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PATENTS BILL, TRIPS AND RIGHT TO HEALTH

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The Patents (Second Amendment) Bill seeks to implement the obligations that India has taken in the field of patents by signing the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs Agreement).¹ The bill generally aims at making the 1970 Patents Act as TRIPs compliant as possible. Given that the 1970 Act is partly incompatible with TRIPs, the present bill in effect makes little effort to preserve the current patent regime. One of the implications is that the bill proposes to remove clauses of the 1970 Act that sought to balance the interests of the patent holders with that of the society at large towards ensuring that the granting of monopoly patent rights did not impair the fulfilment of basic needs. The changes proposed in the bill will have important implications in a number of fields. For a majority of the population, however, it is where patents are granted on inventions directly related to basic food and health needs that the impacts of the new legal regime will be most significant. The health sector is particularly important and interesting.

HEALTH AND PATENTS

Health is one of the fundamental basic needs of all human beings. In legal terms, fundamental human rights treaties recognise the right to the 'enjoyment of the highest attainable standard of physical and mental health'.² Health policies encompass a number of elements, from prevention to cure and access to drugs. While all elements are important, the question of access to drugs stands out in the context of the TRIPs Agreement.

Access to drugs generally requires their availability and affordability. There is thus a strong link between economic poverty and access to drugs. A group of international organisations recently estimated that less than 10 per cent of people living with HIV/AIDS in developing countries have access to antiretroviral therapy.³ Access is conditioned by a number of factors, but the availability of patents constitutes one of the important determinants of price, and therefore access. Indeed, the rationale for granting patents to inventors is to give them monopoly control over the invention so that they have significant leeway in determining the price of the medicine.

While access can be affected at the practical level by the introduction of patents on medicines, there are more general issues concerning the compatibility between human rights and intellectual property. Intellectual property law has traditionally dealt mainly with technical issues related to scientific and technological development. Treaties such as TRIPs thus hardly envisage patents in relation to other fields of law. There is, for instance, no attempt in TRIPs to delineate the relationship between patents and the human rights to health. Patent treaties only recognise that there should be a balance between the rights that are conferred to an inventor and the broader interests of the society in having access to the results of scientific advances.

Equally, human rights treaties have not devoted significant attention to the impacts of intellectual property on the realisation of specific rights such as the right to health. However, the relationship has been considered in general terms.⁴ An analysis of relevant articles and of the intention of states negotiating them brings out several important elements. First, human rights treaties recognise the importance of scientific and technological development. They also acknowledge the possible tension between the interests of inventors and the interests of society at large in benefiting from scientific advances. The balance between the two is tilted in favour of society in general rather than the inventor. Human rights treaties also make it clear that the interests of the inventors are not fundamental human rights. Further, the interests of inventors must be understood within the context of all the other human rights protected, for instance, under the UN Covenant on economic, social and cultural rights. The recognition of the interests of an inventor can in no way qualify fundamental rights such as the right to health or food. Rather, they must be integrated within the framework of these rights.

1 See Patents (Second Amendment) Bill, 1999, Bill No XLIX of 1999 and Agreement on Trade-Related Aspects of Intellectual Property Rights, Marrakech, April 15, 1994 [hereafter TRIPs Agreement].

2 See Article 12 of International Covenant on Economic, Social and Cultural Rights, New York, December 15, 1966, reprinted in 6 *ILM* 360 (1967) [hereafter ESCR Covenant].

3 See, e.g., UNICEF-UNAIDS-WHO/HTP/MSF, 'Sources and Prices of Selected Drugs and Diagnostics for People Living with HIV/AIDS' (May 2001).

