



IP Rights, Innovation and Development Priorities: Need for Balance

Introduction

The Government of India is in the process of rolling out a National IPR Policy to signal an Intellectual Property (IP) friendly domestic business environment to the international audience. IP concerns and complaints have been hurled at India by key intellectual property exporters, given pro-consumer verdicts served by the Indian courts in a handful of cases in the recent past, prominently in the area of pharmaceuticals. Some of these verdicts effectively shielded the domestic generic manufacturers against foreign patent holders fueling discontent among foreign manufacturers. The present policy initiative by the Government of India may be seen in the light of such developments.

The Supreme Court of India had denied a patent application for an important leukemia drug called Glivec (also known as Gleevec) marketed by Novartis, a Swiss Drug Manufacturer on grounds of insignificant novelty. Specific provisions of the Indian patent law define novelty in the stricter sense to discourage ever greening of patents. In 2013, India granted compulsory license (to Natco Pharma Ltd., an Indian generic drug manufacturer) in case of an anti-cancer drug Nexavar manufactured and marketed by a German drug company, Bayer. Over the recent years, judgments by the Indian courts have favoured manufacture of generic versions of other anti-cancer drugs like Tarceva (a lung

cancer drug originally produced by Roche, a Swiss healthcare company) and Sutent (a kidney cancer drug originally produced by Pfizer, an American drug manufacturer). However, in a recent ruling the Delhi High Court allowed temporary injunction against Cipla (a domestic drug manufacturer) on the respiratory drug Onbrez, originally manufactured by Novartis.

We are aware, that in the 2014 Special 301 Report, the Office of the United States Trade Representative (USTR) pushed for an Out-of-Cycle Review (OCR) to be conducted for India, in order to assess progress on engagement with the Government of India on intellectual property rights (IPR) issues.¹ While, India featured as a country in the priority watch list in the Report, it has been on such lists every year since the Report's inception. OCR may be an attempt to prevail upon India on issues of compliance and enforcement to protect market for imported technology based products in India.² India has agreed to set up a bilateral working group with the US on intellectual property as part of the Trade Policy Forum. In July 2014, the Indian government had capped prices of 108 medicines, in addition to the 348 drugs that were brought under the essential list of medicines following the Drug Price Control Order in 2012. But the new guidelines were reversed two months later. Subsequently, USTR announced closure of OCR against India citing progress made over the recent months.

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India has a fully TRIPS compliant IP regime and hence any policy needs to be placed in that context – striving for a balance between rights and obligations. While there are obligations towards the global IPR regime, rights of developing countries and communities in the South need greater acknowledgement and clarity. We revisit the TRIPS and the regime it promotes, to understand the importance of this balance with reference to the underlying trade-off between private rights (on innovation and creativity) and public goods (like knowledge, public health, food security, protection of biological diversity and environment).

The TRIPS Agreement

The TRIPS Agreement is covered under single undertaking of the WTO. The TRIPS provisions were introduced for consideration right at the beginning of the Uruguay round of the GATT negotiations which had finally led to the establishment of the WTO in 1995. The TRIPS agreement is primarily focused on standards, enforcement and disputes settlement. It was agreed that WTO member nations would be obligated to adhere to the WTO norms of IPR protection in their countries for a wide range of subjects including patents, copyrights, trademarks, industrial designs, geographical indications, integrated circuit designs, and undisclosed information. This would enable the WTO system to establish and ensure a harmonised IPR regime across nations facilitating technology trade and reducing fears of revenue loss due to unauthorised use of intellectual assets. The quantum of technology underlying goods transacted through international trade has grown significantly since the days of the GATT. There is some empirical evidence that indicate a positive relationship between trade flows and the strength of IPR protection.³ However, till date TRIPS remains a controversial and often contested subject.

The WTO dispute settlement system also works for TRIPS related disputes.⁴ However,

given national jurisdiction of IPR laws such arbitration has assumed enormous complexity and controversy. This is best summarised in Abbott (1997):

“National legislatures have long interpreted these conventions in adopting legislation compliant with them. National, sub-national and regional courts have long construed these conventions and related national legislation. The IPRs field is one of unusual complexity and subtlety, and which broad-statements of governing law do not easily refine themselves into details of practice. WTO dispute settlement panels may find it quite useful, and perhaps necessary, to refer to the existing body of relevant law in interpreting the TRIPS Agreement. If the GATT dispute settlement system has been insulated from external sources of law, it is unlikely that the situation will continue in the field of TRIPS dispute settlement.”

