

**Legal and Policy Issues Concerning Parallel Trade (aka Re-Importation) Of
Pharmaceutical Drugs in the United States**

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1. Countries that would be candidates for parallel trade in medicines.

Congress has typically sought to limit parallel trade¹ in medicines to countries that have good regulatory systems. This generally coincides with countries that have higher incomes, but not always. For example, in some versions of parallel trade legislation, South Africa has been included. CPTech recommends that parallel trade be limited to only those countries that have adequate regulatory systems, *and* which are classified as high income by the World Bank. The discrimination by income may run afoul of Article 4 of the TRIPS agreement, a point that will be discussed further below, but it is good public policy, and highly unlikely to lead to a WTO complaint, because there would be no aggrieved WTO member motivated to bring a case.

2. International exhaustion of patent rights: The *Jazz Camera* case

To authorize parallel importation of medicines, legislation should make it clear that U.S. patent rights are *exhausted* by the first sale of the patented product by the patent owner, or by a party who is authorized to use the patent. Specifically, it needs to be clear that the United States has elected the rule of *international exhaustion* of patent rights.

Prior to *Jazz Camera Photo v. International Trade Commission*, 264 F.3d 1094 (Fed. Cir. 2001), and in some cases in other circuits following that decision, the general rule in the U.S. was perceived by many to be an international exhaustion rule. *See Curtiss Aeroplane v. United Aircraft*, 266 F. 71 (2d. Cir. 1920) (holding that U.S. patent holder, in consenting to the use of its patent for manufacture of airplanes in Canada, had exhausted its right to control the importation of the resulting aircraft into the United States). In *Jazz Camera*, the Federal

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¹ The term “parallel” trade or importation refers to the practice where products sold by the same firm in more than one country, are imported (by third parties) from the country where prices are low to the country where prices are higher. In the technical and legal literature, “re-importation” commonly means a small subset of parallel importation examples, namely where a good is first sold in the U.S., exported out of the U.S. and then imported back to the U.S. It is our understanding that Congress’s intent is to authorize parallel importation, not simply re-importation.

Circuit held that the sale of products by a patent holder in another country did not exhaust U.S. patent rights, stating:

United States patent rights are not exhausted by products of foreign provenance. To invoke the protection of the first sale doctrine, the authorized first sale must have occurred under the United States patent. *See Boesch v. Graff*, 133 U.S. 697, 701-703 (1890) (a lawful foreign purchase does not obviate the need for license from the United States patentee before importation into and sale in the United States).

The holding of the Federal Circuit has been questioned by legal experts. Nevertheless, it promotes legal uncertainty around parallel importation. If *Jazz Camera* is not clearly overturned by statute, a patent holder could claim that importation into the U.S. of a patented product first sold by the patent holder in another country is a violation of U.S. patent law.

For more technical assistance on this issue, CPTech recommends contacting Professor Fred Abbott at the University of Florida, 850-644-3400, FAbbott@law.fsu.edu

3. Exhaustion of patent rights and the WTO agreement

The WTO TRIPS accord requires that patent owners be given the exclusive right to import products that use the patented invention, but the agreement also provides for a number of exceptions to these exclusive rights. For parallel trade, the important exception is when a government determines that the rights in the patent were exhausted with the sale in the foreign market. This is sometimes referred to as the First Sale Doctrine. The relevant provision in the TRIPS is Article 6, which states in a single sentence that each WTO member can choose whether or not to recognize the exhaustion of intellectual property rights.

Article 6 Exhaustion

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.

The TRIPS provision applies to copyright, trademarks and patents, and covers both domestic exhaustion cases (rights of libraries to lend books) and international exhaustion issues (parallel trade in pharmaceuticals), subject only to the TRIPS provisions on national treatment (Article 3) and most-favored nation treatment (Article 4). Article 4 states, in relevant part:

Article 4 Most-Favoured-Nation Treatment

With regard to the protection of intellectual property, any advantage, favour, privilege or immunity granted by a Member to the nationals of any other country shall be accorded immediately and unconditionally to the nationals of all other Members.

The problem with Article 4 is that it would appear to ban the policy of limiting parallel trade from developing countries. CPTech and some countries have asked the WTO to change Article 6, so that for medicines and some copyrighted goods, parallel trade could be limited to similar or higher income countries. As noted, in practice, it is highly unlikely that any country would choose to bring WTO complaint on this issue. But CPTech believes this is a flaw in the WTO TRIPS that should be fixed.

