Parallel Trade: A User's Guide

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ABSTRACT

This chapter provides guidance about parallel trade to developing country policy-makers and other stakeholders in intellectual property. What is parallel trade? And how can it be utilized to promote access to medicines and support poor farmers in developing countries? Engaging in parallel trade is an option provided by the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) under the World Trade Organization. Furthermore, the 2001 Doha Declaration on TRIPS and Public Health confirmed that developing countries could use parallel imports to support public health. As a result, developing countries can ensure access to lower-priced patented and/or branded products, such as medicines and basic agricultural inputs, by incorporating legislation to allow for parallel imports. When implementing measures to facilitate parallel trade, developing countries can establish and maintain an effective system by adequately regulating the quality, safety, and health of parallel imports. At the same time, developing countries need to prevent low-priced patented products available in their countries from entering high-priced developed country markets.

1. WHAT IS PARALLEL TRADE AND WHY DOES IT HAPPEN?

Parallel trade occurs when products produced under the protection of a patent, trademark, or copyright in one market are subsequently exported to a second market and sold there without the authorization of the local owner of the intellectual property (IP) right. Often, the local owner of the IP right will also be a local dealer who, through a license or other exclusive agreement, has been authorized by the patent, copyright, or trademark holder to market the protected product. Naturally, when the licensed dealer has an exclusive agreement, he or she expects to be the only party supplying the product in the local market.

Parallel trade *does not* refer to unofficial, illegal, or informal-sector activities that may take place inside a country or among countries. Moreover, parallel trade *is not* trade in pirated or counterfeit products. The latter are unauthorized versions of products that infringe an IP right. Parallel imports (also called *gray-market* imports) are genuine, often branded, products that do not violate an IP right. Importing the products from one country to another, however, may not be authorized by the right holder.

The main difference between parallel importation and "official" importation is that the parallel imports probably were produced originally for sale in a particular market and then were passed through an unauthorized dealer before reaching the consumer. Parallel imports may differ in superficial ways from those made available by the local dealer—they may be packaged differently or lack the original manufacturer's warranty—but otherwise they will be identical to the official import being marketed locally.[1]

When parallel importation occurs, the practical effect is that a patented and/or branded

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product becomes available locally from multiple sources. Parallel importing allows dealers to bypass official or authorized local suppliers or licensees and obtain products directly from overseas suppliers. The enhanced market competition between sources of the same products tends to drive prices down.

Indeed, the incentive for parallel importation is the fact that there are price differences between identical products in different markets. Parallel importing usually occurs when the price differences are high, because then the potential gains (price savings, product availability, profit) for most stakeholders are large enough to compensate for the transaction costs, including shipping costs and complying with customs regulations. The price differences can be due to a variety of factors. In the case of the pharmaceutical market, where important price differentials exist between countries, price differences can result from government-enforced price controls, pricing manipulated by the owner of an IP right holder, fluctuations in currency values, a combination of these conditions, and other factors.

2. THE EFFECTS OF PARALLEL TRADE ON STAKEHOLDERS

2.1 *Government-supported parallel trade*

The regulation of parallel trade involves balancing the interests of producers and consumers. An important public policy mechanism for developing countries, parallel importation can be used to protect the interests of consumers, particularly with regard to pharmaceutical and agrichemical products. Countries can introduce legal provisions to permit parallel importing in order to ensure adequate access to imports. Parallel importing also allows the government to shop around in different markets for the lowest price on an IP protected product.

The prospect of parallel imports of products protected by IP rights is particularly important in the public health sector, where prices for medicines in developing countries may be higher than most people can afford. By utilizing parallel imports, developing countries can access alternative sources of medicines at lower prices, guaranteeing greater access and availability of medicines. Hospitals, pharmacies, and health insurance companies can acquire pharmaceutical products at lower prices from other markets through parallel trade, which can potentially lower prices in the local market.

Parallel imports can also be used to access basic inputs to agricultural production (such as pesticides and fertilizers) at lower prices than those charged locally by the owner of an IP right. These reduced costs could contribute to improving poor farmers' incomes and livelihoods. Developing countries can also use parallel importing to curb anticompetitive practices: it allows them to ensure adequate price competition in the local market and a competitive supply of products from a variety of sources. Section 3.0 of this chapter provides more information about how developing countries can make effective use of parallel importing.

2.2 *Benefits to consumers*

Potentially, consumers have much to gain from parallel imports. By increasing the options for alternative supplies of products, parallel imports can allow consumers to gain access to the products they need from another market at lower prices than are being charged in their own market. In developing countries, it is often the case that essential products such as medicines are unavailable or inaccessible to a large portion of the population because they are unable to afford them at the prices charged by the IP right holder, and the government is unable to subsidize their purchase.

