Access to Medicines After 2005: Opening Pandora's Box?

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India is currently in the process of changing its intellectual property laws to conform to the WTO's patent rules for pharmaceuticals. The challenge has large implications given the country's leading position as an exporter of generic medicines and their components.

Developing countries like India that did not grant patent protection for pharmaceutical products prior to the TRIPS Agreement's entry into force, were given until 1 January 2005 to introduce such protection. The introduction of 20-year product patents for medicines in India is significant not only because of its huge population, but also because Indian companies are major suppliers of generic medicines to other developing and developed countries. Thus, India's application of the TRIPS standards is expected to have ramifications far beyond the country's borders.

Under TRIPS' transitional provisions, India had to have a 'mailbox' system in place where applications for pharmaceutical product patents could be filed. Reportedly, more than 5,000 applications are pending in that mailbox [1]. This month, the mailbox will be opened and the assessment of applications will have to commence; if found to be patentable vis-à-vis their filing or priority date, a patent will have to be granted for the remainder of the patent term.

Unfortunately it is not known which applications are pending in the mailbox, nor how Indian authorities will deal with them. Especially, it is unclear what will happen if a 'mailbox-patent' is granted while generic versions are already on the market. Will generic production stop, or will Indian companies challenge such patents? Will they request compulsory licenses? And if so, will those requests be granted?

Because of uncertainty regarding the attitudes and behaviour of the different parties and departments that will shape the answers to these interlinked questions, it is difficult to predict what will happen. So how can access to essential and needed medicines in developing countries be safeguarded? What measures should countries take?

New Drugs: The Problem

The most immediate question that developing countries will have to face is: how can the continuity of supply of generic versions of new medicines be assured?

Compounding factors include the fact that each drug may be protected by multiple patents, resulting in a complex, and country-specific, 'patent thicket'. Furthermore, while in principle patented inventions are disclosed, in practice patents can be difficult to trace. And finally, once obtained, the interpretation of patent claims requires specific expertise, which may be scarce in developing countries.

Short-term Actions

A possible first step would be to identify and make use of 'gaps' in the patent thicket, if any – as Thailand did when initiating the local production of the antiretroviral drug didanosine in powder form, which fell outside the scope of a patent on didanosine tablets [2]. But while a strategy of carefully manoeuvring through the mazes of the patent thicket may in some cases allow for continued supply of generics –and hence facilitate continued access to some drugs in some places – this will not provide a structural solution. Moreover, even though drugs will keep coming off patent over time, ultimately this is a short-term strategy, due to the progressive implementation of TRIPS as well as the gradual replacement of existing drugs by better, future drugs. But where, when and while applicable, this strategy may provide some relief.

Other steps that countries can take include:

- Apply strict criteria for patentability; 'new use' patents, formulation patents and patents for other trivial inventions should not be allowed. Strict criteria will furthermore prevent the patent thicket from expanding unnecessarily.
- Allow for opposition both pre- and post grant, in order to provide ample opportunity for local and generic companies, as well as other interested parties, to challenge and prevent the issuing of trivial patents.[1]
- Make patent information easily accessible, including via an on-line, searchable database. In order to not unduly increase the workload of the patent office, applicants could be asked to provide their application in electronic format.
- Generic industry associations could monitor the publication and issuing of pharmaceutical patents and pass relevant information on to their members. Maybe they could also oppose unjustified patents before they are granted, and thereby help screen out 'bad' patents.
- Set up an alert system that informs about patent revocations in developed countries. This system, which ideally should be publicly accessible, would help stakeholders to decide whether to challenge a patent.
- Ensure that domestic laws provide for TRIPS-safeguards, notably compulsory licensing and government use. These safeguard provisions should be workable and should not create undue delays.
- Gain experience in using existing safeguard provisions under national law. The first time is bound to be relatively slow and cumbersome, so countries should not wait for an emergency situation to use these mechanisms. Testing the provisions will also help to find out whether they are workable.
- Avoid TRIPS-plus measures (such as data exclusivity, linkages between patent and registration status, as well as making patent infringement a criminal offense), and avoid bilateral or regional trade agreements that impose such measures.

