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Richard Wilder[1]

The Value of Intellectual Property Rights

Intellectual property rights in pharmaceuticals are often characterized as having a single benefit; namely, to maximize profits and competitiveness of the owners of the rights. This is a shortsighted and inaccurate perspective, particularly in the healthcare environment. Systems for protecting intellectual property rights, like other regulatory mechanisms, contribute to the establishment of a stronger, more sustainable and more effective public health infrastructure. In particular, patent and trademark systems help public health authorities ensure the quality of pharmaceutical products by preventing introduction of counterfeit or unregulated copies of products onto the market. Without adequate safeguards as to the origin of pharmaceuticals, countries face immense challenges in protecting the safety of their drug supply. Moreover, in respect of newer pharmaceuticals, patent systems facilitate the more rapid introduction of new products into markets by encouraging entry into the market by pioneer pharmaceutical manufacturers. This is a natural consequence of the positive stimulus that patent systems exert on a country's investment climate.

The challenges of providing pharmaceutical products to patients in developing and least developed countries are immense. For example, the regimen for treating patients afflicted with HIV/AIDS can encompass administration of 17 to 30 pills each day for the life of the patient. While this has provided life-sustaining treatment to many HIV/AIDS patients throughout the world, for many patients compliance with this regimen is impractical or impossible. As noted by many others in this conference, the provision of such a complex pharmaceutical therapy is an extremely difficult challenge for countries struggling to maintain the most basic health care services. In order to maximize the reach into this patient population, public health authorities need products that are simpler and more efficient to administer but which provide equivalent long-term benefits. And of course, we all must recognize the ultimate goal of producing a cure.

Research and innovation remain the prerequisite to obtaining these new products. Without investments to support research, one cannot find candidates. Without applied research and investment to develop products, test them and prove that they are safe and effective, one cannot convert candidates into products. In this respect, intellectual property rights play a singularly important role in promoting development and availability of new products to treat diseases. Intellectual property rights are essential for turning ideas into candidates, turning candidates into safe and effective products, and for delivering products into the market.

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[1] Powell, Goldstein, Frazer & Murphy. The views expressed in this paper are personal to the author and should not be ascribed to Powell, Goldstein, Frazer & Murphy or to its clients.

Against this backdrop, the practice of parallel imports presents numerous challenges and concerns. First, it is important to define what parallel importing is and how it can work. Parallel imports arise in response to the possibility of profitable arbitrage; namely, where there is a sufficient difference in the price of a product in two markets to justify a third party (the arbitrageur) procuring the product in a first market, transporting and selling it in the second market. Parallel imports are stimulated by this profit potential, and are not likely to occur in the absence of that profit potential.

The greater the price disparity, the stronger the stimulus to enter. However, companies that are likely to enter the business of parallel trade are not the usual participants in the pharmaceutical industry, such as pharmaceutical manufacturers, distributors, pharmacists or government health authorities. Support of a class of entities who exist outside the normal health care system, and who trade in pharmaceuticals but cannot vouch for the safety or quality of the products they sell, creates immense challenges for public health regulators. Indeed, concerns about quality of internationally traded pharmaceuticals are a priority for the WHO.

Parallel trade, if allowed, also has negative downstream impacts on the pharmaceutical distribution environment. For example, in recent months some pharmaceutical manufacturers have offered HIV/AIDS drugs in sub-Saharan African nations at deeply discounted prices. These price reductions would not be sustainable if the products placed on these lower-priced markets for the benefit of patients there were diverted and exported to higher priced markets. As described earlier in this conference, there are well-grounded economic theories that support freedom for companies setting prices in different markets in a way that most efficiently allows them to recover global costs of producing and marketing such products, including research and development costs. Indeed, in the ideal free market system, product manufacturers should have relative freedom to price their products at levels related to how buyers differ in their true price sensitivity.[2] In this respect, measures that distort or remove the price setting freedom of manufacturers must be viewed as extremely negative factors.