2.3 *Retailers, wholesalers, and traders*

Parallel imports can be attractive to traders when price differences are significant enough to ensure profits. Similarly, parallel importing gives local retailers and wholesalers the ability to obtain patented and/or branded products directly from multiple overseas sources. Doing so may offer better prices than obtaining the products from the local authorized dealer. By bypassing the local licensed dealer, retailers may be better able to meet the needs of their consumers.

2.4 *The view of right holders and local licensed owners*

IP right holders, including authorized importers, licensees, and other agents, generally support restricting parallel trade because they directly benefit from having an exclusive right to import protected products. In the absence of parallel importing, local licensed dealers do not face competition, in terms of price, for the same products. In markets where no alternative sources are available, the product can be sold at the highest price the local market can tolerate. Moreover, restrictions on parallel importing allow right holders to take advantage, on a regional or international scale, of market segmentation and differential pricing strategies. Where parallel imports are not permitted, right holders may charge different prices in different markets. Right holders can also control distribution, pricing, and other aspects of the local market for products produced under IP rights.

Right holders often argue that parallel importation should be restricted because driving down prices might reduce incentive to invest in research and development in the pharmaceutical and agrichemical sectors. Parallel importation may also reduce the incentive for right holders to donate products at low cost or free of charge to developing countries, since there would be a risk that those products would be diverted back into developed country markets and sold at higher prices than were intended. Parallel importation may also hinder the ability of governments in different countries to maintain price controls on pharmaceutical products within their territory. Furthermore, rights holders or licensed local owners may pay marketing costs that the suppliers of parallel traded goods benefit from for free. In the long term, there is the possibility that this will reduce the willingness of rights holders or licensed local owners to supply particular markets.

In developing countries where some type of parallel importation is permitted, local licensed dealers may seek to overcome the competition of parallel traders by offering after-sale service, warranties, and so forth that parallel traders, generally with small profit margins, may be unable to offer. When price differences between markets tend to be large, as in the case of medicines, IP right holders can apply differential pricing policies, charging lower prices for medicines in lower-income markets than in higher-income markets. Price differentiation to ensure lower prices for patented medicines in developing countries may reduce the incentive there for parallel imports. If parallel imports are properly regulated in both exporting and importing countries, however, differential pricing agreements still can function without displacing IP right holders and local licensed dealers.

2.5 *Reimportation and other problems*

Developed countries with parallel trade in products protected by IP rights frequently identify a potential problem: IP right holders, particularly in the pharmaceutical industry, could be discouraged from pricing their products differently in different markets to benefit developing countries. Prices for medicines protected by patents or trademarks in developing countries tend to be high. Some argue that if developing countries allow parallel importation, patented medicines that the industry could potentially sell for a low price in a low-income country may find their way back to high-income markets and sold at higher prices. Reimporting medicines protected by patents or trademarks would mainly benefit intermediaries and reduce the incentive for industry to sell medicines protected by patents or trademarks at lower prices in developing countries. Furthermore, developed countries are concerned that parallel trade could channel counterfeit and/or pirated products into the market.

As noted above, however, parallel trade does not concern substandard products. Moreover, countries can and should address these concerns by adequately regulating and monitoring parallel imports and exports. To reduce the risk of reimportation and to maintain effective pro-poor (or humanitarian) differential pricing arrangements for medicines in developing countries, developed countries can adopt measures to prevent parallel imports into higher-priced markets.[2] For example, developed countries can (and do) enact

national legal provisions to ban parallel imports from developing countries.

3. THE LEGAL FRAMEWORK FOR PARALLEL TRADE

The legal question with regard to parallel trade is: To what extent should countries allow or limit the ability of IP right holders within particular national/regional territories to control the movement of products across different markets on the basis of local ownership of IP rights? Countries are entitled to regulate parallel trade involving intellectual property in their own best interests. Indeed, parallel imports have been admitted in many developed and developing countries on a regional or international scale.[3]

The Agreement on Trade-Related Aspects of Intellectual Property Rights (the TRIPS Agreement) gives World Trade Organization (WTO) members the freedom to design their own regimes for the *exhaustion* of IP rights (exhaustion occurs when a right holder's control over a product ceases). Because the exhaustion of rights cannot be challenged as a violation of the TRIPS Agreement under the WTO dispute-settlement mechanism, the TRIPS Agreement allows parallel importation. According to Article 6:

For 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.

Moreover, the Doha Declaration on TRIPS and Public Health[4] reaffirmed this freedom, giving developing countries greater certainty about their ability to use parallel importation to protect their interests, particularly for safeguarding public health. According to Article 5(d) of the Doha Declaration:

The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.

A country's decision about their exhaustion of rights doctrine will either restrict or allow parallel importation policies in their territories.