4 See Article 15 of the ESCR Covenant, *supra* note 2.

FROM THE 1970 ACT TO TRIPS COMPLIANCE

The 1970 Patents Act generally adopted the western model of intellectual property, seeking to recognise the contribution of inventors by granting them temporary monopoly rights for the exploitation of their inventions. However, the drafters of the 1970 Act introduced a number of safeguards in the act to prevent abuse of these interests and generally to make sure that patent rights would not unduly threaten the fulfilment of basic needs. In the case of health, specific measures were provided, in particular to provide better access to drugs. These included a much shorter duration of the rights granted (seven instead of 14 years), the prohibition of product patents on all medicines and a strong compulsory licensing regime.⁵

Some of the main impacts of the 1970 Act in the health sector have been to promote the rapid development of a domestic pharmaceutical sector producing mainly generic drugs and to improve access to drugs in the general population through relatively cheap drugs, at least compared with countries where no restrictions on product patents were ever introduced.⁶ Indeed, the domestic pharmaceutical industry, which accounted for about 25 per cent of the domestic market by 1970 has increased its share to 70 per cent of bulk drugs and meets nearly all the demand for formulations.⁷

The TRIPs Agreement imposes significant changes to this arrangement. First, it requires the availability of product patents in all fields of technology. Second, it imposes a uniform duration of 20 years for patent rights. Third, compulsory licensing is only allowed within specific limits.⁸ This will foster major changes in the health sector. Indian companies will not be able to legally produce generic versions of drugs currently protected by patents. This in turn will have important impacts for companies mainly manufacturing generic drugs. From the consumer point of view, some of the main impacts will be the unavailability of cheap generic drugs before the 20-year period of protection elapses and the generally higher prices of drugs. The availability of product patents on drugs is generally meant to provide further incentives for private sector R and D in health. While this could theoretically be beneficial to both consumers and producers, it has been noted that the availability of patents does not necessarily lead to preferential investment in medicines needed by the poor.⁹

The patents bill is a direct response to TRIPs obligations but must be understood in a broader context. First, in the early stages of the Uruguay Round negotiations, India was clearly opposed to the inclusion of intellectual property rights in a trade framework. The government eventually changed its mind and accepted TRIPs in 1994. Significant opposition was still noticeable and, in fact, parliament refused to endorse the first amendment to the Patents Act submitted by the government in 1994. This eventually led the US and the EU to challenge India's lagging implementation of its TRIPs obligations in the WTO.¹⁰ It is only after the WTO appellate body concluded that India was at fault that parliament eventually endorsed the amendment in 1999.¹¹ The second amendment must be understood in this context. The current bill clearly shows that one of the main intentions of the drafters is to avoid further confrontation with other WTO member-states on the question of TRIPs implementation. In the process, the bill does not make full use of the flexibility offered in TRIPs even though the act is being modified because of TRIPs and not because it has been found to be defective. Further, the bill does not take into account India's other international obligations, in particular in the field of human rights and environmental law.

The bill generally provides stronger protection to patent holders. This implies that the balance of interests between inventors and the general public is being shifted in favour of the former. More specifically, the bill includes the main TRIPs requirements such as a 20-year uniform duration and a narrower framework for compulsory licensing.

5 See sections 53, 5 and chapter 15 of the 1970 Patents Act.

6 See, e.g., Shekhar Chaudhri, 'The Evolution of the Indian Pharmaceutical Industry', in Greg Felker et al (eds) *The Pharmaceutical Industry in India and Hungary – Policies, Institutions, and Technological Development* (World Bank, 1997, Washington, DC), p 6.

7 Department of Chemicals and Petrochemicals, Annual Report 1999-2000.

8 See respectively Articles 27.1, 33 and 31 of the TRIPs Agreement, *supra*, note 1.

9 'World Health Organisation, 'Globalisation, TRIPs and Access to Pharmaceuticals' (WHO Policy Perspectives on Medicines No 3, 2001).

10 See India – Patent Protection for Pharmaceutical and Agricultural Chemical Products (US complaint), Report of the Panel, September 5, 1997, WTO Doc WT/DS50/R; India – Patent Protection for Pharmaceutical and Agricultural Chemical Products (US complaint), Report of the Appellate Body, December 19, 1997, WTO Doc WT/DS50/AB/R and India – Patent Protection for Pharmaceutical and Agricultural Chemical Products (EC complaint), Report of the Panel, August 24, 1998, WTO Doc WT/DS79/R.