The TRIPS agreement sought to pave the way for stronger market power for producers of technology (innovators). Economic logic suggests that this should necessarily lead to increase in prices and reduce trade volumes. However, strong IPRs are also likely to increase the size of the market for technology led products due to reduced chances of imitation and eventually pushing up export volumes. In terms of FDI, IPRs would end up in mixed results because while on the one hand stronger IPRs would encourage arms-length transaction in knowledge and necessarily reduce the number of MNC subsidiaries that are often meant to retain know-how, a harmonised IPR regime may promote FDI by bringing down uncertainties.⁵

The TRIPS agreement raised the minimum levels of intellectual property protection much at the behest of the developed countries that were net exporters of technology to the rest of the world. This was most stark in case of provisions that allow patent protection across countries including patentability standards, duration and scope of rights. Each of these formed separate domains of legal and philosophical debates. It is natural that

for countries who have traditionally pursued technology and science in a more open environment would be unwilling to switch to regimes that are meant to disproportionately benefit a handful of countries that are leaders in technology and anticipate business prospects from intellectual property rights protection. Nevertheless, a large constituency of developing countries was virtually coaxed into agreeing to stronger IPR norms through careful economic diplomacy promising gains in other areas of trade in goods and services. However, the developing countries did manage to secure “some” concessions like extended time frame for implementation of the TRIPS provisions. Several other forms of flexibilities were instituted for developing countries. Although such flexibilities are in the form of rights, many a time these have been contested by the developed countries. It is still true that despite flexibilities the minimum TRIPS standards remain a burden for poor countries (Maskus and Reichman 2004). Enforcing IPRs also requires extensive, effective and functioning legal systems that can support public and private claims to intellectual property. Developing countries may not consider funding enforcement to be a priority.

An assessment of whether the TRIPS Agreement has succeeded in balancing private rights and public good rightly points that the IPR system has only worked for some, where private rights have received undue precedence over public good concerns.⁶ Public goods in terms of knowledge, science, innovation as well as creativity are indispensable for progress and welfare. However, if we want the price system to solve supply dilemmas it should capture all externalities that such a class of ‘good’ necessarily generate. This may be difficult. At the same time restricting scope of compensation for creativity and innovativeness is unjust and may turn out to be untenable. Critics therefore call for replacing stronger forms of IPR like patents with new instruments that are less prone to

rent seeking. One common suggestion keeping in mind the downstream cost of monopoly pricing is to institute a system of reward that might be superior to the existing system of monopolies.⁷ What we continue to see is the dominance of lobbying for TRIPS plus provisions with the aim of deepening (*read* ever greening of patents) and expanding (new areas like data exclusivity) rent seeking through IPRs. This may be reckless with loads of disconnect between private rights and public good.

IPRs and Development

As the name suggests, intellectual property rights are meant to be ownership rights for intellectual assets in the spirit of similar rights for physical assets that are transacted. The ability to transact goods and commodities defines the scope of most economic activities and the well defined property rights on physical assets facilitate such transactions. In the absence of ownership rights transactions would simply be impossible leading to chaos over acquisition and possession of economic goods. However, the intangible character of all forms of intellectual assets has baffled many over the last few centuries towards institutionalising a system that can potentially conclude the nature of such rights for similar intellectual assets. That would ensure right compensation for intellectual property and hence facilitate transactions. Patents have been the most debated of all IPR instruments given their reach, frequency and economic value.

