1 33 I.L.M. 1197, 1208.

⁶³ Lawrence Welch, Assistant General Patent Counsel, Eli Lilly and Co., personal communication, November 18, 2009.

⁶⁴ TRIPS Article 30, 33 I.L.M. 1197, 1209.

⁶⁵ TRIPS Article 66.2, 33 I.L.M. 1197, 1222.

⁶⁶ *Id.*

developing countries. When EU member governments impose price control structures, they are not providing incentives to enterprises or institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country members. Instead, they are discouraging such aid. Drug companies are forced to limit production and realize minimal profits in countries that can afford to pay fair price. This limitation means that they are unable to provide assistance to those who genuinely cannot afford to pay for desperately needed drugs. If fair price were paid by those able to pay it, pharmaceutical companies could have the flexibility to suffer a loss here and there by providing low cost new drugs to least-developed countries.

TRIPS Article 8.1⁶⁷ does not provide justification for price controls because price controls are not necessary, and do not protect public health. TRIPS Article 8.1 allows member countries to “adopt measures necessary to protect public health and nutrition”,⁶⁸ however price controls are not necessary in developed EU countries to protect public health, and even decrease public health and nutrition. These developed countries have average annual incomes similar to those in the United States⁶⁹, and their citizens are fully able to afford similar relative prices to what US consumers pay; therefore the price controls are by no means a necessity. Further, because price controls limit drug production and slow introduction of new drugs, they actually weaken public health. Therefore, price controls find no justification in TRIPS Article 8.1.

Similarly, TRIPS Article 8.2 also does not provide justification for price controls. Article 8.2 states: “Appropriate measures... may be needed to prevent the abuse of

⁶⁷ TRIPS Article 8.1, 33 I.L.M. 1197, 1201.

⁶⁸ *Id.*

⁶⁹ US Dept. of Commerce. International Trade Administration, *Supra* note 10.

intellectual property rights... which unreasonably restrain trade...⁷⁰ By charging market price in a country, pharmaceutical companies are not abusing their intellectual property, or restraining trade in any way. Therefore, price controls find no justification in TRIPS Article 8.2.

6. Governmental Recourses Against the EU's Pharmaceutical Price Controls

The Obama administration has committed to policing and enforcing their international agreements and international IP far more than in the past.⁷¹ The US Government has the power to remedy insufficient IP protection and unfair trade, and the issues of price controls and parallel importing of pharmaceuticals should be the place to start. It has been established that the EU's disregard of pharmaceutical patent holder's rights violates international treaty, burdens US consumers directly, and indirectly burdens healthcare worldwide. The question now is what can be done to remedy this. One option is to assert that price controls are not TRIPS compliant by filing a complaint with the WTO Dispute Settlement Body (DSB). Another option is via the US Trade Act, which allows the US to take retaliatory action against unfair and unreasonable trade practices regardless of whether or not they violate international agreements. Finally the Bipartisan Trade Promotion Authority Act provides the President substantial power to enter into trade negotiations and agreements to remedy unfair trade practices. Hopefully the Obama Administration will follow through on their commitment and utilize these options to remedy the issue of EU drug price controls to promote fair health care worldwide.

⁷⁰ TRIPS Article 8.2 33 I.L.M. 1197, 1201

⁷¹ Office of Science and Technology Policy, Executive Office of the President, [A Strategy for American Innovation: Driving Towards Sustainable Growth and Quality Jobs](#), 2009 at 15.

The US would be well within its rights to file a complaint to the WTO DSB for the EU's violations of TRIPS Articles 7, 28.1 and 66.2. The WTO dispute settlement process is fairly complex and beyond the scope of this paper.⁷² In brief, a complaint would be filed by one country against another. This complaint would then be considered by the DSB. The WTO dispute settlement process is governed largely by the WTO Dispute Settlement Understanding (DSU), which sets forth guidelines for handling the dispute.⁷³ Once a decision is rendered, the DSB's decision is supposed to be followed by any WTO member.

It is important to remember that as a matter of international law, any country can make whatever laws they wish, so the DSB's ruling is enforceable only by foreign economic retaliation, and fear of international scorn. Since EU member's price control practices have been going on for 20-30 years, and no action has been taken in the WTO, it is unlikely that recourse would be found through a complaint by the US against the EU to the WTO DSB.⁷⁴ That said, in light of the Obama administration's stated strong enforcement policy, perhaps the possibility is not so far fetched.⁷⁵

Another attractive avenue for recourse against these price controls would be

⁷² For a detailed discussion of the WTO dispute procedures *See generally* Overview of TRIPS Agreement – Enforcement, http://www.wto.org/english/tratop_e/trips_e/intel2b_e.htm#enforcement (last visited Feb. 10, 2010); *See also* Darya Haag, Time to Pay the Dues or can Intellectual Property Rights Feel Safe with the WTO?, Richmond Journal of Global Law and Business, 8 Rich. J. Global L. & Bus. 427, 432-436 (Fall 2009).

