Two Decades of Struggle

AMIT SENGUPTA

The Supreme Court judgment in the Novartis case is important as it vindicates the entire process leading to health safeguards being incorporated in the Indian Patents Act. The article discusses this process, from the General Agreement on Tariffs and Trade and popular mobilisation in India to the enactment of and amendments to the Act, in the backdrop of the judgment.

Amit Sengupta (*asengupta@phmovement.org*) is co-convenor of Jan Swasthya Abhiyan (People's Health Movement, India) and is also associated with the All India People's Science Network.

The judgment by the Supreme Court of India, denying the claim of a patent on the anti-leukaemia drug Glivec (imatinib) by the Swiss multinational Novartis, is important at many levels. In this article we discuss, in the backdrop of the judgment, the long and protracted course leading to the enactment of the Indian Patents Act of 2005.

The Uruguay Round

In 1986, a new round of negotiations was initiated under the General Agreement on Tariffs and Trade (GATT), otherwise known as the Uruguay Round of negotiations. In the Uruguay Round, developed countries introduced a number of issues on the agenda – which were hitherto not considered trade issues – related to intellectual property (IP) rights, investment and services.

Initially, developing countries led by India and Brazil were able to stall the introduction of these new issues (Shukla 2000: 14-15), while the US continued to press for their inclusion. The latter's position was dictated by the state of the US economy. Having lost its competitive edge in the manufacturing sector and with its own agricultural exports threatened by state-subsidised agricultural exports from Europe, the US was keen to open up the services sector – especially for financial services. At the same time, the US had an interest in protecting its IP-dependent industries where it still had an advantage, specifically in pharmaceuticals, software and audiovisual media (ibid: 20-21).

India had a clear interest in not agreeing to these new demands. India's pharmaceutical sector had flourished in the wake of its 1970 Patents Act, which did not allow product patents on medicines and agro-chemicals. India only allowed process patents on pharmaceuticals, and had leveraged on this to develop capacity in process technologies.

By the beginning of 1989, the resistance by developing countries was broken down. Enormous pressure exerted by the US resulted in the two main hold-outs changing their position. India went to the extent of replacing India's chief negotiator at GATT, S P Shukla, because of his strong opposition to the inclusion of IP issues in the negotiating agenda (Marcellin 2010: 87).

The significance of the negotiations was not clear to most popular movements and civil society groups in different parts of the world. A key to the development of the resistance in India was the formation of the National Working Group on Patent Laws (NWGPL). In spite of its relatively small numbers, the NWGPL was hugely influential in shaping opposition to the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, right from the late 1980s. It was composed of a group of former civil servants, lawyers, scientists, representatives of the domestic pharmaceutical industry and representatives of trade unions in the pharmaceutical industry.[1]

The NWGPL, itself not a mass movement, became a catalyst for advocacy and mobilisation. It was the principal source of evidence-based arguments against the proposed regime on IP. Strong support from the domestic industry found resonance among a wide range of political actors. Over the next decade, the NWGPL organised the "Forum of Parliamentarians", which had representation from virtually the entire political spectrum. Several political and social movements, non-governmental organisations and mass organisations in India formed alliances against the GATT negotiations. Many subsequent developments had their roots in the popular mobilisations between 1990 and 2005.

Tortuous Path

The path towards the final formulation of India's Patents Act was also increasingly informed by, from 1991, the formal introduction of neo-liberal reforms. From an earlier position that India was forced to concede to in the GATT negotiations, there was now an attempt to argue that strong IP protection would promote domestic interests. However, popular sentiment continued to be hostile.

The TRIPS Agreement provided a three-stage time framework for developing countries: introduction of a "mailbox"

facility and Exclusive Marketing Rights (EMRs) from 1995; provisions on rights related to term of patent protection, compulsory licensing, reversal of burden of proof, etc, by 2000; and introduction of product patent protection in all fields from 1 January 2005.

