Notes

Should IPR Protection for Pharmaceuticals be included in the EU-India FTA?

Rajat Acharyya¹

and

Gerrit Faber²

In its new bilateral trade agreements, the EU tries to include more Intellectual Property Rights (IPR) protection than is provided by the Trade Related Intellectual Property Rights (TRIPS) agreement of the WTO. This has often some far reaching implications. For example, attempts to include IPR protection for pharmaceuticals and drugs in FTA talks with India and Mercosur may threaten the lives of millions of poor all over the world. This note highlights the costs that the world has to bear for such IPR protection. A review of the IPR protection in health care with an open mind is urgently needed to find an answer to why it has not delivered the good for most of the poor in the world.

JEL Classification: I1

Keywords: Pharmaceuticals; WTO; IPR protection; Parallel Imports; Health care.

Two recent events have added new and somewhat contrasting dimensions to the bilateral trade relations of the EU with India and the Mercosur. First is the ninth round of talks between senior European and Indian negotiators in Brussels during April 28-30, 2010, that focused on the prospective accord’s provisions on intellectual property rights, particularly in the area of pharmaceuticals and drugs. There has also been a revival of the long-stagnating talks on a comparable agreement with Mercosur (Argentina, Brazil, Paraguay and Uruguay). Second is the launching of a WTO dispute by Brazil and India.

¹ Department of Economics, Jadavpur University, Kolkata 700032. Email: rajat.acharyya@gmail.com
² Utrecht University School of Economics, Utrecht, the Netherlands. Email: g.faber@uu.nl

© Jadavpur University.
against the EU and the Netherlands on the seizure by Dutch customs officials of a shipment of generic drugs in transit from India to Brazil [Bridges (2010)]. Three other comparable detentions have taken place. Consultations between the countries have been started in May 2010.

The medicine in question is the generic version of the hypertension drug *Losartan potassium* that is patent protected in the EU but not in India or in Brazil. DuPont is patent owner, while Merck & Co. has the manufacturing and marketing rights. This case of detention in transit reflects many interests. *First*, the patent owner in the EU requested the action by the customs officials, which was defended on the grounds of a possible violation of patent rights. Pharmaceutical industries are dependent on patent enforcement to recoup their research cost and after that to cash rents. *Second*, the competitiveness of EU industries depends to a large extent on its innovative nature in terms of creativity, research and design. The EU developed a strategy to better protect and exploit this position in its *Lisbon Strategy* and in its 2006 *Global Europe* document. As a result, the EU tries to include more Intellectual Property Rights (IPR) protection in new bilateral agreements than is provided by the Trade Related Intellectual Property Rights (TRIPS) agreement of the WTO [Faber and Orbie (2009)]. Europe is also negotiating a multilateral Anti Counterfeiting Trade Agreement (ACTA) that will include a section on measures with respect to goods in transit. It is likely that the EU would like to enforce its own rules on IPR protection in other countries by these border measures.

*Third*, India, having a strong and well developed pharmaceutical sector based on its expertise and skill in chemicals, took full advantage of the flexibility granted in the TRIPS agreement to wage its own war against malaria, tuberculosis, AIDS and other diseases. In the amendment of the Indian Patent Act of 1970 in 1999, in keeping with India's commitments for implementation of TRIPS with effect from the year 2005, a "mailbox facility" was created by which all applications claiming pharmaceutical inventions would be accepted and put away in a mailbox to be examined in 2005. By this "mailbox facility", applications would be judged for novelty on the basis of filing date and not with reference to 2005. The act provides that in regard to the "mailbox applications" that result in the grant of patents, an automatic compulsory license would be issued to those generic companies that made significant investment and were producing and marketing a drug covered by the mailbox application prior to 2005. This has benefited many of the Indian pharma-firms producing generic drugs. A good example is Cipla Ltd., an Indian pharma-firm rich in tradition, which introduced the AIDS drug *Zidovudine, Stavudine* and *Lamivudine* between 1993 and 1998. Cipla offered the AIDS
drugs at significantly lower prices than other companies. This in turn provoked the lowering of prices by the international competitors on the Indian market. Today, a packet of ten 100-milligramme capsules of Zidovudine, produced by Cipla in India, costs less than US$5 (150 rupees). The original product of the British firm Glaxo Wellcome is sold for more than double the price in India, Pakistan and Indonesia - and costs five to six times more in the USA and Great Britain. Fourth, for millions of poor patients in developing countries the generic drugs imported from India are lifesaving as a result of their low prices. The Indian pharmaceutical industry has grown fast in size and in exports, and thanks to its low prices, India has become the pharmacy of the developing world. Will this pharmacy be closed?

When striking a balance between the four interests mentioned, access to cheap and effective medicines for poor patients should have priority, while research to find better drugs has to be stimulated as well. Rich countries have used the WTO to protect their IPRs through the TRIPS agreement. Under pressure of public protest and developing country opposition they had to accept compulsory licensing and trade in drugs produced under compulsory licensing in case of public health crises such as the HIV/AIDS epidemic. The EU now tries to reinforce the international IPR protection by again reverting to trade policy instruments: seizing goods in transit and including IPR protection in bilateral trade agreements. The EU – and other rich countries for that matter - should stop to impose their IPR regime on other countries through trade policy measures as this is a counterproductive way of taking care of the health problems of the poor, while it does not stimulate research in therapies for tropical diseases. What is needed is an international agreement on the protection of IPRs in general with special rules for innovations in areas of life and death.