Early industrialisation created technological leaders in the west. The large constituency of developing countries elsewhere only had the option of maturing through technological learning. When it comes to developing countries, productivity growth in the strict neoclassical sense (discreet shifts of the frontier) may not apply. Technological change in the latter context would imply technological learning, improvements in the cognitive abilities of the workforce and firm level adoption and adaptation of technologies leading to productivity gains. Immediate effects in terms of technical change may be

in the form of minor innovations which are equally important as source of productivity improvement as major jumps in the frontier (Lall 1986). Utility model filings (also called petty patents in some jurisdictions) have emerged as a much sought after instrument to protect incremental innovations beneficial to small and medium enterprises. However, the utility model filings are still not allowed in India, unlike in China or South Korea. The US has a liberal patent system which allows patents on incremental innovations under utility patents.⁸

It has been argued and substantiated that countries at different levels of development would require different degrees of IPR protection that allows them their right of gradual and steady technological learning. Sudden imposition of strong IPR regimes that largely restricts practices like reverse engineering would abruptly halt prospects of technological self-reliance and make technology more costly.⁹ The TRIPS agreement might have put the cart before the horse in many developing countries given that its adoption is now a matter of obligation rather than a strategic decision linked with level of education, R&D and international trade. IPR regimes greatly facilitate and influence the extent of technological learning that a country achieves. For developing countries a weak IPR regime would encourage spontaneous technological learning and catch-up. In many of the developed nations, in the initial stages of development a not-so-strong IPR environment helped rampant industrialisation. Moreover, strategic use of IPRs lead to reduced competition and sequential innovation as is often found in the industrialised countries.¹⁰

The government sponsored patent systems have been vulnerable to pressures and tend to benefit those who own patents and can lobby for strong patent protection. There has been intense lobbying by pharmaceutical companies in the US to invoke stronger measures for international IP compliance,

particularly against countries like India which is a large exporter as well as an importer of such products. The Pharmaceutical Research and Manufacturers of America (PhRMA) alleged that India systematically undermines medicine patents and supported out of cycle review of India which would have led to India being called a Priority Foreign Country as per US parlance.¹¹ According to the US Chamber of Commerce's Global Intellectual Property Centre, India continued to score lowest in its International Intellectual Property Index (for 25 countries), most notably in categories relating to patents, copyrights, and international treaties. India did slightly better in categories like enforcement, trademarks and trade-secrets.

What lies at the core of the development debate is whether IPRs, and for that matter TRIPS, are conducive for technology transfer and indigenous innovation in developing countries. It is through technology transfers that the 'north' had promised to compensate the 'south' for their lost space in terms of stringent IPRs.¹² In some cases there has been an increase in north-south trade, where the south imports more of technology embedded products.¹³ Evidence indicates that stronger IPR in the South accelerates the rate at which multinational production is transferred to Southern countries (Branstetter *et al.* 2007). However, this may not be uniformly true for all products/sectors of production (Bilir 2014). Multinationals are more likely to respond to changes in the IPR regime when products have longer life cycles (e.g. in automobiles) suggesting lagged imitation risks in the South that gets further minimised due to stronger IP protection. In segments, where life cycle of products are short (computers and electronics) imitation risks are low and hence there may not be any perceptible change in the behaviour of multinationals in response to changes in the provisions of IPR laws. To some extent TRIPS may have induced larger royalty and license fee payments by developing countries (Kanwar 2010).¹⁴ However, such predictions

fail to establish any link between patenting by foreign affiliates and R&D capabilities of domestic firms for many countries including India.¹⁵ In the Indian case, if we take the example of the pharmaceutical industry, which is not only important in terms of IPR but also a leading sector in India, royalty payments by domestic pharmaceutical companies have been small indicating low rates of technology transfer.¹⁶

A lot of discussion has focused on the effect of TRIPS compliance on the pharmaceutical sector around the world. Knowledge of therapeutic remedies and the science of drugs is of course a public good. Private rights, i.e. patents, have been dominant instrument that ensures 'supply' of innovations in this area in developed countries. Before TRIPS, some of the developing countries like India relaxed such rights in favour of process and low cost innovations which they were capable of. However, post-TRIPS, when new drugs have become exclusive monopoly of the innovating firms, there is a possibility that the generic market will be adversely affected. Some argue that in the absence of strong IPR protection, countries may be at disadvantage if new products (in pharmaceuticals) are made available with significant lags.¹⁷ However, it has been shown that post-TRIPS, multinationals in India have started marketing new patented drugs at higher prices, particularly for life threatening diseases such as cancer. Imports of highly priced finished formulations are expanding rapidly with manufacturing investments lagging behind. The aggregate market share of the MNCs in the formulations market has gone up dramatically with the acquisition of some Indian companies by foreign MNCs (Chaudhuri 2011).

