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Amended Patents Act and Access to Medicines after Doha

The Doha Declaration constitutes a major step forward insofar as it acknowledges in the WTO context that the introduction of patents in the health sector has significant impacts on access to drugs. However, the Declaration neither amends the TRIPS Agreement nor provides a basis for developing countries to link their patent and health legislations. The Patents (Amendment) Act, 2002 closely follows TRIPS and in the process does away with provisions of the 1970 Act that constituted India's own response to the challenge of providing exclusive commercial rights in a field concerned with the fulfilment of basic health needs.

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The last WTO ministerial conference specifically addressed the issue of access to medicines in the context of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). This was in response to the growing controversy concerning the impact of TRIPS in the health sector for most developing countries, and in particular the HIV/AIDS tragedy in sub-Saharan Africa.

The TRIPS Agreement requires among other things that all WTO member-states introduce product and process patents in all fields of technology. Exceptions in fields related to the fulfilment of basic needs such as health are not granted. This is in contradiction to the Patents Act, 1970, which provided specific exceptions to patentability in the fields of health and food. The provisions of the 1970 act and similar legal regimes in other developing countries have been the source of significant complaints by the private sector pharmaceuticals industry in developed countries. The US pharmaceuticals lobby estimates that it currently loses more \$1.7 billion annually because of India's insufficient intellectual property protection.¹

Following the WTO ministerial conference, the joint parliamentary committee on the Patents (Second Amendment) Bill, 1999 finalised its report in December and submitted an amended version of the

amendments to parliament.² The recently passed legislation must therefore be analysed in the context of the declaration on the TRIPS Agreement and public health (Doha Declaration) and other relevant factors.

Doha Declaration on Health

The Doha Declaration is a direct consequence of the multiple controversies concerning patents in the health sector, in particular in the context of the HIV/AIDS epidemics. Its importance is linked to the recognition that the existence of patent rights in the health sector does not stop states from taking measures to protect public health. More specifically, it affirms that TRIPS should be "interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all".³ This strengthens the position of countries that want to take advantage of the existing flexibility within TRIPS. In other words, the declaration does not open new avenues within TRIPS but confirms the legitimacy of measures seeking to use to the largest extent possible the in-built flexibility found in TRIPS.

The declaration focuses mainly on questions related to the implementation of patents, such as compulsory licensing. Compulsory licensing has long been used

as a tool to regulate the exclusive rights conferred by patents. In the case of health, the rationale is to make sure that the existence of a patent does not create a situation where a protected medicine is not available to the public because of non-health related factors. The Patents Act, 1970 provided an elaborate regime that included both compulsory licences and licences of right.⁴ The TRIPS Agreement has not done away with the notion of compulsory licences but provides a more restrictive framework than the current regime in force in India. The recognition in the Doha Declaration that TRIPS member-states can use the flexibility provided in the agreement and can, for instance, determine the grounds on which compulsory licences are granted must thus be understood in the context of a generally increasingly restrictive international patent regime.

The declaration has been hailed as a major step forward in the quest for making the TRIPS Agreement more responsive to the needs of developing countries and more specifically all individuals unable to afford the cost of patented drugs. In fact, it addresses a number of important issues related to the implementation of medical patents. However, it fails to take up the much more fundamental questions of the scope of patentability and the duration of patents in the health sector. The Doha Declaration remains an important instrument in India for two main reasons. Firstly, at a political level, India was among the most vocal developing countries at the ministerial conference in putting forward developing countries' interests.⁵ Secondly, the declaration was adopted while the joint committee was finalising its report.

Patents (Amendment) Act, 2002

The Patents (Amendment) Act, 2002 must be analysed with the 1970 patent regime in mind. The adoption of the Patents Act, 1970 was based on a lengthy legislative process and careful consideration of the socio-economic impacts of patents in sensitive fields such as health. As a result, the Patents Act drastically restricted the rights of patent holders in fields linked to basic needs. In the pharmaceuticals sector, the Patents Act and associated measures such as price control have had a number of positive impacts. Firstly, relative drug prices have decreased significantly since

the 1960s compared with those in other countries. Secondly, India now has a vibrant local generic pharmaceuticals industry. Thirdly, some of the local companies have developed sufficient expertise to produce their own new medicines. The TRIPS Agreement requires fundamental changes to the current legal regime. This constitutes an important reason for the initial reluctance of the government to accept TRIPS in the context of the Uruguay Round and parliament's reluctance to adopt the first amendment bill.⁶

