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Voluntary Licensing: Access to Markets for Access to Health

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ABSTRACT

The expansion of access to affordable drugs will play a central role in addressing present and future global health challenges. Given the vast social implications of increased access to medicines, the Indian patent system has historically maintained a pro-public health stand. However, the international political community is increasingly advocating for stricter patent regimes and India can no longer continue to ignore the pressure exerted by developed countries. In this context, this paper argues the viability of the voluntary licensing approach in

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reconciling the protection-versus-access debate. The voluntary licensing model provides a balance between intellectual property rights protection and public health concerns, and shows that one does not have to impinge on the other. While voluntary licenses maximise access and allow generic drug companies to circumvent the time-consuming process of patent-oppositions, they also offer pharmaceutical giants a more effective business model to enter developing markets.

INTRODUCTION

Access to essential medicines is a pressing public health issue. According to the World Health Organization (WHO), even today, as much as two-thirds of the global population do not have access to the most essential drugs and vaccines.[1] In fact, every year, 10 million individuals – the majority residing in the lowest-income countries– could be saved by plugging the access gap.[2] While multiple barriers to access exist, the price of drugs has been found to be the primary obstacle: High drug costs have segmented the market to such a degree that 90 percent (by value) of all pharmaceutical products produced in the world are consumed by a mere 15 percent of the global population.[3] This is because consumers in developing countries, on top of being poor, generally rely on out-of-pocket payments for health-related expenses, and therefore bear a disproportionate burden of the high drug prices. The Indian population is a classic example: According to latest WHO data, out-of-pocket expenditure made up 85.9 percent of the total private expenditure on health in 2013.[4] Further evidence is the fact that in 2014, a measly 17 percent of the country's population was covered by medical insurance.[5]

The international community recognises this challenge and the central role that modern medicines play in the overall global development agenda. Target 8E of the Millennium Development Goals (MDGs) dealt with access to affordable drugs.[6] Similarly, target 3.8 of the Sustainable Development Goals—the successor to MDGs—engages with the issue.[7] The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) also realises the unique link between medical patents and drug prices, and provides for certain flexibilities to safeguard public health.[8] However, the TRIPS agreement is itself a result of the long-standing pressure from developed nations to ensure patent protection across countries and mandates all WTO members to establish a patent system for medicines.[9] India has also had to restructure its patent laws to comply with these stricter norms on Intellectual Property Rights (IPR). In fact, developed countries are now advocating for even higher levels of protection – referred to as TRIPS-plus conditions – through regional free trade agreements (FTAs). The Trans-Pacific Partnership (TPP) and the Anti-Counterfeiting Trade Agreement (ACTA) are two well-known examples. Given the large social implications of such increased protection, this paper investigates the merits of the Voluntary Licensing (VL) approach in reconciling the traditional debate of 'protection' versus 'access'.

Part I examines the qualitative shift in the normative framing of global health tools[10] and the consequent development of innovative arrangements like the VL approach. Part II analyses the domestic journey of the Indian patent system – its evolution from an insulated policy in a closed economy to the current format. Based on the two parallel but closely-related trajectories, Part III makes an assessment of the viability of the VL system in the existing global and domestic governance structures. In light of the emerging global political climate, the paper then concludes with an exploration of new mechanisms that maximise access despite a trend towards stricter IPR regimes.

CONCEPTUALISING MEDICINES AS GLOBAL PUBLIC GOODS[11]

The last decade and a half has witnessed a dramatic shift in the way global health is understood especially in the treatment of IPRs for health. The HIV/AIDS epidemic brought this issue to the fore: As HIV/AIDS affected large populations on both sides of the globe – the North and the South – governments and civil society across national jurisdictions came together to seek potential curative solutions. However, Sub-Saharan Africa – a region with the highest HIV prevalence – faced the additional challenge of lack of affordable drugs to address the epidemic. Even as late as 2000, when most HIV-infected individuals in the US or Western Europe were able to lead relatively normal lives through the administration of antiretroviral (ARV) treatment, 2.4 million Sub-Saharan Africans died from AIDS.[12]

The price of ARV emerged as the major bone of contention in international health discussions. On the one hand, the biggest pharmaceutical manufacturing corporations were making concerted efforts to curb the spread of generic versions: In 1998, 39 of the 'Big Pharma' companies sued the South African government for attempting to import low-cost generic anti-AIDS drugs.[13] On the other, generic drug manufacturers in countries like India had started manufacturing much more affordable versions. In 2001, Cipla (one of India's largest generics manufacturers) made history by offering to sell the triple-therapy ARV drug for as low as $350 a year per patient, when proprietary companies were selling the AIDS drugs for $10,000 to $15,000 for the same dose.[14] This meant that while the development of drugs to combat such diseases was indeed necessary, it was certainly not sufficient to address the entire spectrum of challenges posed. The AIDS crisis highlighted the need for new creative solutions that take into account the demands of developed as well as developing countries, and thus, brought with it a paradigm shift in the approach to health solutions. It lent legitimacy to the integration of access concerns in IPR discussions, and re-conceptualised medicines from its earlier interpretation as *private goods* to *global public* goods.[15]

