Balancing Affordability and Availability in a Drug Patent Regime

VISWANATH PINGALI, CHIRANTAN CHATTERJEE

India needs to find an optimal patenting regime that will safeguard incentives for innovation while simultaneously ensuring that medicines are available at reasonable prices.

> That reminds me to remark, in passing, that the very first official thing I did, in my administration—and it was on the first day of it, too—was to start a patent office; for I knew that a country without a patent office and good patent laws was just a crab, and couldn't travel any way but sideways or backways.
>
> — *Mark Twain*[1]

A recent empirical study indicates that between 2000 and 2009, out of 184 new drugs approved by the United States Food and Drug Administration (USFDA), only about 90 have been marketed in India.[2] The study further argues that one of the factors for lower availability is weaker patents.

At the same time, another study has claimed that India follows a "Patent Law 2.0"—an intellectual property (IP) regime that is more aligned towards improving access. In the pharmaceutical markets of developing economies, the trade-off between the twin concerns of affordability and availability have been dominating the discussion on how pharmaceutical patent policy needs to evolve. In this article, we argue that perhaps a new status quo in patent laws is emerging in India that seems to balance these twin concerns—we call it Patent Law 1.5. This law in our mind is not as weak as Patent Law 2.0 mentioned above; at the same time it will maintain affordability from the perspective of a social planner. This is one step forward from the erstwhile regime in India, which only protected process patents in the country from the 1970s till 2005. But while doing that, Patent Law 1.5 will also provide innovators protection for their innovations.

One likely evidence of Patent Law 1.5 emerged with a Supreme Court of India's interim ruling in May 2015, refusing permission to an Indian pharmaceutical manufacturer (Glenmark) to copy Merck, Sharp and Dohme's (MSD) molecule, sitagliptin phosphate (marketed under the brand name Januvia, which belongs to the class of DPP–4 inhibitors within the oral antidiabetic drugs).[3] This seems to suggest that patents would be respected in India in future, a rare situation that has not been witnessed too frequently in the the past.[4]

This ruling follows past decisions, where, in contrast, the Supreme Court had allowed an Indian pharmaceutical company (Natco Pharma) to sell generic versions of Bayer's anti-renal cancer drug sorafenib (brand name Nexavar) via compulsory licensing. The key difference between these past and recent cases

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Viswanath Pingali (*viswanath@iimahd.ernet.in*) is at the Indian Institute of Management, Ahmedabad. Chirantan Chatterjee (*chirantan@gmail.com*) is at the Indian Institute of Management Bangalore.

is that while Nexavar was being sold at the prices prevailing in the developed countries,[5] Januvia is being sold in India at 40% of the prices prevailing in the United Kingdom (UK) and 15% of the prices in the United States (US). Further, MSD also voluntarily licensed the sale of sitagliptin to a local Indian pharmaceutical company (Sun Pharmaceuticals).

These two cases provide us with a rough contour of the evolving position on the potential new patent regime (Patent Law 1.5) and its functioning in India: while patents and other IP are potentially going to be respected, accessibility and affordability through "reasonable pricing" might also be the key. We first discuss the traditional arguments on the role of stronger patent laws in incentivising innovation. We then discuss the key ideas behind differential pricing and voluntary licensing, which might be the way ahead.[6]

Pros and Cons of Patents

The economic arguments for the weakening of Patent Law are rather straightforward.[7] Given that prices of life saving drugs could be substantially higher than the marginal cost of production, it could lead to substantial deadweight loss because of limited reach, especially in developing economies where a majority of the population is uninsured.

Pro-patent arguments tend to posit that research and development is a costly and risky exercise, while mimicking the drugs is not. Since the market can get competitive very fast without patents, innovating firms are given temporary monopoly power in order to recover their sunk expenditure.[8] Therefore, while static consumer welfare is lower in the initial periods when the patent is in force, it improves significantly once the patent expires. If, on the other hand, the patent regime is weakened, high levels of consumer welfare are realised from the beginning; however, future consumer welfare associated with future innovations would reduce significantly, thereby harming aggregate consumer welfare in the long run.[9]

A question that is more important in the Indian context is whether or not access to novel medicines is reduced in markets (especially the developing countries) where patent protection is weaker. Recent empirical literature points out that patents and associated policy choices that enhance IP play a significant role in the diffusion of new drugs.[10] Further, countries with stringent price regulations are less attractive to innovators; they tend to delay the launch (or do not launch) in such markets.[11] Studies have also shown that the probability of a new drug being launched is lower in countries like India, China and Brazil, where patent protection is relatively weaker.[12] Some industry players have also echoed this sentiment that "not respecting the IP norms" has led to a loss of significant investments in the country.[13] Further, Healthcare Global Enterprises (HCG), India's largest chain of cancer hospitals has claimed that access to advanced cancer drugs is becoming difficult in India, thereby suggesting that lack of access can affect both acute and chronic diseases.[14]