The first version of the amendments as drafted in 1999 did not reflect this genesis. In fact, they were noteworthy for sticking quite closely to the letter of the TRIPS Agreement. The result of the 1999 draft would have clearly been to remove most of the specificities of the Patents Act, 1970, in particular in the field of health. It would have drastically altered the balance between the interests of patent holders and the interests of society at large, in favour of the former.⁷ This included raising the duration of patents in the health sector from seven to 20 years. The 1999 draft also proposed the deletion of an important provision of the act seeking to oblige patent holders to manufacture their inventions in India. It made use of some of the exceptions and flexibilities provided in TRIPS but only at a superficial level. In other words, while the bill incorporated exceptions such as those provided in Article 27.2 in TRIPS, it did not attempt a broader reading of TRIPS in the light of Articles 7 and 8.2, which provide the objectives and principles that should guide the interpretation and implementation of the whole treaty.

The 2002 amendments adopted by parliament substantially follow the first draft of 1999. In particular, they do not seek to provide an exception to the 20-year duration for pharmaceutical patents in the light of the broader interpretative framework proposed by the Doha Declaration. However, it is significant that the three dissenting opinions appended to the joint committee report lamented the fact that the committee did not propose any modifications to the 20-year rule in the health context.⁸ There are, however, a number of new elements in the 2002 amendments. One noteworthy addition is at Section 3 of the act, where it is suggested that traditional knowledge be excluded from patentability. This clause has the potential to be significant in practice given the existence of various indigenous systems of medicine in India. This provision, however, only restates the uncontroversial position that knowledge in the public

domain cannot be patented. The real issue is whether inventions based on traditional medicines can also be denied patentability. This refers to a broader problem concerning the definition of patentable inventions. In fact, TRIPS does not impose on member-states a specific definition of what constitutes non-obviousness and parliament could choose to provide an extensive definition which restricts not only the patentability of ayurvedic medicines but also derived medicines, which are essentially laboratory copies of the original.

The 2002 amendments are also substantially different from the 1999 draft with regard to compulsory licensing. Section 83, which provides a general framework to guide the issuance of compulsory licences is particularly noteworthy. It constitutes a broader endeavour to incorporate some of TRIPS' in-built flexibility into the Patents Act. Interestingly, Section 83 specifically mentions that patents granted should not "impede protection of public health", should not prohibit the central government from taking measures to protect public health and that patents should be granted to make the benefits of the patented invention available to the public at reasonably affordable prices.⁹

The new compulsory licensing regime deserves further comments. Firstly, this is the only place in the act where a specific attempt has been made to make TRIPS responsive to domestic needs and priorities. Secondly, the emphasis put on the compulsory licence regime is indicative of the regressive nature of the debate concerning patentability in health and other basic need-related sectors. Chapter XVI on compulsory licensing makes a real attempt to use TRIPS flexibility. However, what is noteworthy is that the amended act stops short of proposing similar clauses as guiding principles for the whole Patents Act. If a similar section to Section 83 were inserted at the beginning of the act, this would allow the Patent Office to use similar criteria in examining patent applications. The Patents (Amendment) Act, 2002 only proposes to apply flexibility at the level of the implementation of already granted patents and thereby dramatically restricts the potential effectiveness of the proposed clauses. Thirdly, the 'progressive' nature of the amended act must be judged against the regime inherited from the 1970s. If the 1970 Patent Act is taken as a benchmark, the 2002 amendments provide a more restrictive regime and noticeably do away with licences of right.¹⁰ Fourthly, it is doubtful whether focusing on compulsory licensing as the main tool to redress the perceived inequities of the

international patent system constitutes an appropriate strategy. In the TRIPS era, it is not very likely that developing countries will have the liberty to widely use compulsory licensing provisions. They may be useful as bargaining tools in negotiations with specific companies as highlighted in the case of Brazil, but they should only be complementary measures. The adoption of a strong compulsory licensing regime cannot be a substitute for strong health-related provisions in the main part of the act.

Forthcoming WTO Negotiations

The Doha Declaration constitutes a major step forward insofar as it acknowledges in the WTO context that the introduction of patents in the health sector has significant impact on access to drugs. However, the declaration neither amends the TRIPS Agreement nor provides a basis for developing countries to link their patent and health legislations. In this regard, the Patents Act as adopted in 1970 was one of the most interesting attempts to link the fundamental right to health and the introduction of patents in the health sector. At this juncture, the WTO is far from providing a comprehensive response to the needs of developing countries in the field of health in general. At the most, the Doha Declaration provides a temporary respite in some limited areas. The declaration does not even indicate that negotiations in the new round of trade negotiations will necessarily go towards a relaxation of the TRIPS requirements in this field. In fact, the recent aggressive posturing of the US pharmaceuticals industry seems to suggest that significant lobbying for further strengthening of patent rules is likely to take place in the future.