The doctrine describes three types of exhaustion of rights:

- **national exhaustion** (first sale doctrine). Also known as first sale doctrine, national exhaustion holds that the exclusive rights of IP right holders over protected products cease after the first sale of the product within national borders.
  Implication: Right holders can block parallel imports from entering the local market, even though their rights are exhausted in that market. Example: United States.
- **regional exhaustion**. The exclusive rights of IP right holders over protected products cease after the first sale in the regional market.
  Implication: Parallel trade is allowed within the group of countries, but right holders can ban parallel imports from countries outside the region. Example: European Union.
- **international exhaustion**. Right holders' exclusive rights over protected products cease after the first sale in any market.
  Implication: Right holders cannot exclude parallel imports from entering the local market because their rights with respect to that market are exhausted. Example: Kenya.

Accordingly, developing countries can incorporate into their national laws the principle of international exhaustion of rights, thus allowing for parallel imports on an international scale.[5] Put differently, developing countries can decide whether or not to allow parallel importation for all or particular IP rights. Allowing for parallel imports of patented or trademark protected products, that is, the application of the international exhaustion principle to the rights of patent holders, is an option made available by TRIPS to developing countries. Though relevant to all fields, the potential benefits of parallel importing are particularly important for patents and public health. As noted above, importing patented medicines from a market where they are sold at lower prices may give those who need

them in the importing country greater access. Concerns about the possible negative effects of parallel imports, moreover, can be dealt with through adequate monitoring and regulation, rather than through trade restrictions.

4. MODEL PROVISIONS FOR ENABLING PARALLEL IMPORTATION OF PATENTED PRODUCTS

This section provides TRIPS-compliant model provisions that would enable parallel importation of patented products into a country when incorporated into a national patent law. The model provisions adopt the principle of international exhaustion (see Box 1).

Model provision 1 is the narrowest interpretation of the international exhaustion principle, allowing only for parallel importation of patented products that have been placed on the market by the patent holder. Model provision 2 extends the exception by allowing for parallel importation of patented products that have been placed on the market by any authorized agent (that is, a local licensed dealer) of the patent holder. Finally, model provision 3 provides the broadest exception to the exclusive rights of a patent holder allowing parallel imports originating from any country. Under this provision patent holders' rights may also be exhausted based on the sale or marketing of the product authorized by a government under a compulsory license. Hence, patented products that have been produced and placed on the market by a compulsory licensee may be parallel imported.[7]

While each of the three provisions have been adopted, it is questionable whether provision 3 is TRIPS compliant.[8]

5. CONCLUSIONS AND RECOMMENDATION

Policy makers in developing countries should seek to utilize fully the options available under the TRIPS Agreement for promoting access to medicines and supporting poor farmers. Since these options include applying the principle of international exhaustion, policy-makers in developing countries should seek to take full advantage of the possibilities afforded by parallel trade. They can ensure that a patent holder does not have the right to prevent imports of a product covered by a patent when the patent holder has put that product on the market in another country. To utilize this flexibility to the fullest, countries should consider adopting a version of the model provisions for enabling parallel importation. ■

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BOX 1: MODEL PROVISIONS[6]

1. A patent holder shall not have the right to prevent acts of importation of a product covered by a patent that has been put on the market in any country by the patent holder or with his or her consent.

2. A patent holder shall not have the right to prevent acts of importation of a product covered by a patent that has been put on the market in any country by the patent holder, with his or her consent or in any other legitimate manner.

3. A patent holder shall not have the right to prevent acts of importation of a product covered by a patent that has been put on the market in any country by the patent holder or by an authorized party.

1 Maskus KE. 2001. Parallel Imports in Pharmaceuticals: Implications for Competition and Prices in Developing Countries. *Final Report to the World Intellectual Property Organization*. WHO: Geneva, p. 2. www.wipo.int/about-ip/en/studies/pdf/ssa_maskus_pi.pdf.

2 UNCTAD-ICTSD. 2005. *Resource Book on TRIPS and Development*. Cambridge University Press: Cambridge. p. 446. www.iprsonline.org/unctadictsd/ResourceBookIndex.htm.

3 Correa C. 2000. *Integrating Public Health Concerns into Patent Legislation in Developing Countries*. South Centre: Geneva, p. 74. www.southcentre.org/publications/publichealth/publichealth.pdf.

4 www.worldtradelaw.net/doha/tripshealth.pdf.

5 Sisule M and C Oh. 2005. The Use of Flexibilities in TRIPS by Developing Countries: Can They Promote Access to Medicines? Study Paper 2a, Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH). World Health Organization: Geneva. p. 31. www.southcentre.org/publications/flexibilities/FlexibilitiesStudy.pdf.

6 See *supra* note 3.

7 Third World Network. 2003. Parallel Import. In *Manual on Good Practices in Public Health-Sensitive Policy Measures and Patent Laws* (chapter 4). Third World Network: Penang, Malaysia.

8 Abbott F. 2002. WTO TRIPS Agreement and Its Implications for Access to Medicines in Developing Countries. Study Paper 2a, UK Commission on Intellectual Property Rights (CIPIR): London. www.iprcommission.org/graphic/documents/study_papers.htm.