# TOWARDS USING THE RIGHT TO HEALTH TO PREVENT CONSTITUTIONALLY INTOLERABLE DENIAL OF ACCESS TO PATENTED DRUGS IN INDIA

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TRINITY 2020

# ABSTRACT

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India has often been held up as an example of a country whose patent law regime demonstrates that it is possible for a country to be TRIPS compliant while addressing its unique local demands, especially those that relate to public health. What this narrative ignores, however, is the fact that the patent law levers designed to meet these public health demands have thus far largely remained merely on paper. They have not been meaningfully deployed to prevent the detrimental consequences flowing from overbroad legal monopolies enabled by patents.

In this project, therefore, I seek to study how specific patent law levers can be operationalized in a well-structured and transparent fashion. More narrowly, I will study how the right to health can be used as a resource to urge courts to engage with the executive to enable the chosen patent law levers to come alive. It is hoped that this contribution will help further the debate on how human rights law can be used to influence the working of intellectual property law, through the instrumentality of courts.

Further, I will propose a model of judicial intervention where the right to health is used to influence the working of these levers. This model indicates how Indian courts can apply the right to health in a nuanced and rigorous fashion. Finally, the project will anticipate counterarguments against my proposals and offer a robust defense against them. If implemented, my proposal has the potential to make India become a more deserving recipient of the accolades for having a well-balanced patent law regime that have perhaps been prematurely bestowed.

**Word count: 30,000 words.**

# ACKNOWLEDGEMENTS

I'd like to dedicate this thesis to three main people. First, my family. For providing me access to the opportunities, resources and confidence that positioned me to pursue a world-class education at this great university. Born blind in a small town in India, my journey to Oxford has been uniquely difficult and challenging, and I am grateful to them for being with me every step of the way.

Second, my supervisor, Dr. Dev Gangjee. Whenever feelings of self-doubt overcame me during this year (and they often did), Dev encouraged me to stay the course and offered a way out. His confidence in my abilities and instincts, and his ability to hold me to the most exacting standards without ever being unkind, are rare and precious qualities.

Third, my interest in studying the interaction of intellectual property and human rights law took root thanks to my late mentor, Professor Shamnad Basheer. It was through the work that I did with him that I was exposed to many of the ideas I have explored in this project. And so I'd like to also dedicate this thesis to his memory.

I'd also like to thank a whole host of people for helpful conversations and comments. These are, in no particular order, Professor Sandra Fredman, Professor Kate O'Regan, Judge Edwin Cameron, Justice Ravindra Bhat, Lord Kitchin, K.M. Gopakumar, Dr. Arghya Sengupta, Professor Srividhya Ragavan, Mark Haywood, Sanya Samtani, Katarina Foss-Solbrekk, Gauri Pillai, Professor Paul Craig, Anuj Bhuwania, Prashant Reddy, Tom Westwell, Justice Prabha Sridevan, Professor N.S. Gopalakrishnan, Aradhya Sethia, Mihika Poddar, Arushi Garg, Yashaswee Sarkhel and Malini Aisola. I'd also like to thank my close friends in Oxford (you know who you are) for providing companionship and support.

Lastly, but equally importantly, I'd like to thank my support worker, Felix Neubauer, for his painstaking work in addressing the deficiencies in the thesis occasioned by my lack of sight.

All errors remain mine.

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# List of Abbreviations

A2M: access to medicines.

BI: Boehringer Ingelheim

BMS: Bristol Myers' Squibb.

CDPA, 1988: Copyright, Designs and Patents Act.

CG: central government.

CGPat: Controller General of Patents.

CJEU: Court of Justice of the European Union.

DIPP: Department of Industry and Policy Promotion.

DPSPS: Directive Principles of State Policy.

DSB: Dispute Settlement Body

DSM: Dispute Settlement Mechanism

DSU: Dispute Settlement Understanding.

FRs: Fundamental Rights.

GC: General Comment

GSK: GlaxoSmithKline.