Use of flexibilities granted by the TRIPS in the pharmaceutical sector, like compulsory licensing and parallel imports, has received reprimand from vested interests in the developed world and has been termed as anti-business. US apprehensions in this regard have been clearly stated in the 2014

Special 301 Report. Although the Report acknowledges that the Indian government has issued only one compulsory license, the US appears to be concerned about the fact that India views compulsory licensing as an important tool of industrial policy in areas other than pharmaceuticals. The Report points out, that India has promoted compulsory licensing in its National Manufacturing Policy as a mechanism available for government entities to effectuate technology transfer in the clean energy sector. The Report also highlights India's stand to multilateralise compulsory licensing approach in ongoing negotiations under the UNFCCC.¹⁸

The issue that shows gross inadequacies of the IPR system is management of knowledge held by communities in developing countries. This is what is called traditional knowledge known for medicinal value and that it offers significant science so far unknown outside isolated communities. The community held nature of the knowledge and undated origins make it elusive for establishing private rights. However, many in the developed countries are keen on exploring such knowledge and a step in the direction of refinement would enable them to claim intellectual property protection. This would mean that communities and countries who were custodian of such knowledge are left out; and may be further taxed if they are made to buy camouflaged products from others by paying a price.¹⁹ Similarly, many forms of art originating in developing countries and driving traditional industries in those countries may be wrongly commercialised in the absence geographical indications for those products. What is blatant is the intention and efforts that some of the MNCs devote towards locating agricultural produce that grows outside the developed world and owning them to be commercialised under brand names. The developing countries are adversely situated in this respect as well.

Concluding Remarks

Generation of knowledge in developing countries happens largely through technological learning and often these countries are neither in a position to purchase proprietary knowledge nor appropriate indigenous knowledge resources. Hence, knowledge is vehemently looked upon as a public good by them and universal access to knowledge resources is of critical importance. The TRIPS has helped developed countries to adopt protectionist practices and powerful business interests extensively influence trade and intellectual property policies as well as jurisprudence. This is most evident in the case of ever widening boundaries of patentable subject matter. The institutions and organisations implementing policies on intellectual property in the developed world have increasingly favoured owners of intellectual property ignoring pro-consumer and pro-competitive concerns.

The optimum level of patent protection remains a puzzle. It is generally accepted that although patents create incentives of innovations; they could, however, potentially limit chances of innovations through extended monopoly. The patent system should be vigilant towards IPRs posing a hindrance to innovations and that it does not suppress innovation potential of developing countries. Jeopardising local innovation capabilities could come at a cost for the developing world and hamper local supply of knowledge. Hence, a private rights driven model would end up supplying globally sub-optimal level of knowledge. This has been overlooked.

Policy making towards prudent IPR norms has been a relentless exercise both in the developed and in the developing countries. These are motivated by ever evolving understanding of costs and benefits of IPRs, and as pointed out in the beginning by unfathomable trade-off between private rights and public goods. While, TRIPS secured an overwhelming mandate for itself,

the balance between IP rights, innovation and developmental priorities appear nonetheless elusive. At a time, when reforms in the global institutional approaches seem slow, national policies could go some way in experimenting with this balance and defining national interest.

Endnotes

- ¹ In the 2014 Special 301 Report, USTR placed India on the Priority Watch List and noted that it would conduct an OCR of India focusing in particular on assessing progress made in establishing and building effective, meaningful, and constructive engagement with the Government of India on IPR issues of concern. An OCR is a tool that USTR uses to encourage progress on IPR issues of concern and can provide an opportunity for heightened engagement with a trading partner to address and remedy such issues.
- ² Section 182 of the US Trade Act requires USTR to identify countries that deny adequate and effective protection of IPR or deny fair and equitable market access to U.S. persons who rely on intellectual property protection. The provisions of Section 182 are commonly referred to as the “Special 301” provisions of the Trade Act. According to such provisions, those countries that have the most onerous or egregious acts, policies, or practices and whose acts, policies, or practices have the greatest adverse impact (actual or potential) on relevant U.S. products are to be identified as Priority Foreign Countries. In addition, USTR has created a “Priority Watch List” and a “Watch List” under Special 301 provisions. Placement of a trading partner on the Priority Watch List or Watch List indicates that particular problems exist in that country with respect to IPR protection, enforcement, or market access for persons relying on intellectual property.
- ³ See Maskus and Penubarti (1995), and Primo Braga and Fink (1997).
- ⁴ There have been a host of multilateral conventions governing the international IPR system that have continuously evolved since the end of the nineteenth century. The provisions of these conventions have directly or indirectly been included in the TRIPS agreement. The practice of granting patents originated in Venice in the early fifteenth century, eventually spreading throughout Europe. Much later, the Paris Convention for Industrial Property