Given the magnitude and gravity of the HIV/AIDS problem, debates on drug access has generally, and deservedly, focused on the disease. However, the current trend towards increased globalisation means higher cross-jurisdiction mobility, which in turn means increased vulnerability to infections. Further, developing countries are now grappling with the so-called dual disease burden of

simultaneously addressing infectious diseases and non-communicable ones. This emerging set of threats to global health demands new approaches to the overall health innovation framework and underscores the urgency of crafting solutions that are 'low-income friendly'. The following sections analyse the relevance of VL in this context and in India's own internal dynamics.

EVOLUTION OF INDIAN PATENT LAWS

(a) Pre-Liberalisation

Work on an indigenous patent framework in India commenced soon after Independence in 1947. On 10 January 1948, a committee was appointed to review existing patent laws and ensure that they were adequately aligned to domestic interests.[16] Following this, two reports were produced: first, the Chand Report[17] and second, the Ayyangar Report, which is said to have formed the backbone of the existing Indian patent system.[18] However, the first patent law – the Indian Patent Act, 1970 – only came into being on 20 April 1972.[19] One of the most distinct aspects of this Act was its repeal of the patentability of food items and pharmaceutical drugs. While processes could be patented, the final product itself was not eligible for patents. In fact, the process patents were granted for a limited period – the shorter of five years from sealing or seven years from the date of patent.[20] Moreover, the Indian Patent Act, 1970 also reflected a pronounced caution against the "abuse of patent rights". It explicitly mentioned how patents "are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article ..."[21] The Act also included provisions for the issuance of Compulsory Licenses (CLs) – a license that the government issues to a third party without the consent of the proprietor.

The patent system promoted the proliferation of Indian generics firms and, consequently, led to a sharp fall in drug prices. For instance, the generic version of Glaxo's anti-ulcers Zantac was 100 times cheaper than the marketed price of the original product in the US.[22] Thus India gained a niche in the global pharmaceutical market as a key supplier. It earned a reputation of being a 'pirate' nation among developed nations,[23] and became known globally as the "pharmacy of the developing world".[24]

(b) Post-Liberalisation

Economic liberalisation in the 1990s and the integration of India to the world economy ushered in a new phase where the country had to begin paying heed to international pressures. For one, it reversed its anti-TRIPS stand and became an official member of the World Trade Organization (WTO) on 1 January 1995.[25] This membership meant that India had to restructure its internal IPR framework to accommodate TRIPS conditions. As mandated by the WTO, the Patent Act was amended within a 10-year period.[26] The compliance effort took place in three stages: The first introduced the mailbox facility, which required India to establish

a repository for pharmaceutical patent applications filed during the 10-year interim period. The second, the Patent Act amendment in 2002, extended the term of patents to 20 years. The final stage, and the most relevant to this paper, was the Patent Amendment Act, 2005. Under this amendment, pharmaceutical products were finally brought into the domain of patents.[27]

Despite ceding to external pressure, India has largely maintained a pro-public health regime. The 2005 amendment was neither a fully westernised model that the pro-TRIPS countries pressed for, nor was it an anti-IPR system that they were fiercely against. What was born out of the two contradictory stances was a delicately balanced patent framework with certain exclusions. For instance, India has a strict anti-evergreening policy, meaning that in contrast to the US and EU patent regimes, Section 3(d) of the Indian Patent Act, 1970 (2005) excludes the patent-eligibility of "... any new property or new uses of a known substance".[28] The country has not been shy in using this provision to reject applications on successive and secondary patents for new forms and uses of existing drugs. The Patents Act also provides for pre-grant and post-grant oppositions on patent applications under section 25 and 23, respectively.

As per TRIPS flexibilities, India allows the granting of CLs under Section 92 A of the amended Act. Apart from national emergencies and public health crises, CLs can be issued for various other situations such as the "failure to work the invention in India"[29] or the lack of access to the patented drug at "reasonable affordable prices".[30] Contrary to popular belief, the extensive purview of India's CL provisions have not led to a flurry of licenses. Post-2005, only one CL was granted in 2012, for a cancer treatment drug patented by Bayer. While Bayer marketed the drug for Rs 280,428 per month, Natco Pharma (the license applicant) was selling the generic version for a mere Rs 8,500 per month.[31] However, there has been increasing scrutiny over India's IPR treatment, especially by the US and EU.