HR: Human rights.

ICESCR: International Covenant on Economic, Social and Cultural Rights.

IP: intellectual property.

IPAB: Intellectual Property Appellate Board

MoH: Ministry of Health

PBU: Patent-based unaffordability of medicines.

PC: Price control measures

PLV: Patent law levers

PPP: pharmaceutical product patents.

RtH: Right to health.

RTI: Right to Information

SC: Supreme Court

TAC: Treatment Action Campaign.

USIBC: US-India Business Council.

VCLT: Vienna Convention on the Law of Treaties.

WHO: World Health Organization

WTO: World Trade Organization.

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# INTRODUCTION

It has become increasingly clear that the introduction of product patents for pharmaceuticals ('PPPs') in 2005 has translated into greater unaffordability of patented medicines in India. [1] While it was hoped that the negative impact of this move would be offset by the patent law levers ('PLVs') contained in the Patents Act, 1970 ('the 1970 Act') [2], this hope has not been realized. The reasons for this are varied, but chiefly include the fear of retaliation if these PLVs are worked and lack of sufficient independence and competence in the functioning of the Controller General of Patents ('CGPat').[3] The need for their operationalization has assumed (arguably) unprecedented significance due to the Corona Virus ('COVID 19') pandemic. [4]

The use of these PLVs, however, should not just be confined to circumstances rising up to the level of a global pandemic. In this thesis, therefore, I seek to provide a roadmap for how this state of affairs can be reversed. Anchoring my contribution in the theoretical tradition on adopting a human rights ('HR') framework through which to interpret intellectual property ('IP') law, I argue that the right to health ('RtH') can be used as a resource to urge the courts

[1] n12 and n21.

[2] n42 and n43.

[3] n44 and n51.

[4] V Tandon, 'Revocations, special compulsory licenses, patent strategies & COVID-19: A note on Indian Patent Law' (IPKat, 11 May, 2020) <http://ipkitten.blogspot.com/2020/05/guest-post-revocations-special.html> accessed 22 July 2020; M Kar, 'Covid-19, Patents and Access to Medication in India' (OHRH, 11 May 2020) <https://ohrh.law.ox.ac.uk/covid-19-patents-and-access-to-medication-in-india/> accessed 22 July 2020; P Reddy, 'The Need for an IP Policy to Build a Strategic Stockpile for Pandemics' (SpicyIP, 26 March 2020) <https://spicyip.com/2020/03/the-need-for-an-ip-policy-to-build-a-strategic-stockpile-for-pandemics.html> accessed 22 July 2020 and R Bajaj, 'COVID-19: Invoking Fundamental Right to Health to Push Govt to Use Patent Law Levers' (SpicyIP, 29 March, 2020) <https://spicyip.com/2020/03/covid-19-invoking-fundamental-right-to-health-to-push-govt-to-use-patent-law-levers.html> accessed 22 July 2020.

to ensure that the executive provides access to expensive patented drugs on an affordable basis. As Brennan and colleagues note, the strategy of using the RtH to influence patent law in domestic court cases carries the greatest promise of producing 'real results for access' amongst the available avenues for deepening this relationship.[5]

My contribution will therefore build on the existing thinking on how the RtH is influencing Indian patent law. I will finally provide a set of strategies that India can deploy to persuasively counter any repercussions it might face against the operationalization of my proposal.

## Contribution

The relationship between IP and HR law generally, and patent law and the RtH in particular, has received much academic attention. What has thus far not been studied meaningfully, however, is the methodology by which the patent law and RtH relationship can be deepened through judicial intervention. This project will address that gap. Further, it seeks to provide a doctrinally robust account of the RtH jurisprudence in India to establish a firm base for its use in the manner proposed. Given that the RtH case law in India thus far lacks coherence, this project can help infuse some clarity in this area of law. Lastly, it offers a roadmap for constructive and thoughtful judicial intervention using the RtH and therefore seeks to

[5] Brennan and others, 'A Human Rights Approach to Intellectual Property and Access to Medicines, Global Health Justice Partnership Policy Paper 1' (Yale School of Public Health, 2013) 1 (Brennan and others).

harmonize the conflicting views in the literature assessing the efficacy of judicial intervention in the health domain.