4. Use of contracts to prevent parallel trade

Sellers often seek to use contracts to prevent parallel trade. In the European Union, such contracts are typically not enforceable, because of European Commission policy to promote a single European market.

For a US legislative authorization of parallel trade to be effective, the U.S. Trade Representative must be dissuaded from the pursuit of, and Congress must reject, trade agreements that recognize a right of pharmaceutical patent holders to ban parallel trade through contract. Two trade agreements recently entered by the U.S. are problematic. Both the U.S. – Australia and U.S. – Singapore trade agreements contain language requiring the parties to recognize a right of patent holders to restrict importation through contracts. The U.S. Australia agreement is particularly clear in this regard.

Article 17(9)(4) of the US-Australia FTA

Each Party shall provide that the exclusive right of the patent owner to prevent importation of a patented product, or a product that results from a patented process, without the consent of the patent owner shall not be limited by the sale or distribution of that product outside its territory at least where the patentee has placed restrictions on import by contract or other means.

Article 16(7)(2) of the US-Singapore Free Trade Agreement

Each Party shall provide that patent owners shall also have the right to assign, or transfer by succession, a patent and to conclude licensing contracts. Each Party shall provide a cause of action to prevent or redress the procurement of a patented pharmaceutical product, without the authorization of the patent owner, by a party who knows or has reason to know that such product is or has been distributed in breach of a contract between the right holder and a licensee, regardless of whether such breach occurs in or outside its territory. [Footnote 16-10] Each Party shall provide that in such a cause of action, notice shall constitute constructive knowledge.

Footnote 16-10:

A Party may limit such cause of action to cases where the product has been sold or distributed only outside the Party's territory before its procurement inside the Party's territory

5. The Hague Convention on Jurisdiction and Enforcement of Foreign Judgments

Another possible problem concerns a current negotiation on a treaty on cross-border jurisdiction, and in particular, the provisions that would make contractual choice of court provisions automatically enforced globally. Sellers of medicines would routinely choose courts that uphold restrictions on parallel trade. CPTech has asked the US Department of State to exclude from the proposed Hague Convention on Jurisdiction and Enforcement of

Foreign Judgments cases involving parallel trade or the exhaustion of intellectual property rights. For information on this issue, see:
<http://www.cptech.org/ecom/jurisdiction/paralleltrade.pdf>

6. Quality control

It should not be necessary to have any other FDA approval than that the same product has been approved for sale in the U.S. by the same company or its licensee. For example, if Pfizer or a subsidiary or licensee sells product X in the U.S. and Canada, then imports of the same product from Canada into the U.S. should be allowed with no additional regulatory approval of the product. In the European Union, parallel trade in medicines is not only legal, but in many respects encouraged, as a mechanism to create a more efficient European market. In some regions of Europe, parallel trade accounts for almost 20% of products utilized.

IMS is the leading source of statistics on pharmaceutical sales worldwide, and offers a number of consulting services. In an October 30, 2002 report on parallel trade in Europe,² IMS made the following observations:

The belief that parallel traded goods are of poorer quality is actively encouraged by the pharmaceutical industry. . . . But for the most part, parallel traded products are as good as the local product because they are identical - the only difference is that they were packaged in a box of a different design to appeal to the needs of a different European market, a market which has exactly the same high quality requirements. Parallel traded products are high quality, well-packaged and well-distributed and cannot be criticized for their inferior quality compared with branded products. The market is growing.

To the degree that there are concerns over the quality of parallel traded goods, the U.S. can follow the European example, and regulate companies that sell parallel traded medicines through licensing financed by user fees on the parallel traders. Such licenses can be revoked for illegal practices.

7. Research and Development Options

Opponents of parallel trade also say that as innovator profits decline, the pharmaceutical industry will reduce R&D outlays, slowing the development of new drugs. This issue can be addressed constructively in the following manner. The U.S. could require that firms that engage in parallel trade of pharmaceuticals report the price they pay for the drug in the foreign market, and pay a fee of 10 to 15 percent of the difference between the manufacturer's US price and the foreign price, into a transparent R&D fund. The 10 to 15 percent represents the percentage of sales that companies now invest in R&D (according to the IRS or PhRMA). Funding research and development in this way could enable focusing research and development on public health priorities and increase transparency in R&D flows.

² http://open.imshealth.com/IMSinclude/i_article_20021030.asp