Patent Reform in India: The campaign to protect public health

The Issue

Concerns regarding public health and the development of the domestic pharmaceutical industry lay at the core of the century old debate in India on how to shape the patent system to best serve the national interest. The Indian patent system has suffered continuous modifications over the past decade, partly as a reflection of the diverging standpoints and changing priorities of government, national industry, public health NGOs and other stakeholders. More recently, Indian patent laws have been amended to comply with the World Trade Organisation (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

Since the 1970s, former government officials, parliamentarians, legal and political experts, trade unionists and social activists have organised in NGOs and worked in alliance with the national pharmaceutical industry to influence the process of reform of the Indian patent system. Their goal has been to ensure that the patent system does not hinder but promotes the availability of medicines at affordable prices that meet national public health needs. The development of the national pharmaceutical industry in India is linked to the extent that national patent laws have allowed them to legally produce quality generic versions of many medicines even while these are under patent in other countries. By and large generics are less expensive than patented medicines. Moreover, increased generic competition often leads to a drop in the overall prices of medicines. Given that India remains the major global supplier of generic medicines,[1] public health activists have been working to ensure the production and availability of generic medicines to treat patients in India and other developing countries. Up until the latest amendment of the Indian Patents Act in 2005 that introduced protection for product patents, the alliance has rejected changes to the patent law perceived to limit the production, availability and distribution of generics and have pressured the government to introduce provisions to give pre-eminence to public health over intellectual property.

The Indian patent system, dating as far back as 1856, has suffered several modifications at different times that have strengthened or relaxed patent rights. The Patents Act, 1970 that came into force in April 20, 1972 was a response to the growing national debate on how to best strike a balance between patent rights as incentives to innovation and the need to protect the public interest and to boost industrial development. Up until the 1960s foreign multinational pharmaceutical companies supplied almost 85 percent of medicines in India, and prices were among the highest in the world.[2] To redress this problem and with a view to make the patent law compatible with Indian developmental objectives, in the post independence period from 1947 to 1970, the Indian Parliament vehemently debated amendments to the Patents Act.[3] One of the main changes of the Patents Act, 1970 was that it allowed process patents in pharmaceutical and agrochemical based products, but not product patents.[4] This allowed the national pharmaceutical industry to develop technical expertise in reverse engineering of existing medicines – modifying the manufacturing process – and thus to become an efficient producer of generic medicines.

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Despite strong opposition from civil society, in 1994 India signed the General Agreement on Trade and Tariffs (GATT) and became in 1995 party to the nascent WTO TRIPS Agreement.[5] By way of TRIPS, India acquired new, far-reaching international obligations on the protection of all types of intellectual property rights that would require modifications to its patent regime by 2005.[6] For example, the TRIPS agreement requires countries to extend patent protection for any invention whether products or patents in all fields of technology, for a 20 year term, subject to patentability criteria. Accordingly, in the process of implementing the TRIPS Agreement, India had to revise several of the main aspects of its patent regime. This process was undertaken progressively through several amendments to the Patents Act, 1970. The Patents (Amendment) Act, 1999 introduced exclusive marketing rights (ERMs)[7] and established mailbox applications for patents for pharmaceuticals and agrochemicals from 1 January 1995.

The Patents Act, 1970 was amended for a second time in 1999, and again in 2002 and 2005. The Patent (Third Amendment) Act, 2005, extended product patents to products from all industry sectors, including pharmaceuticals. It also set the term of patent protection to 20 years to meet the TRIPS deadline for January 1, 2005.[8] This closed the option of reverse engineering that largely contributed to the growth of the Indian pharmaceutical industry. It will not be possible to produce the patented product by adopting a different process. Some safeguard measures and flexibilities contained in the TRIPS Agreement were introduced in the patent system to protect public health, such as the

provision for compulsory licensing to support access to sources of generic medicines, restricting pharmaceutical patents to new chemical and medical entities, and the introduction of pre-grant opposition to patent applications.[9]