## Chapterization

In the first chapter, I will lay out the quantitative empirical evidence that supports the proposition that the introduction of PPPs has made medicines more unaffordable in India. Second, I will situate the problem of patent-based unaffordability of medicines ('PBU') within the range of other factors that make medicines unaffordable and explain my focus on PBU. I will then discuss the available avenues for redress and make the case that PLVs represent the most promising solution. I will finally examine why they have thus far remained unutilized, to establish the institutional suitability of courts to help reverse this state of affairs.

In the second chapter, I will outline the theoretical framework of my argument of ushering in patent law reform through the use of the RtH and analyze the existing RtH case law in India. In the third chapter, I will propose a model of judicial intervention to effectuate the activation of the selected PLVs. In chapter 4, I will offer a roadmap for India to resist any pressure against implementing my proposals.

## Research questions

- Within what paradigm of the literature on applying an HR framework to IP does this project fit?
- How can we foster a better quality inter-institutional conversation between courts and the executive in India to effectuate the activation of the selected PLVs?
- Can we identify a methodologically rigorous process by which the RtH can be used as a prompt to operationalize the selected PLVs?

## Methodology

The project adopts a mixed methods approach. It is primarily doctrinal but also draws on the comparative method. It adopts an internal doctrinal approach. This is because it works with existing primary materials, chiefly legislation and case law, in the field of study i.e. patent law and the RtH. It focuses on modes of reasoning adopted by the legal profession, and Its primary audience is participants within the system (judges and practitioners). It draws on the comparative method as a deliberative resource to study the RtH case law in other jurisdictions. While being cognizant of relevant textual and contextual differences across jurisdictions, it relies on comparative experiences to examine the efficacy of different approaches and to propose a model of judicial intervention.

References to the para numbers of all Indian judgments are to their copies available on Manupatra.

# CHAPTER 1

## Part 1 – Identifying the nature and scale of the problem

In this segment, I will demonstrate how the introduction of PPPs in 2005 in India has been causally responsible for the relative unaffordability of medicines. This analysis, drawing on empirical studies, will clear the ground for the subsequent argument of using a rights-based solution to remedy this problem. The passage of the 1970 Act brought about a seismic shift in Indian patent law.[6] In a decisive break from the past, India decided that patent protection would no longer be available for, inter alia, medicinal products per se. This brought about a radical shift in the make-up of the Indian pharmaceutical market and drug prices. The absence of PPPs created a facilitative environment for the generic industry in India to flourish. By 2004, the generic industry had assumed control over 77% of the Indian pharmaceutical market, as compared to 23% control by multinational companies ('MNCs').[7] As I shall demonstrate below, the introduction of PPPs in 2005 fundamentally changed this position.

### 1.1 Impact of the introduction of PPPs on the affordability of medicines

After India became a party to the Agreement on Trade-Related Aspects of Intellectual Property Rights ('TRIPS Agreement'), it was required to undertake large-scale reforms to its patent system, to make it TRIPS compliant. This was achieved through a series of three amendments

[6] For a general overview of the Act and the circumstances surrounding its passage, see S.S. Joshi,, J. V. Rajan and S. K. Subramanian, 'The Indian patent system and indigenous R&D' [1974] 3.3 Research Policy 292.