11 Patents (Amendment) Act, 1999, Gazette of India, March 26, 1999.

It also provides for the deletion of some important sections, like the provision seeking to oblige patentees to manufacture their inventions in India and the section concerning licences of right.¹² It does not yet introduce product patents because India benefits from a further delay until 2005 in this field.

The bill takes advantage of some of the exceptions allowed by TRIPs itself. For instance, it incorporates the environmental and health exceptions of Article 27.2 in Section 3 which determines the scope of patentability. Thus, the bill now specifically rules out the patentability of living things or non-living substances occurring in nature and further rejects the patentability of plants and animals. The most notable feature of the bill, however, is not how far it makes use of permitted TRIPs exceptions but rather how strictly it follows the text of the agreement on the whole. Apart from some sections of the act going beyond TRIPs that have not been removed in the bill,¹³ the bill does not attempt to go beyond a strict interpretation of TRIPs. This is surprising because of the significant opposition to changes to the act. Further, this does not coincide with the government's own views in the WTO, where it has asserted that Articles 7 and 8.2 of TRIPs which recognise, for instance, the need to balance the rights and obligations of patent holders are overarching provisions that should qualify other provisions of TRIPs meant to protect intellectual property rights.¹⁴

SOUTH AFRICAN AND BRAZILIAN EXPERIENCE

Some countries have had much less amicable reactions to TRIPs. South Africa and Brazil stand out with regard to the health issue. Both countries have successfully attempted to chart out a new course, which goes much beyond what would have been deemed acceptable under TRIPs until recently. This is remarkable because both legal regimes were challenged and the challenge was abandoned in each case.

In South Africa, the debates have concentrated on the 1997 Medicines and Related Substances Control Amendment Act. This amendment was partly a reaction to the severe HIV/AIDS crisis that the country has been facing and the lack of access to drugs because of their unaffordability.¹⁵ Two of the sections of the act were particularly controversial. The first authorises the government to determine to what extent a specific drug patent will apply. The second entitles the government to authorise parallel imports from other countries where the same medicine is also manufactured.¹⁶

The possibility for the government to determine the extent to which patent rights apply was a direct challenge to the pharmaceutical industry which reacted by moving the high court.¹⁷ The petitioners wanted the disputed sections to be declared unconstitutional because it gave too much latitude to the government to determine the circumstances under which rights under the patents act could be curtailed and because it authorised the government to determine the extent to which rights conferred under the patents act should apply. Eventually, the petition was abandoned in April 2001 in the face of strong public opposition.

In Brazil, the government decided to take measures to facilitate access to drugs in the context of the HIV/AIDS crisis. This includes, for instance, a strong compulsory licensing regime.¹⁸ The US government objected to the requirement that unless it is economically unfeasible, inventors have the duty to manufacture the product in Brazil. A WTO dispute was initiated by the US in February this year but was withdrawn in June. Interestingly, the US specifically indicated that it was not targeting another section relating to national emergencies. The possibility to provide easier compulsory licensing in case of national emergencies is recognised under TRIPs. Brazil has, however, gone much further and adopted a decree establishing rules concerning the granting of compulsory licences in cases of national emergency and public interest.¹⁹ The definition of what falls into the public interest is of great

12 Patents (Second Amendment) Bill, clauses 37 and 39.

13 *See, e.g.* Section 90 e of the 1970 Patents Act which provides that one of the grounds for compulsory licences is where imports are preventing or hindering the working of the patent on a commercial scale.

14 World Trade Organisation, Communication from India, WTO Doc IP/C/W/195 (2000).

15 *See generally* Patrick Bond, 'Globalisation, Pharmaceutical Pricing and South African Health Policy – Managing Confrontation with US Firms and Politicians', 29/4 *International Journal of Health Services*, (1999).

16 *See* Section 15C of the Medicines and Related Substances Control Amendment Act, 1997 (Republic of South Africa, Government Gazette, December 12, 1997).

17 *See* The Pharmaceutical Manufacturers' Association of South Africa et al vs The President of the Republic of South Africa et al, Notice of Motion, High Court of South Africa (Transvaal Provincial Division), February 18, 1998.