The campaign to ensure public health protection

The process of patent reform in India has been characterised by strong involvement of the national pharmaceutical industry and NGOs. The activism of civil society groups help explain why India was one of the countries that most strongly opposed the TRIPS Agreement and refused to implement product patents on pharmaceuticals until the deadline of January 1, 2005, despite intense external pressure[10]. During the TRIPS Agreement negotiations and through the 1990s, Indian national pharmaceutical firms and NGOs worked together to pressure government and resist changes to the national patent system. The national pharmaceutical industry viewed the implementation of TRIPS obligations as being detrimental to their interest in generic manufacturing and favouring foreign firms, while NGOs were mainly concerned with the effects on access to generic medicines. The Indian Drug Manufacturers Association (IDMA) representing generic firms such as CIPLA, and Ranbaxy Laboratories Ltd., a large national pharmaceutical firm and generic producer that was part of IDMA in the 1990s, in lobbying the government to protect the generic market and support the domestic pharmaceutical industry, found common ground with NGOs such as the National Working Group on Patent Laws (NWGPL), an informal public interest expert group established in 1988.

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The NGWGL has been active on patent and public health issues since the Uruguay Round of GATT negotiations. Given the presence of high-profile individuals in the NGWGL, including legal experts such as B.K. Keayla,[11] the NGWGL carried substantial political weight. It played the important role of mobilizing political opposition against patent reform in the 1990s and later strived to influence the process of patent reform directly. Through studies, conferences and political involvement the NWGPL provided an important source of information to support the joint resistance movement of the national generic industry and NGOs, brought other stakeholders into the discussions and helped raise awareness among the public on the impact of the implementation of TRIPS on access to medicines.

From 1988 to 1990 the NWGPL worked closely with Parliament through the Forum of Parliamentarians on Intellectual Property and WTO Issues, which included senior parliamentarians from different political parties. The NGWGL also established four People's Commissions on TRIPS that included leading senior former government officials and experts as members and held public consultations that recollected the views of experts, NGOs, industry associations and government officials.[12] The reports produced by the People's Commissions studied the debates in parliament on amendments to the Patents Act, 1970 and provided specific suggestions on changes to ensure the amended Act would prioritise the national interest and access to medicines.[13] Other NGOs important in mobilising the public and nourishing political opposition were the Research Foundation for Science, Technology and Nature Resource Policy led by Vandana Shiva, and public health NGOs part of the Jana Swasthaya Abhiyan (JSA) and the Public Health Movement in India. The Federation of Medical Representatives Association of India (FMRAI), acting in a similar way to a union, also played an important role in providing technical knowledge, access to a wide cross-country network of medics and leading or facilitating mass awareness-raising campaigns. The Affordable Treatment and Action Campaign (AMTC) launched in 2001 by a wide group of public health NGOs also contributed to create both national and international awareness of the public health and access to medicines problem in India and to mobilise support.[14] A critical factor to the success of the AMTC was the legal expertise of NGO groups such as the Lawyers' Collective HIV/AIDS Unit that helped convert the campaign demands into concrete proposals for legal reform.[15]

In the late 1990s the position and dynamics of the national pharmaceutical industry and NGO coalition that had united around the common stance to oppose amendments to the Patents Act, 1970 and had effectively stalled reform until then, began to change. Larger players in the generic market such as Ranbaxy were interested in joining the more research-intensive market, and thus began to break away from the position of smaller generic manufacturers and shifted towards a more pro-reform stance on patent law while seeking to maintain their dominant position in the generic market.

The changing dynamics within the Indian pharmaceutical industry were reflected in the reordering of the industry associations.[16] NGOs also became divided on whether to oppose amendment or engage in the patent reform process but helped to continue to mobilise public opinion and sustain pressure on government. For example, from 1999 to 2005, several protests against the patent amendments took place, including a walk-out by left-wing parties in the lower house of the Indian parliament in 1999.[17] The NWGPL led efforts to make specific proposals for amendment, although it was supported by other NGOs whether they engaged on the debate on reform or opposed the amendments.[18] When the Patents Ordinance was issued by the government in December, 2004 national NGOs, supported by international NGOs[19] campaigned strongly against the ordinance and supported left

political parties in parliament who were opposed to passing the government bill, as it was seen to include many problematic provisions and not enough public health safeguards. The fact that the government would be unable to pass the ordinance unless it received support in parliament allowed for some concessions from the government on the bill's wording, mainly regarding the ability to introduce pre-grant opposition in patent applications and on the issue of compulsory licensing, although NGOs were disappointed with the end result.[20] The final third amendment to the Indian Patents Act was approved by the Indian Parliament in March 2005. NGOs continue to express concern that product patents on pharmaceuticals will prevent generic competition and that the 20 year patent period will drive up prices for medicines.[21]