[7] *Novartis AG* v *Union of India and Ors*., AIR 2013 SC 1311 (Indian Supreme Court) [48].

to the 1970 Act, in 1999, 2002 and 2005.[8] The most crucial and relevant amendment was enacted in 2005, allowing for the grant of PPPs. [9] At the time of its enactment, the Amendment was seen by health activists as having the potential to reverse the hard-won gains made by India in fostering greater access to medicines ('A2M'). [10]

The impact of this move is contested. Duggan and colleagues argue that the introduction of product patents only led to a rise in prices by 5%.[11] However, an emerging body of empirical evidence unmistakably vindicates the prescience of the Amendment's critics. Most notably, Chaudhuri assesses the impact that the expiry of the patent term had on

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[8] The 1999 amendment retroactively implemented the mailbox procedure for patent applications relating to medicinal and agrochemical products and allowed for the grant of exclusive marketing rights. For a description of these procedures, see Janice M. Mueller, 'The Tiger Awakens: the Tumultuous Transformation of India's Patent System and the Rise of Innovation' [2007] University of Pittsburgh Law review 491, 521. The 2002 amendment extended the term of patent protection to 20 years. It also helped operationalize India's entry into the regimes created by the 1883 Parris Convention and the Patent Cooperation Treaty. ibid 526-528.

[9] The Patents (Amendment) Act, 2005 (India), § 4 (providing that 'Section 5 of the principal Act shall be omitted']; The 1970 Act,(India), § 5(1)(a) [providing that no patent would be granted on claims directed to 'substances intended for use, or capable of being used, as food or as medicine or drug'].

For a background to this amendment, see Patents (Amendment) Act, 2005 (India) – Statement of Objects and Reasons, [noting:

'Any slippage in meeting the January 01, 2005 deadline had the potential of inviting retaliatory action under the WTO disputes mechanism... India had no legal basis to defend its default on the deadline'.]

Notably, the constitutionality of this amendment was upheld in the case of *Jeevan Jyoti Health & Welfare Society v Union of India and Ors*, (2008) ILR 1 Delhi 1088. (Delhi High Court, India). This was attributable to the petitioner's failure to empirically establish that the amendment would translate into drug unaffordability and the existence of PLVs which could serve as a corrective - see [9].

[10] Mueller (n4), 542–543.

See also Editorial, 'India's Choice' NYTimes (New York, 18th January 2005) A20, [noting that the Amendment constituted 'a double hit—cutting off the supply of affordable medicines and removing the generic competition that drives down the cost of brand-name drugs'.]

[11] M. Duggan, C. Garthwaite and A. Goyal 'The Market Impacts of Pharmaceutical Product Patents in Developing Countries: Evidence from India' (2006) American Economic Review 99, 102-103.

the price of the concerned drugs. Three drugs in his study met this criterion. Post-patent term expiry, the most dramatic fall in price was seen in a drug called Cabazitexal whose price fell by 94%.[12] A second drug, Luliconazole, witnessed a 33% decline, and the expiry of the patent term translated into 39 other sellers entering the market. [13] A third drug called Micafungin showed the least meaningful impact, in that its price only fell by 9%. [14]

Second, Chaudhuri maps the prices of 135 molecules: molecules for which patents were granted [26], those for which patents were not granted [43] and those for which they were rejected [66].[15] His study shows that the prices of drugs made from patented molecules were quite high. For instance, the price of Cetuximab was Rs 1,01,110 and that of Ixabepilone was Rs 71,175.[16] The proportion of products that were priced highly was higher in the patented molecules category, relative to the category of rejected patents. Similarly, when it comes to the comparison between patented and non-patented products, the former were priced higher, even though the gap was relatively narrower.[17] This evidences the manner in which the grant

[12] Sudip Chaudhuri, 'Impact of Product Patents on Pharmaceutical Market Structure and Prices in India' (2018), IIM Calcutta Working Paper Series, Working Paper 813, 14. <https://www.researchgate.net/publication/327790894_Impact_of_Product_Patents_on_Pharmaceutical_Market_Structure_and_Prices_in_India> accessed 13 July 2020.

[13] ibid 14.

[14] ibid.

See also F. Abbott, *'Indian Policies to Promote Local Production of Pharmaceutical Products and Protect Public Health'*, (2017), World Health Organization, 23 [noting that the Indian generic industry witnessed significant growth in the absence of PPPs and that their reintroduction in 2005 has fundamentally altered the position].

