Capitulation on IP: Reaching a Point of No Return?

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The government has chosen the occasion of Prime Minister Modi's visit to the US to articulate a vision on Intellectual Property (IP) protection that promises to radically reshape the Indian IP system (as reported in this column a couple of weeks back). What is of particular interest is the contrast between the BJP led government's present stance on IP and the BJP's position on the floor of Parliament when India's Patent Act was being amended in 2005, in order to make it compatible with the TRIPS agreement.

During the debate in Parliament on the Patents Amendment Bill, BJP leader V K Malhotra had commented: "The government will be now responsible for the consequences of the bill and the hardships that will heap upon the people". Senior BJP leaders Murli Manohar Joshi and Yashwant Sinha had further argued that the new 'product patent' regime would deliver a death blow to the Indian generic drug industry, as a result of which, many African nations would be deprived of low cost anti-AIDS drugs from India. The BJP, then, was expressing its concerns regarding the switchover to a 'product patent' regime, and its consequences on Indian generic manufacturers and their ability to continue production of low cost versions of new medicines that were patented. Sitting in the opposition benches, the BJP's utterances could be seen as a ploy to embarrass the incumbent UPA government. To the latter's credit, however, the final Patents law that the Indian Parliament enacted did substantially incorporate many 'health safeguards' of the TRIPS agreement (higher patentability standards, compulsory licensing, pre and post-grant opposition provisions, etc) designed to mitigate the impact of the TRIPS compliant law on poor patients in India and many other developing countries. In fact, many commentators have since labeled the Indian Patents Act as a 'model law'.

Attack on Indian Patents Act of 2005

The Indian Patent Act of 2005, since the day it became law, has attracted adverse reactions from big pharmaceutical companies and their host countries in North America and Europe. The United States, arguably the most powerful and vocal proponent of its pharma industry, has been particularly active in spewing venom against the Indian law. In its 'Special 301' report for 2005, the United States Trade Representative had commented: "… the U.S. pharmaceutical industry reports shortcomings in this patent legislation that we hope India will correct. … ( ) we will monitor closely India's implementation of the patent amendment…" India, in fact, has been on the 'Priority Watch List' of the USTR since 1979. In early 2014 there were several reports that India might be downgraded further to the USTR's 'Priority Foreign Country List' which would allow (based on its domestic law) to initiate unilateral trade sanctions. While this did not happen, the US has been particularly unhappy in recent years with India over several IP related issues. In its 2013 'Special 301' report, the USTR had passed particularly adverse comments on two issues – the denial of a patent to the Swiss MNC, Novartis, for its anti leukemia drug (Glivec), and the grant of a compulsory license to an Indian generic company, NATCO, for Bayer's anti-cancer drug (Nexavar). Recently members of the US Congress have also demanded an investigation of India's alleged IP 'protectionism' at the US International Trade Commission.

The US government and its pharmaceutical industry have consistently identified several areas in India's patent laws and administrative procedures as being 'contrary to American interests'. These include the high standards of patentability incorporated in the Indian Act – including the much reviled Section 3(d) that bars trivial changes in existing medicines from receiving patent protection, 'inadequate' enforcement of intellectual property laws, 'liberal' compulsory licensing provisions, and the lack of legislation to protect test data. The moot point is that the Indian law, in all these areas, is TRIPS compatible and

therefore legally tenable. Further, all these objections, if acted upon, would further compromise access to medicines for millions of poor patients.

Indian Patent Act out of Sync with Neo-liberal Reforms

While the US administration has continued to ratchet up pressures on India to change its laws and procedures on Intellectual Property protection, there has also been a continuous change in the discourse regarding IP protection in India. The incorporation of health safeguards in the Indian Act in 2005, was itself rather fortuitous – the product of the UPA government's dependence on the Left parties at that time. Thus, in a manner, India's relatively 'progressive' patent regime, since its inception, has been out of sync with the consensus among India's two largest political formations – led by the Congress and the BJP respectively – to aggressively push for neo-liberal reforms. Saddled with a law that the UPA government did not entirely wish upon itself, the government has never pushed for a complete realisation of the possible benefits of the flexibilities in the Indian Act. Thus, in nine years, only one Compulsory license has been issued to break a patent monopoly. Even countries such as Zambia and Zimbabwe have done better! While some of the higher court judgments have been positive and have upheld the basic tenets of India's Patent Act, there is a disquieting trend today of courts granting ex-parte injunctions against generic manufacturers in cases involving alleged IP infringement. This has been accompanied by a continuing trend of inviting US and EU patent office representatives to train Indian patent examiners and judicial officers. Many patents are being granted in India, that shouldn't have passed muster if the Indian Act was correctly interpreted by patent examiners.