Successes and lessons learned

The campaign on patent reform in India to protect public health and safeguard the public interest took different turns during various periods, creating alliances and breaking up coalitions at different points in time. NGOs, together with common-minded politicians and national pharmaceutical industry groups, were able to lobby government to a point were patent reform was stalled for years, despite strong foreign pressure and strong pro-reform factions inside government. While the alliance was unsatisfied with the result of the Patent (Third Amendment) Act, 2005, they were able to include important provisions in the Act that otherwise might have been missed; such as the case of pre-grant opposition and compulsory licences.

An important part of the campaign in its ability to drive mass mobilisation and influence the outcome of the specific piece of legislation was the mixture of stakeholders and coordination of efforts that were involved. For example, the NWGPL since the beginning lead the campaign in terms of technical expertise and political acumen. Technical expertise was crucial in order to translate the political stance of the campaign into a legal one. A challenge in the campaign was that expertise on patent law was generally lacking in the campaign, as it remains an emerging issue in India and its effects in terms of access to medicines are not yet fully visible.

The linkages between NGOs and political leaders, whether former or in government, and understanding of the political dynamics was instrumental in devising the strategy on how to influence the government decision and legislation-making process. Furthermore, the campaign earned legitimacy as high-profile individuals and experts were associated to it, and were providing constructive and pro-active proposals on alternative text to the amendment of the Patents Act, 1970 and others thereon. The fact that groups such as the NWGPL included carried out multi-stake consultations to inform their positions and provided evidence-based arguments also increased the credibility and robustness of the campaign. Finally, the relationship between the national generic pharmaceutical companies and the NGOs helped give weight to the demands on the government and to increase the credibility of the campaign.

Some NGOs that opposed patent reform most strongly had difficulty in understanding the pressures that the government faced in the process and how the national patent system should respond to the changing interests of the national pharmaceutical industry. Perhaps the main challenge that the campaign faced was the disjointed efforts and diversity of positions that develop through the years; the division among NGOs, the national pharmaceutical industry and the supportive political parties.

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[1] See for example, Medicins Sans Frontières, "Will the lifeline of affordable medicines for poor countries be cut?: Consequences of medicines patenting in India", Briefing Document, February 2005, www.msf.org

[2] See B.K. Keayla (2005), "Amended Patents Act 1970: A Critique", Combat Law, Vol.4, Issue 2, with reference to the findings of the United States Kefauver Subcommittee, http://www.indiatogether.org/combatlaw/vol4/issue2/patents.htm. From 1959 to 1960 the Senator Estes Kefauver, chair of the Senate Subcommittee on Anti-Trust and Monopoly, conducted investigations of the pharmaceutical industry. See Administered Prices: Drugs, 87 Cong., I ses., Senate Rep. 448 (1961).

[3] For a discussion on some of the key changes of the 1970 Patents Act, see B.K. Keayla (2005), supra, note 2.

[4] For example, the Indian Patents and Designs Act of 1911 made available product patents and composition of matter patents.

[5] One example is the hearings and submissions made to the Peoples' Commission on GATT in 1995, and the Commissions' report. See V.R. Krishna Iyer, O. Chinnappa Reddy, D.A Desai, Rajinder Sachar (1996) "Peoples' Commission on GATT", Centre for Study of Global Trade System and Development.

[6] India, being a developing country, was allowed 10 years from 1995 to make the transition to a full patent regime.

[7] India's domestic patent law describes the EMR as the exclusive right to sell and distribute the substance or article concerned. TRIPS mandates a five-year EMR in the interim in exchange for letting the corresponding product patent application lie in the mailbox to be opened only after January 1, 2005 and until it is thereafter decided.