[15] Chaudhuri (n12) 3.

[16] ibid 15.

[17] ibid.

of product patents translates into high drug prices. This evidence underscores the need to find constructive ways of remedying this problem – the mandate of this project.

Further, an econometric study found that the introduction of PPPs translated into a 260% hike in the prices of patented drugs.[18] A 2019 inter-ministerial panel report further cites examples of highly priced patented drugs in different categories. For instance, the price of a 50MG capsule of Sunitinib, sold by Pfizer, was Rs. 8715. A 50 MG tablet has to be taken once daily over a 4-week period for treating gastrointestinal stromal tumor (GIST) and advanced renal cell carcinoma (RCC).[19] This works out to Rs. 2,44,020, more than twentyfold India's monthly per capita income for that time period.[20] On this basis, the report concludes that there is a need to bring in some form of price regulation of these highly priced drugs.[21]

Finally, a key contribution that this project makes is to argue for the development of a mechanism to monitor the impact of patents on A2M. This can be done by strengthening the form 27 process [discussed in chapter three]. The data obtained through such filings can feed

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[18] Pradeep Guin and others, 'Effects of New Patents Regime on Consumers and Producers of Drugs/Medicines in India, Revised Report Submitted to the UNCTAD' (Institute of Economic Growth, University of Delhi 2010), 16 <http://wtocentre.iift.ac.in/UNCTAD/09.pdf> accessed 18 July 2020.

[19] rxlist.com, 'SUTENT' (rxlist.com, 17 May 2019) <https://www.rxlist.com/sutent-drug.htm> accessed 18 July 2020.

[20] 'India's per-capita income rises 6.8% to Rs 11,254 a month in FY20', (Business Today, 7 January, 2020), <https://www.businesstoday.in/current/economy-politics/india-per-capita-income-rises-68-to-rs-11254-a-month-in-fy20/story/393333.html> accessed 13 July 2020.

[21] 'Report of The Interministerial Committee on Price Regulation of Patented Medicines in India' (Inter-Ministerial Committee Department of Pharmaceuticals (Ministry of Chemicals and Fertilisers) 2019) 11.

See also Pronab Sen, 'Report of the Task Force Set up by the Department of Pharmaceuticals to Explore Options Other than Price Control for Achieving the Objectives of Making Available Life-Saving Drugs at Reasonable Price' (Department of Pharmaceuticals 2005). [It Noted That All Drugs and Formulations Should Either Be Subjected to Price Negotiations on an Ex-Ante Basis or to Price Controls and compulsory licenses on an Ex-Post Basis].

into a government mechanism to map the affordability of patented drugs, also discussed in chapter three. As a result, any exercise to determine the precise scope of the problem is, absent a robust data-gathering mechanism, by definition, limited.

## 1.2 Role of the patent barrier

To be sure, patents are only one of the many factors that make medicines unaffordable in India. Research indicates the role that other barriers have played in the unaffordability and unavailability of medicines.[22] Illustratively, the inadequate availability of essential medicines in the public health system in India is well documented.[23] Further, the share of healthcare in India's gross domestic product is 1.28% and has not gone up, notwithstanding government undertakings to the contrary.[24] This, inter alia, is one of the reasons why 43.12% of the out of pocket expenditure PER CAPITA is on pharmacies.[25]

The above problems are doubtless important and require appropriate interventions. However, for the purpose of this project, I am distinguishing between unavailability (for

[22] See generally, Frederick M. Abbott and Graham Dukes, The Challenges We Face in Graham Dukes and Frederick Abbott (eds), *Global Pharmaceutical Policy: Ensuring Medicines for Tomorrow's World* (Edward Elgar Publishing 2009) 15.

