

Access to Medicines: Solving the Export Problem under TRIPs

By James Love

This year the WTO is supposed to address paragraph 6 of the Doha Declaration on the TRIPs Agreement and Public Health, and perhaps the larger issue of the rules under which countries can export health care technologies. The issues that are imperfectly raised in the Declaration are important, as they involve the ability of a country to seek an efficient supplier for a medicine or other health care technology, when the domestic source is too expensive.

The significance of this may not be readily apparent, because today India and a handful of other countries can freely export copies of medicines that are patented in other countries. This exemption will expire in 2005, however. India has already modified its patent laws for medicines, and other countries are also under pressure both from WTO rules and bilateral trade negotiations to enact new and tougher patent rules. The major issue at stake is: will the so-called 'flexibilities' of the TRIPs accord, as they relate to government-sanctioned non-voluntary use of a patent, be meaningless except in a handful of countries with large domestic markets?

Paragraph 6 of the Doha Declaration on TRIPs reads:

We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPs Agreement. We instruct the Council for TRIPs to find an expeditious solution to this problem and to report to the General Council before the end of 2002.

The first sentence is of course true, but incomplete. First, this is not only a problem of access to pharmaceuticals, but also to medical devices and other technologies. Second, countries without patents on medicines also face difficulty, if patents exist in potential export countries. There may also be scarce know-how or trade secrets needed to manufacture a specific product, even when a country has capacity to manufacture other products. Finally, even if a country could manufacture a specific product, the domestic market may be too small to justify production for domestic use only. Thus, to characterize the issue as the 'capacity' to manufacture is much too narrow.

Nor it is this only an issue for the poorest countries. Korea, for example, is currently facing a request for a compulsory license on Gleevec, a drug that is very effective against two rare forms of cancer. Korea has a world-class pharmaceutical industry, and is now the most efficient global supplier for some important medicines. It would be possible, but not efficient, for Korea to manufacture Gleevec for its domestic market alone. This is so because, although it accounts for 15 to 20 percent of all adult Korean leukemia cases, chronic myelogenous leukemia afflicts only about 500 people each year. A much more efficient solution would be to allow generic producers to make Gleevec for sale in several countries, where the combined markets would justify the fixed costs of production.

Gleevec is not an isolated case. There are many products where it would be very costly to have autarky in domestic production. Even wealthy countries like Sweden, Denmark, Canada, Australia,

New Zealand, Singapore or Spain could not justify manufacturing products such as Ceredase, Epogen, or other countless other products, for the domestic market alone. A typical treatment of Epogen – used, among other applications, to treat chronic anemia in kidney dialysis patients – may cost US\$10,000 per year, but some patients may need far more. Gleevec is priced at nearly US\$50,000 per year, as a chronic treatment. Ceredase can cost more than US\$500,000 for a single year of treatment. In situations of excessive pricing, where a government determines it needs to override a patent owners' exclusive rights, and authorize the use of a generic product, it is essential that it is both technologically feasible *and* economically efficient to find an alternative source.

The fundamental problem is the right to export and overcoming the importing country's difficulty of finding a source of affordable drugs.

There is also much evidence that the number of suppliers is quite important in determining prices. The WHO has a 'rule of five,' which means it gets the best price on a drug when there are at least five suppliers. When Brazil began to purchase generic copies of 3TC, an important HIV drug, it was paying US\$20,000 per kilo for the imported raw materials for the drug. Today there are more suppliers, and

Brazil pays around US\$500 per kilo for the raw materials, only 2.5 percent of the original price. This is important since it is almost impossible for most countries to develop even one domestic supplier for certain products, let alone several.

TRIPs Restrictions to the Right to Export

Most WTO Members would benefit from rules that would permit them to buy medicines or other health care inventions from any efficient supplier, no matter where they are located, and even domestic suppliers would be better off if they could also export. The TRIPs Agreement, however, presents problems.

The problem is not on the import side, as TRIPs clearly permits imports, both in cases where the product is off patent in the importing country, or where the government overrides the patent rights under government use, emergency or compulsory licensing provisions. The difficulty for the importing country is to find a source. This is the so-called 31(f) issue.

Under the TRIPs Agreement, a country may authorize non-voluntary non-exclusive use of an invention, but if this is done under Article 31 of the TRIPs, it must adhere to certain conditions, including paragraph 31(f), which reads:

f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;

Article 31(f) is a general rule that limits exports when the product is manufactured under a compulsory license. The limitation is not complete; a non-predominate amount may be exported. There is also an exception to 31(f) in Article 31(k) which says that 'Members are not obliged to apply the conditions set forth in . . . (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive.' The primary reason for concern over 31(f) is that few developing countries have implemented Article 31(k) in a way that would easily allow

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compulsory licenses to be issued, and some government officials mistakenly believe that Article 31(k) can only be used after expensive and time-consuming antitrust litigation.