[8] See "The Patents (Amendment Act), 2005" No.15 of 2005, The Gazette of India. http://www.patentoffice.nic.in/ipr/patent/patent_2005.pdf.

[9] On March 20, 2006 three Indian NGOs, the Indian Network of People Living with HIV/AIDS (INP+), the Manipur Network of Positive People (MNP+), and the Lawyers' Collective HIV/AIDS Unit submitted their opposition, based on technical and health grounds, to a patent application filed by Glaxo Group Limited for Combivir, a fixed-dose combination of two AIDS drugs. See MSF Press Release, "Patent application for AIDS drug opposed for first time in India", March 30, 2006, http://www.msf.org/.

[10] For example, the United States filed a complaint under the WTO dispute settlement procedure against India for failing to

implement the TRIPS Agreement. The dispute settlement panel ruled that India must reform its patent law by April 1999.

[11] In addition to being convener of the NWGPL, B.K. Keayla is managing trustee and Secretary General of the Centre for the Study of Global Trade System and Development. He has been a senior civil servant of the Indian government as Commissioner of Payments and Officer on Special Duty, Drugs and Pharmaceutical Industry, Chief of Corporate Planning of Indian Drugs and Pharmaceuticals Ltd., Resident Director of the Organisation of Pharmaceuticals and Producers of India and Director of Ranbaxy Laboratories Ltd.

[12] Some of the members of the Peoples' Commission on Patent Laws for India have included senior advocates and former judges of the Supreme Court of India, and the Honorable Shir.L.K Gujral, former Primer Minister of India, has been chairman to the Commission.

[13] See for example, (2004) "Fourth Peoples' Commission Report on Patent Laws for India", National Working Group on Patent Laws and Public Interest Legal Support and Research Centre, Delhi, India.

[14] See Affordable Medicines and Treatment Campaign, http://www.lawyerscollective.org/lc_hivaids/amtc.

[15] For example, the Lawyers Collective HIV/AIDS Unit have made submissions on behalf of the AMTC to the Technical Expert Group (TEG) (Mashelkar Committee) constituted in March 2005 by the Ministry of Commerce and Industry of India to study all outstanding issues related to patentability of new chemical entities and micro-organisms. See http://www.lawyerscollective.org/lc_hivaids/amtc/folder.2005-12-20.9074366315/folder.2005-12-20.9333345933/

[16] In 1999 the Indian Pharmaceutical Alliance (IPA), a new association that included Ranbaxy, CIPLA and Dr. Reddy's was formed. IPA evolved out of the Indian Drug Manufacturers Association (IDMA), now composed of small-scale generic manufacturers.

[17] See for example, "Demonstration by trade unions", The Hindu, January 6, 2005.

[18] One example of groups opposing reform where the Joint Action Committee (JAC), a forum of trade unions, political parties and NGOs formed to oppose the amendment of the Indian Patents Act, 2005. Participating NGOs included the Research Foundation for Science, Technology and Ecology, the Centre of Indian Trade Unions (CITU), and the Federation of Medical and Sales Representatives' Associations of India (FMRAI). See "JAC Formed against Amendment of the Indian Patents Act", People's Democracy, Vol. XXIX, No. 1, January 2, 2005. See also "Declaration by the Joint Action Committee (JAC)", December 29, 2004, http://www.cptech.org/ip/health/c/india/ngodeclaration12292004.html

[19] For information on the position of international public health NGOs on the amendment to the Indian Patents Act, 1970 and their support to Indian public health NGOs, see http://www.cptech.org/ip/health/c/india/patents-act-amendments.html.

[20] See "The Beginning of the End of Affordable Generics", Joint NGO Statement by Affordable Medicines and Treatment Campaign (India), Medecins Sans Frontieres, Lawyers Collective HIV/AIDS Unit, and the Alternative Law Forum, March 22, 2002, http://www.cptech.org/ip/health/c/india/ngos03222005.html.

[21] See B.K. Keayla (2005), supra, note 2.