[23] A Kotwani, 'Commentary: will generic drug stores improve access to essential medicines for the poor in India?' [2010] 31(2) J Public Health Policy 178; AC Roy , ' Logistics and supply management system of drugs at different levels in Darbhanga District of Bihar' [2009] 53(3) Indian J Public Health 147; U Isalkar, ' Basic medicines unavailable in several state PHCs' (The Times of India, 20 February 2013) <http://timesofindia.indiatimes.com/city/pune/Basic-medicines-unavailable-in-several-state-PHCs/articleshow/18584049.cms> accessed 13 July 2020.

[24] 'Twelfth Five Year Plan (2012–2017) Volume III' (Planning Commission Government of India 2013) 12,18.

[25] Prachi Singh, Shamika Ravi and David Dam, 'Medicines in India: Accessibility, Affordability and Quality' (Brookings India 2020) 50.

example, due to poor public health infrastructure) and unaffordability (which links to the prices that can be charged when property rights grant exclusivity). The focus of this project is only on the latter. As Helfer and Austin point out, there are many impediments to accessing drugs in developing countries and determining where patents rank on that list of impediments has been hotly contested. As they suggest, one way to address this problem is to focus on addressing the patent barrier, rather than getting bogged down by debates about its scale. While this will not be a perfect solution to the problem of unaffordability, it will nonetheless meaningfully facilitate affordable access to drugs to impoverished populations.[26]

## Part 2: Why patent-based levers?

In this section, I justify why the focus of my project is on PLVs and not other remedies to address unaffordable drug pricing. Such other remedies include price control ('PC') measures, competition law and health insurance schemes.[27] Nonetheless, I focus on PLVs, for the reasons below. The alternative options I consider are PC measures and competition law. Demonstrating that PLVs are the best solution is a critical step in my broader argument of establishing that this is the solution that the government's obligation to ensure affordable access to patented drugs requires it to reach for.

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[26] Laurence R. Helfer and Graeme Austin, *Human Rights and Intellectual Property: Mapping the Global Interface* (Cambridge University Press 2011) 142-143.

[27] Ellen 't Hoen and Kaitlin Mara, 'Ensuring that Essential Medicines are also Affordable Medicines: Challenges and Options' (2016) Unitaid Discussion Paper, 29-31, 35 <https://medicineslawandpolicy.org/wp-content/uploads/2017/09/Ensuring_that_essential_medicines_are_also_affordable_medicines_challenges_and_options.pdf> accessed 13 July, 2020 [articulating the list of options to ensure affordable pricing as including, inter alia, price negotiation, trips flexibilities, voluntary licenses and Sustainable supply of low-cost generic essential medicines].

## 2.1 PLVs versus PC measures

The PC regime in India is administered under the Drug Price Control Order of 2013, and its legislative origins can be traced back to the Essential Commodities Act of 1955. In 2019, the Central Government ('CG') prized out of this regulatory regime new patented drugs and drugs created through a patented process.[28] This exclusion has been challenged in the Delhi High Court, in pending litigation. [29] Further, PC measures do not address the high degree of insulation from competition and regulation that is conferred by virtue of a patent, which legitimizes high pricing.

## 2.2 PLVs versus competition law measures

I next turn to competition law, to argue that it is not viable. A leading example to support the use of competition law to curb high pharmaceutical pricing is the South African Competition Commission's case of Hazel Tau. This was a case brought by eleven plaintiffs against GlaxoSmithKline ('GSK') and Boehringer Ingelheim ('BI') on the premise that they were unlawfully fixing excessive prices for antiretroviral medicines.[30] The chief claimant, Hazel Tau, argued that, while the total cost of the ARVs was R1000 per month, she could only afford

[28] Drugs (Prices Control) Amendment Order 2019, sr and o. 2019/39(e) (India), para 2(ii)a.

[29] Sanya Talwar, 'Delhi HC Issues Notice On Plea Challenging Exemption Of New-Patented Drugs From Price Control' (Live Law, 7 February 2020) <https://www.livelaw.in/news-updates/delhi-high-court-issues-notice-in-a-petition-challenging-exemption-of-new-patented-drugs-from-price-control-152449> accessed 13 July 2020.

