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Drug Patents in India: Turf Battles

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The debate on India's intellectual property (IP) regime and its implications for pharmaceutical innovations and generic drugs has come into sharp focus following the Supreme Court of India's recent judgement on the global pharmaceutical major Novartis's appeal for patenting and exclusive marketing of Glivec in India. Glivec is a drug administered on patients suffering from Chronic Myeloid Leukemia (CML), a rare form of blood cancer. The Court judged that Glivec does not satisfy the patentability criteria of 'enhanced efficacy' as mentioned in Section 3(d) of the Patents Act of 2005 and hence Novartis cannot be granted patent on Glivec in India.

The decision has been widely hailed as a victory for domestic manufacturers, particularly generic drug producers. Generic drugs are those that are introduced after patents expire on their original formulations. Novartis's patenting of Glivec in India would have implied that Indian producers could not have produced generic versions of the drug, which they are able to do now.

From an affordability perspective, availability of more generics makes a difference to healthcare costs for consumers. This is evident from the differences between costs of patented and generic versions. *Glivec*, for example, costs INR 120,000 (SGD 2723) per month, which is roughly fifteen times more expensive than its locally produced generic version (SGD 182

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per month), manufactured by the Indian pharmaceutical firms *Natco* and *Cipla*. Similar cost differences exist between several other branded and generic drugs.[2]

While generic producers in India, several low-income countries particularly in Africa that are major buyers of generic drugs from India, and civil society organisations campaigning for greater access to cheaper medicines are exulting over the judgement, global drug majors have expressed their dissatisfaction over the verdict. A disappointed *Novartis* reacted to the ruling by suggesting that it is likely to discourage multinational investment in drug research and development (R&D) in India and will also affect Indian patients by delaying the introduction of new drug discoveries in the Indian market. *Novartis* itself is planning not to invest any further in R&D in India though it will continue to introduce its products in the domestic market. The Organisation of Pharmaceutical Producers of India, a body comprising several major global drug multinational corporations (MNCs), echoed concerns similar to those expressed by *Novartis*.

The judgment has cast renewed attention upon the struggle of Indian IP policy makers to balance between the apparently irreconcilable objectives of ensuring affordable access to medicines for consumers, on one side, and offering to pharmaceutical producers market-based incentives for encouraging innovations, on the other side. It has also underlined new challenges for some of the trade negotiations that India is currently involved in with respect to the new standards for IP rules being introduced by several major economies and significant economic groupings.

Enhanced Efficacy

Novartis's failure to obtain a patent in India, on account of it not being able to satisfy the 'enhanced efficacy' condition for *Glivec,* has raised questions on what constitutes such efficacy. The Supreme Court has taken the view that only an increase in therapeutic efficacy over and above the current and known use of the drug can satisfy the demand for 'enhanced efficacy'. Improvement in physico-chemical properties leading to better consistency and delivery of the drug – claimed by *Novartis* as valid grounds for patentability – clearly does not constitute enhanced efficacy.

Limiting enhanced efficacy to increase in therapeutic value can discourage patenting of marginal innovations and steady 'ever-greening' of patents for minor formulations of the same drug without significant therapeutic value-addition. But it can also be a disincentive for higher investment in R&D on the part of drug producers. R&D investment in pharmaceuticals

[2] *Pfizer's Sutent* used for kidney cancer costs INR 196,000 (SGD 4445) for a one-and-half month period of medication compared with INR 19,000 (SGD 445) for the generic version. *AstraZeneca's* patented *Iressa* for treating lung cancer costs INR 105,000 (SGD 2382) for 30 pills compared with INR 4250 (SGD 96) for local versions.

is uncertain in outcomes and bears fruit only over a long period in time. With overhead expenses accounting for large chunks of R&D spending and producers keen on recovering the costs, the urge to patent incremental innovations, involving minor and not necessarily therapeutic improvements, is always high. Substantive therapeutic gains can come from only innovations entailing discovery of new chemical compounds, which are rare, and uncertain to predict.

Stronger than TRIPS

India had to shift from a process-based to a product-based patent regime in line with its obligations under the Trade-Related Intellectual Property Rights (TRIPS) Agreement of the World Trade Organisation (WTO). The Patent Law of 2005 effected the change. However, India was anxious about the effect of the new law on affordability of medicines for its large population. It therefore tried to introduce 'checks and balances' in the domestic regulation for minimising the exercise of monopoly power by patent holders.

Section 3(d) of the Patent Law of 2005 was one such effort where, in addition to the globally accepted and TRIPS-ratified patentability criteria of novelty and enhanced usefulness, enhanced efficacy was plugged in as a requirement. India also secured the right of compulsory licensing of patented drugs, under which the patent holders' rights could be waived after royalties to the original holders[3] are paid, thus paving the way for introduction of generics.

While Section 3(d) does introduce an additional yardstick for patents over and above the TRIPS, the compulsory licensing provision is widely applied across the world. Indeed, the first instance of the provision coming into force in India was when *Natco* was allowed to compulsorily license the *Nexavar* drug manufactured by the *Bayer Corporation* for treating kidney and liver cancer, last year. As such, use of compulsory licensing as a TRIPS-compliant provision is fairly widespread, with not only emerging markets like India, Indonesia and Malaysia applying it, but OECD countries like Canada and Italy also using it frequently. The United States has also been trying to achieve the same objective through Executive Orders issued by the President and Anti-Trust Laws. Thus while compulsory licensing cannot be held by global pharmaceutical majors as a specific grudge against India, Section 3(d) of the 2005 Law would be construed as one.

