Access to Essential Medicines in Developing Countries: Does the WTO TRIPS Agreement Hinder It?

Jayashree Watal

Visiting Fellow, Institute for International Economics, 11, Dupont Circle, NW, Washington, DC 20036

Tel.: 1 (202) 328-9000; (202) 234-4795 Ext. 327 Fax: 1 (202) 328-543
E-mail: watal@iie.com Web: http://www.iie.com

Abstract: TRIPS could, in certain cases, lead to higher prices for patented medicines, including for important diseases such as HIV/AIDS. However, policy instruments available under TRIPS, such as compulsory licenses or government use, parallel imports and price controls, if designed with care, could attenuate such adverse effects on the affordable access to medicines considered essential.

Keywords: TRIPS agreement, medicine, patented medicine, disease, HIV/AIDS, imports, price controls, access.

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The impediment allegedly caused by intellectual property rights (IPRs) to the access to essential medicines by the poor in developing countries has been a subject of raging controversy since the finalization of the agreement in the World Trade Organization (WTO) on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in April 1994. This chapter aims to examine whether or not it is true that the provisions of TRIPS impede access to essential medicines.

The problem in accessing essential medicines:
Expenditures on medicines can represent up to 66% of total health spending in developing countries and could be a major cause of household impoverishment, as 50-90% of such expenditures are out-of-pocket expenses. Today, over one-third of the world’s population and over one-half of the poorest in Asia and Africa still lack access to essential drugs. According to the WHO such access should cover the therapeutic, physical and financial aspects i.e. cover priority health problems, be available within easy physical reach and be affordable to all. [1]

For the poor in developing countries, availability and affordability of essential medicines are both key problems. Some fear that with the introduction of strong product patents for medicines, through the world-wide uniform standards of the WTO TRIPS Agreement, prices of essential drugs would be even higher and therefore, even less affordable for the poor. This is because such patents give their owner the right to exclude all others from unauthorized making, using, selling or distributing the product, thus giving a ‘legal monopoly’ right. However, others quibble that few medicines, listed as essential by WHO, are presently covered by patents. This is almost by definition, as affordability is one of the criteria used in the selection of these drugs.[2] Further access to medicines will continue to be poor even in the absence of patents, due to lack of adequate purchasing power and necessary infrastructure.

The case of HIV/AIDS in developing countries has focused attention on patents and prices. An estimated 95% of those suffering from this disease live in developing countries where the disease is showing no signs of abatement. With over half of such persons belonging to the most productive age of below 25 years, this disease is causing serious social and economic consequences. Being a relatively new disease, many of the medicines are still under ‘live’ patent protection, with expiry dates of a decade or more.

Prior to TRIPS, most developing countries and some developed countries excluded medicines from being patented even if they met the criteria of being new and inventive. Today, almost all these countries are members of the WTO and have to implement TRIPS, thus allowing for the filing of patents for new pharmaceutical inventions at least from 1995 and the grant of product patents or similar exclusive marketing rights on them, where eligible.

It must be noted that even under the TRIPS regime, patents are to be granted only on applications received from 1995 onwards for new, patentable pharmaceutical inventions. Thus, prices of existing drugs already on the market, or even those covered by patent applications prior to 1994 anywhere in the world, should not be affected by TRIPS, as these markets could continue to be as contestable as before. The required patent term is 20 years from the date of application. Patent owners typically file for patents only in important markets or where they particularly anticipate piracy. Therefore, even when patents are available, patents may not be requested in every developing country.

Moreover, the ability of the patent owner to price the product above his marginal cost is largely governed essentially by the availability of close substitutes: the higher the number of effective substitutes, the lower is the ability of the patentee to raise price without losing revenues and profits. It is rare to find a disease condition that can be treated with only one, patented medicine. Quite often a successful patented medicine gives rise to a spurt of “me-too” products that invent around it.

Innovator pharmaceutical companies defend product patents as the necessary incentive for investment in research and development, although they perversely argue that lack of patent protection impedes the competition that can lower drug prices since consumers do not benefit from generic entry! [3] It is true that no-patent pharmaceutical markets are also often fairly
concentrated on account of brand loyalties and other factors. What then, if any, is the extent of the price difference between patented and non-patented medicine?