[30] *Hazel Tau et al. v GlaxoSmithKline, Boehringer Ingelheim, et al.* & *Aids Healthcare Foundation et al* v *GlaxoSmithKline, Boehringer Ingelheim, et al.* Case Numbers: 2002sep226 & 2002jan357 (South African Competition Commission).

R400 per month.[31] The matter was eventually settled. [32] This example might make competition law appear as a good solution to the problem of PBU. However, for the following two reasons, it is not so.

First, as a matter of positive law, India's competition law allows patentees to 'impose reasonable conditions, as may be necessary for protecting any of his rights'. [33] This provides patentees a degree of insulation from competition law scrutiny. By a proposed amendment, the scope of this insulation is sought to be widened. It was thus far only applicable to anticompetitive agreements.[34] It is now sought to be added to the analysis for abuse of dominance.[35] As was noted by India in its submission to the Organization for Economic Co-operation and Development, 'CCI has adopted a very cautious approach while dealing with

[31] Edwin Cameron, *Witness to AIDS* (Tafelberg/NB 2005) 180.

[32] ibid 166.

[33] Competition Act, 2002 (India), Section 3[5][I].

[34] These are agreements which cause or are likely to cause an appreciable adverse effect on competition within India. ibid, section 3(1).

[35] The term 'abuse of dominance' refers to a dominant undertaking engaging in any of the activities proscribed by Section 4[2] of the Competition Act, 2002.

Competition Law Review Committee, 'Report of the Competition Law Review Committee 2018' (Ministry of Corporate Affairs 2019) 144.

See also Draft Competition (Amendment) Bill, 2020 (India), clause 5: 'Nothing contained in section 3 or section 4 shall restrict the right of any person to restrain any infringement of, or to impose reasonable conditions, as may be necessary for protecting any of his rights which have been or may be conferred under: (b) the Patents Act, 1970 (39 of 1970)'.

cases where IP issues were involved, so as not to chill dynamic incentives of firms to innovate'.[36] This makes competition law a less appealing pathway to curb high patent pricing.

Second, as a conceptual matter, the use of competition law would be inapposite here. As Robin Feldman points out, the two fields use concepts with similar terminology 'but with differing meanings, contexts, and implications'.[37] The conceptual difference between these two bodies of law also stems from the fact that they are grounded in different economic rationales. While the economic justifications for IP law can be located in utilitarian and cost-benefit analyses[38], the economic justification for antitrust law is rooted in the need to correct market imperfections.[39]

## 2.3 PLVs – the legislatively chosen solution

More fundamentally, the PLVs forming the subject matter of this project were statutorily engrafted by Parliament in the 1970 Act, premised on the clear recognition that they had to be used as a corrective against unaffordable drug pricing. Differently stated, this was Parliament's answer to the question of what should be done when the grant/exercise of a patent is found to undermine public health. Their role and relevance in this context is also evident from the fact

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[36] 'Licensing of IP Rights and Competition Law – Note by India' (Organisation for Economic Co-operation and Development 2019) 9.

[37] Robin Feldman, 'Patent and Antitrust: Differing Shades of Meaning' [2008] 13(2) Virginia Journal of Law and Technology 1, 20.

[38] See RA Posner, *The Economic Structure of Intellectual Property Law* (HUP 2003).

[39] Shouvik Guha, 'The economic and jurisprudential underpinnings of the interface between intellectual property and antitrust: drifting closer or further apart?' [2015] 57(3) Journal of the Indian Law Institute 401, 402.

that they were frequently cited in the debate that took place in Parliament on the 2005 Amendment.