⁷³ The full text of the Dispute Settlement Understanding can be seen at: WTO | Dispute Settlement Understanding – legal text, http://www.wto.org/english/tratop_e/dispu_e/dsu_e.htm (last visited Nov. 15, 2009).

⁷⁴ Kyle, *Supra* note 4.

⁷⁵ Office of Science and Technology Policy, *Supra* note 71.

through the US Trade Act, particularly Section 301.⁷⁶ The full power of this act is beyond the scope of this paper, but section 301 and related provisions will be discussed in regards to their application to pharmaceutical price controls.⁷⁷ To begin, each year the Office of the US Trade Representative (USTR) releases a report called the “Special 301” report based on the provisions set forth in section 301 and related provisions of the Trade Act.⁷⁸ The Special 301 Report identifies countries that are violating, disregarding or circumventing IP protection and publicly reports on what these countries are doing.

Section 301 of the Trade Act identifies acts that require mandatory action by the USTR, or acts that allow action at the USTR’s discretion. Action *must* be taken by the USTR under §301 part (a)(1)(B) if:

- an act, policy, or practice of a foreign country —
- (i) violates, or is inconsistent with, the provisions of, or otherwise denies benefits to the United States under, any trade agreement, or
- (ii) is unjustifiable and burdens or restricts United States commerce;⁷⁹

Action *may* be taken by the USTR under part (b) of Section 301 if:

- (1) an act, policy, or practice of a foreign country is unreasonable or discriminatory and burdens or restricts United States commerce, and
- (2) action by the United States is appropriate...⁸⁰

This paper demonstrates that all parts of both sections (a) and (b) are satisfied, and therefore the USTR does have the authority to take action against price controls. Section 301 goes on to state that the USTR and the President have the authority to do anything within their power with respect to trade or “Any other area of pertinent relations with the

⁷⁶ United States Trade Act §301, 19 U.S.C. §2411 (2009).

⁷⁷ For an overview of Section 301 of the US Trade Act, *See generally* Lynne Puckett, Rules, Sanctions and Enforcement Under Section 301: At Odds with the WTO?, 90 Am. J. Int'l L. 675 (October, 1996).

⁷⁸ 19 U.S.C. 2242 (2009).

⁷⁹ 19 U.S.C. §2411 (2009).

⁸⁰ *Id.*

foreign country”.⁸¹ Such actions may include: suspending concessions of a trade agreement, imposing duties or import restrictions, or entering into agreements with the countries that compensate or remedy the problem.⁸² While a complete elimination of price controls is unlikely, it is probable that if the US Government committed to discouraging EU price controls, the economic impact could at least be lessened to the point where more profit could be realized in the EU.

In fact, pharmaceutical price controls have been addressed in Special 301 reports since 2005, though it seems little progress has been made. Beginning in 2005, in response to a US Department of Commerce report⁸³, the Special 301 Report has identified the need to address the issue of price controls beginning with international negotiations. Starting with fairly strong language in the 2005 Report, the language becomes increasingly vague and suggests that little progress has been made.⁸⁴ Notably between 2006 and 2008, the language on the subject is nearly identical, indicating that the US Trade Representative will “continue to promote expanded dialogues”.⁸⁵ Finally in 2009, the report does not specifically target any EU countries, and seems to be quite timid in condemning price

⁸¹ 19 U.S.C. §2411(b)(2) (2009).

⁸² 19 U.S.C. §2411(c)(1)(A)-(D) (2009).

⁸³ US Dept. of Commerce. International Trade Administration, *Supra* note 10.

⁸⁴ *Compare* Office of the United States Trade Representative 2005 Special 301 Report, 2005, at 9-12, *and* Office of the United States Trade Representative 2006 Special 301 Report, 2006, at 12-13, *with* Office of the United States Trade Representative 2007 Special 301 Report, 2007, at 13-15, *and* Office of the United States Trade Representative 2008 Special 301 Report, 2008, at 14-16, *and* Office of the United States Trade Representative 2009 Special 301 Report, 2009, at 7-8.

