

TRADE HOT TOPICS

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TRIPs, HIV/AIDS and Access to Medicines

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1. INTRODUCTION

The HIV/AIDS pandemic has claimed more than 17 million lives in sub-Saharan Africa. Of the 36,000,000 people infected with the HIV virus more than 25,000,000 live in sub-Saharan Africa. The scale of this disaster has triggered a global dialogue involving states, groupings of states such as the G8, international organisations, health activists, professional associations, researchers, business organisations and pharmaceutical companies. Much attention has focused on the high cost of anti-retroviral therapies used to keep HIV in check, and the cost of other drugs used to treat diseases which accompany HIV. According to OXFAM, these drugs typically cost between 3 and 15 as much as their generic equivalents.

2. ACCESS TO MEDICINES

The World Health Organization (WHO) in its *WHO Medicines Strategy: Framework for Action in Essential Drugs and Medicines Policy 2000 – 2003* defines access to mean “equitable availability and affordability of essential drugs with an emphasis on diseases of poverty”. Price is therefore one of the pillars of access. Other factors identified by the WHO as crucial to access are rational selection, sustainable and adequate financing and reliable health care and supply systems.

3. PATENTS AND PRICE

A patent is legal monopoly which enables the patent owner to exclude others from making the patent invention. A legal monopoly does not necessarily entail an economic one. The extent to which the patent owner can charge monopoly prices depends on: consumer demand (high for life-saving drugs); the ability to pay (low in developing countries); and the degree of substitutes for a given chemical compound).

Depending on the interaction of these factors patents on drugs may or may not lead to monopoly pricing. Other intellectual property rights are also relevant to the price of pharmaceutical products. Trade marks may also allow their owners to price well above marginal cost. Trade marks are a vital price tool for pharmaceutical companies in the post-patent period for a drug.

Within the context of patents, price and access to essential medicines two points are generally made.

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4. TRIPS

Campaigners have been particularly concerned about the effects of international trade rules as embodied in the WTO's TRIPS (trade related aspects of intellectual property rights) accord. Under that agreement, members are required to provide exclusive marketing rights to holders of patents on pharmaceutical products for a period of at least 20 years. This imposes restrictions on what governments can do in regard to production, marketing and import of low-cost copies of patented medicines (generic drugs). The effects of these restrictions are felt in two ways: (a) reduced competition and (b) increased prices for drugs essential in the treatment of HIV/AIDS and other common illnesses.

Key features of TRIPs include:

1. The requirement in Article 27.1 that patents shall be available for product and process patents in all fields of technology (including, therefore, pharmaceutical products);
2. The requirement in Article 27.1 that patents be available and patent rights be enjoyable without discrimination as to field of technology or whether patented products are imported or locally produced. (The precise effect of TRIPs on local working is currently the subject of a WTO dispute resolution proceeding between the US and Brazil.);
3. Discretions in Article 27.1 allowing Members to exclude from patentability inventions on the grounds of protecting order public or morality, as well as diagnostic, therapeutic and surgical methods for treatment of humans or animals. Members are obliged not to exclude micro-organisms and non-biological and microbiological processes from patentability. (Depending on the definition of these terms gene-based treatments for HIV/AIDS may fall into the category of patentability.);
4. A provision on compulsory licences Article 31 making the use of such licences conform to a comprehensive set of conditions;
5. Obligations creating data exclusivity in relation to test data for new chemical entities submitted to national regulatory bodies as part of the process of obtaining marketing approval;
6. Stronger trade mark protection (relevant to post-patent, brand name pricing strategies).

5. * TRIPS AND THE REGULATION OF THE PRICE EFFECTS OF PATENTS

(a) *Regulating the Price Effects of Patents*

In the past states have dealt with the market power/price effects of patents in the pharmaceutical sector using one or more of six options:

1. Excluding pharmaceutical products and/or processes from patentability.
2. Issuing compulsory licences.
3. Purchasing patented pharmaceutical products in those markets where they are the cheapest and importing them (referred to as parallel trade or importation).
4. Using competition law to regulate the conduct of a patentee in the market.
5. Bringing the patented product or process within a regime of price controls.
6. Developing a regulatory environment that encouraged a return to competitive market conditions for a patented product.

(b) *Assessment of Availability of Options*

Option 1 has been largely excluded by TRIPs. It is true that Article 27(1) of TRIPs is subject to Article 27(2) which allows Members to exclude from patentability inventions, "the prevention within their territory of the commercial exploitation of which is necessary to protect order public ... including to protect human health". The scope of this exception is probably narrow.