Such delay/denial of launch can hurt consumer welfare. In one of our earlier studies, we have shown that if sitagliptin were to come under the ambit of compulsory licensing, and in response, the other two DPP–4 molecules (vildagliptin and saxagliptin) are not launched in India, then the welfare of diabetes population in India could be hurt significantly by more than Rs 14 crore.[15] Moreover, such losses can be more if the recommendations of the Roy Chaudhury Committee Report (2013)—mandating localised clinical trials before launching a drug—are implemented. [16]

In sum, while the anti-patent group argues that the patents deny accessibility of drugs to several people, especially in the developing world, the pro-patent group argues that the patents are essential for innovation, which, in turn, leads to better accessibility in the long run. Since the empirical evidence seems to suggest that the launch of new drugs might be delayed in case of weak patent laws, the relevant question in this context is: How can the developing economies balance the need for new and innovative drugs while making sure that the affordability is not compromised?

Patent Law 1.5

Differential pricing, where the innovators charge lower prices in developing countries vis-à-vis the developed world, is one solution to this problem. In other words, innovators could set prices that are country specific. Academic research has also advocated differential pricing as a means to improve access in the developing countries.[17] As pointed out earlier, such a practice is already prevalent in India, where some innovators charge lower price for their products when compared to the developed countries.

For example, as Figure 1 (p 22) points out, oral anti-diabetics belonging to the class of DPP–4 inhibitors are priced substantially lower in India when compared to Japan, the UK and the US.[18] We estimate that if the prices of sitagliptin, saxagliptin and vildagliptin (the three DPP–4 molecules currently available in India) are priced at the prices prevailing in the UK, consumer welfare reduces substantially.[19] Even if the innovators charge local profit-maximising price in a developing country, prices tend to be lower than

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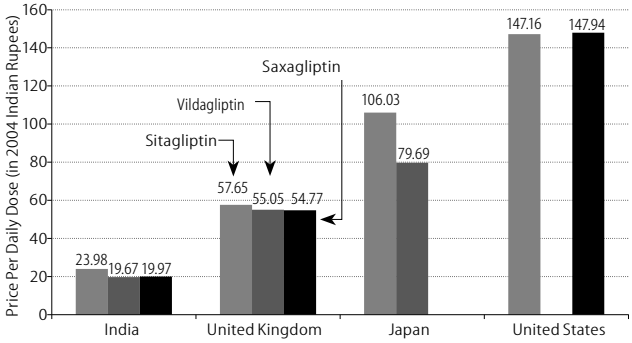
Figure 1: International Price Comparison of DPP–4 Inhibitors in 2011



(1) The daily dosages are 5mg for saxagliptin, 100mg for sitagliptin, and 100mg for vildagliptin. (2) In 2011, saxagliptin was not yet approved in Japan and vildagliptin was not yet approved in the US.

Source: IMS India, UK National Health Service Website, internationaldrugmart.com, and Corporate Press Releases.

the ones prevailing in the developed countries. This is because the demand in developing countries tends to be more elastic mainly due to affordability reasons, primarily because of lack of health/prescription insurance.

The main problem with the implementation of differential pricing is the issue of parallel pricing, or spillover effects that exist due to the presence of arbitrage opportunities. If cross-border trade is not properly regulated, the arbitrage opportunities that exist due to the price difference can lead to a loss in more lucrative markets. Sign boards indicating the sale of anti-cancer medicines in Chinese, Arabic and Korean are ubiquitous at major international airports in India, suggesting parallel trade.

Improved accessibility of medicine could also be achieved through voluntary (instead of compulsory) licensing of marketing of the drug to Indian pharmaceutical companies. Presumably, Indian companies are more established in terms of market reach vis-à-vis the innovator. Therefore, voluntary licensing improves accessibility without the innovator having to incur setup costs. Again, this practice is prevalent in India. Two of the three DPP–4 inhibitors (sitagliptin and vildagliptin) are licensed by their innovators (MSD and Novartis, respectively) to Indian pharmaceutical companies.[20] For instance, MSD's version of sitagliptin is sold under the brand name of Januvia, whereas that of Sun Pharmaceuticals is sold under the name of Istavel. Chatterjee, Kubo and Pingali (2013) point out that withdrawal of a voluntary licence could hurt consumer surplus significantly.

Another option in the price and accessibility debate is the direct local manufacturing of pharmaceuticals by the innovators themselves. Lower cost of manufacturing allows the innovators to keep the operating expenses reasonably low;[21] this might enable them to further potentially subsidise the drugs within India. Local manufacturing could also get support from the current government through its "Make in India" initiative. Without necessarily coercing innovators to manufacture, appropriate incentives, which encourage innovators to produce locally, can be thought of. For example, appropriate tax breaks for manufacturing and selling their products cheaper in India could be considered.