18 Brazil, Industrial Property Law, Law No 9.279 of May 14, 1996.

19 Brazil, Presidential Decree on Compulsory Licensing, Decree No 3,201, October 6, 1999.

interest. Public interest includes public health, nutrition, the protection of the environment, and elements of primordial importance for technological, social or economic development. The possibility to provide compulsory licensing in each of these cases implies that the fulfilment of most basic needs would be covered.

The experience of Brazil and South Africa indicates that the provisions they have adopted are now 'acceptable', if not strictly speaking TRIPs compliant, since they are unlikely to be challenged again. The idea that health emergencies provide sufficient ground for rules derogating from the TRIPs model is now established. The limits of permissible exceptions are not known but there is no reason to think that TRIPs cannot be further qualified to foster the realisation of basic needs. Indeed, only a few months ago, it would have been very difficult to assert that the South African and Brazilian positions were acceptable under TRIPs. In practice, India also faces health emergencies like South Africa and Brazil. There are, therefore, good grounds for redrafting the bill in a way that takes into account the needs of the local population. Today, it is accepted that there is flexibility in interpreting TRIPs in the health sector and there is no reason why similar flexibility should not be forthcoming in other areas, such as the food sector.

HUMAN RIGHTS PERSPECTIVE

As noted, the relationship between human rights and intellectual property requires further elaboration. On the one hand, intellectual property does not provide much guidance concerning its links with other fields of law. On the other hand, human rights treaties show that the interests of the patent holder are recognised but not as fundamental rights and that the interests of the community at large come first.

TRIPs was adopted as a stand-alone agreement which makes no mention of the impacts it can have, for instance, in the field of health. Nevertheless, WTO member-states that are also parties to human rights treaties cannot draft legislation to implement WTO obligations without considering its compatibility with other international obligations, such as human rights commitments. In fact, the UN Committee on Economic, Social and Cultural Rights has specifically indicated in the case of the right to health that states should not agree to measures that are manifestly incompatible with their previous international legal obligations.²⁰

Even though the formulation of the right to health at the international level is vague, it gives at least a broad framework within which health policies should fall. Thus, it imposes on governments to progressively facilitate access to drugs. Since patents on drugs tend to push prices up, governments have a duty to ensure that the introduction of product patents does not jeopardise access to drugs. Indeed, not only should states refrain from taking any steps that limit access to drugs but they should also actively pursue better access over time. In this sense, it is doubtful whether the amendment to the Patents Act of 1970 can stand scrutiny under human rights treaties. The 1970 Act introduced a number of limitations on the scope of the rights granted to patent holders with specific public health goals in mind. As widely acknowledged, the provisions of the 1970 Act may not have solved the problem of access to drugs, but they contributed to improving access. Dismantling the whole regime amounts to taking several steps back in terms of access to drugs. This seems even truer in the context of the HIV/AIDS crisis, where some of the existing drugs are often available only at prices that are prohibitive for the general public.

The patents bill attempts to put India in compliance with its TRIPs obligations. In the process, it sets aside some of the most salient elements of the current legal regime which, together with other instruments such as the Drugs Price Control Order, have generally served well the interests of the country and its inhabitants. It is likely to bring about a legal regime that is less favourable from the point of view of access to drugs for the people of this country. The rationale for introducing the bill in this form was partly that TRIPs does not provide much flexibility in the way it can be implemented. This has now been proved wrong as the examples from South Africa and Brazil indicate. There is today scope for flexibility within TRIPs itself. Further, TRIPs cannot be implemented in isolation. India has a number of other international obligations, in particular in the field of human rights. As interpreted by UN human rights organs, the right to health requires that countries progressively take positive steps towards facilitating access. Dismantling the 1970 regime may constitute a violation of India's obligations under the Covenant on economic, social and cultural rights. There are thus compelling reasons for redrafting the patents bill in a way which neither threatens the country's interests nor constitutes a potential violation of human rights.

²⁰ See Committee on Economic, Social and Cultural Rights, General Comment No 14, 'The right to the highest attainable standard of health', UN Doc E/C 12/2000/4 (2000).

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