On the whole, the Patents (Amendment) Act, 2002 closely follows TRIPS and in the process does away with provisions of the 1970 Act that constituted India's own response to the challenge of providing exclusive commercial rights in a field concerned with the fulfilment of basic health needs. This is unexpected for several reasons. Firstly, there has been no official change in the policy underlying the Patents Act to justify such drastic changes. Secondly, India's domestic and international commitments regarding the fundamental right to health of all individuals have not changed in the past decade. Thirdly, it appears likely that the introduction of product patents in 2005 will adversely affect access to medicines for crores of people. One factor pushing the government in this direction may have been the desire to favour its own private sector

pharmaceuticals industry. However, it is striking that there is no unanimity on the part of the industry, which remains today completely or mainly domestic. Some large companies that produce mainly generic drugs have been completely opposed to changes in the 1970 Patents Act, some large companies that have developed significant R and D facilities feel that the new regime may provide them an opportunity to grow overseas while small companies generally seem to have understood that they are not important enough to influence policy-making significantly and must concentrate on surviving either independently or by linking up with bigger domestic or foreign companies.¹¹

Overall, the likely negative impacts of the new patent regime for patients who purchase medicines should sway the balance in favour of maintaining the status quo in all areas that do not absolutely have to be amended for compliance with the TRIPS Agreement. This includes using the Doha Declaration to maintain the reduced duration of patents on medicines and taking into account the fact that the revision of an important provision like Article 27.3.b of TRIPS is yet to be completed, offering

good ground for not implementing it before an agreement is found among all TRIPS member-states. Indeed, it appears inconceivable that such major changes should be introduced without a full-fledged rethinking of the policy underlying the patent system.

Given the importance of the issues at stake, the debate concerning the impact of medical patents on access to drugs is unlikely to subside in the near future even though the Patents (Amendment) Act, 2002 has just been adopted. One more crucial moment will come in 2005, when the Patents Act will have to be again amended to allow product patents on medicines. This still leaves several years for further open debate concerning the final response to be given to TRIPS in the health sector. **EW**

Notes

- 1 See Pharmaceutical Research and Manufacturers of America, PhRMA 2002, 'Special 301' Submission (2002).
- 2 See Parliament of India, 'The Patents (Second Amendment) Bill, 1999 – Report of the Joint Committee', 2001.
- 3 Paragraph 4, WTO, 'Declaration on the TRIPS Agreement and Public Health', Ministerial Conference – Fourth Session, WTO Doc WT/

MIN(01)/DEC/2 (2001) (Doha Declaration).

- 4 See Chapter XVI, Patents Act, 1970.
- 5 See, e.g., Statement by Murasoli Maran, Minister for Commerce and Industry in the Rajya Sabha on 21/11/2001 and in Lok Sabha on 22/11/2001 – regarding the Fourth Ministerial Conference of the WTO, 3/9 India and the WTO (Oct-Nov 2001).
- 6 See, e.g., A V Ganesan, 'Intellectual Property Rights – Standard and Principle Concerning its Availability, Scope and Use, Ministry of Commerce', New Delhi, September 28, 1989, reprinted in V R Krishna Iyer, 'Peoples' Commission on GATT on the Constitutional Implications of the Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations', Centre for Study of Global Trade System and Development, New Delhi, 1996 and Patents (Amendment) Act, 1999, *Gazette of India*, March 26, 1999.
- 7 Cf N S Gopalakrishnan, 'The Patents (Second Amendment) Bill, 1999 – An Analysis', (2001) 1 *Supreme Court Cases* 14.
- 8 See 'Notes of Dissent, Parliament of India', The Patents (Second Amendment) Bill, 1999 – Report of the Joint Committee (2001).
- 9 See Section 83.d, e and g of the Patents (Amendment) Act, 2002.
- 10 Licences of right were defined at Sections 86 ff of the 1970 version of the Patents Act.
- 11 Personal communications. See also, Anitha Ramanna, 'Policy Implications of India's Patent Reforms – Patent Applications in the Post-1995 Era', *Economic and Political Weekly*, May 25, 2002, p 2065.