The pursuit of neo-liberal reforms has also brought about changes in the industrial climate. Indian generic drug companies are increasingly tying up with foreign MNCs, given their interest in developed country export markets. While domestic demand for medicines has stagnated due to poor public investment in healthcare, the major source of expansion for large Indian companies is this export market in the EU and US. A recent case in point is the voluntary license signed by several Indian companies, including Cipla, with the US based Gilead Sciences for manufacture and distribution of a Hepatitis C drug, Sorafenib. 13 years ago Cipla led the charge against Big Pharma and changed the fate of millions of HIV-AIDS patients across the world by offering HIV-AIDS drugs at 1/40th the price charged by them. That Cipla chose not to do so in 2014 and collaborate with Big Pharma illustrates the sea change in the legal, economic and political environment in the country over the last 15 years.

BJP Abandons Pretence of Supporting Public Health

Given this backdrop, it should come as no surprise that the Narendra Modi led NDA government has decisively abandoned the fig leaf of adherence to public health goals, which the UPA government had nominally retained. A self-proclaimed proponent of a decisive style of governance, the BJP has cleared all doubts regarding its intentions. The first indication regarding the BJP's game-plan was the minister of commerce, Nirmala Sitaraman's statement in a press conference on September 8, when she said: "India does not have an IPR policy. This is the first time we are coming out with an IPR policy. We are very strong in IPR and we certainly want to protect our interest. IPR policy issues have been hanging for quite a long time and the new policy will give direction in terms of protecting IPRs of India. With the US we have (certain) issues. India has become a brand in terms of pharma. Because India does not have any policy, developed nations are picking holes in India's IPR laws". Apart from the minor issue that her reference to India not having an IP policy is factually incorrect, the intent was clear – to signal prior to Prime Minister Modi's visit to the US that India was willing to wash its sins and address the concerns that the US has about India's IP policy. Along with an admission that we are at fault for not having an IP policy that developed countries support, it signaled India's willingness to tailor its IP policy based on developed country concerns.

That the Indian government was intent on currying favour with the politically powerful US pharmaceutical industry was soon to become clearer still. On September 22, the ministry of chemicals issued an internal memo cancelling an earlier order (issued on May 29) by the National Pharmaceutical Pricing Authority (NPPA) that placed a ceiling on the prices of several drugs – thus curbing the rampant profiteering by drug companies, including several US based companies. This directly addresses a long-standing complaint by

the US regarding drug price controls being harmful to the commercial interests of its pharmaceutical companies. The precipitate order from the ministry is especially confounding given that the NPPA's order had been challenged by the Organisation of Pharmaceutical Producers of India (OPPI – the industry lobby of foreign drug companies) in the Delhi High Court and the matter was sub-judice. The government, in its haste to clear the air before Prime Minister Modi's visit, was even willing to compromise its position in the ongoing court case.

The icing on the cake was yet to come, however. The joint communiqué at the end of Prime Minister Modi's visit, contained the following language: "Agreeing on the need to foster innovation in a manner that promotes economic growth and job creation, the leaders committed to establish an annual high-level Intellectual Property (IP) Working Group with appropriate decision-making and technical-level meetings as part of the Trade Policy Forum". Significantly, this sentence is embedded in the section on economic growth, thereby inferring that strong IP protection fosters economic growth. In fact, evidence points to the contrary for countries at India's stage of economic and technological development. Historically, all developed countries have used low standards of IP protection while 'catching up' with others (i.e., while attempting to achieve parity with other developed countries. The US used this ploy in the late nineteenth and early twentieth century in its competition with Europe, Japan followed suit in the middle of the last millennium, and Taiwan and South Korea did likewise in the late twentieth century. Indian and US interests will continue to be different as regards IP protection, because the two countries are very differently placed as regards economic and technological development. The US has always used joint working groups to pressure countries to adopt positions that conform to US interests, and clearly the IP working group will be used for the same purpose. By agreeing to its formation the Indian government has clearly indicated that it is ready to compromise. For 35 years, every Special 301 report of the USTR has detailed the sins of omission and commission of India's IP system. We do not need a working group to understand this, but the US needs the working group to intensify its pressure on India.

It will really be a sad day for millions across the world if India continues to walk the talk and succumbs to the designs of Big Pharma, mediated through the government of the United States. At stake are poor patients in three continents, who look towards India with hope for medicines that are cheap and effective. The question really is, are we fast reaching a point of no return?