

Some Implications of India's New Patents Act

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On 23 March, the Indian Parliament passed a new Patents Act, which brought the country into compliance with its WTO obligations. Heavily politicised amendment negotiations secured the continuation of pharmaceutical exports to least-developed countries, as well as the right to oppose patent applications on a number of grounds. However, some flexibilities under the TRIPS Agreement were lost.

The TRIPS-plus provisions of the Act can be attributed to a number of factors, not least the government's desire to spur economic liberalisation. This resulted in a lack of political will to incorporate the flexibilities confirmed in the Doha Declaration on TRIPS and Public Health.

The Act is likely to significantly impact access to medicines in India and across the world. The amendments incorporate ambiguous language and include loopholes that may benefit patent holders. Most notably, access to medicines may be affected as the entry of generic medicines is delayed through lengthy waiting times and arduous procedures. The affordability of medicines could be affected due to increased market dominance by a handful of drug companies, in addition to increasing the end cost and delaying drug production through royalties and related litigation. The key provisions and their potential impact on access to medicines are analysed below.

Scope of Patentability

The new definition of 'inventive step' allows for the criteria to be met if the invention is a 'technical advance' *or* has 'economic significance'. The latter requirement is problematic, as it undermines the basic conceptual underpinnings of patenting, i.e. that innovation and inventiveness, not economic justification alone, should be the grounds for protection. Economic significance, left undefined, should not be the sole (or primary) criteria for patentability. Using economic criteria, such as a 'commercial success' standard, without simultaneously examining the technical advance itself widens the scope of patentability and allows for weak or questionable patents.

The second issue of concern is the patentability of an 'enhancement of the known efficacy' of a known substance. This may allow for ever-greening. The explanation to this provision states that isomers, salts, ethers, combinations and the like may

be patentable if they 'differ significantly in properties with regards to efficacy'. The purview of patentable medicines is thus potentially increased.

To illustrate, the highly controversial anti-cancer drug Gleevec (imatinib mesylate), produced by Novartis, is a beta isomer of an already known alpha isomer. The beta isomer's anti-cancer properties differed from the alpha isomer's known use, and under the new Act, it is arguable that these isomers 'differed significantly in properties with respect to efficacy'. In India, after exclusive marketing rights were granted to Novartis, the price of Gleevec has increased from roughly US\$230 to US\$2,740 per annum, making the drug unaffordable for most patients requiring it.

Compulsory Licensing

According to the Act, Indian drug companies will have to wait three years after the grant of a patent to even apply for a compulsory license, and a further six months before the Patent Controller can intervene. Such intervention occurs if the application and ensuing negotiations fail. Additionally, the procedures to obtain a license from the Controller are unduly cumbersome. Finally, there is no ceiling on the royalty rate due to the patent holder. As demonstrated by the South African experience of licensing Pfizer's HIV drug Diflucan, a lack of clarity on royalty ceilings may lead to protracted litigation or high royalties to the patent holder, both of which restrict access and increase the end cost of the medicine.

These obstacles to compulsory licensing could cause lengthy delays before desperately required drugs are made available. However, Section 92 of the Act allows for immediate compulsory licensing for national emergencies, extreme urgency and public non-commercial use, as determined by the Patent Controller. It is important to note here that many necessary medicines are not for 'emergencies' – medicines for diabetes, asthma and other common, ongoing health conditions will not be available for immediate licensing. Additionally, Section 92 allows for immediate compulsory licensing for cases including public health crises relating to HIV/AIDS, tuberculosis or malaria. To date, this provision has never been exploited in India, and it is now up to the Patent Controller to ensure its optimal use.

Exports to LDCs

Importantly, the Patents Act was amended regarding the export of generics to least-developed countries (LDCs), which is now allowed without requiring the importing country to issue a compulsory license. However, there is one insertion that should be noted as a potential concern: an LDC must now – either through notification *or* the issuance of a compulsory license – allow importation of the drug. The question arises as to why the option of the importing country issuing a compulsory license was retained. This provision must be monitored to ensure that companies do not demand that LDCs that have created patent regimes earlier than 2016, often under bilateral pressure, be mandated to issue a compulsory license: notification alone should be sufficient.