In sum, there needs to be an open discussion between the innovators and the policy makers with regard to pricing practices, wherein public interest is served without hurting innovators' interests. Negotiated price within the country, with restrictions on exports that discourage parallel trade seems to be a solution that the Patent Law 1.5 regime needs to move towards.

Conclusions

To summarise, research so far seems to suggest that availability of novel medicine and affordability of the same move in opposite direction. A policy intervention herein needs to achieve a fine balance where neither of the objectives is unduly compromised. In this, the innovator pharmaceutical industry has shown the way through differential pricing and voluntary licensing. Moreover, the Supreme Court ruling regarding sitagliptin suggests that from a social planner's lens, respecting the innovator's patents might be the appropriate quid pro quo in return going forward.

Patent Law 1.5, a middle ground, might also help in ushering inward foreign direct investment in the pharmaceutical sector. A major concern expressed by some innovator companies has been a lack of clear understanding of tax laws and patent protection.[22] Therefore, these

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are the two major areas that the Government of India's "Make in India" and "Atal Innovation Mission" initiatives need to focus on while re-engineering Indian patent laws in future.[23]

Interestingly, the problem of finding an optimal patenting regime is not just restricted to India alone. Any developing country that is balancing availability with affordability needs to contemplate on this issue. In that context, the policy that India adopts will be observed keenly in the international arena, and India can provide thought leadership on obtaining such an optimality in affordability and availability of medicines to other countries like South Africa, China, Brazil and Argentina.

NOTES

1 Twain (1889).

2 See, Berndt and Cockburn (2014).

3 Reuters (2015).

4 See Krishna and Whalen (2013).

5 As of July 2012, Bayer's sorafenib was available at over Rs 2 lakh, whereas Cipla's and Natco's versions were available for Rs 5,000 and Rs 7,000, respectively, for a month's supply.

6 Please notice that we have not discussed the merits or demerits of Section 3d of the Indian Patent Act—a key section that discusses incremental innovation. Section 3d differentiates the Indian patent system substantially from the other countries, and has attracted significant media attention. Our arguments, therefore, are about fostering intellectual property of those drugs that have obtained patents with Section 3d in place.

7 See Rockett (2010) for a comprehensive academic review of theoretical economic intuitions between the relationship between property rights and invention.

8 For details on risks associated with drug discovery process, and the associated costs, see Grabowski (2007). Also, see some recent evidence from the Tufts Institute here, http://csdd.tufts.edu/files/uploads/Tufts_CSDD_briefing_on_RD_cost_study_-_Nov_18,_2014..pdf, accessed on 1 June 2015.

9 This argument is based on the idea of "Napsterization of Pharmaceuticals" posited by Hughes, Moore and Snyder (2002). Also, Filson (2012) shows that in the US, innovation would reduce by more than 40%, if the US adopts a price control mechanism that is similar to the one prevailing elsewhere. Also see Lichtenberg (2003).

10 See Cockburn, Lanjouw and Schankerman (2014).

11 See Kyle (2007).

12 See Berndt, Blalock and Cockburn (2011). Also see Berndt and Cockburn (2014) cited earlier for the Indian example.

13 Rajgopal (2015).

14 "Global Cos Reluctant to Introduce Latest Cancer Drugs due to the Fear of Patent Infringement Allegations," Pharmabiz.com, 9 July 2014, http://www.pharmabiz.com/NewsDetails.aspx?aid=82842&sid=2, accessed on 26 May 2015.

15 See Chatterjee, Kubo and Pingali (2013).

16 See Shankar (2013) and Roy Chaudhury Committee Report (2013).

17 See Danzon and Towse (2003).

18 When we approached innovator pharmaceutical firms regarding differential pricing, we heard similar arguments. Shivkumar, the managing director of Eisai Pharmaceuticals India, noted, "Pricing in India is determined based on two key concerns: reasonable volumes and sustainable margins."

19 See Chatterjee, Kubo and Pingali (2013) for detailed analysis.

20 *Improving Health, Improving Lives*, Merck, Sharp and Dohme Website, http://www.msdindia.in/about/Pages/home.aspx, accessed 21 May 2015. For Novartis–USV deal relating to vildagliptin, see Mehta (2008).

21 *Invest India* website, http://www.investindia.gov.in/pharmaceuticals-sector/, accessed on 26 May 2015.

22 Dey and Beniwal (2014).

23 See, "Department of Industrial Policy and Promotion," website http://dipp.nic.in/English/Investor/makeinindia.aspx, accessed on 23 May 2015: and "Atal Innovation Mission to be set up," http://pib.nic.in/newsite/PrintRelease.aspx?relid=116186, accessed on 23 May 2015. Also refer to academic research on FDI & property rights [Glass and Saggi (2002), Grossman and Lai (2004), Branstetter et al (2006) and Bilir (2014) among others].

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