While these strategies could (and probably should) be applied by all developing countries, their implementation in India and China is especially crucial, since, as major generic producers, the policies of these two countries will

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have ramifications for the availability of generics throughout the developing world.

Other strategies that countries may consider include price negotiations and voluntary licenses on reasonable terms – although if recent experiences with antiretroviral drugs in Brazil and South Africa are any indication, these strategies are bound to be most successful when they are backed up by a realistic 'threat' to use TRIPS safeguards or competition laws.

Future Drugs: The Issues

Whereas the thinking about existing drugs can solely focus on access, the discussion on future drugs – i.e. those that have yet to be invented – will have to touch on R&D as well.[2] It should include thoughts on how to provide incentives for research focused on 'neglected' diseases. For instance, several public-private partnerships, dedicated to finding new cures for specific diseases, have been launched in recent years; examples include the Medicines for Malaria Venture and the Drugs for Neglected Diseases Initiative. While it is too early for any of these initiatives to have delivered new drugs yet, it will be important to evaluate their performance in the future – including with regard to the actual availability and affordability of the products thus developed in developing countries. In fact, any model found to be successful on both accounts may well provide important clues as to how to proceed.

Domestic Production?

Meanwhile, domestic production of medicines appears an attractive option for facilitating access to medicines because of the real or perceived independence it entails. Moreover, one of the crucial TRIPS-safeguards (compulsory licensing) is easiest to implement via local manufacturing. Yet local production will only enhance access in case needed medicines of good quality are produced, and are sold at an affordable price. The latter will depend largely on economies of scale; hence domestic production should not be seen as a panacea.

Furthermore, local production is often limited to formulation, using active pharmaceutical ingredients (APIs) that are imported (mainly from China and India). With product patents in place in both these countries, sourcing of patented APIs may become a bottleneck. While APIs were included in the '30 August Decision', it is likely that they will only be offered at interesting prices once their production reaches economies of scale – that is, once the relevant medicines come off patent and generic sales take off in the large markets of the developed and/or major developing nations.

Medium-term Actions

Additional strategies to protect people's access to medicines, which build on and expand the before-mentioned actions, include:

- Insisting on sufficient disclosure of the invention in patent documents. Disclosure of inventions is a basic part of 'the patent bargain', though it is not always respected [3]. Adequate disclosure can help domestic researchers and industry; there is no conceivable benefit in foregoing it. Generic or domestic industries or their associations could again play a role here, as 'watchdogs'.
- Ensuring that both a research exemption and 'bolar provision' are incorporated in the national patent law, and that they apply to bio-pharmaceuticals as well as conventional pharmaceuticals.
- National (human) resources could be pooled by setting up a regional patent office that has the capacity to really examine patents critically and to apply strict criteria; this could be a 'virtual' regional office, i.e. a network of national offices, each specializing in certain areas of technology.

Building Blocks

While the list of recommended and potential actions pertaining to the intellectual property system seems long, a few principles underlie them all. These are:

- a critical attitude towards standards and criteria for patentability, and toward efforts to further expand the realm of exclusive rights;
- openness and transparency, to facilitate the dissemination of information about patents and the full disclosure of inventions;
- an assertive stance with regard to trivial patents and the use of safeguard mechanisms such as compulsory licensing;
- inclusiveness, and collaboration with all concerned government departments and other stakeholders; and
- co-ordination of policies and actions, within and possibly even between countries.

Conclusion

In order to safeguard access to medicines, developing countries should prepare and enact appropriate intellectual property laws. Yet a change in attitude towards and administration of intellectual property rights is at least as important.

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ENDNOTES

[1] Pre-grant opposition is important, since it could prevent the issuing of trivial patents without litigation, which is often time consuming and expensive, and may be beyond the means of local companies and organisations.

[2] There is no absolute distinction between existing and future drugs, since, once a future drug has been developed, the challenges described for existing new drugs will apply.

REFERENCES

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