India's anti-evergreening stance has been controversial since its introduction in 2005. The rejection of Swiss pharma giant, Novartis's patent application for its cancer drug after a six-year-long battle trained the spotlight on this issue,[32] which was further aggravated by the granting of the CL for Bayer's Nexavar in 2012. Echoing the view of the influential pharmaceutical industry, the US International Trade Commission (USITC) has been conducting multiple investigations into India's trade and investment policies.[33] The reports of the investigations have cited India's IP system as a major impediment to US businesses. The annual Special 301 Report by the US Trade Representative (USTR) has also included India in the warning list for a number of years and, in the 2014 edition, the country was included in the Priority Watch List for the second time.[34] The same 2014 edition also outlined key issues such as Section 3(d) provisions, pre-grant oppositions and CLs.

A further wave of external pressure has emerged in the form of the TRIPS-plus conditions: developed countries negotiating regional free trade agreements (FTAs) with India are demanding for the inclusion of much stricter IPR protection than those required under the TRIPS. For example, negotiations on the bilateral trade pact between India and the EU have been put on hold due to disagreements

on IP protection.[35] Under the proposed FTA, Regional Comprehensive Economic Partnership (RCEP), Japan is also reportedly pushing for TRIPS-plus provisions.[36]

The Indian government seems to be relenting to the mounting pressure. Following Prime Minister Narendra Modi's visit to the US in September 2014, both countries released a joint statement stating their "commitment 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."[37] Moreover, India is also in the process of developing a national IPR policy[38] despite an already functional, effective, TRIPS-compliant patent law.

Given the current international political climate, the best option for India to maintain its traditional pro-public health position is Voluntary Licensing.

WHY VOLUNTARY LICENSING?

The growing trend of restrictive patents regime has exacerbated the existing global health disparities. It is becoming clear that India can no longer continue to ignore the pressure exerted by developed countries, particularly the US, to limit domestic generic drug production. At the same time, giant pharmaceutical companies are also facing acute criticism regarding the exorbitant prices that they charge for their products, especially in low and middle income countries (LMICs). Voluntary licensing emerges as a mutually beneficial arrangement in this situation.

Under a VL, a patent holder (the originator company) through its own discretion offers third parties (generally, generics manufacturers) a license to produce, market and distribute a patented drug. Unlike compulsory licences, the non-confrontational nature of VLs allows access while taking into account the concerns of all parties affected by such licenses: drug consumers and public health interest groups, generic drugs manufacturers, and originator pharmaceutical companies.

(a) Drug Consumers/Public Health Interest Groups

Given that VLs are generally provided to expand access to cost-effective drugs in poorer countries, drugs under VLs are sold at significantly reduced prices in comparison to the exclusively patented ones. For instance, Gilead Sciences – a major US pharmaceutical company – recently entered into VL agreements with 11 Indian generic companies allowing them to supply its new Hepatitis C treatment drug at marginal costs in 101 developing countries.[39] While the drug, Sofosbuvir, is marketed at $84,000 per patient in the US, the Indian license holders will be able to sell the generic version at about $900 with an additional 10-percent royalty in the specified developing countries.[40] A more time-tested example is that of Viread – an ARV medication marketed by Gilead that is listed under the WHO's list of essential medicines. According to one of Gilead's policy briefs, production of the generic version by licensees has resulted in a sharp price decline of 80 percent

since 2006 and now sells for as low as $4 per patient per month in low-income countries.[41] This price drop has led to a spurt in access from 30,000 consumers in 2006 to 8.7 million in 2015, with a majority of them consuming the generic version.[42] Another factor that could potentially contribute towards further price reduction is non-exclusivity. When originator companies such as Gilead provide licenses to a fair number of generic drug manufacturers – 11 in the Hepatitis C example above[43] and 17 Indian companies in the case of Viread[44] – it could lead to higher competition among the VL holders, which in turn, can result in lower prices.

Apart from pricing, VLs can also speed up the access process. Because most developing countries, including India, are WTO members, they are now TRIPS-compliant and operate under stricter patent frameworks. By signing a VL agreement, generic manufacturers do not have to wait for patent outcomes, pre-grant patent oppositions or even apply for a CL. This, then, allows licensees faster production and delivery of various life-saving drugs. Sharing of key information between the license holder and licensees can also accelerate access. In cases where proprietary companies share their own pharmaceutical data with the generics manufacturers, these generics companies may be able to bypass extensive clinical trials, leading to both speedier delivery and lower costs.