In this respect, there appears to be a general agreement on the need for protection against parallel imports. In the background papers for the workshop, both the secretariat of the World Health Organization (WHO) and the consultant to the World Trade Organization (WTO) recognize the important role that patent rights play in preventing the practice of parallel trade, and the consequential benefit of preventing diversion of lower-priced products into higher priced markets.[3] This paper, then, starts from the proposition that protection against parallel trade is desirable and provides a brief overview of the relevant provisions in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) and examples in national and

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[2] Danzon, Patricia, *The Economics of Parallel Trade,* Pharmacoeconomics: 13(3) 293, 295 (1998) (discussing so-called Ramsey pricing). In the real world, Ramsey pricing logic is subject to perturbations caused by interventions such as price controls, import duties, local taxes, differing retail mark-ups and differing regulatory regimes.

[3] *See More Equitable Pricing for Essential Drugs: What do we Mean and What are the Issues?, Background Paper for the WHO-WTO Secretariat Workshop on Differential Pricing and Financing of Essential Drugs*, Prepared by WHO Secretariat, p. 21 (2001) (Identified the need for controls "to keep products within intended markets" to allow differential pricing to succeed.)(hereinafter "WHO secretariat document"); *See also Workshop on Differential Pricing and Financing of Essential Drugs,* Background Note Prepared by Jayashree Watal, Consultant to the WTO Secretariat, p. 5-6 (2001) (hereinafter "Watal") ("For market segmentation to be effective for the purposes of differential pricing, it is necessary that not only should there be adequate means to prevent the diversion of the lower-priced product into the higher priced markets, but also an insulation of prices in the higher-priced market from any materially significant psychological or political effects that might flow from the existence of lower prices in the other markets.").

regional systems. Particular attention is given to patents as the form of intellectual property protection that most directly implicated in trade in pharmaceutical products.

Legal Issues Arising Under the TRIPS Agreement
National and Regional Law on Parallel Trade

With respect to patented products, "parallel imports" refers to goods that have been placed into circulation in a first market by or with the permission of the holder of the patent and then imported into a second market without the permission of the holder of such rights. The ability of the holder or licensee of intellectual property rights in that second market to prevent importation depends on the way "exhaustion" of rights are treated in that second market. Typically, patent rights in a particular product are "exhausted" only within the country of sale when products that embody such rights are first sold in that market. The European Community applies this concept on a regional basis (i.e., "regional exhaustion") by using the same concept of *limited* exhaustion within the single economic market. Thus, while products sold in one country of the European Union will exhaust rights in all countries making up the single market, this rule will not extend to products sold in a country outside the single market. In contrast, countries that apply "international exhaustion" hold that placing a product on a market anywhere in the world exhausts the patent rights in their market, even where the patent owner has prohibited such uses or actions by contract or terms of the sale.

Most countries, including most developing countries, provide for national, rather than international, exhaustion of patent rights in their national legislation. This is consistent with the view that Article 28.1(a) of the TRIPS Agreement confers on the patent owner the exclusive right to prevent others from importing patented products. Moreover, it is consistent with view that patents are independent legal instruments under the Paris Convention.

Some commentators have argued that the TRIPS Agreement removes any obligations to follow a national exhaustion only policy with respect to patents for WTO Members as a consequence of Article 6, which provides that:

> [f]or the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.

Article 6 has been variously described as an "agreement to disagree"[4] or proof that the TRIPS Agreement "says nothing about exhaustion."[5] The import of Article 6 should not be overstated. As a consequence of Article 6 of the TRIPS Agreement, WTO dispute settlement panels will not have subject matter jurisdiction over measures that address the exhaustion of intellectual property rights. Article 6 does not suspend the substantive obligations in Article 28.1 of the TRIPS Agreement. Thus, WTO Members are still obliged to provide an unconditioned right to prevent third parties from importing patented products.

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[4] Bronckers, Marco C.E.J., *The Exhaustion of Patent Rights Under WTO Law,* Journal of World Trade 32(5): 137, 142 (1998).

[5] Abbott, Frederick M., Commentary: The International Intellectual Property Order Enters the 21st Century, 29 Vand. J. Transnat'l L. 471, 478 (1996) (Abbott, 1996).