The political instability in India, post-1996, meant that further discussions on amendments to India's 1970 Act resumed only in 1998 after the installation of the Bharatiya Janata Party (BJP)-led National Democratic Alliance (NDA) government. Indian Parliament enacted two legislations through the Patents (Amendment) Act of 1999 and 2002, which addressed the first two requirements of the TRIPS Agreement.

After assuming office, the NDA government was clearly subsumed by the neo-liberal logic while engaging with public policy on a range of issues.[2] The NDA government then circulated the draft Third Patents (Amendment) Bill in 2003, but it could not be discussed because of the change of government in 2004.

In 2004, there was a clear consensus between the two principal parties in India – the Congress and the BJP – and the United Progressive Alliance (UPA) government circulated an almost unchanged version of the NDA's Third Patents (Amendment) Bill draft. In the then political spectrum only the left parties (along with some regional parties) stood firmly against the draft Bill. But towards the end of 2004, the BJP started voicing opposition to the draft Bill. While this is in the realm of speculation, BJP's volte-face had little to do with any opposition to the substance of the Bill (given that this was identical to the Bill they had circulated) and more to do with an intent to embarrass the UPA government. With support for the bill now unsure, the UPA government decided to beat the 31 December 2004 deadline by promulgating an ordinance on 26 December 2004 (The Patents (Amendment) Ordinance 2004).

Patents Ordinance of 2004

The Ordinance, if ratified by Parliament, would have made it impossible for Indian companies to continue producing cheaper versions of new drugs. In early 2005, with the BJP engaged in a bitter tussle with the Congress in Bihar and Jharkhand over formation of ministries, it became clear that the Ordinance would be defeated in Parliament and the Congress was now forced to seek the left's support.

In the consequent negotiations between the left and the government, the left largely depended on advice provided by people associated with the NWGPL. These negotiations also allowed other interested parties to suggest new language. At the end, several important amendments were made to the 2004 Ordinance (ICTSD 2005), including the insertion of Section 3(d), which has been the subject of much discussion after its use by the Supreme Court to strike down the appeal by Novartis.

The negotiations were held in the backdrop of protests across the country, as well as in different parts of the world – all demanding that the "pharmacy of the South" should not be jeopardised. By 2005, the global Access to Medicines campaign was a powerful force and organisations such as Médecins Sans Frontières (MSF) and others were able to organise support across the globe. Protest letters were sent to the prime minister, including one where the co-signatories included Jim Yong Kim, the present World Bank chief (then director, Department of HIV/AIDS, World Health Organization) (Khor 2013).

Important Amendments

While there has been considerable focus on Section 3(d) of the amended Act, many important amendments

to the 2004 Ordinance were adopted, including:

(1) **Restrictions on Patentability**: The amendments clarified that an "inventive step" means a feature of an invention that "involves technical advances as compared to the existing knowledge or having economic significance or both". It incorporated a new definition for "new invention":

> any invention or technology which has not been anticipated by publication in any document or used in the country or elsewhere in the world before the date of filing of patent application with complete specification, i e, the subject matter has not fallen in public domain or that it does not form part of the state of the art.

It also provided a definition for "pharmaceutical substance" as being "a new entity involving one or more inventive steps".

(2) Restoration of Pre-grant Opposition to Patents: The amendments restored all the original grounds in the previous Act for opposing grant of a patent and also provided that: "the Controller shall, if requested by such person for being heard, hear him". The time for filing such opposition was extended from three to six months.

(3) Export to Countries Without Manufacturing Ability: The amendments clarified that a country could import from India if it "by notification or otherwise allowed importation of the patented pharmaceutical product from India".

(4) Continued Manufacture of Drugs with Applications in Mailbox: The amendments clarified that Indian companies that were already producing drugs that were the subjects of mailbox applications could continue to produce them after payment of a royalty, even if the drug was subsequently granted a patent.

(5) Time Period for Considering Compulsory Licence Application: Concerns that the process of granting compulsory licences could take too long were addressed by specifying that the "reasonable time period before the Patents Controller considers issuance of a compulsory licence when such a licence is denied by the patent holder shall not ordinarily exceed six months".