(b) Generic Drugs Manufacturers

To a great extent, the concerns of the generics industry overlap with those of patient communities: accelerated drugs production and delivery through VLs provides huge commercial benefits for generics pharmaceutical companies as they now do not have to go through the cumbersome process of applying for CLs or challenging patent grants, which consume plenty of time and money. Natco's withdrawal of its patent challenge against Gilead's drug Sofosbuvir is a case in point. The mid-level Indian pharmaceutical company, which had initially challenged Gilead's patent application, has instead opted for a VL.[45]

Technology transfer is another area in which generics companies stand to gain from such licensing agreements.[46] Transfer of critical information related to clinical databases and manufacturing processes can help avoid duplication of effort. This, in turn, will play a significant role in driving down costs.

(c) Originator Pharmaceutical Companies

VLs embody what originator companies term as 'responsible use of intellectual property'. The primary justification for patents and other forms of IP protection is that these rights reward innovation and incentivise further investment in R&D. However, special cases such as public health bring to the table other equally important concerns like barriers to accessing affordable life-saving medicines. VLs offer a unique platform where the two conflicting interests can be reconciled and thus, complying with IPRs of originator companies. Because these

arrangements are non-coercive, originator companies are also able to set their own terms and conditions as opposed to the CL system.

VLs also help proprietary companies gain lost goodwill. Giant pharmaceutical proprietors have come under sharp criticism regarding the high prices of their patented products. For instance, Médecins Sans Frontières (MSF) – an international humanitarian-aid NGO and a Nobel Peace Prize laureate – has been one of the harshest critics of access barriers that have been created by the proprietors. In India, health advocacy groups such as Initiative for Medicines, Access & Knowledge (I-MAK), and Delhi Network of Positive People (DNP+) have persistently challenged many of the patent applications in the country. By marketing their products at much lower prices to the world's poorest countries, VLs act as a goodwill creation tool.

Even from an economic viewpoint, VLs offer considerable benefits to originator companies by expanding market size. Big Pharma companies have traditionally operated on the "high profits but low volume" business model. However, time has shown that this is ill suited for markets in developing countries. Prior to 2005, when most developing countries did not have a patents regime for medicines in place, the branded US pharmaceutical industry acquired merely five to seven percent of its profits from LMICs.[47] Partnering with generics manufacturers help originator companies gain access to markets that they have previously failed to capture. Because bigger generics companies have already established stable supply chains in most developing country markets, originator firms are able to tap into these markets without much investment. For example, India, the world's leading manufacturer of generics, reportedly supplies about 80 percent of the anti-HIV ARV drugs in Africa. In 2011, 17.7 percent of Africa's total pharmaceutical imports came from India.[48] Most of these exports are carried out by major generics companies such as Ranbaxy, Cipla, and Dr. Reddy's; by entering into VLs with these companies, Big Pharma companies can, for instance, potentially penetrate the US$ 30-billion worth African market.[49]

CONCLUSION

The critical role played by medicines in curative healthcare means that access to drugs, or the lack of it, can determine the well-being of millions. From a social perspective, this highlights the need to divorce issues of access from those of affordability. However, development of drugs requires huge sums of money – various stages like research and clinical trials figure much more prominently in the overall cost than the production process itself. The question then is how drugs development can be funded without it necessarily inhibiting access.

VLs are one such approach: Through a cross-subsidisation financing strategy, it aligns drug prices to an individual's ability to pay. Thus Big Pharma companies are able to offer low-priced generic versions that essentially cover merely the production costs in low- and middle-income countries. In terms of the global IPR discourse, voluntary licensing provides a balance between IPR protection and public health concerns, and shows that one does not have to impinge on the other.

While VLs facilitate access maximisation and allow generic drug companies to circumvent the time-consuming process of patent-oppositions, it also offers pharmaceutical giants a more effective business model to enter developing markets.

The increasing range of global health threats discussed in the first part of the paper further highlights the need to explore additional mechanisms aimed at expanding drug access. For instance, the shift in the conceptualisation of medicines from a private to a global public good means that the benefits of a curative solution must extend across nations and be made accessible to all. If benefits are to be globalised, then so should the costs – alternative financing systems such as a health impact fund have already been put forward.

Low drug prices also correspond with India's pro-public health position. Apart from domestic public health demands, pharmaceutical drug pricing in a key supplier country like India, affects access across the globe. India's IPR framework is closely followed by most developing countries: the African region – a major export destination for Indian generics – have expressed concerns over the possibility of higher IPR protection policies. This issue was repeatedly brought up at the Third India Africa Summit in October 2015, by countries like Kenya and Gambia.[50] Thus, while arguments for a stricter IPR framework must be considered, public health issues – both domestic and global – call for a well-functioning VL system to ensure that India remains the pharmacy of the developing world. ORF

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