Some commentators have looked outside the TRIPS Agreement in evaluating the question of exhaustion of patent rights.[6] For example, it has been argued that "[r]ules restricting parallel importation are non-tariff barriers to trade that are inconsistent with the general terms, structure and spirit of the WTO and GATT 1994."[7] However, this is a perspective that contrasts markedly with the perspective expressed by other noted authors that "the TRIPS Agreement balances two principles: trade liberalization as well as increased intellectual property protection, with the restrictions on trade this entails"[8] Moreover, the TRIPS Agreement, by providing specific protection for rights holders to prevent importation of protected products established the "new rules" envisioned in the preamble to the GATT 1994, and should not be nullified through a strained reading of certain provisions of the GATT 1994.[9]

The specific examples of protection against parallel imports – in particular those of the United States and the European Union provided in this paper[10] - should be seen against the

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[6] There is more at work in the purported conflict between intellectual property and free trade than this short paper will allow me to address. Carsten Fink of the World Bank has written persuasively on the fallacy of drawing such a distinction, saying that

> the exhaustion doctrine is primarily an issue of IPRs policy--and not an issue of free trade or restricted trade. The free trade argument in the context of parallel trade has two fundamental shortcomings. First, the conditions surrounding parallel trade do not fit into the assumptions on which standard static (short-term effects) trade models supporting the case for laissez-faire trade are built. Second, a static analysis with regard to IPRs is insufficient . . . [it] would require the removal of all rights to intellectual property! . . . [T]he main rationale for protecting IPRs lies in their dynamic effects. . . . By granting exclusive rights and thus enhancing market power, rights to intellectual property allow title holders to appropriate their investments in creating intellectual property. Fink, C, *Does National Exhaustion of Intellectual Property Contradict the Principle of Free Trade?* P. 3-4 (Draft Paper for Conference on Exhaustion of Intellectual Property rights and Parallel Importation in World Trade, Geneva, Switzerland) (November 6-7, 1998).

[7] Abbott, First Report, p. 632 (citing Articles III and XI:1 of GATT 1994 as problematic in this regard).
[8] Bronckers, Marco C.E.J., *The Exhaustion of Patent Rights Under WTO Law*, Journal of World Trade 32(5): 137, 144 (1998)
[9] Specifically, some have cited Article III:4, which requires national treatment in respect of imported products, and Article XI:1 bans prohibitions or restrictions on importation of products, as examples of measures that would promote a concept of international exhaustion. Article III:4, however, is not violated if a WTO Member provides for national or regional exhaustion. In the case of national or regional exhaustion, products of local and foreign origin are accorded *the same treatment.* Each product is subject to the same national or regional laws for the protection of intellectual property – including restrictions on the ability of one other than the right holder to make a first sale of the product in that market – and intellectual property rights in each product are exhausted upon its placement on the national or regional market. Moreover, even if the enforcement of intellectual property rights were found to be a "quantitative restriction" within the meaning of Article XI, Article XX(d) of GATT 1994 permits WTO Members to take measures "necessary to secure compliance with laws or regulations which are not inconsistent with the provisions of this Agreement, including those relating to . . . the protection of patents, trade marks and copyrights, and the prevention of deceptive practices." Thus, arguments suggesting that national exhaustion only policies are inconsistent with GATT 1994 obligations simply do not hold.
[10] Further examples from developed countries that should be considered include Japan and Switzerland. Patent rights in Japan may be exhausted in respect of a product that is sold outside Japan without any reservations as to the patent rights in Japan. *See BBS Kraftfahrzeug Technik v. Kabushiki Kaisha Racimex Japan,* Case No. Heisei 7 (wo) 1988 (delivered July 1, 1997). In Switzerland, parallel imports are allowed in respect of products protected by trademarks, but are not allowed in the case of patented goods. *See Kodak (Suisse) v. Jumbo Markt Ag,* Case 4C.24/1999 (1999). Moreover, Brazil provides for protection against parallel trade in its patent law through the scope of rights granted and limitations of exhaustion of rights to national exhaustion. *See* Law No. 9,279 (May 14, 1996) (Article 42 provides the right to prevent

backdrop of the policy objectives of patent systems and patent exclusivity for specific products.[11] The exclusivity of the patent grant allows the patent holder to obtain sufficient profit to cover not only costs of production, but also of research and development.[12] The availability of strong and guaranteed patent rights creates a strong stimulus for investments, particularly from capital markets, due to the capacity of the innovator/patent owner to deliver strong returns. As discussed above, economic theory supports the idea of recovering those research and development costs as a global joint cost of serving all consumers worldwide. This can be achieved, it is suggested, by setting prices for pharmaceutical products at levels "inversely related to the price sensitivity of the consumer in different markets."[13] Maintaining barriers to parallel imports helps to achieve this goal – in particular where, as is being discussed in this workshop, the desire is to establish conditions supportive of decisions by individual manufacturers to significantly discount the price of their products in least developed countries.[14] Protection against parallel trade in patented products supports all of these goals.

Practices in the the United States of America

An authorized sale in the United States of a product that embodies a patented invention exhausts the U.S. patent rights as to use and sale of that product within the United States.[15] As a general rule a purchaser of such a product may use or resell the product without having to ask the patentees permission – but may not make a new version of the patented product.[16] This general rule does not apply where the patentee has placed conditions on the sale of the product.[17]

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third parties from importing a product that is the object of the patent. Article 43.IV indicates that the provisions of Article 42 do not apply to, *inter alia*, products that have been "introduced onto the *domestic market* directly by the patent holder or with his consent.")

[11] *See* Abbott, First Report, p. 612.

[12] Profits are less to "provide a reward" or "cover costs" for past research and development and more to pay for current and future research and development costs of an enterprise. This is consistent with the view of intellectual property protection promoting dynamic efficiency. *See* Maskus, K., *Intellectual Property Rights in the Global Economy*, p. 216 (2000) ("Over the long term . . . patents could result in new drugs coming onto the market, a dynamic gain.") (hereinafter "Maskus").

[13] Watal at 13.

[14] Protection against parallel trade also encourages investment in establishing distribution, service, and information networks in a given market. This is particularly true in the case of pharmaceuticals where the manufacturers continually update and provide information to physicians about their products. Arguments against parallel trade generally focus on price, in particular "as a useful policing device against the price collusion emanating from exclusive territorial restraints." *Maskus*, p. 211.

[15] *Hewlett-Packard Company, v. Repeat-O-Type Stencil Manufacturing Corporation, Inc.*, 123 F.3d 1445, 1451 (Fed. Cir. 1997) ("When a seller sells a product without restriction, it in effect promises the purchaser that in exchange for the price paid, it will not interfere with the purchaser's full enjoyment of the product purchased.")

[16] *Id.* at 1451 ("The authority to use and sell a purchased device, however, does not include the right to make a new device or to reconstruct one which has been spent. Reconstruction, i.e., the re-creation of a patented combination, is an infringement because such activity is beyond the implied authorization to use and sell a patented device.").

[17] In *Mallincrodt v. Medipart*, 976 F.2d 700 (Fed.Cir. 1992), the defendant in a patent infringement action had stated that a single use restriction associated with sale of medical devices was unenforceable under two theories, one of which was exhaustion. The Court of Appeals for the Federal Circuit rejected both theories of the defendant, noting in respect of exhaustion, that "[t]he rule is, with few exceptions, that any conditions which are not in their very nature illegal with regard to this kind of property, imposed by the patentee and agreed to by the licensee for the right to manufacture or use or sell the [patented] article, will be upheld by the courts." *Id* at 703.

When products subject to a U.S. patent are sold in a market outside the U.S. and subsequently sought to be imported, U.S. patent law gives the owner of a patent the right to prevent importation of such products.[18] Even prior to the introduction of the specific right to preclude importation of patented products, U.S. Courts have consistently held that in the event a product is placed on the market outside the United States, they will look for indications of *intent* of the owner of the U.S. patent to affirmatively relinquish rights under the corresponding U.S. patent.[19] This is the logical consequence of the territorial nature of patent rights.[20] Actions to enforce U.S. patents are brought in U.S. District Courts or – for the purpose of obtaining enforcement by U.S. Customs – in the U.S. International Trade Commission (ITC).[21]

Thus, under U.S. law a patent owner can stop a parallel trader from importing products protected by patents into the United States.