Option 2 has not been excluded by TRIPs. Article 31 does not confine the use of compulsory licences to specific circumstances. Rather it imposes conditions upon the use of such licences. In three cases - national emergency, circumstances of extreme urgency or public non-commercial use - there is no obligation on the user of a patent to obtain authorization from the patent owner prior to the use. The HIV/AIDS crisis in Africa would qualify as a national emergency.

There is debate about the scope of the compulsory licensing provision. It has been suggested, for example, that a state might issue a compulsory licence to a foreign third party to manufacture drugs in circumstances where there was no local manufacturer to take up the authorisation. There is nothing in Article 31 which expressly prohibits such an option. The capacity of a foreign third party to take up such a licence would be affected by whether the relevant patent was registered in the country in which the third party proposed to make use of the licence. Under the principle of territoriality, the immunity from infringement that a licence confers would only operate in the territory of the state granting the licence.

The issue of foreign third parties being able to rely on a compulsory licence is of enormous importance to developing countries, since a large number of them (59) have no pharmaceutical industry at all. Only five

developing countries have pharmaceutical industries capable of producing drugs by reverse engineering a drug and developing new processes of production - Argentina, China, India, Korea and Mexico.¹ The capacity of these five countries to issue compulsory licences themselves for the purpose of exporting drugs to other developing countries is affected by Article 31(f) of TRIPs, which says that such licences must be predominantly for the supply of the domestic market of the state issuing the licence. States have the option of deciding that the limitation of domestic supply may not apply in cases of anti-competitive practices (see Article 31(k)). This, however, makes the supply of export markets contingent upon the effects of competition practices within the authorising state.

Option 3 also remains the subject of uncertainty. Parallel importation is one means by which states secure drugs at cheaper prices. The essence of parallel importation involves goods put on the market by a manufacturer in one country being purchased in that country by another party and imported into a second country because the goods are cheaper than the price at which the manufacturer sets for those goods in that country. If the goods are the subject of intellectual property rights the manufacturer may oppose the importation relying on those rights. Patents, copyright and trade marks are all relevant to the importation of drugs. The manufacturer's legal capacity to stop importation depends on the theory of exhaustion that prevails in the importing state.

The intention behind Article 6 was to leave TRIPS neutral in terms of its effects on the exhaustion of intellectual property rights. Article 6 prevents states from using TRIPS provisions to address the issue of the exhaustion of rights for the purposes of dispute settlement. The position on exhaustion would, therefore, be governed by international treaties and the domestic law of states as it existed prior to TRIPS. There is the added complication, however, that TRIPS incorporates some international treaties such as the Paris Convention by reference. In addition, Article 28 of TRIPS states that the right of importation is one of the exclusive rights of the patent owner. The upshot is that the position on exhaustion has to be worked out on a case by case basis.

Option 4 is recognised in Articles 8 and 40 of TRIPs.

Option 5 in principle is available to states under TRIPs.

Option 6 consists of states enacting laws encouraging generic pharmaceutical manufacturers to make a version of the patented product so that the patent owner faces price competition in the post-patent period. A law of this type, which is common in developed countries, is one that enables a generic manufacturer to make use of a patented product for the purpose of obtaining scientific and other data needed for regulatory approval of the generic version. Provisions of this kind in Canada's Patent Act were the subject of a WTO Panel decision (WT/DS114/R). Canada argued that Article 30 of TRIPs permitted the measures in its patent law and that it had not discriminated against a field of technology. The WTO Panel found that the regulatory review exception was not inconsistent with Canada's obligations under TRIPs but another provision permitting stockpiling was inconsistent.

It is not possible to conclude much from this one decision about the availability of option 6. Much will depend on the drafting of the domestic measure in question. It is clear that Article 30 of TRIPs offers no easy route to states wishing to pass measures to encourage the entry of generic manufacturers and that the obligation in Article 27.1 not to discriminate against a field of technology forms an obstacle to such measures. The provisions in TRIPs on product patents, patent term and data exclusivity delay the entry of generic manufacturers into the market.

Differential Pricing/Tiered Pricing

Differential pricing is the "adaptation of prices charged by the seller to the purchasing power of governments and households in different countries".² There is considerable agreement that its use would improve the access of poor countries to essential medicines. In order to induce global pharmaceutical companies to price differentially on a much wider scale than at present cheap drugs destined for poor markets would have to be stopped from leaking back into markets that can bear higher prices. To this end the following suggestions have been made.³

- the use of different labelling and packaging by manufacturers.
- secure supply chains that ensured the drugs reached their intended recipients.
- involving drug regulatory authorities which authorise the importation of drugs into developed countries from developing countries.
- using customs authorities in developed states to stop importation.
- seeing whether some poor countries could offer export controls.
- using intellectual property rights to restrict parallel imports (it should be noted that this last option is not an enforcement mechanism, but merely a right that calls for an enforcement mechanism).