Continued Generic Production

Under the new law, companies can continue generic production of drugs for which patent applications were filed during the transitional period, which expired on 1 January 2005. Nevertheless, this continued production is subject to an ambiguous clause requiring 'significant investment' on the part of the company producing the generic version, leaving open the question of whether the generic producer only has to pay royalties when it has made a prior significant investment in the drug, or whether the company must demonstrate significant

investment in order to continue production. The ambiguity in this clause may impact access by holding up the production of generic versions due to royalty negotiations or differences in legal interpretation.

The Commerce Minister has instituted a six-member Technical Experts Committee to look at two issues: whether it is TRIPS-compatible to define patentable new entities as 'new chemical entities' and whether micro-organisms may be excluded from patentability.

Conclusion

As the rules supporting the Act are yet to be finalised, the impact of the new law remains to be seen. Ultimately, there is wide latitude for interpretation, and it will be up to the Patent Controller to determine how to precisely define patentability in a way that guarantees

licensing of drugs in a timely, efficient and fair manner. Advocates will have to undertake a drug-by-drug, case-by-case fight to ensure that access to affordable medicines remains a reality for people in India and abroad.

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Impact of India's Patent Law on the Generics Industry

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The last-minute changes to the Patents Act are significant in so far as they provide against patenting of trivial changes and allow automatic licensing for all drugs commercialised before 1 January 2005. Both these measures will ensure continued availability of medicines currently in production and will let the generic industry supply these drugs to least-developed and developing countries under appropriate authorisation.

This also means that India's generic industry can continue to work on its ambitious target of six-fold growth in its export business to US\$20 billion by 2010. The export driven growth will spur significant domestic investment in the manufacturing sector, creating new jobs for educated youth and making India a dominant player in the global generics market. The surplus generated from exports will also help fund increased investment in research.

However, new drugs that were not commercialised before 1 January 2005 will remain beyond the generic industry's reach until after the expiry of patents. This is so because of the government's reluctance to invoke the compulsory license mechanism for fear of retaliation and the cumbersome and unworkable procedures and rules under the new law.

Section 92A, introduced in the Indian Patents Act to incorporate the 30 August Decision of the TRIPS Council, was amended to exclude a provision related to the grant of compulsory licenses by LDCs. However, Rule 97 stipulates that the Controller General of Patents will determine whether the application by a generic company to manufacture solely for export shall be approved or refused. In other words, an officer in India will sit judgement on another country's sovereign government before permitting a domestic company to manufacture and export the product.

In this, the Indian law not only exceeds the country's obligations under the TRIPS Agreement but also violates the sovereignty of the importing country. First, India need not have taken upon itself the responsibility of checking the importing country's decision; and second, it has no jurisdiction or basis to determine the veracity of health problems in the importing country.

The procedure for granting a compulsory license for the domestic market is also mired by rules that will allow the right-holder to litigate the application to the point of defeating the very purpose of compulsory license. Why would a generic company devote its resources to an activity that is *prima facie* futile and non-productive?

There are more substantive issues related to the production of a new drug under a compulsory license. As the necessary products are still readily available from India's pre-2005

patent regime, the significance of the time and cost of developing generics is not yet fully realised. Typically, bringing a generic version of a product to the market will take at least three and a half years.

Nor is it just a question of time: the cost of development and approval of regulatory agencies is estimated at US\$2 million per product. Furthermore, even after investing time and money, a generic producer has no certainty of success. The risks involved are daunting:

- the compulsory license may be rejected by the exporting country, i.e. India;
- regulatory approval may not be granted by the importing country;
- the rights-holder may offer a price reduction to the importing country;
- the discovery of a new drug may render the licensed drug obsolete; and
- the size of the potential market under compulsory license may be too small.

Thus, a generic company will have to evaluate whether the production of a new drug under a compulsory license is economically and commercially viable in light of the risks associated with the activity. The dice seem loaded against the working of the compulsory license provision, but time alone will prove it. But by then, for those suffering from disease time may have run out.

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