(6) Export by Indian Companies of Patented Drugs: The amendments provided that when patented drugs are produced under compulsory licence in India "the licensee may also export the patented product".

Several of the amendments are being used today by different groups to try to safeguard access. In particular, the pre-grant opposition provisions have been used extensively by domestic companies and civil society groups, and combined with restrictions on patentability, the provisions have allowed many important drugs to be kept off patents. Further, a number of drugs introduced in the transition phase (1995-2005) were not patented as the amended Act allowed generic companies to manufacture and sell drugs introduced in this period.

The language for Section 3(d) was provided by the Indian Drug Manufacturers' Association (IDMA). The left parties had asked for a more stringent definition of patentability by limiting grant of patents for pharmaceutical substances to "new chemical entities" or to "new medical entities involving one or more inventive steps". Section 3(d) was a compromise and the government had agreed to refer the matter to an expert panel.

Subsequently, the government constituted a Technical Expert Group under the chairmanship of R A Mashelkar, former director general, Council of Scientific and Industrial Research. The Group, in its report in 2007, opined that restriction of patents to new chemical entities would be incompatible with the TRIPS Agreement. Evidence surfaced that parts of the report had been plagiarised from a study by the UK-based Intellectual Property Institute, funded by Interpat, an association of 29 drug companies including Novartis (Padma 2007: 392). The report was withdrawn and press reports indicated that Mashelkar had resigned from the committee (ibid). Yet, the same committee resubmitted a new version with the same conclusions in 2009. These recommendations were expeditiously accepted by the government.

Vindication of Struggle

The Supreme Court judgment in the Novartis case, thus, needs to be read not just as an instance of the application of one section (Section 3(d)) of the Indian Patents Act. The judgment is important as it vindicates the entire process that led to health safeguards being incorporated in the Indian Act.

The judgment, in fact, refers clearly to this process by noting (in para 26):[3]

> …to understand the import of the amendments in clauses (j) and (ja) of section 2(1) and the amendments in section 3 it is necessary to find out the concerns of Parliament, based on the history of the patent law in the country, when it made such basic changes in the Patents Act. What were the issues the legislature was trying to address? What was the mischief Parliament wanted to check and what were the objects it intended to achieve through these amendments?

The judgment is a vindication not just of a legislative process, but of popular resistance and mobilisation – in India and across the world – that challenged corporate power. Small victories such as this become inspirations for larger battles.

NOTES

1 For more information about the formation of the NWGPL, see Sen Gupta (2010).

2 See, for example, Arulanantham (2004).

3 Text of final judgment is available at: http://judis.nic.in/supremecourt/imgs1.aspx? filename =40212 (viewed on 20 June 2013).

REFERENCES

Arulanantham, David P (2004): "The Paradox of the BJP's Stance Towards External Economic Liberalisation: Why a Hindu Nationalist Party Furthered Globalisation in India", Asia Programme Working Paper, December, Royal Institute of International Affairs, Chatham House, London.

ICTSD (2005): "Indian Parliament Approves Controversial Patent Bill", *Bridges Weekly Trade News Digest*, 9(10), International Centre for Trade and Sustainable Development, viewed on 20 June 2013, http://ictsd.org/i/news/bridges weekly/7294/

Khor, Martin (2013): "A Victory for Patients' Access to Medicines", Global Trends Series, Third World Network, 8 April, viewed on 20 June 2013, http://www.twnside.org.sg/title2/gtrends/2013/gtrends426.htm

Marcellin, Sherry S (2010): *The Political Economy of Pharmaceutical Patents: US Sectional Interests and the African Group at the WTO* (Farnham, England: Ashgate Publishing).

Padma, T V (2007): "Plagiarised Report on Patent Laws Shames Indian Scientists", *Nature Medicine*, 13(4): 392.

Sen Gupta, Amit (2010): "B K Keayla: A Personal Reminiscence", *Economic & Political Weekly*, 45(51): 25-26.

Shukla, S P (2000): "From GATT to WTO and Beyond", Working Papers No 195, United Nations University/World Institute for Development Economics Research, Helsinki, Finland.