¹ See K. Balasubramaniam, 'Access to Medicines: Patents, Prices and Public Policy: Consumer Perspectives', Oxfam International Seminar on Intellectual Property and Development, Brussels, 20 March 2001, 7.

² See Report of the Workshop on Differential Pricing of Essential Drugs, WHO and WTO Secretariats, Norwegian Foreign Affairs, Global Health Council, 8-11 April 2001, Høsbjør, Norway, 3.

³ See Report of the Workshop on Differential Pricing and Financing of Essential Drugs, WHO and WTO Secretariats, Norwegian Foreign Affairs Ministry, Global Health Council, 8-11 April 2001, Høsbjør, Norway, 21-22.

5. US, EUROPE, TRIPS AND ACCESS TO MEDICINES

(a) US

In the 2000 Special 301 Report issued by the USTR it was stated that should a state avail itself of the flexibility that TRIPs provides to address a health care crisis the US would raise no objection provided the policy employed was consistent with TRIPs.

In May of 2000 the Clinton Administration issued an Executive Order aimed at ensuring that US trade tools would not be used against sub-Saharan states passing laws regulating the availability of pharmaceuticals in relation to HIV/AIDS, provided that those laws were consistent with TRIPs standards. The Bush Administration has indicated that it will not overturn the order.

Under US trade law 'Special 301' a "foreign country may be determined to deny adequate and effective protection of intellectual property rights notwithstanding the fact that the foreign country may be in compliance" with TRIPs (See 19 USC Section 2242(d)(4)).

A Bill introduced by Senators Dianne Feinstein and Russ Feingold on March 6 2001 would, amongst other things, modify this position. If a country undergoing an HIV/AIDS-related public health crisis passes laws that are consistent with TRIPs then it will be construed to provide adequate and effective protection of intellectual property rights for the purposes of US trade law.

(b) European Community

In September 2000 the European Commission adopted a policy framework on major communicable diseases within the context of poverty reduction. This policy framework was amplified in the 'Programme For Action: Accelerated Action on HIV/AIDS, malaria and tuberculosis in the context of poverty reduction' (COM (2001) 96), which was adopted by the Commission on 21 February 2001.

On the issue of intellectual property legislation the programme for action states -

- that the European Community is committed to supporting TRIPs implementation by developing countries.
- that, within the TRIPs Agreement, there exists a flexibility allowing countries to issue, in certain circumstances, compulsory licences in order to address urgent public health concerns.

The European Community also favours the establishment of a "global tiered pricing system for key pharmaceuticals for the poorest developing countries" (see para 3.2.1). It would like to see tiered pricing become the norm for such countries.

6. CONCLUSION

The US and the EC share similar positions on the issue of TRIPs and access to medicines. Both would like to see developing countries press on with the implementation of TRIPs. Both acknowledge that there is some flexibility in TRIPs for states to set national intellectual property laws that allow them to deal with a public health crisis. Neither has indicated that it is prepared to consider a radical reform of TRIPs in ways that would see public health goals override the minimum standards set down in TRIPs. Both support a policy approach based on the goal of differential or tiered pricing for pharmaceutical products. Both continue to negotiate bilateral agreements that contain provisions on intellectual property rights. In some cases these provisions set higher standards of protection than those to be found in TRIPs. Both support a continued dialogue between the WHO and the WTO on this issue.

At the multilateral level, the WTO and WHO have sought to promote dialogue on issues that lie at the intersection of health and trade problems. Thus at a WTO/WHO workshop on Differential Pricing and Financing of Essential Drugs, held in Norway in April 2001, the WHO Director General stated that patents on Pharmaceuticals should be managed in a balanced way and support should be given to competition mechanisms (e.g. promoting generic policies and parallel imports) which improve access to essential drugs. On the other hand, the WTO has taken the line that current TRIPs standards permit states to meet their healthcare objectives. Thus, the position to date seems to be that strategies for access to essential drugs will have to operate within the parameters set by TRIPs.

Precisely what those parameters are may be determined by states through a dialogic process within the WTO itself. At the April session of the TRIPs Council the Africa Group obtained agreement that a TRIPs Council meeting in June would be devoted to the issues raised by TRIPs and access to medicines.



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