European Communities

The European Communities (EC) practice regional exhaustion of patents, whereby patent rights are exhausted when the patented product is placed on the market of a Member State of the EC, but not when that product is placed on a market outside the EC. This result is as much a creature of EC law as it is a result of the application of theories about intellectual property law. While Articles 30-34 of the Treaty of Rome generally preclude prohibitions or restrictions on imports, exports, or goods in transit, Article 36 allows such prohibitions or restrictions under certain circumstances, including when justified for the "protection of industrial and commercial property."

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[18] *See* 35 U.S.C. 271 ("whoever without authority . . . imports into the United States any patented invention during the term of the patent therefor, infringes the patent."). U.S. patent law was changed to include this specific right to prevent importation to implement Article 28.1 of the TRIPS Agreement. It should be noted that the Medicine Equity and Drug Safety Act of 2000, Appropriations Bill for Food and Drug Administration, P.L. 106-387 was enacted to permit the re-importation into the United States of certain pharmaceutical products from certain nations. The Secretary of Health and Human Services, by letter to President Clinton on December 26, 2000, stated that the reimportation provisions of the law could not be implemented as it was not possible for her to "demonstrate that it is safe and cost effective." Moreover, the Act did not address intellectual property protection and is not, therefore, further addressed in this paper.

[19] *See Curtiss Aeroplane*, 266 F. 71 (2d Cir.1920) (finding a clear intention of the patent owner to convey all rights held under a collection of patents to the British Government and as a consequence relinquishing U.S. rights); *Kabushiki Kaisha Hattori Seiko v. Refac Technology Development Corporation*, 690 F. Supp. 1339, 1342 (S.D. N.Y. 1988) (The court stated the general principle that "the first sale of a product by a patentee or licensee exhausts the patent monopoly, and deprives the holder of patent rights of any further control over resale of the product." It stated, however, that that principle could be constrained by limitations on the sale made abroad. In particular, the court observed that the patent owner was sophisticated and that had it "intended geographically to limit [the purchaser's] right to sell, it could and should have included appropriate words of restriction."); *Sanofi v. Med-Tech Veterinarian Products*, 565 F.Supp. 931, 938 (D.N.J. 1983)(denying an injunction sought by a U.S. patent holder against the distribution of a product sold by the U.S. patent holder in France "without restriction.")

[20] The Supreme Court reaffirmed and broadened this doctrine in *Deepsouth Packing v. Laitram Corp*., 406 U.S. 518, 531 (1972) (stating that "[o]ur patent system makes no claim to extraterritorial effect . . . and we correspondingly reject the claims of others to such control over our markets"). It is also a logical consequence of patent rights differing from country-to-country, whether because of differences in national laws, or because of differing decisions taken by national offices granting patents. In short, a patent in a first country may be different in scope from a patent covering ostensibly the same subject matter in a second country.

[21] U.S. Customs has no authority to prevent the importation of goods which infringe a patent unless directed to do so by an exclusion order issued by the ITC under the provisions of section 337 of the Tariff Act of 1930, as amended.

The European Court of Justice (ECJ) took up the question of parallel imports of patented goods *within* the Communities in *Centrafarm v. Sterling Drug*,[22] ruling that

> [t]he exercise by a patentee of the right given him by the laws of a member-State to prohibit the marketing in that State of a product protected by the patent and put on the market in another member-State by such patentee or with his consent would be incompatible with the rules of the EEC Treaty relating to the free movement of goods in the Common Market.[23]