Estimates of price differences of medicines on account of patents

There are few reliable estimates of differences in prices of medicines in developing countries, on account of patents alone. A simple and appealing methodology often used is inter-country comparisons of drugs of similar composition and presentation. However, such comparisons are clearly faulty as, without more information, one cannot attribute the differences to the presence or absence of patents alone. Even price comparisons between countries at similar levels of economic development only give a partial picture.

The more meaningful study would be of the effects of generic entry on drugs coming off patent, for which of course, data is not yet available in these countries. Several studies done using data on the US market show considerably significant and rapid price decreases with generic entry upon patent expiry. For instance, one study shows an average generic/branded price ratio of 0.59 after patent expiry with just one generic manufacturer and 0.17 with twenty such manufacturers. This is partly because, perversely, the price of the lead brand, which has lost patent protection, actually increases to protect total revenues.[4] Another more recent report shows that the average retail prescription price for innovator drugs from a single source could be as high as 300% that of prescription generic drugs.[5] A simulation study done by this author for the Indian pharmaceutical market, controlling for substitutes, shows similar price differences. The price increase on account of product patents alone could be as high as about 250% under certain assumptions. [6]

Policy instruments available under TRIPS

Although, the poor may still not have affordable access to essential medicines for reasons of low purchasing power and poor infrastructure, fortunately, there are several policy options open to the governments of WTO member countries under TRIPS to attenuate the adverse price increases associated with product patents.

i. Compulsory licenses:

Under a compulsory license, the right holder is forced to license his patented invention to a third party, decided by governments or courts, and obtain an ‘adequate remuneration’ in return. Indeed, several studies have found evidence that important patented inventions are generally not licensed voluntarily for financial considerations, particularly in the pharmaceutical sector.[7] Thus, non-voluntary licenses can be an important way for governments in developing countries to make patented inventions available at more competitive prices. The very existence of statutory provisions on compulsory licenses may, in fact, be adequate to encourage voluntary licenses.

There are no restrictions on the purposes for the grant of compulsory licenses or use by governments, although TRIPS Article 27.1 disallows discrimination in the enjoyment of patent rights between imported and locally produced products.[8] The conditions listed in TRIPS Article 31 have been called “strict safeguards”. However, some of the crucial conditions are entirely dependent on the purposes and merits of such grant, as laid down in national laws. This gives considerable leeway to policy makers in developing countries to construct the grounds such that the conditions do not become restrictions. For example, if the purpose is to lower prices, it can be tackled by making the sale of patented inventions on unreasonable terms a ground for compulsory licenses.[9] Alternatively, an undertaking in the public or private sector could, in public interest,
be authorized by government to manufacture a patented pharmaceutical product for sale to the public through government hospitals or health centers on a non-commercial basis. Indeed, the patent laws of several developed and developing countries contain such provisions, although only one, Canada, actually used this instrument extensively in the past for medicines.

However, in cases where the cooperation of the right holder has to be ensured to work the invention, voluntary licenses should be preferable. Also, many developing and least developed countries do not have a generic drug industry and thus, may have to rely on imports. TRIPS only conditions the grant of a compulsory license on predominant ‘supply of the domestic market’, thus allowing both entire imports and partial exports. Through inter-governmental cooperation amongst developing countries, those with generic industries and strong domestic demand can grant compulsory licenses for partial export to those without such an industrial base. However, extensive use of this policy instrument could adversely affect trade relations, and, in some cases, domestic innovation. Therefore, developing countries must incorporate the flexibility available in Article 31 into their patent laws, even while using this instrument sparingly in practice. In addition, they can also use competition policy instruments to ensure that patent licensing conditions are not unduly restrictive or beyond the scope of the patent rights or that the patent owner’s behaviour is not anti-competitive. If remedies in such cases result in compulsory licenses, the TRIPS conditions are somewhat more lenient.

ii. Parallel imports

Generally speaking, IPRs are exhausted once the goods or services, which incorporate these rights, are put on the market. The controversy arises when goods, legitimately and consensually placed on the market in one country by the IPR owner, are imported into another country without the authorization of the IPR owner in that country.

Article 6 of TRIPS does not prohibit members from following their national laws on the question of parallel imports or exhaustion of IPRs as long as there is no discrimination amongst IPR owners on grounds of nationality. WTO members are explicitly prohibited from using the dispute settlement mechanism to address this issue.