was ratified by eleven European countries in 1883, joined by the United States in 1887 (today it has 172 signatories) and till date is the foundation for all patent legislations around the world and the original platform for commitments around common understanding of patent rules. Similarly, the Berne convention for the protection of Literary and Artistic Works of 1886 is for copyrights. The more recent Rome convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organisations of 1961 extended copyright protection for the first time to the creators and owners of particular physical manifestations of intellectual property, such as audiocassettes or DVDs. The modern day institution of the World Intellectual Property Organisation (WIPO), an inter-governmental organisation, is responsible for overseeing and interpreting all IPR conventions.

⁵ Branstetter *et al.* (2007).

⁶ For example, as pointed out in Ladikas and Chaturvedi (2014), “notwithstanding the need to acknowledge and reward innovation, the current IPR system actually works as barrier to increasing access to medicines rather than a facilitator. Reward has taken precedent over need and current global legislation is developing on this premise.”

⁷ We are aware of innovative approaches like the Health Impact Fund, originally introduced by Prof Thomas Pogge of Yale University, which is based on alternative ideas of compensating innovators. The Health Impact Fund (HIF) proposal is promoted by Incentives for Global Health, a non-profit organisation devoted to advancing market-based solutions to global health challenges. The HIF proposes a new way of paying for pharmaceutical innovation by incentivising the development and delivery of new medicines through pay-for-performance mechanisms. All pharmaceutical firms worldwide would have the option of registering new medicines with the HIF. By registering, a firm would agree to provide its drug at cost anywhere it is needed, and in exchange for foregoing the normal profits from drug sales, the firm would be rewarded based on the HIF’s assessment of the actual global health impact of the drug. Governments and other donors would finance the HIF (<http://healthimpactfund.org/>). There is scope that HIF may be applied to sectors beyond pharmaceuticals, to traditional medicines

and agricultural innovations (as suggested in Chaturvedi and Srinivas 2014).

⁸ Not so recent estimates show that post liberalisation, during the period 1990-2002, patenting from India in the USPTO was mainly in utility patents (Bhattacharya *et al.* 2007).

⁹ Some estimates for India suggested that under alternate post-TRIPS scenarios, if widely used domestic pharmaceutical products like antibiotics are replaced by costly foreign products there would be a definite loss in consumer welfare (Chaudhuri *et al.* 2006).

¹⁰ In their book titled *Patent Failure*, James Bessen and Michael J. Meurer argue that patents are a source of costly disputes and excessive litigation that outweigh positive incentives.

¹¹ See <http://www.phrma.org/media-releases/phrma-statement-on-2014-special-301-report>

¹² The obligation for developed countries to provide incentives for technology transfer is mandated in Article 66.2 of the TRIPS Agreement. However, it has been difficult in general to assess the progress made under such provisions.

¹³ Ivus (2010) finds that between 1994 and 2000 the increase in Patent Rights made in response to the TRIPS agreement added about \$35 billion to the value of developed countries’ patent-sensitive exports into 18 developing countries.

¹⁴ Branstetter, Fisman and Foley (2006) find IPR reforms in host countries lead to greater intra-firm royalty payments and increased R&D expenditure and patenting activity by affiliates in case of US multinationals.

¹⁵ Mani (2009).

¹⁶ Abrol *et al.* (2011).

¹⁷ Cockburn *et al.* (2014).

¹⁸ See 2014 Special 301 Report, Office of the United States Trade Representative.

¹⁹ India has already created a Traditional Knowledge Digital Library (TKDL) which has been a significant repository of over 250,000 traditional medicine formulations (James 2014). This database is being used by several patent offices and has been very useful in thwarting illicit intellectual property claims.

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