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Patents and Access to Medicines: What Can be Done at National Level

by Martin Khor

Access to medicines, which is part of the human right to health services, has emerged as a major public health issue, especially with the impact of patents on the prices of drugs. The patenting of medicines has become more prevalent after the establishment of the Trade-related Intellectual Property Rights (TRIPS) Agreement in the World Trade Organisation in 1995. That agreement made it compulsory for WTO members to include medicines in their regime for product and process patents.

A few years ago, there was a public outcry after public health and development organizations highlighted how the monopoly granted by patents enabled the maintenance of excessive prices of medicines for HIV-AIDS. The cost of treatment of patented drugs per patient per year was US$10,000-15,000 in developed countries, whereas some generic producers in developing countries were able to provide them for as low as US$300. If developing countries are able to make or import these generic drugs at cheaper cost, that would significantly increase access to medicines.

Whilst mandating that WTO members have to allow patenting for medicines, the TRIPS Agreement does contain flexibilities. For example, if patented drugs cost too much, the government authorities can take measures such as issuing a compulsory licence to an agency or company to manufacture or import a generic version of that patented drug, which can then be made more available to patients more cheaply.

At the WTO's Ministerial Conference in 2001, the Doha Declaration on the TRIPS Agreement and Public Health was adopted as a response to the public concerns. The Declaration reaffirmed and clarified the flexibilities available under TRIPS Agreement, and proclaimed: "We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health….We affirm that the Agreement can and should be interpreted in a manner supportive of WTO Members' right to protect public health and in particular, to promote access to medicines for all." It spells out several flexibilities that WTO members can use to the full, such as the right to grant compulsory licences and the freedom to determine the grounds for these.

If the Doha Declaration is to benefit patients of AIDS and other ailments in developing countries, these countries now have to establish appropriate provisions in their national patent legislation by using "to the full" the flexibilities in the TRIPS Agreement. They also need to formulate and implement national policies aimed at providing access to medicines for all. In doing so they would be operationalising, at national level, the aims of Doha Declaration. If such laws and policies are not introduced, the gains made at international level through the Declaration will not translate into actual benefits for patients.

In other words, whilst in recent years the goal for access to medicines had been significantly fought at the international level, action is now equally or even more important at the national level, where policy makers should focus on policy and practical measures to get medicines to poor patients.

TWN THIRD WORLD NETWORK is a network of groups and individuals involved in bringing about a greater articulation of the needs, aspirations and rights of the people in the Third World and in promoting a fair distribution of world resources and forms of development which are humane and are in harmony with nature.

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The Manual

With this in view, the Third World Network (TWN) in 2002 and 2003 organized a series of international, regional and national meetings involving legal experts, NGOs and policy makers to discuss the options available to developing countries for policies and legal provisions that are oriented to meeting public health concerns. The outcome of these meetings is a "Manual on Good Practices in Public-Health-Sensitive Policy Measures and Patent Laws", recently published by TWN.

The Manual contains three parts. Part I describes options for countries to establish policy measures to import, produce and export affordable medicines through measures that are consistent with the TRIPS Agreement. These measures include such as compulsory licensing, "government use" procedures, and parallel importation of drugs that are patented in these countries, thus enabling the use of cheaper generic versions of the patented branded drugs, and also cheaper versions of the same branded products. The advantages and disadvantages of each of the policy options are discussed, as well as the legal requirements for their implementation under the TRIPS Agreement.

Part II provides model legal provisions for national patent laws, that are sensitive to public health concerns, and at the same time consistent with the TRIPS Agreement. The model provisions are accompanied by explanatory notes that describe and explain the provisions, including how they comply with the TRIPS Agreement, with examples of "good practices" in national laws from around the world.

Part III contains proposals for an appropriate institutional and administrative framework to implement the proposed patent laws and policy measures. The framework should incorporate an administrative system for implementing compulsory licensing and government use of patents, based on fair and transparent decision-making processes and clear and easy-to-apply guidelines, including for compensation to the patent holder.

As the Manual points out, governments can take a range of policy measures to facilitate access to affordable medicines, including the following:

Importing the Drug

A country can import a generic version of the patented product by issuing a compulsory licence to a company or agency to import the drug, and the government has the freedom to determine the grounds upon which such licences are given. The imported drug can be from a country in which the drug is not patented, or in which the drug is patented (in which case the exporting country has also to issue a compulsory licence). The applicant has to firstly negotiate to obtain a voluntary licence from the patent holder, and if that fails, then a compulsory licence can be granted. Adequate compensation has to be paid to the patent holder.