⁸⁵ Office of the United States Trade Representative 2006 Special 301 Report, 2006, at 12-13; Office of the United States Trade Representative 2007 Special 301 Report, 2007, at 13-15; Office of the United States Trade Representative 2008 Special 301 Report, 2008, at 14-16.

control practices.⁸⁶ Understandably negotiation progress is slow, however based on the progression of the language of the Special 301 reports, it appears that the issue has been pushed to the back burner. It is time for the President, through the USTR, to bring the issue to the forefront of EU-US relations, and put serious pressure on EU members to remedy the price control issues.

Finally the Bipartisan Trade Promotion Authority Act identifies a number of goals that are essential to fair trade, allocates a substantial amount of power to the President, and directs the President to act.⁸⁷ The Act specifically addresses two objectives of fair trade that are stifled by pharmaceutical price controls: preventing the circumvention of IP rights, and the inherent unfairness of price controls in any market.⁸⁸ With these objectives in mind the Act states that the President has the power to negotiate for more fair provisions, or for the elimination of offending provisions.⁸⁹

19 U.S.C. 3802 (b)(4)(B) states that a principal trade negotiating objective is: “to secure fair, equitable, and nondiscriminatory market access opportunities for United States persons that rely upon intellectual property protection”. Pharmaceutical price controls fail to do this, because by restricting the right to sell granted by a patent, a patent holder is not allowed fair market access.

Congress directly addresses the issue of price controls in 19 U.S.C. 3802(b)(8)(D). This section addresses the elimination of price controls as being a principal trade negotiating objective: “to achieve the elimination of government measures such as price

⁸⁶ Office of the United States Trade Representative 2009 Special 301 Report, 2009, at 7-8.

⁸⁷ Bipartisan Trade Promotion Authority Act, 19 U.S.C. 3801-13 (2009).

⁸⁸ 19 U.S.C. 3802 (b)(4)(B) (2009); 19 U.S.C. 3802(b)(8)(D) (2009).

⁸⁹ 19 U.S.C. 3802(c) (2009).

controls and reference pricing which deny full market access for United States products.”⁹⁰ It is important to note that Congress has directly stated that price controls constitute unfair trade, yet the practice by EU countries seems unimpeded.

The Act goes on to describe the powers allocated to the President; stating that if the President determines that any distortion of international trade adversely affects the US economy, and the purposes of the act will be promoted, the President may enter into a trade agreement and negotiations to remedy the issue.⁹¹

Utilizing the Bipartisan Trade Promotion Authority Act is the most probable course of action since it is the most diplomatic of the three options available. While the Act does not authorize the President to impose penalties on offending nations, it is a powerful tool to engage these nations in negotiations and dialogue in the hope of coming to a mutual resolution in the form of a trade agreement. A trade agreement may not be the perfect solution, but it could be a good start to alleviate the damage caused by drug price controls.

Regarding negotiations, one powerful approach the President could take would be to point out that if generic drug price floors were removed, the savings to consumers would nearly or fully compensate the savings from on-patent drug price controls.⁹² Price floors supposedly are in place to stimulate generic drug production in the EU. This may have been useful at a time when there was no generic drug production, but since there is a sufficient generic industry throughout the EU, generic drug price floors are wasteful. Moreover, removal of price floors would allow drug buyers (individuals or governments)

⁹⁰ 19 U.S.C. 3802(b)(8)(D) (2009).

⁹¹ 19 U.S.C. 3803(b)(1)(A) (2009).

⁹² US Dept. of Commerce. International Trade Administration, *Supra* note 10.

to pay less for generics and allocate more of their budget for new, patented drugs.⁹³ It does not make economic sense to have price floors in place for generics because their R&D costs are negligible, so their expenses are limited to what it costs to produce and distribute the product. Generic drug producers should be allowed to compete, in order to lower the cost of generic drugs.

7. Conclusion

The circumvention of patent rights by the wealthy EU member nations is unacceptable. The issue of pharmaceutical price controls must be brought into the political spotlight so that more of the world knows what the EU is doing: not paying their fair share for drugs, thereby limiting drug development, shifting costs to US consumers, and limiting health benefits to under-developed countries. Due to the nature of international relations, it is impossible for one country to force another country to change its laws. Despite this, there are avenues that the US government and drug companies can take to address the issue of EU price controls.

Ultimately, every country has the right to structure their laws however they like. Countries will continue to tiptoe the line established by TRIPS. However the EU's schemes for not paying fair value for what they get should be considered in international relations, negotiations, and trade. The above listed avenues must be pursued to ensure that new drugs continue to be developed, to curb the increasing cost of drugs to US consumers, and to allow low priced drugs to be provided to those in under-developed countries who cannot afford to pay.

⁹³ *Id.*