Given the fact that there are huge price variations in the prices of identical medicines across countries, some see this provision as a major policy option for developing countries to attenuate the ill effects of strong intellectual property protection, apart from eliminating unfair duplication of the rights of IPR holders. Others argue in favour of clearly prohibiting parallel trade in products protected by all IPRs, particularly pharmaceuticals, to protect the incentive to innovate. They attribute price differences to many factors outside the control of pharmaceutical companies and argue that prices do not fall even with parallel imports.[10] However, such a prohibition would require TRIPS to be amended.

South Africa recently amended its Medicines Act to allow for parallel imports of medicines, leading to strong pressure from US and Europe based pharmaceutical companies, through diplomatic and legal channels, to amend its policies. However, with domestic and international sensitivities on finding rapid solutions to the AIDS problem in Africa, the USTR announced an agreement with South Africa to respect TRIPS and the pharmaceutical companies were forced to hold their hand on this issue for the time being.[11] Similarly the Thai patent law allows the importation of patented products if the patentee has consented to the manufacture or sale of the product elsewhere. It is alleged that Thailand receives a relatively high level of parallel imports of pharmaceuticals from other parts of Asia.[12] Argentina too has, in its new patent law,
specifically permitted international exhaustion. Brazil, however, has opted for national exhaustion of rights i.e. prohibition of parallel imports.

However, it has to be noted that consumers in developing countries from which parallel imports originate may experience a rise in prices or may face inadequate availability of the product subjected to parallel exports. However, this is a matter of empirical study and verification. Also, it is not clear, a priori, which countries would be parallel exporters and which parallel importers as this would differ with product and perhaps, over time.

iii. Price controls

Almost all countries in the world regulate prices of medicines, particularly of patented medicines, through review mechanisms or cost-reimbursement limitations or through administratively fixed cost-plus prices. This policy instrument is not prohibited by the TRIPS Agreement. India, for example, has established a cumbersome, and relatively inefficient, system of administrative price controls.[13] However, the costs of effectively administering such a system may well outweigh the benefits. Reference pricing systems may lead to uniformly higher global prices and strictly enforced price regulation could lead to shortfalls in the availability of essential medicines.

iv. Generic drug approvals and other measures:

Developing country members of the WTO should be aware that TRIPS does not, even under its provisions on test data, explicitly prohibit countries from permitting the regulatory approvals of generic drugs to occur before the patent term expires. Thus, generic drug companies can be ready to put out substitutes very soon after patent expiry.[14] Also, TRIPS does not require patent term extensions granted now in many countries for pharmaceutical products to compensate for regulatory delays. Similarly, TRIPS does not require patents to be granted for human genes, new therapeutic uses of known substances nor on methods of medical treatment. New formulations and dosage and delivery forms of patented medicines need not be given fresh patents or other forms of market exclusivity, unlike in the case of many developed countries.

Conclusion

TRIPS requires the availability of product and process patents for pharmaceuticals virtually from 1995, dramatically changing patent laws in developing countries that earlier allowed such exclusions. This change will, almost certainly, lead to higher prices up to about 200-300% for patented medicines, including for important diseases such as HIV/AIDS, in countries where such patents are valid. Policy instruments available under TRIPS such as compulsory licenses or government use, parallel imports and price controls could attenuate such adverse effects on the affordable access to medicines considered essential. None of these instruments is without certain disadvantages and must be used with care. Finally, despite pressures from certain quarters, developing countries need not go beyond what TRIPS requires.

References

1 See “Access, Quality and Rational Use of Medicines and Essential Drugs” at [www.who.int/medicines/edm-concept.html](http://www.who.int/medicines/edm-concept.html)

2 Several countries have their own national essential drug lists, which they use for various policy measures, including price regulation.


This is generally interpreted to mean that a compulsory license cannot be granted solely on the ground that the patented invention is not being manufactured locally.

Watal (2000) estimates price reductions of over 90% in some medicines in India with the use of compulsory licensing.


See [www.cptech.org](http://www.cptech.org) for a flavour of the debate on this issue. See also [www.phrma.org/issues/intl/safrica.html](http://www.phrma.org/issues/intl/safrica.html) for the US pharmaceutical’s industry’s stand on the issue.

See [www.phrma.org/issues/intl/thailand.html](http://www.phrma.org/issues/intl/thailand.html)

Use of such a system could reduce prices by a maximum of about 40% from patent monopoly levels, if costs can be correctly determined. See Watal (2000).

A WTO ruling in the EU-Canada dispute on this issue is expected to confirm this shortly.