Import of a generic version of the patented drug can also be imported for "public, non-commercial use" by the government. Under this "government use" procedure, the prior consent of or negotiations with the patent holder is not required, but adequate compensation has to be paid. This method is suitable if the imported drug is to be used by the government.

There can also be "parallel importation" of a patented product (i.e. not the generic version) from another country, where the same patented product is being sold at a lower price than in the importing country. This is allowed under Article 6 of the TRIPS Agreement on exhaustion of rights, and the Doha Declaration affirms this by stating that each WTO member is "free to establish its own regime for such exhaustion without challenge." There is no need for an importer to obtain a compulsory licence, nor to pay compensation to the patent holder.

Local Manufacture

If a drug is patented in a country, generic versions of the drug can be locally manufactured by a local company or agency that has been granted a compulsory licence. The applicant has to negotiate with the patent holder for a voluntary licence and failed to obtain such a licence, before applying for a compulsory licence. This requirement however does not apply if the compulsory licence is issued on grounds of public non-commercial use, for national emergency or situations of extreme urgency and to remedy anti-competitive practices. Compensation has to be paid.

The government can also assign to a public or private agency the right to locally manufacture a patented product without the patent holder's permission, provided it is used for a public non-commercial purpose. Compensation has to be paid.

Export, Including to Countries with Inadequate Manufacturing Capacity

A local producer of generic versions of patented products under a compulsory licence or government-use provision may export a portion of its output. However Article 31(f) of the TRIPS Agreement requires that this production shall be "predominantly for the supply of the domestic market" and thus there is a limit to the amount that can be exported. This restriction does not apply when the compulsory licence is granted to correct anti-competitive practices.

The restriction on export quantity has posed a problem for developing countries with insufficient or no drug manufacturing capacities, as they may find it difficult to import the required medicines since there is a limit to the amount the potential exporting countries can supply to them.

The Doha Declaration recognized this problem could also affect access to medicines, and mandated the WTO to find a "expeditious solution". After a lengthy negotiation, the WTO General Council in August 2003 adopted a decision on a "temporary solution" in the form of an interim waiver to the Article 31(f) restriction, such that countries producing generic versions of patented products under compulsory licences would be allowed to export the products to eligible importing countries, without having to limit the exported amount.

However, the Decision also obliges importing and exporting countries that wish to make use of the waiver to undertake several measures and fulfill several conditions. It has been pointed out by some experts and NGOs that these measures and conditions are difficult for the relevant companies and governments to comply with.

The importing country wishing to import from a country which requires the waiver has to notify the WTO by specifying the names and quantities of the drug required, confirm it has insufficient or no manufacturing capacities and that it intends to grant a compulsory licence. It also has to take measures to prevent re-exportation of the products imported under the system.

The generic manufacturer in the exporting country will require a compulsory licence if the medicine is under patent protection on its country. The exporting country has to notify the WTO of the grant of the CL and its conditions, including the product, the quantities for which it has been granted, and the importing countries. Only the amount needed by the importing Member may be manufactured under the licence, and all of this output must be exported to the importing country. The products must be clearly labeled or marked through special packaging and shaping of the products, provided it does not significantly impact on price And adequate compensation should be paid.

There are additional requirements under a "Chairperson's Statement" linked to the decision, such as that the system should be used in good faith and not pursue a commercial policy objective, and members concerned about how the decision is implemented can bring matters for review in the TRIPS Council.

As the waiver and the conditions for its use are an "interim solution", the WTO has mandated that a "permanent solution" to this problem be found by the middle of 2004, but this deadline was not met. A new deadline was fixed for March 2005.

Other Measures

The policy options available to developing countries have to be backed up with the appropriate provisions in the national patent laws. Whist the policy measures oriented to public health needs are allowed under certain conditions by the WTO rules, they must also be consistent with the national laws. The Manual provides model provisions for parallel importation, compulsory licensing and government use, as well as exceptions to patent rights. These model provisions are accompanied by detailed explanatory notes and examples of the relevant legal provisions in various countries, developed and developing.

Finally, the Manual has a section discussing the establishment and operation of an institution (or competent authority) to process compulsory licences, which should ensure the decision-making process has considered that the conditions and criteria in reviewing and awarding such licences have been met and are also consistent with the TRIPS Agreement.

Also discussed in the Manual is the question of how "adequate remuneration" or compensation to the patent holder can be fixed. The experience of various countries is examined, and the rates suggested by various organizations, including in the UNDP's Human Development Report, are looked at. The Manual then provides guidelines for determining compensation.