Possible Solutions

In the current WTO negotiations, several different proposals have been made to deal with the paragraph 6 issue. The US has lobbied the WTO to adopt a time-limited, conditional moratorium on WTO challenges to such exports of drugs for public health crises, a rather meaningless gesture because the problems for such exports are mostly a future issue, since India can already export older products.

The EU has raised the possibility of either amending Article 31(f), or accepting a limited exception to patent rights under TRIPs Article 30, but only under a set of restrictive conditions. The EU has also discussed approaches that involve a third country honoring a compulsory license in another country and, in its internal consultations, has even discussed liberal definitions of the term 'predominately,' to include members of a trade union, which would of course, benefit the EU itself.

Developing countries have raised a number of different strategies for dealing with the export issue, from the use of the principle of the exhaustion of rights to overcome the restrictions in Article 31(f), to modifications of Article 31(f) – under less restrictive conditions than those proposed by the EU – as well as the use of Article 30. Another approach being considered by some countries is to use the existing language under Article 31(k) to authorize exports, unencumbered by the restrictive provisions proposed by the EU for a modified Article 31(f) or a new Article 30 exception.

When the TRIPs Agreement was first proposed, it was understood that Article 31(f) would present problems for compulsory licensing of medicines, and most of the early attention focused on the ways that Article 31(k) might be used to authorize exports. The operative provision that Article is that 'Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive.' Many developing countries do not have effective competition authorities, and are uncertain about both the type of evidence necessary to justify issuing a license to remedy an anticompetitive practice, and the role of the WTO in reviewing such actions. To many, the prospect of bringing an antitrust case against a patent owner is a daunting, expensive and time consuming prospect.

Another view of 31(k) is that governments can create purely administrative procedures and craft fairly simple tests to justify 31(k) licenses. Some of the grounds that have been proposed focus on the need to authorize exports in order to obtain sufficient economies of scale to encourage entry and create competition.

History of Article 30 Proposals

In April 1999, the Canadian Drug Manufacturers Association (CDMA) asked the Canadian Parliament to allow a generic drug manufacturer to export its product to other jurisdictions where patent protection was not in place, as a limited exception to patent rights under Article 30.

The issue of exports was also featured in the recent Canadian 'bolar' case, the first WTO review of Article 30. The EU sought to

overturn Canada's use of Article 30 to permit both pre-expiration testing and the warehousing of products, both designed to speed introduction of generic drugs once a patent expires. The WTO upheld the pre-expiration testing, but rejected warehousing.

Importantly, the US raised concerns about the Canadian provisions allowing the export of products to obtain foreign registrations. Canada responded by noting that in smaller countries, generic industries had to 'export in order to be able to manufacture in sufficient quantities to achieve economies of scale, so that domestic consumers could receive the benefits of cost-effective generic products'. Canada noted that 'exceptions that had the effect of confining all activities to a single country were of little use to countries that, unlike the United States, depended on international trade to obtain generic products.' Canada also noted that the US 'bolar' exception permits the import or export of medicines for pre-expiration testing that is related to US regulatory requirements.

A broader use of Article 30 was proposed in the United States right before Doha in November 2001, in response to the Anthrax crisis. H.R.3235 would allow generic companies to 'export medicines or other health care products that are needed to address global public health emergencies, when the legitimate rights of the patent holder are protected in the export market.'

NGOs Seek Article 30 Approach

In May 1999, NGOs held discussions with WIPO to explore how Article 30 might be used to address the export issue. Article 30 was considered an important approach, because a typical Article 30 exception to patent rights was automatic, and did not require time consuming or expensive litigation. The argument to WIPO was that there existed significant differences between medicines and other inventions, which would justify the Article 30 approach.

Specifically, while patent owners can face difficulty in protecting rights for products sold through unregulated distribution channels, sales of medical inventions are typically regulated, at least in markets of economic significance. This makes it much easier to protect patent owners' rights.

Under the Article 30 approach, patent owners would have incentives to obtain patent protection where the invention would be consumed, providing the economic incentives for investments in new inventions, while ensuring a practical framework for countries to find efficient generic supplier when needed for public interest or to address abuses of patent rights.

NGOs have continued to push governments to accept Article 30 as a vehicle for exports of medicines. One example is the Trans-Atlantic Consumer Dialogue, a trade dialogue for 65 consumer groups in the United States and Europe, which has passed several resolutions to support the use of Article 30 for exports, and told the US and EU that such exports are needed for both rich and poor countries, to allow countries to obtain more efficient supplies of products.

In 2001, developing countries took the lead in pushing for the Doha Declaration on TRIPs and Public Health. They suggested several strategies for addressing the export issue, including a September 2001 proposal to use TRIPs Article 30 to permit exports of medicines, but did not embrace a single strategy, and the issue was deferred for negotiations this year.

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