[3] Compulsory licensing is a TRIPS-compliant provision. This also helped several developing countries with inadequate domestic manufacturing capacities to import the generics from countries like India where compulsory licensing provisions were applied.

Generic vs. Branded

India is one of the largest and fastest-growing pharmaceutical markets in the world, with the size of the market expected to cross US$ 70 billion by 2020 from its current level of US$ 11 billion.[4] With a share of 35 per cent in the global generics market, India is expected to remain a major supplier of generic medicines to the rest of the world.

The success of Indian pharmaceutical firms like *Dr Reddy's Labs, Cipla, Natco, Sun Pharma and Glenmark* in becoming leading global producers of generic drugs has much to do with their making good use of India's earlier policy of patenting processes, not products. It is, however, ironical that generic drugs do not have a large share in India's domestic market and are essentially confined to distribution networks in government hospitals and pharmacies. With commercial retailers buying generics at discounted rates from their producers and selling them at maximum retail prices (MRPs), low-income households outside the purview of government hospitals and medical systems are hardly benefitting from the country's huge production of generics.

Generics in India got a shot-in-the-arm through the government policy announced last year for procuring generic drugs and distributing them free through the public health system. While this will enable more than 50 per cent of the population to access cheap generics, the policy prevents doctors from prescribing branded drugs. It clearly drives in a wedge between indigenous generics and branded drugs produced by multinationals.

To many of the latter, the Supreme Court's judgment on *Novartis* appears to be confirming the policy slant in India favouring generics. The support extended by government procurement policies, the *Novartis* ruling and the large number of 'blockbuster' drugs[5] going globally off-patent, are expected to ramp up generic production in India with the range of drugs expanding from life-saving treatments of fatal diseases such as cancer and HIV to lifestyle ailments like diabetes and hypertension.

International Obligations

Despite complying with international IP obligations under the WTO, India has utilised the flexibilities under the TRIPS by setting higher patentability standards for its domestic market. While this has made it difficult for pharmaceutical MNCs to obtain patents on many of their incremental formulations, compulsory licensing and procurement policies have additionally abetted growth and expansion of generics. In the process, however, India's patent regime has

[4] 'The importance of generic drugs in India', Ajay Bera and Ashish Mukherjee, *International Journal of Pharmaceutical, Chemical and Biological Sciences*, IJPCBS 2012, 2(4), 575-587; http://www.ijpcbs.com/files/2106-22.pdf (Accessed on 5 April 2013)

[5] Blockbuster drugs are popular drugs with annual sales of at least US$ 1 billion.

been criticised for being unfavourably inclined towards R&D and innovation. This is expected to be a thorny issue in India's future trade negotiations with advanced economies that have stronger domestic IP regimes.

Several upcoming regional trade and economic framework agreements are focusing on 'WTO plus' issues such as domestic IP regulations. The Trans-Pacific Partnership (TPP) is one such example. Though India is not a member of the TPP, it cannot overlook the implications of the IP framework adopted by the TPP, which is expected to award much higher protection to innovations than that currently available under the TRIPS. The growing gap between India's IP rules and those of frameworks like the TPP is likely to slow down R&D investments in India from members of these blocs and delay introduction of new products in the Indian market. Greater IP protection and less domestic flexibilities might also creep into the Regional Comprehensive Economic Partnership (RCEP), a major trade deal being negotiated by the Association of Southeast Asian Nations (ASEAN) and its existing bilateral FTA (free trade agreement) partners, including India.[6] India faces the critical dilemma where it might get isolated and marginalised in influential regional trade negotiations due to its relatively weak IP rules, which, however, it needs to maintain on grounds of affordable healthcare. The immediate implication of this dilemma, reinforced by the Supreme Court ruling, will be felt during the conclusion of the impending India-European Union FTA.

Not the Last Word

The euphoria of generic drug manufacturers and civil society groups over the *Novartis* ruling being a major step towards bringing relief to poor patients in India should not obliterate the fact that till now these patients have hardly benefitted from cheap generics. While generic drug output from India has expanded rapidly due to historic circumstances, favourable domestic regulations and government subsidies, the low-cost products have not reached most of the domestic poor. Price ceilings on essential drugs have encouraged generic manufacturers to focus more on export markets. This is unlikely to change even if government procurement of generics increases by large amounts as profit margins are higher in overseas markets. Benefits of cheap generics are unlikely to extend to poor patients across India and outside the government healthcare system unless incentives change.

The Supreme Court's judgement, particularly the application of Section 3(d) of the Patents Act of 2005 for judging patentability, highlights the uncertainties that global innovators have faced over prospects of R&D and innovations in India. While India has utilised the TRIPS flexibilities to ensure that 'public benefit' supersedes private gains when it comes to exercise

[6] The TPP includes Australia, Brunei, Canada, Chile, Malaysia, Mexico, New Zealand, Peru, Singapore, US and Vietnam. Japan has recently decided to join the TPP negotiations while South Korea and Thailand have expressed interest. The RCEP comprises the 10-member ASEAN and Australia, China, India, Japan, New Zealand and South Korea.

of monopoly rights of patent holders, it has not, unfortunately, been able to project itself convincingly as a major hub of innovation and R&D in the eyes of the international business community. In the process, it has failed to strike the right balance between concerns of effective distribution of affordable healthcare services and mobilising the much-needed foreign investment for innovation-intensive drug development.

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