The focus in subsequent decisions concerning exhaustion of patent rights within the EC has been on whether the product had been marketed with the consent of the patentee. In *Pharmon v. Hoechst* the requisite consent was absent as the product was marketed in the exporting country in the European Communities by virtue of a compulsory license[24] because "[i]t is . . . necessary to allow the holder of a patent to prevent the import and marketing of products manufactured under a compulsory license in order to ensure that he obtains the substance of the exclusive rights which flow from the patent."[25] Where a manufacturer consents to marketing a product in a Member State where no patent protection exists, patent rights may still be exhausted in other Member States of the EC.[26] The requisite consent that could lead to exhaustion of patent rights may not be found if the "holder of the patent can prove that he is under a genuine, existing legal obligation to market the product in that Member State."[27] Again the touchstone is whether the product was marketed in the exporting EC Member State with the consent of the party exercising patent rights in the importing EC Member State. Further, the EC does not practice international exhaustion of patent rights. That is, rights in the Member States of the EC will not be exhausted as a consequence of placing the patented product on a market outside of the EC.

If a product protected by a patent is placed on the market of a Member State of the EC by the owner of such rights, or with the owner's consent, the rights in respect of those products are exhausted. In the absence of consent, there is no exhaustion. Moreover, there is no exhaustion in the event such a product is placed on a market outside the EC. The applicability of the "European rule" of regional exhaustion should not be read broadly to cover other regional groupings of countries. The EC has achieved a degree of harmonization of intellectual property laws and economic integration that is unique. Even so, differences in market conditions among EC

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[22] *Centrafarm v. Sterling Drug*, Case 15/74, [1975] F.S.R. 161.

[23] Id. at 187. An exception in this regard was made for Spain and Portugal in their respective Acts of Accession to the EC. In their Acts of Accession, Spain and Portugal agreed to introduce product patents for pharmaceuticals by fixed dates. The Acts of Accession further provided that the rule of EC-wide exhaustion was not to apply to pharmaceutical products until the end of the third year after such products become patentable in these States.

[24] *Pharmon v. Hoechst*, Case 19/84 [1986] F.S.R. 108, 113 ("It should be emphasised . . . that when the competent authorities in a member-State . . . grant a compulsory license to a third party which allows him to carry out manufacturing and marketing operations which the patentee would normally have the power to prohibit, the patentee cannot be regarded as having consented to the actions of the third party. In fact, the holder of the patent is deprived by such an official act of his right to decide freely on the conditions under which he will place his product on the market.")

[25] Id. at 114.

[26] *Merck v. Stephar*, Case 187/80 [1982] F.S.R. 57 ("It is up to the patentee to decide, in full knowledge of the facts the conditions under which he will market a product; this will take into account the possibility of its being sold it in a member-State where patent protection for the product in question does not exist at law. If he decides to do this, he must then accept the consequences as regards free circulation of the product in the Common Market . . .")

[27] *Merck v. Primecrown* ,Case 267/95 and 268/95, [1997] F.S.R. 237, 250.

Member States – in particular in respect of price controls – result in price differences and arbitrage opportunities.

Conclusion

The background papers prepared for the workshop by the WHO and WTO focus on the need to control parallel trade in pharmaceuticals in order to allow for deeply discounted prices in the least developed countries. Intellectual property rights are an important tool that can be used by national authorities to control such diversion of pharmaceuticals. Diversion of products through parallel trade depletes the available medical resources in the original country, and taints the quality of products in the recipient country. In both cases, precious health resources are burdened.

Examples of how intellectual property policies that prevent parallel trade strengthen national health care systems have been provided above. Where national law – in particular patent law – provides for the right to prevent importation and where the holder of the patent makes it clear that rights outside the intended market will be retained, parallel trade into other markets may not be allowed.

Those who argue for reliance on parallel trade as a cheap fix for health care are promising a health care fiction, as such systems are not sustainable. HIV/AIDS patients need therapies that are available for the long term. Complex HIV/AIDS therapies can only be delivered in a consistent, sustainable manner when the products are protected by intellectual property laws, and the public health authorities who must provide this care can be assured of their quality, safety and efficacy. In order to create this system, health authorities need broad-based political support from groups represented here at this conference – governments, the private sector and non-governmental organizations.