The main argument for IPR protection is that the innovator must be allowed to extract rents from the buyers to recover the huge amount of research & development costs for its innovation. Otherwise, the MNCs will not undertake research & development and that would mean a smaller number of innovations. While this seems obvious and justified, there are several caveats to this argument though. First, to what extent and how long the innovator should extract rents to recover its research & development costs? The second part of this question is how to deal with the length (or life) of patent protection granted to the innovator, which is fixed at 20 years from the filing date of the patent application in the TRIPS Agreement. However, the cost-benefit analysis underlying this number is not clear at all. Second, how far should the above argument be extended to the market for health care and drugs for deadly diseases like AIDS, malaria and tuberculosis?
The monopoly power that patent protection confers upon the patent holder firm has resulted in quite high prices for essential drugs for AIDS in the developing and the poor countries. Of course, country-based or income based discrimination allows the low-income developing countries to access the drugs at a lower price than the richer developed countries. Yet, in absence of any competition, prices remain quite high and drugs remain unaffordable for a vast majority of poor patients in the developing countries. The cost of individual AIDS-combination therapy in India a few years ago had been more than US$300 per month, which was prohibitively high as a vast majority of the Indian population does not even earn a monthly income of US$100. A similar situation prevails in Pakistan, Indonesia and other low-income countries. Given that more than 95% of all HIV-infected people - 34 million worldwide - live in developing countries, IPR protection for medicines and drugs simply imply denying these patients access to the available drugs and consequently their rights to live. In India alone, eight million people are estimated to be HIV-positive of whom five hundred thousand people have already developed AIDS. Often, AIDS patients die of tuberculosis, an illness still prevalent in India, because they lack the necessary resistance.

The situation is further worsened for them by high and upper-middle income countries like Australia, the EU, Japan, Hong Kong, New Zealand and Singapore that allow parallel imports of patented drugs from the low-income developing countries. Once a country allows parallel imports, a patented drug can be bought and imported from other countries, usually from the low-income countries where the patented drugs are priced lower than they are priced in a richer country, without the permission of the patent holder. Parallel imports got their first endorsement from the European Court of Justice and the Treaty of Rome and is known in the EU as the internal rule of market: patent-holder’s sales right is exhausted EU-wide once the on-patent product is marketed within EU. Subsequently, the Article 6 of TRIPS allows countries to set their own rules of exhaustion of patents and copyrights. However, the national rules on parallel imports (or exhaustion of patents and copyrights) vary widely across the globe according to whether a country is an importer or an exporter. The USA allows only national exhaustion of patents and copyrights and even incorporates such clauses (the so-called TRIPS-Plus features) in bilateral trade negotiations to protect the interests of their MNC-exporters.

3 Under such a provision, the exclusive right to sell and distribute a patented drug by a patent-holder MNC would be exhausted after the drug is being marketed, and traders reselling the drug would not need permission from the patent holder. This parallel trade in original patented drugs is altogether different from imitation of the patented drug which is the production and sale of drugs closely similar to the patented drug without the permission of the patent holder.
Parallel imports are allowed by the richer countries to prevent cross-county price discrimination by the patent holder pharmaceutical firms and to ensure access to patented drugs for their poor patients. Drug prices across countries tend to converge but at a level higher than what would have prevailed in the low-income developing countries without parallel imports. Thus, patients in the high-income countries gain at the expense of poor patients in the low-income countries. The general theoretical consensus now is that price convergence makes the richer countries unambiguously better off but the poorer countries unambiguously worse-off [Danzon (1998), Maskus (2000) and Richardson (2002)]. There are other issues like adverse effect of parallel imports on the level of innovation and consequently the quality of drugs developed by pharmaceutical MNCs [Acharyya (2008), Acharyya and Garcia-Alonso (2008a), Maskus (2000), Valletti (2006)] and market access for the poor patients in the poorer countries [Acharyya and Garcia-Alonso (2008b)]. Worse still, to prevent price arbitrage through parallel imports, the pharmaceutical MNCs often price the patented drugs high enough to exclude low-income countries from accessing the drugs altogether and thus preventing these countries becoming potential sources of parallel imports, as has been argued by Malueg and Schwartz (1994).

Two interesting facts emerge out of the discussions above. First, benefits of TRIPS -- both product patent and flexible clauses and exceptions like parallel imports-- are neither unequivocal nor uniform across nations. Second, ensuring market access for poor patients is the common element in both not implementing a strict IPR (i.e., not allowing product patent) and allowing parallel imports. Since parallel imports adversely affects innovation as shown by Valletti (2006) of late, there has been an equally interesting conflict between a strict IPR and allowing parallel imports in terms of generating incentives for innovation.

To sum up, difficult questions will have to be addressed in arriving at an international consensus on IPRs in health care, such as the acceptable remuneration for the innovator, and the length of the IPR protection. Parties will have to agree on the regime to be applied in the market for health care and drugs for deadly diseases like AIDS, malaria and tuberculosis. It may be more promising to consider the idea to establish an international authority that can buy IPRs on drugs and issue licenses to produce at low prices. Working along these lines is more promising than addressing these global issues in a bilateral trade agreement between the EU and India, and imposing sanctions on India for producing generic drugs and saving millions of lives across the world. It is high time that we review the IPR protection in health care with an open mind and find an answer to why it has not delivered the good for most of the poor in the world.
References:


