PRICE CONTROL ON PATENTED DRUGS IN INDIA

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ABSTRACT

In this work, the author looks at the bigger question: whether the demands of abolition of price control by the pharmaceutical innovator companies have any merit, and the policy options with a government post-TRIPS to ensure launch of new drugs by Big Pharma without compromising affordability. The aim of this Article is to study the impact of price regulation on launch of patented drugs in India, and whether the faults can be corrected simply by removing price ceiling for five years and if doing so is an ethical and constitutional step.

The author also seeks to examine the importance of standard of patentability and how patent authorities implement it, and their expertise in instilling a conscious understanding of the inherent effect of patenting on right to health.

The Article solves these questions in the context of implications of price control in the Indian pharmaceutical industry with its unique history of generic drug production, in terms of balancing accessibility (the launch of new drugs by foreign companies) with affordability (the purchasing capacity of the people). The author also examines whether changes in the patent process, reforms in price-control processes and a cost-based approach would be a viable approach forward.

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INTRODUCTION

If one were to put it briefly, the problems in healthcare are quite straightforward: most medicines and medical treatments, especially the new ones, are too costly, and the new medicines are not developed for certain sections of people, that is those customers who lack the purchasing capacity to incentivise innovation. Access to medicine has, thus, two foundational aspects: affordability and accessibility. This ostensibly straightforward problem might have had simpler solutions earlier, such as government hospitals and subsidized healthcare, but it has been unkindly complicated with the advent of intellectual property rights ('IPR'). At the most fundamental level, the aim of a neo-liberal society is to maximise profits with only a secondary regard to the question of essentiality of that service to people. The predominance of the West exists in pharmaceutical innovation as much as it exists in other areas, and a new drug is launched in a market only if the innovator expects it to be profitable. There are a wide range of factors both economic and non-economic that determine profitability.

A new drug is not always a drug that can be patented. To be granted a patent, it needs to meet certain thresholds and in India these are: novelty, industrial application, and inventive step.[1] The focus of this Article is on patented drugs and not all kinds of new drugs. Broadly speaking, two factors have played a role in the decision to launch a patented drug—the strength and efficiency of the patent regime, and price regulation of patented drugs. One should be mindful to not underestimate other (overlapping) factors such as the income-group of the country, population size, local competition, coverage under public health care system, etc. Normally, the price of a drug is the *numero uno* factor particularly so in a country that lacks a public healthcare or expansive insurance system.[2] As their financial constraints dictate, the R&D in low-income countries has historically never been strong, especially in comparison to Big Pharma. This makes the global South and/or the low and middle-income countries not only dependent on their innovations, but also compel the governments to protect the West's specious superior right on knowledge over their domestic needs.

[1] The Patents Act, No. 39 of 1970, INDIA CODE.

[2] Sakthivel Selvaraj, How Effective Is India's Drug Price Control Regime? (Jul. 30, 2007) (unpublished comment) (on file with the Harvard School of Public Health).

The term 'Big Pharma' refers to multinational companies, mostly based out of the United States that command a superior name in market, both in their role as lobbyists and as manufacturers and innovators (and even conspiracy theories).[3] When a new drug is made by a foreign company, they might choose to not launch it elsewhere, or they might get a patent for it but choose to not market it for a multitude of reasons. The effect of an extensive patent system is that if the originator chooses to not launch or price it at an unaffordable rate, patients are left untreated or undertreated respectively. The alternative to overpriced or unavailable drugs is the production of affordable generics that are based on the original drug as was the practice in India for decades.[4]

The freedom of governments to implement policies expediting the right to health in their jurisdiction was severely limited and systemised with the World Trade Organisation's Agreement on Trade-Related Aspects of Intellectual Property Rights ('TRIPS') in 1995. India, as a country that had campaigned and implemented an open and thriving market prioritising public health since its independence, was a leading opponent to the Agreement but in vain.[5] TRIPS required all signatory countries to provide *both* product and process patents, and when the grace period exhausted in 2005, India passed the Patent (Amendment) Act, 2005. TRIPS was heavily criticised for dangerously linking health rights to trade sanctions and benefits. It institutionalised prioritising of patents and rights of patent holders over needs of access. Médecins sans Frontières ('MSF') together with other non-governmental organizations had formulated the following concerns in its relation:

– The increased patent protection would invariably lead to higher drug prices.

– The legal reinforcement of the monopoly of multinational firms will be a huge blow to domestic industries.[6]

These concerns that arose globally, especially from the developing countries, resulted in the Doha Declaration in 2001 to adjust public health in the structure of TRIPS. As per the Doha

[3] Robert Blaskiewicz, *The Big Pharma conspiracy theory*, 22(4) MEDICAL WRITING 259, 259-261 (2013).
[4] Jayashree Watal & Rong Dai, *Product patents and access to innovative medicines in a post-TRIPS era* (WTO Staff, Working Paper No. ERSD-2019-05).
[5] FREDERICK M. ABBOTT, *WTO TRIPS Agreement and its Implications for Access to Medicines in Developing Countries* (United Kingdom Commission on Intellectual Property Rights, Study Paper 2a, 2002), http://iprcommission.org/papers/pdfs/study_papers/sp2a_abbott_study.pdf
[6] Alan O. Sykes, *TRIPs, Pharmaceuticals, Developing Countries, and the Doha 'Solution* (John M. Olin Program in Law and Economics Working Paper No. 140, 2002).

Declaration, countries retained latitude on some aspects such as compulsory licenses and its thresholds, standards for what constitutes a national emergency, etc.

Bearing in mind the expected price increases that were bound to follow TRIPS, especially for essential medicines with inelastic demands, Jayashree Watal, Counsellor at WTO and India's representative in the TRIPS negotiations, had recommended cost-based price control and compulsory licensing as the two policy options that India would have to implement if it wanted to prevent an imbalance that would sink the domestic manufacturers. In theory, both policies were executed, and as one could expect these have been a source of relentless lobbying by the Big Pharma. This ultimately prompted a shift from cost-based to market-based pricing under the Drug Pricing Control Order passed in 2013. With regard to compulsory licensing as a solution, does it offer a permanent and sustainable path, especially in light of the frequency of its use being so uninspiring?[7] There are concerns that compulsory licensing raises, including shifting burden on the people in the form of civil society organisations and local companies to prove before authorities the requirements for a compulsory license. After TRIPS came into effect in 2005, the legal complexities associated with generic production were bound to increase, and this meant that Indian manufacturers would have to make a timely shift to investing in research and development in order to survive in the globalised landscape of pharmaceuticals. While there have been efforts in this direction, very few Indian companies have the resources and scale in comparison to the Big Pharma such as Pfizer or GSK, to sustainably invest into molecules that might never result in a success. This means that there is even less incentive to explore original solutions for 'neglected' diseases as the margins expected would naturally be lower.[8]

India has historically implemented policies that promote generic production and low drug prices. The policies have been carefully crafted on the principles of indigenisation and self-sufficiency. The post-independence the Patents Act was passed in 1970 ('1970 Act') based on recommendations of the Ayyangar Committee Report, 1959 with a limited scope of patentability, that is process patents only. Process patents are relatively weak as the innovator exercises a monopoly only for a limited time because eventually another entity can legally

[7] Dina Halajian, *Inadequacy of TRIPS & the Compulsory License: Why Broad Compulsory Licensing is Not a Viable Solution to the Access Medicine Problem*, 38(3) BROOK. J. INT'L. L. 1191, 1220-1231 (2013).
[8] Murphy Halliburton, *The View from Hyderabad: The "Indian" Pharmaceutical Industry and the New Patent Regime, in* INDIA AND PATENT WARS 116, 120-130 (ILR Press, 2017).

devise (and patent) a new method that gives the same product. Many countries chose a process-only patent regime to foster domestic industry which was built on inventing around the originators' manufacturing processes. According to the 1970 Act, the term of process patents was 7 years and compulsory licenses could be issued after three years. By essentially legalising reverse engineering, the Act gave the desired space to domestic producers for expanding rapidly.[9] Even today India's drug manufacturing capacity and capability to reverse engineer is considered one of the top in the word and many developing and under-developed countries rely on its exports. As a large number of Indian manufacturers have expanded from their roots to export, some have even reached wealthier economies such as the US. Names such as Sun Pharma and Dr. Reddy are famous and reputed multinational companies today.

India's model of suiting pharmaceutical production to the level of development of a country inspired a change at a global level, before TRIPS. The 2005 Amendment changed the system legally but policies within the ambit of Doha Declaration continued to preserve the culture through high standards of patentability and preventing evergreening. The *Novartis* judgement in April 2013 proved the strong standards for patent that the judiciary is committed to maintaining and this premier decision fell in line with India's tradition of protecting public health.[10]

Since the 1970s the Government of India has also pursued a National Drug Policy under the Essential Commodities Act, 1955, to promote domestic generic production and price controls on selected products. In 1995, the Government issued a Drug (Prices Control) Order in 1995 which included 74 bulk medicines within its ambit and the pricing of the drugs were fixed on the basis of manufacturing costs declared by the drug manufacturers.

In 2013, the Government replaced the 1995 Order with a new Order which empowers the National Pharmaceutical Pricing Authority ('NPPA') to regulate prices of essential drugs under the National Pharmaceutical Pricing Policy ('NPPP') passed in 2012 by the Department of Pharmaceuticals. As per the new DPCO, all strengths and dosages specified in the National List of Essential Medicines ('NLEM') would be under price control. In the earlier avatar of DPCO, 74 drugs were subject to price control, but the 2013 version expanded the list five-fold. However, the NPPP 2012 withheld any comments on price

[9] Dinar Kale & Steve Little, *From Imitation to Innovation: The Evolution of R&D Capabilities and Learning Processes in the Indian Pharmaceutical Industry*, 19 TECH. ANALYSIS & STRATEGIC MGMT. 589 (2007).
[10] Rory Horner, *The Global Relevance of India's Pharmaceutical Patemt Laws,* 48 ECON. POL. WKLY. 16 (2013).

control for patented drugs as this was under consideration of a special committee. The Report of the Committee on Price Negotiation for Patented Drugs looked at different point of views and substantiated on the concerns of various shareholders. It categorically rejected eliminating price control in India and expressed that as the medicine market does not feature perfect competition, price control was necessary. The Committee had invited comments from stakeholders on price negotiations as a mechanism for setting price limits. Inputs from the industry were broadly that price negotiation should be used only for government purchases, and reference pricing should be done vis-à-vis the developed countries such as UK, Australia, and New Zealand. There were some associations that favoured of price negotiations but expressed fear of dilution of compulsory licensing as a consequence. The Indian Drug Manufacturer Association submitted that price negotiation should take place for all patented drugs, and government forms should be formalised that each producer submits along with breakup of the costs involved. It also submitted, and correctly so, that compulsory licensing is a lengthy process and it should run separately from price negotiations.

In 2017, the Draft Pharmaceutical Policy was released which made the following note makes a crucial point in its new policy initiatives:

> "DPCO will include only 'off-patent' medicines in its schedule. 'InPatent' medicines will not be subjected to price ceiling by NPPA. They can be regulated through compulsory licensing under the Patents Act or by use of emergency powers under paragraph 19 of DPCO-2013, that too, only when expressly directed by the government in the Department of Pharmaceuticals to do so."

If this policy had been implemented, it would have wreaked havoc on accessibility because of how rare and lengthy the process of compulsory licensing is, not to mention the precondition that it requires a generic competitor which might not always exist early enough or possess the requisite evidence for it. The Indian government has, so far, issued only one compulsory licence.

For understanding context behind the Draft Policy 2017, it becomes important to assess the international pressure, especially from the US that has been piling up on the Indian government. United States Trade Representative ('USTR') conducts an annual review of IP laws in its trading partners, essentially to check how well they fare in supporting US right holders, and India is one of the 12 countries placed on the Priority Watch List by USTR,

and the report describes its longstanding issues as "narrow patentability standards, the potential threat of compulsory licensing and patent revocations, as well as overly broad criteria for issuing such licenses and revocations under the Indian Patents Act."[11] Furthermore, in the 2016 review assurances were exchanged by representatives of the U.S-India Business Council that compulsory licences provisions would not be put to use by it for commercial purposes.[12] In response to such statements, the Ministry of Commerce and Industry issued a clarification that India's IP system was within the confines of TRIPS and the Doha Declaration, and it retained the sovereign right to issue compulsory licenses.[13] While India should develop on concerns on a timely application process, unauthorised commercial production, and informing patent holders of likely disputes based on market approval applications, the adverse remarks on the requirement to produce locally seem discriminatory to needs of the Indian population, and unjust wriggling with its IP laws.

By good fortune, the Draft Policy 2017 did not progress beyond consultations with stakeholders. It was never released publicly for comments and there have been reports that the Department was ordered to prepare a new policy as Prime Minister was not satisfied with it.[14] Jai Priye Prakash, Secretary, Department of Pharmaceuticals spoke to the media that in view of an impending amendment to the Drug Price Control Order (DPCO), 2013, the need for the policy had been obviated.

On 3 January, 2019 the DPCO ('The Amendment') was amended to exempt newly patented drugs from price control for five years from the date of commencement of its commercial marketing by the manufacturer including 'orphan drugs' that are used to treat rare genetic disorders. Prior to the Amendment, such an exemption was available only to drugs which were not produced elsewhere and were developed through indigenous R&D. The Amendment means that a drug can be launched at *any* price if it is patented under the Patents Act, 1970 and developed and produced by the patentee *anywhere* in the world. Even if the

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[11] OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2018 SPECIAL 301 REPORT 49-50 (2018).

[12] *Special 301 Review Public Before the Office of the United States Trade Representative* 202-203 (2016) (statement of Mukesh Aghi, President of the US-India Business Council).

[13] PRESS INFORMATION BUREAU, GOVERNMENT OF INDIA, CLARIFICATION ON MEDIA REPORTS REGARDING COMPULSORY LICENSE (2016), https://pib.gov.in/newsite/PrintRelease.aspx?relid=138271&utm_source=twitterfeed&utm_medium=twitter.

[14] Sohini Das, *Draft pharma policy fails to impress PMO, may take time to see light of day,* BUSINESS STANDARD (Sep. 18, 2018), https://www.business-standard.com/article/economy-policy/draft-pharma-policy-fails-to-impress-pmo-may-take-time-to-see-light-of-day-118091701341_1.html.

exemption is only for five years, it marks a stern change from the policy of price control and reflects the political will and external pressures that the developing countries are subjected to. Assuming that the Amendment is not a mere manner of preparing for the worst (which would be eventually removing price control altogether), it is given to understand that by limiting the exemption to the first five years from "date of manufacture", which should be international manufacture, it intends to entice companies into launching sooner.

The debate of price control vis-à-vis the notion of patent rights in a field of human rights has been of huge significance to policy makers, activists, courts and political parties. As might now be evident, from the start the discourse has heavily disfavored low and middle-income countries and it continues as governments attempt to balance innovation with access to medicine.

The aim of this Article is to study the impact of price regulation on launch of patented drugs in India, and whether the faults can be corrected simply by removing price ceiling for five years and if doing so is an ethical and constitutional step. Since the pharmaceutical industry of India is unique owing to its history of generic drugs and heavy exports, the exogamous factors that push India towards a stricter patent regime should not be ignored. The author also seeks to examine the importance of standard of patentability and how patent authorities implement it, and their expertise in instilling a conscious understanding of the inherent effect of patenting on right to health.

DISCUSSION

One should not be too quick to assume that the regime of IPR is inescapable if the society wants to encourage innovation. On the subject of medicine access, there exist two viewpoints that deserve equal consideration. The first is the approach stemming from Prof. Amy Kapczynski's arguments in her article titled 'The Cost of Price: Why and How to Get Beyond Intellectual Property Internalism'.[15] She argues that before assuming *a priori* that IPR is the most efficient method for innovation, we need to draw fair comparisons to other methods such as prizes and government contracts, which she called an external perspective to IP.

[15] Amy Kapczynski, *The Cost of Price: Why and How to Get Beyond Intellectual Property Internalism*, 59 UCLA L. REV. (2012).

A. External Perspective of Pharma Innovation and Right to Health

Is it right to presume IPR as an inevitable structure despite its obvious contradictions with distributive justice? According to Prof. Kapcznski, an internal perspective from within the field of IPR cannot support this because its scholarship addresses only those questions that pertain to this world of property rights— for example, how broad or narrow should exceptions to IP rights be? Here, the supposedly manifest connection between innovation and IPR is that if the rights over one's innovation are not protected then they have no reason to continue. So the 20 years of patent protection is the reward during which it is assumed or hoped that the innovator will fairly reap benefits of their innovation, and finally upon completion the innovation will revert to the society for further use. In a neo-liberal society, such monopoly is viewed from the lens of exploitation for economic benefits. Therefore, patents are based on a simple yet dangerous premise that the exclusion of society in access to patented information goods is justified because of the economic outcomes that incentivise the innovator. However, does the element that healthcare is a basic human requirement not necessitate re-evaluation of these assumptions to a fairer allocation where surpassing power to decide prices does not rest with private innovators?

Prof. Kapczynski argues that the primacy given to IPR is not justified in terms of innovation and efficiency and more so in light of the deepening of existing injustices and inequalities. In neo-liberalism, government's non-interference is the rationalised on the ground that 'price' is the correct indicator of demand and it signals to the manufacturers the direction in which innovation should move. Since signalling is done by people, social welfare is ensured. This is the signalling function of price. The argument that private companies are more efficient in using this information than the government is, is put forth against prizes and government contracts. But scholars have brought our attention back to this overestimation of benefits by suggesting models of government supported innovation that would escape the bureaucratic hurdles of innovation, such as *ex ante* prizes. Moreover, as experience of the past few decades tells bureaucratic delays and corruption cannot be escaped entirely even in market driven innovation because of our dependence on patent officials and courts for enforceability.

The reason that all policy makers seem to struggle with balancing the interests of their electorate with IPR is not because of personal deficiencies in their analysis. The problem lies in the sheer contradiction of the two systems that are attempted to be balanced. IPR pertains

to private rights and to juxtapose it with human rights in one policy is bound to result in theoretical and ideological conflicts. As much as the industry likes to advocate for IPR, it is a structure (in-hands with trade preferences and sanctions after the TRIPS Agreement) that develops rights only of the innovators. This tension was evident in the making of the Doha Declaration.[16] Human rights and IPR are formalistically distinct and intellectually inconsistent, and to expect that they can be put to work together with ease is a misrepresentation of the two.

These contradictions do not reflect with equal vigour in society because of the existing inequalities in distribution of goods and resources, and therefore IPR strengthens multinational companies and the developed countries.[17] A shift in regime from IPR to human rights is difficult because of the resources that are invested in lobbying to retain the focal point of this conversation on how human rights can be adjusted *within* intellectual property rights, which at the same time must be protected at all times. Conversations within mainstream media and in international organisations are limited to how far we can stretch the boundaries of IPR—which prevents purposive thinking of real external options. As long as the background norm and the setting of our political norms continues to be private property and profit maximisation, policy makers will be misguided and they will continue struggle to make space for generic and low-priced medicines with the overarching threat of WTO.[18]

An external perspective has to be conformed to at the global level because without a multilateral agreement the only recourse that countries can conceivably offer is through courts and TRIPS flexibilities in individual cases. It is required that academicians and scholars broaden the horizon by bringing to forefront the impact that IPR has on political, social, and economic landscape by furthering neo-liberalism.

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[16] Ellen 't Hoen. *TRIPS, Pharmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond*, 3 CHI J. INT'L L. 27 (2002).

[17] Siva Thambisetty, *Improving Access to Patented Medicines: Are Human Rights Getting in the Way?* (London School of Economics and Political Science, Working Paper No. 03, 2018).

[18] Amy Kapczynski, *The Right to Medicines in an Age of Neoliberalism,* HUMAN. J. (Apr. 26, 2019), http://humanityjournal.org/issue10-1/the-right-to-medicines-in-an-age-of-neoliberalism/.

B. Internal Perspective of Pharma Innovation and Right to Health

Product patents provide market exclusivity stronger than process patents by creating incentives for originators to enter markets on the guarantee that their products will be safe from generic competition. The risks of product patents were apparent to the developing countries that could not fathom meeting their healthcare requirements through the Big Pharma. After TRIPS, some scholars suggested that the risk was 'minimal' for the Indian domestic industry only because price control already existed, compulsory licensing was legal and there was a general culture in the country and its bureaucracy against granting of patents easily.[19]

Empirical Studies

From an internal perspective the question posed by the 2019 Amendment is simple: whether exemption of price control actually encourage foreign firms to launch their drugs in India so substantially early that it will offset the high prices?

Jayashree Watal, wrote in 2000 that among the possibilities that India had after TRIPS was enforcement of selective and effective price controls that would balance the benefits and costs of product patenting. She advocated for a cost based price determination, and that in any case compulsory licensing would be a better policy.[20] In other works as well, it has been proposed that if the price control is selective in nature and there are reasonable but strict mark-ups on the profit that is permitted based on the innovation undertaken, such price regulations would be a balanced policy.[21]

A study in 2005 showed that the probability of a drug launch in a low or middle-income country (LMIC) within two years was about 9%. In countries with a strong R&D such as India, new pharmaceuticals were less likely to come quickly without strongest level of patent production because of the fear of generic competition. The study found that price regulation did not make an impact on whether the drugs were eventually launched but only on the speed of this release. The 2019 Amendment has a similar intent. In other words, it did not appear

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[19] Janice M. Mueller, *Taking TRIPS to India — Novartis, Patent Law, and Access to Medicines*, 356(6) NEW ENG. J. MED. 541, 541-543.

[20] Jayashree Watal, *Pharmaceutical Patents, Prices and Welfare Losses: Policy Options for India Under the WTO TRIPS Agreement* 23(5) THE WORLD ECON. 733 (2000).

[21] F.M Scherer & Jayashree Watal, *Post-TRIPS Options for Access to Patented Medicines in Developing Nations.* 5(4) J. INT'L ECON. L. 913 (2002).

that price regulation was severely limiting the ultimate entry of new products, and there were other reasons why companies might make that decision. The most seminal observation was that it distinguished between the price regulation in different countries between the strictness of the regulation. It showed that extensive price regulation slows launch, but moderate price regulation on average had no effect. In a country (such as India) which is marked by acute income inequality, the innovator firm has two options. It may set low prices with small profit margins in an attempt to achieve extensive market penetration, that is economics of scale, or it can set high prices with the expectation of reaching only the elite. The study showed that the chances of launch in a lower-income country increase if income distribution is unequal so the foreign firms appeal only to the "elite". This also sheds light on the allegations that even if patent protection and higher prices do incentive more R&D, in so far as the developing countries are considered this will necessarily flow to research on neglected tropical diseases.

In a study, launch data in 25 countries from 1994 to 1998 was used to look at the effect of price regulation on the launch delay of new drugs. It was established that there was a strong positive effect of higher expected prices (proxy for less price regulation) on the probability of launch. But since the study focused on parallel imports in the European market, it found that the price spillovers due to parallel trade and external referencing was a main deterrent from a speedier launch, which could be a huge factor for India. Companies would launch drugs as long as the price regulation was not so low that they could not meet the fixed costs and the marginal costs of production and transportation, and price spill-overs played a major role in this decision.[22]

In another study in 2014, authors compared drug launches in US, Germany and India and found that among the 97 drugs that were at risk of launching in India, only 8 percent became available in a year, 30 percent within three years and 43 percent in five years of the first worldwide launch.[23] It must be kept in mind that this study was dealing with new drugs, not necessarily drugs that were patented. There was no direct cause to show the cause of delay, and neither is it reasonable to expect a single cause. They recommended India to have

[22] Patricia. M. Danzon, Richard Wang & Liang Wang. *The impact of price regulation on the launch delay of new drugs? Evidence from twenty-five major markets in the 1990s*, 14 (3) HEALTH ECON. 269 (2005).
[23] Ernst Berndt & Iain M. Cockburn, *The Hidden Cost Of Low Prices: Limited Access To New Drugs In India*, 33(9) HEALTH AFF. 1567 (2014).

stronger patent protection as it was found that in India over one-third of new drugs were multi-sourced in the same calendar year, and over 85 percent were multi-sourced three years after their launch there. Here, the fear of foreign firms was largely concluded to be the generic competition. In contrast, in Germany none of the drugs for which the authors determined single-source or multisource status faced generic competition in the fifth year after launch, and in the United States only 2 percent were genericized after five years.

In 2016, a study of 642 new molecules in 76 countries during 1983-2002 showed that price regulation delays launch, while longer and more extensive patent rights accelerated it. The results were constant for developing and high-income countries. It was noted that the same policies that bring drugs faster are also the ones that make them costlier and therefore, these are the trade-offs that a government has to decide on.[24]

Another study examining drugs statistics after TRIPS found that on average, access had since increased. The study recorded instances where prices of patented drugs had decreased, but this could only be attributed to policies such as price controls or threat of compulsory licensing, and not the competitive pricing by the manufacturers.[25]

A recent research paper from IIM Ahmedabad on the impact of price controls under the new DPCO 2013 on drug sales found that there was a decrease in sales post-price control as many firms were either exiting or cutting their marketing as they were finding it difficult to survive. This means that when another possible effect of extremely stringent price control is that pushes the smaller and medium-sized manufacturers as they do not have enough sales to sustain on low margins for long.[26]

A working paper that studied short term changes since DPCO 2013 found that after the Order even prices of exporter and local firms decreased if their previous prices were within the range of the price ceiling. This was a result of the revision pricing in which the multinational firms had slashed their prices. The prediction on producer's exit found that if the price ceiling were set reasonably then it would not necessarily lead to exit of companies,

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[24] Iain M. Cockburn, I., Jean. O. Lanjouw & Marl Schankerman, *Patents and the Global Diffusion of New Drugs* 106(1) AM. ECON. REV. 136 (2016).

[25] Margaret Kyle & Yi Qian, *Intellectual Property Rights and Access to Innovation: Evidence from TRIPS* (National Bureau of Economic Research, Working Paper No. w20799, 2013).

[26] Arvind Sahay and Saravana Jaikumar, *Does Pharmaceutical Price Regulation Result in Greater Access to Essential Medicines? Study of the impact of drug price control order on sales volume of drugs in India* (Indian Institute of Management Ahmedabad, Working Paper No. 2016-02-01, 2016).

and to the extent that it would, local firms would exit because of the difference in their marginal costs of production. This meant that price sensitive customers and those living in rural areas where the multinationals are unlikely to reach are negatively affected. In such a scenario, the last mile problem comes to forefront as multinationals withdraw from areas that have a high transaction costs such as far off and low-income regions, which is a catastrophic in a country that does not have a public health system to cover the gap. If generic competition is experiencing a decrease then the gap would have to be filled by the government by on one hand instituting policies for domestic R&D and manufacturing, as well as adopting methods of bulk procurement for remote areas. The study showed that even after the five-fold increase in the number of price-controlled drugs, there was no increase in the number of MNCs withdrawing from India. However, two MNCs requested to withdraw when the prices of knee stents were capped.

USA is one of the only countries which does not have a federal drug law though it has systems for discounts for specific people and rebates. The pricing strategy that companies use in US sheds light on the repercussions of a completely unregulated industry. A study of anti-cancer drug prices in US revealed that companies used reference pricing in which prices of drugs in a similar therapeutic class would be used to calculate the new drug price. Since this calculation is in the hands of the industry broadly speaking so, each time a new drug is launched, the prices move up which encourages repeated players to push for higher prices by others in the industry for a shared benefit to all.[27]

The Study read:

> "market structure effectively provides no mechanism for price control in oncology other than companies' goodwill and tolerance for adverse publicity" (Anand 2007). The observation begs the question: What is to stop a manufacturer from setting the price of a drug at $1,000,000 or more?" Drug manufacturers are able to set higher prices for new drugs, but they must be mindful of physicians' ability to exact retribution when manufacturers violate physicians' norms of fairness in pricing."

Duggan, Garthwaite and Goyal in their study of market effects of the Patents Act 2005 noted that while the number of domestic firms engaged in the business had not depleted, the concentration of sales had significantly changed in the favour of foreign firms. More

[27] David H. Howard et al., *Pricing in the Market for Anticancer Drugs*, 29(1) J. ECON PERSPECTIVES 139 (2015).

importantly, they recorded that an increase in prices of product patents, which was concluded to be relatively small at an aggregate level meaning that molecules issued prior to 1995 (TRIPS) had little price change but the price change after that was larger and growing. To the extent that the price increase had not exceeded 10% even among the recent molecules, this feature was attributed to India's price control policy. [28]

Claims of Pharmaceutical Companies

The industry makes claims for removal of price control at various platforms through interviews with media, submissions to government bodies, and sponsored empirical data. The common thread in all their averments is that the cost of R&D that they would have to make good through sales. These claims have created a perception of truthfulness because of who they are, and the power and resources that is put into lobbying these claims.[29] However, civil society organisations and scholars have time and again pointed out several lapses in their claims. Evidence shows that companies spend a lot more on marketing than on R&D. The industry has advocated a free market to assert that competition will maintain low prices even without price ceiling.

Firstly, in such a case, a reasonable price ceiling does no harm to recovering costs as all competitors are evenly subjected to it. The companies' focus should be on putting in place a price regulation policy that is not excessively strict and disproportionate instead of the outright removal of one. *Secondly*, evidence on the price controlling character of a free market shows that this claim is utterly unfounded. For instance, a comparison of prices of drugs that were controlled under DPCO, 1987 but decontrolled under DPCO 1995 showed an upward movement and some categories even had a double digit rise.[30] Moreover, several companies that base their prices on high R&D costs actually benefit immensely from government subsidies and grants for it.[31] A report titled 'Promoting Access to Medical Technologies and Innovation – Intersections between public health, intellectual property and

[28] Mark Duggan, Craig Garthwaite & Aparajita Goyal, *The Market Impacts of Pharmaceutical Product Patents in Developing Countries: Evidence from India,* 106(1) AM. ECON. REV 99, 132-133 (2016).
[29] Marcia Angell, *Why do drug companies charge so much? Because they can*, THE WASH. POST (Sep. 25, 2015), https://www.washingtonpost.com/opinions/why-do-drug-companies-charge-so-much-because-they-can/2015/09/25/967d3df4-6266-11e5-b38e-06883aacba64_story.html.
[30] *Supra* note 1.
[31] UACT SUBMISSION TO USTR ON SPECIAL 301 OUT-OF-CYCLE REVIEW OF INDIA (2014), https://cancerunion.org/files/UACT-Special301-OCR-India.pdf.

trade' was published by the WTO, WIPO, and WHO in 2012 ('Trilateral Study') which also revealed that estimations of R&D costs made by the companies varied more than nine fold.

James Love has played a remarkable role in access to medicine and public health campaigns in USA has called this "a deliberate veil of ignorance". This has led to the dawn of a movement for delinking the incentive to research through prices, which has recently been attested to by the UNSG's High Level Panel on Access to Drugs as well. This would mean that patent laws and policies across the world have to be adequately amended to reflect the realities of expenditure on innovation so that these laws justify their own consequences objectively and not profits of companies.

However, a noteworthy problem with relying R&D data as indicator of innovation is that it is difficult to verify it without requisite disclosures, which companies are very reluctant to make. There are other added complications such as change in the definition of R&D over time.[32] As stated above, the US permits drug companies to charge patients whatever they choose.[33] This has led to criticisms and public research initiatives pressing the government to pass regulatory laws. For the first time, a suit has been filed by the federal government against Gilead accusing it of infringing government patents of preventing H.I.V. with a daily pill and the lawsuit has placed prime emphasis on the public funding of the R&D by which the medicine came about. Gilead had claimed that the patents held by the government should be cancelled because its researcher had conceived this idea before. The two drugs that constitute the drug regime for H.I.V. priced exorbitantly high at 20,000 dollars by Gilead as opposed to 60 dollars of its generic form which is available in other countries.[34]

Most studies that are sponsored by the pharmaceutical industry stimulate interest for the public welfare by putting the act of concern for the poor and needy and making policy recommendations. The most common recommendation is the setting up of a public healthcare system that either insures the people or offers reimbursements, or the bulk

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[32] Iain M. Cockburn, WORLD INTELL. PROP. ORG., *Intellectual Property Rights and Pharmaceuticals: Challenges and Opportunities for Economic Research,* in *The Economics of Intellectual Property: Suggestions for Further Research in Developing Countries and Countries with Economies in Transition* 161 (2009).

[33] Amy Kapczynski & Aaron S. Kesselheim, *Three things Trump can do to bring drug prices 'way down'*, THE WASH. POST (Nov. 21, 2017) https://www.washingtonpost.com/opinions/what-trump-should-do-if-he-actually-wants-to-cut-drug-prices/2017/11/21/f7522422-be4f-11e7-8444-a0d4f04b89eb_story.html.

[34] Donald G. McNeil Jr., & Apporva Mandavilli, *Who Owns H.I.V.-Prevention Drugs? The Taxpayers, U.S. Says*, THE N.Y. TIMES (Nov. 8, 2019) https://www.nytimes.com/2019/11/08/health/hiv-prevention-truvada-patents.html.

procurement of medicines by the government. Two countries have had a particularly difficult past in their attempt to cover as many medicines as possible for their people—Brazil and Columbia. Brazil incurred billions in paying for expensive drugs for its people under a public health care system. Such policy initiatives therefore lead to a public healthcare that fails under the increasing profit demands of the industry and the countries are forced to put aside a substantial chunk of their GDP for filling their pockets in the garb of unverified R&D.[35]

In US that has relied on the market to give low prices, the outcome is clearly disastrous. Since the companies are aware that they need to provide drugs at discounted rates to certain patients under other regulations, they accordingly increase prices for other customers. This can either be catastrophic for the economy of that country, especially if the courts interfere to the extent that they can and order the executive to expand their list of procedure medicines, or the country would be pressurized to not have a public healthcare system. In both cases, companies would have it their way. Increased coverage does not give companies an incentive to reduce prices and the ultimate consequence is that government has to reduce its coverage. These price increases in the US have finally started to take shape in terms of legislative efforts, for instance through fair pricing bills. Fair pricing bills seek directly to constrain the soaring prices of pharmaceuticals. Several states have proposed—and two states have passed—legislation requiring drug manufacturers (1) to justify certain prices increases or face penalties; or (2) to provide rebates when prices exceed a certain threshold.

It is notable that in the same year as the amendment to DPCO in India, Canada moved to stricter price regulatory system for patented drugs in light of soaring prices. It is the biggest reform since the introduction of the Patented Medicines Regulations in 1987. Under the new rules, Canada will drop USA and Switzerland as the countries that are referred to for the purpose of price setting. The agency will have the power to look into the cost-effectiveness of new medicines.[36] A very promising change is that companies will now be obligated to disclose confidential discounts. The review is only of the patented drugs and this marks a

[35] *Healthcare in Brazil: An injection of reality*, The Economist (Jul. 30, 2011), https://www.economist.com/the-americas/2011/07/30/an-injection-of-reality.

[36] Allison Martell & Anna Mehler Paperny, *In Canada, a little-known drug regulator shows its teeth*, REUTERS (May 8, 2019) https://www.reuters.com/article/us-canada-pharmaceuticals-pricing-insigh/in-canada-a-little-known-drug-regulator-shows-its-teeth-idUSKCN1SE0E0.

huge distinction from India because India is yet to act fully on the Report of the Committee on Price Negotiations for Patented Drugs.

Patentability

The single greatest challenge to incorporation of 'human rights thinking' in domestic patent law is the way in which the grant of patents is separated from consequences of exploitation of patents. According to TRIPS, patents can be granted on any inventions that are "new, involve an inventive step and are capable of industrial application". Thus, evergreening is when a company uses deliberately prolongs its patent usually by speciously claiming a "new use". According to the Access Campaign of Doctors without Borders, evergreening is a major problem in India where because companies regularly rely on marginal improvements in patented drugs to continue their monopoly. For example, in 2017 the Patent Office granted a patent to a pneumonia drug when the patent had been revoked in Europe and challenged in other countries like South Korea and USA.[37]

As discussed in the WHO Commission on Intellectual Property Rights, Innovation and Public Health, eradicating secondary patents is not analogous to dismissing innovations that are creative but fall short of the patent standard. Incremental innovations should not be conflated with evergreening as in the former there are genuine modifications to drugs that are not ground-breaking but provide better results than existing ones.[38] The Trilateral Study shared these concerns and stated that to obliterate secondary patents from our patent systems, changes would need to be made to the following:

- the patentability criteria defined by national law and interpreted by case law and practice
- the manner in which examiners apply the patentability criteria and whether it is in line with the established definition and interpretation.

WHO urged that WTO Members should use the options in TRIPS itself called TRIPS flexibilities, such as Article 27, to put a stop to evergreening by setting by administering

[37] *Indian patent office delivers major blow to affordable pneumonia vaccine hopes*, MÉDECINS SANS FRONTIÈRES ACCESS CAMPAIGN (Aug. 22, 2017) https://www.msfaccess.org/indian-patent-office-delivers-major-blow-affordable-pneumonia-vaccine-hopes.

[38] WHO, REPORT OF THE COMMISSION ON INTELLECTUAL PROPERTY RIGHTS, INNOVATION AND PUBLIC HEALTH. (2006).

rigorous definitions of invention and patentability in favour of public health.[39] In India S. 3(d) of the Indian Patents Act protects from evergreening states:

> "...the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant."

A study on secondary inventions in India, Brazil and Argentina, found that S. 3(d) is a sorely underutilised provision. Though it is overused by organisations for objecting to patentability and there is a huge overlap between raising oppositions on primary patentability and secondary patenting, the officials rarely focus on holding independent assessments for primary and secondary patentability. This means that there is almost never a finding of evergreening.[40]

A report released in 2018 found that the error rate of the Indian Patents Office is 72% and a total of 1654 patents had been granted.[41] It is thus important that officers are well trained and informed about the consequences of granting patents. As those discussing norms for grant or denial of patents do not and cannot directly analyse the outcomes of such grants on the healthcare of the population and because the faith in the incentive effect of patents is so strong, there is very little reflexive space for consideration of human rights in the patent system. The UN has called for action at the international level through WHO, WIPO and WTO to strengthen the capacity of patent examiners so that standards of patentability are in sync with public health needs. This particular recommendation needs more attention and changes must be introduced to patent check lists and qualification standards for patent officers. This is especially important because a treaty or resolution by a UN body that is widely ratified would take the burden from the developing world to fight every single battle individually in fear of trade retaliations. The enforcement of strict patentability standards based on a regional or multilateral treaty would frustrate direct pressure politics employed by developed countries on LMICs.

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[39] WHO, HEALTH STATISTICS 2016: MONITORING HEALTH FOR THE SDGS (2016).

[40] Bhavan N. Sampat & Kenneth C. Shadlen, *Indian pharmaceutical patent prosecution: The changing role of Section 3(d)*, 13(4) PLOS ONE (2018).

[41] Dr. Feroz Ali et al., *Pharmaceutical Patent Grants in India: How Our Safeguards against Evergreening Have Failed, and Why the System Must Be Reformed*, ACCESSIBA (2018), https://accessibsa.org/media/2018/04/Pharmaceutical-Patent-Grants-in-India.pdf.

For better accountability and communication between demands of the people of the patent office, it becomes crucial to allow representations from experts and public-spirited entities such as MSF. Therefore, use of S. 25(1) of the Patents Act which allows opposition proceedings against patent applications needs to be encouraged and the patent officials should be trained to undertake a rigorous assessment of facts.

RECOMMENDATIONS

The author posits that price control is absolutely essential for people to be treated, but it should not be seen is the be-all and end-all of ensuring the right of health. First and foremost, the standard of patentability has to be strict and effectively implemented by all patent offices to ensure that these drugs that are then treated separately under a policy are well-deserving and truly innovative drugs. This ensures that transaction and administrative costs in dealing with these innovations does not become overpowering and protection from generic competition is not given to frugal innovations.

Once it is ensured that only well-deserving innovations are granted patents, then the next step is to have an effective and transparent method of price control that is based on conducting price negotiations on the basis of cost-based pricing along with reference pricing. Reference pricing can be harmful if it based on launch in developed and high income countries, so the social and economic capabilities of the patients in the referred countries should be the same as those in India and comparisons should not be made from the narrow point of view of economic growth or size of the GDP. Furthermore, price control should not be imposed on all patented drugs and drugs should be distinguished on their therapeutic value and essentiality. The Report of the Committee on Price Negotiations for Patented Drugs had recommended a similar distinction among differently valued patented drugs. The criterion of excessive pricing was provided for the category of breakthrough or drugs that give substantial improvement, which should not exceed prices of comparable products in the therapeutic class and the international median price of the said medicine.

Price negotiations are made effective with the support of a healthy and active healthcare system which is relied upon by a majority of its population. This gives the government bargaining power vis-à-vis the manufacturer, especially in India, which is a huge market for medicines, by threatening the company with non-coverage. Similarly, compulsory licensing

is another provision that puts the government in a better position to claim its space as the primary decision-making authority.

The broad theme across all problems that India and many other countries face today from both the internal and external perspective is the over-reliance on private multi-national companies to innovate. The task of finding new life-saving drugs has been completely relegated to it and this has made all other considerations subject to the one question of whether we are doing enough to please these companies so that they undertake R&D for us. In such a scenario the society is a slave to the demands of companies and their choices of which disease gets drugs and in which areas the drugs reach. Therefore, an underappreciated but crucial element of ensuring access to medicine is for the government to undertake and/or fund research in institutions that are not guided by profit, such as independent research centres, generic manufacturers (government contracts) and universities. From the perspective of long-term gains and innovation, the route has to be of public funded but effective research, with opportunities of public private collaborations.

By choosing to ignore the detailed recommendations of the Report of the Committee on introducing price negotiations and other aspects on patented drugs, and passing a short amendment excluding application of DPCO the government implicitly rejected efforts to cater to price settlements on patented drugs through a transparent manner. The 2019 Amendment was not backed with any public empirical research. There was no data released to prove that there were lags in launches in India as compared to other countries with similar income levels and unequal distribution of income, and that if lags existed then they could be directly attributed to the price control policy. It is possible that the choice to not launch is made as the drug is not innovative enough to be covered by patent law standards in India and the threat of generic production is too high. The absence of coverage in India also makes it a less lucrative of market because the companies cannot rely on the government to bring more patients to the pharmacy to buy their expensive medicines. After empirical research and negotiations with stakeholders, the government should examine the viability of offering market exclusivity instead of exemption from price control. This simply means that the government will create limited periods of market exclusivity for first entrants independent of the patent system, such as the five-year period of market exclusivity given to new drugs by the FDA in the United States. The advantage of this system is that price is regulated and manufacturer's concerns about generic competition are also taken care of. Of course, if

market exclusivity was implemented without price control it would not lead to only bigger problems.

A cost-based approach should be adopted for pricing that uses input costs and costs of R&D along with other factors such as risk of failure to assess the base price, and adds a mark-up over and above that by reference to the price of that drug in other socially and economically similar countries as well as costs of the other drugs in the same therapeutic class in India. This is within the earlier categorisation of patented drugs where some might be completely ground-breaking in their therapeutic effects and there might not be parallel drugs that offer the same results. In such a case, prices can be allowed to be higher and the government's public health care system can fill in with higher coverage. In cases where a large portion of the R&D was funded by the government of the multinational firm or cases where the drug has been in circulation for a sufficiently long period to have recovered the sunken costs the mark up should be decreased accordingly. This approach requires submission of data and research, and it will also include factors and risks that are either difficult to convert to monetary terms or are difficult to be converted to an equivalent value in India. Clearly the transaction costs of cost-based pricing are high and the government should put in place advisory committees, and review boards with members from the industry, civil society organisation, academicians and consumer right groups. These members should be well-trained and the capacity of such committees should be reasonable. It is not uncommon to see laws that require the manufacturer to put evidence before the government to justify the price it seeks to impose. An example is the bill passed recently in Maryland, USA which prohibits "unconscionable" price increases for essential generic drugs and drug-device combinations and requires such manufacturers to provide justifications for increases.[42]

Similarly, under the federal drug-pricing bill in US called "Improving Access To Affordable Prescription Drugs Act" a progressive rebate can be imposed on any price increase which is greater than the rate of medical inflation and to avoid this rebate, justifications need to be provided. While it is true that the difficulties that India and US face are remarkedly different because US is a first market in which multinational firms launch as compared to India which has to take steps to attract these companies. Firstly, the intent of the Amendment is precisely not that, it only caters to companies that were planning a launch and are being encouraged

[42] Jared S. Hopkins, *Maryland Takes Step Toward Capping Drug Prices*, WSJ (Apr. 30, 2019) https://www.wsj.com/articles/maryland-takes-step-toward-capping-drug-prices-11556616600.

to do it sooner. In such a case, the provision to submit data and costs to the government is a step that they would need to take eventually. Secondly, the purpose of giving instances from the USA is only to show that the costs of studying data given by the company and engaging with it does not amount to unbearable transaction costs for our government.

Lastly, transparency laws should be introduced to encompass the entire drug industry requiring manufacturers to annually submit information including the costs of production, marketing and advertising costs, profits, discounts and charity by the company or opening of company run patient assistance programs, clinical trial phases, public funding etc.[43] These laws should apply uniformly to domestic and foreign firms. This information is neither central to drug companies' business model nor is it comprehensively secret. Given the significant budgetary and public health interests, states are well-positioned to require public disclosure of substantial information. The intent to introduce such laws is not to only easing the government in its assessment of price caps or caps on annual price increase, but it is also to equip the civil society and patients with better information so that the current information asymmetry which shields the pharmaceutical industry ends. In the current environment, manufacturers' arguments are frequently based on exaggerated and unsubstantiated claims and a law that puts costs of R&D in public domain will allow both patients and regulators to make more informed decisions about whether prices are excessive, and introduce rationality and evidence into pricing debates.[44] A transparency law that operates independently of the price control policy will also immensely bring down the transaction and administrative costs of the latter police. This will be especially effective and safe if transparency laws become a global phenomenon, perhaps suggested and pushed by the WHO and WIPO, and so large amount of calculations and assessments could be simply re-submitted without additional costs. Keeping in mind interests of the companies, it should provide for protection of trade secrets provided the company submits evidence to substantiate such an exemption claim.

Though NPP 2012 did not comment on patented drugs, there are some key takeaways on disclosures and availability of information by companies. The 2012 Policy exclusively relies on IMS Health for information of the pharmaceutical market. IMS health is a

[43] WHO, HIGH-LEVEL PANEL ON ACCESS TO MEDICINES (2016).

[44] Aaron Berman et al., Curbing Unfair Drug Prices: A Primer for States (Aug., 2017) (Global Health Justice Partnership Policy Paper, Yale Law School).

pharmaceuticals market data specialising *company* which means that the government is foregoing any possible responsibility by outsourcing its job and compromising on objectivity.

CONCLUSION

In conclusion, by exempting patentees the 2019 Amendment takes an easy and narrow approach to solving the health crisis in India. It is the government's attempt at a middle path between correcting the dangerous disadvantages of market-based pricing, and a complete exemption from price regulation. However, it failed to understand depth of the problems and the intersection of various factors that come together in the decision into launch lag. To add to that, the move to a market-based pricing to avoid the task of a cost-based price could possibly be a huge deterrent for companies fearing that average price of the generic competitive market in India will actually result in extensive and unreasonable price regulation. Any step forward would need that India makes empirical research that is conducted or funded by the government its foremost priority so that only policies that are free from on myths and false claims are formulated.

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