Conclusion

Patents can and often do affect the access of patients (especially the poor) to medicines, and the TRIPS Agreement also does affect the space available to developing country Members of WTO to formulate the drug patent policies of their choice.

However, despite these problems, developing countries can and should take full advantage of the measures that are permitted by the TRIPS Agreement in pursuit of the goal of promoting access to medicines for all.

In order to exercise their right to "use to the full" these flexibilities in the TRIPS Agreement (in the words of the Doha Declaration), developing countries can study the policy options available to them, and introduce the appropriate laws and concrete measures. In the longer term, revisions to the TRIPS Agreement may also be desirable, in order that the existing flexibilities be expanded to meet the needs of patients and consumers. As millions of lives are at stake, both the shorter and longer term tasks are urgent.

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(The Manual on Good Practices in Public-Health-Sensitive Policy Measures and Patent Laws is available through TWN at twnet@po.jaring.my)

Policy Measures to Facilitate Better Access to Medicines

POLICY MEASURE		REQUIREMENTS
IMPORTING THE DRUG		
Compulsory licensing	A country can import a generic version of the patented product by issuing a compulsory licence to a company or agency to import the drug, and the government has the freedom to determine the grounds upon which such licences are given. The imported drug can be from a country in which the drug is not patented, or in which the drug is patented (in which case the exporting country has also to issue a compulsory licence).	The applicant has to firstly negotiate to obtain a voluntary licence from the patent holder, and if that fails, then a compulsory licence can be granted. Adequate compensation has to be paid to the patent holder.
'Government use' procedure	A generic version of the patented drug can also be imported for 'public, non-commercial use' by the government. This method is suitable if the imported drug is to be used by the government.	Under this 'government use' procedure, the prior consent of or negotiations with the patent holder are not required, but adequate compensation has to be paid.
Parallel importation	There can also be 'parallel importation' of a patented product (i.e. not the generic version) from another country where the same patented product is being sold at a lower price than in the importing country. This is allowed under Article 6 of the TRIPS Agreement on exhaustion of rights, and the Doha Declaration affirms this by stating that each WTO member is 'free to establish its own regime for such exhaustion without challenge.'	There is no need for an importer to obtain a compulsory licence, nor to pay compensation to the patent holder.
LOCAL MANUFACTURE OF GENERICS		
Compulsory licensing	If a drug is patented in a country, generic versions of the drug can be locally manufactured by a local company or an agency (including government agency) that has been granted a compulsory licence by the government.	The applicant has to have negotiated with the patent holder for a voluntary licence and to have failed to obtain such a licence, before applying for a compulsory licence.This requirement however does not apply if the compulsory licence is issued on grounds of public non-commercial use, for national emergency or situations of extreme urgency, or to remedy anti-competitive practices. Compensation has also to be paid to the patent holder.
'Government use' procedure	The government can also assign to a public or private agency the right to locally manufacture a patented product without the patent holder's permission, provided it is used for a public non-commercial purpose.	Under the 'government use' procedure, the prior consent of or negotiations with the patent holder are not required. Compensation has to be paid.
EXPORT, INCLUDING TO COUNTRIES WITH INADEQUATE MANUFACTURING CAPACITY		
Exporting	A local producer of generic versions of patented products under a compulsory licence or government-use provision may export a portion of its output. However, Article 31(f) of the TRIPS Agreement requires that this production shall be 'predominantly for the supply of the domestic market' and thus there is a limit to the amount that can be exported. This limitation may cause supply to be restricted to countries with inadequate manufacturing capcity of their own. Recognising this problem, the WTO in August 2003 decided to give an interim waiver to an exporting country from having to adhere to this Article 31(f) restriction, if it is exporting to countries with no or inadequate manufacturing capacity.	The Article 31(f) restriction does not apply when the compulsory licence is granted to correct anti-competitive practices. Adequate compensation should be paid. To obtain the waiver, several conditions must be met. The importing country has to notify the WTO of the quantities of the drug required, confirm it has insufficient or no manufacturing capacities and that it intends to grant a compulsory licence. It also has to prevent re-exportation of the products. The generic manufacturer in the exporting country will require a compulsory licence. The exporting country has to notify the WTO of the grant of the compulsory licence and its conditions, the quantities for which it has been granted, and the importing countries. Only the amount needed by the importing country may be manufactured under the licence, and all of this output must be exported to the importing country. The products must be clearly labelled or marked through special packaging and shaping of the products, provided it does not significantly impact on price. And adequate compensation should be paid.