Specifically, Pavan Bansal, a government representative, noted that measures like compulsory licenses ('CLs') and the government's power to acquire patents could be used as a corrective against rise in medicinal pricing.[40]

An example of the efficacy of PLVs vis-a-vis other available avenues is illustratively helpful. An oral dosage for Valganciclovir (four-month therapy) – a drug used for patients with AIDS to prevent blindness – used to cost USD 10,000. After price negotiation, it was brought down to USD 1899 which is still very unaffordable. The grant of a CL, on the other hand, would have translated into the emergence of multiple suppliers for the drug, thereby creating the conditions for its price to meaningfully decrease. [41]

I will now turn to assess how far these PLVs have actually been deployed in India, with a view to diagnosing the reasons for their under-utilization. This will then feed into the prescriptions to be proposed in the third chapter.

[40] Lok Sabha debate, Discussion On Statutory Resolution Regarding Disapproval Of (Amendment) Ordinance & Patents (Amendment) Bill, 2005 (21 March, 2005).

[41] Médecins sans frontières, 'Price control and patented drugs' (Website of National Pharmaceutical Pricing Authority, Ministry of Chemicals & Fertilizers, Government of India, 12 April 2008) <http://www.nppaindia.nic.in/wp-content/uploads/2018/10/Price-control-and-patented-drugs.pdf> accessed 13 July 2020.

## Part 3: Exploring the reasons for the under-utilization of PLVs

In this segment, I will outline two of the main reasons to explain the underutilization of these PLVs: fear of retaliation, translating into the absence of political will; and lack of independence of the CGPat.

### 3.1 Fear of retaliation

When India allowed for the grant of PPPs, capturing a commonly held hope and sentiment at the time, Basheer argued that Indian Patent Law contained enough safeguards to ensure that the negative impacts of this development would be appropriately offset.[42] Similarly, Mueller argued that safety valves such as CLs and PC measures could be used to ensure affordable A2M.[43] However, these PLVs have thus far just remained on paper.

Kapczynski ascribes this implementation gap to three factors – resource constraints, the existing transnational legal culture and threat of unilateral retaliation.[44] On the third factor, she points out how this threat emanates principally from the US, which has a special procedure in place to 'take to task' countries which, in its assessment, do not provide adequate and effective IP protection. More concretely, under the U.S. Trade Representative ('USTR')'s 301 procedure, the Office of the USTR can identify a list of priority countries i.e. countries which

[42] Shamnad Basheer, 'INDIA'S TRYST WITH TRIPS: THE PATENTS (AMENDMENT) ACT, 2005' [2005] 1 Indian Journal of Law and Technology 15.

[43] Mueller (n8) 544.

[44] Amy Kapczynski, 'Harmonization and its Discontents: A Case Study of TRIPS Implementation in India's Pharmaceutical Sector' [2009] 97(1) California Law Review 1571, 1617.

adopt ‘the most onerous or egregious acts, policies, or practices’ that deny ‘adequate and effective intellectual property rights,’ or ‘deny fair and equitable market access to United States persons that rely upon intellectual property protection’.[45] As she points out, there is a widespread belief that this threat of retaliation means that India may feel disenabled from using PLVs.[46]

Jain and Darrow interviewed several stakeholders, such as NGOs, academics and policymakers, to determine the extent to which this was seen as a genuine threat. Research participants acknowledged that the U.S. threatens developing countries with repercussions through the 301 process.[47] They therefore opined that the CG might lack the will to issue CLs, especially given the response that Thailand faced when it decided to use the CL lever freely.[48] This response was in the shape of Thailand’s elevation to the priority watch list in the USTR’s report[49] and withdrawal of duty-free access on three Thai products.[50]

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[45] ibid 1628.

see also S Sharma, ‘A Survey of Intellectual Property Issues Between the United States and India under the Special 301 Report’ (2018) 44 NCJ Int’l L 1.

[46] Kapczynski (n44) 1630.

[47] Dipika Jain and Jonathan Darrow, 'An exploration of compulsory licensing as an effective policy tool for antiretroviral drugs in India' [2013] 23(2) Journal of Law- Medicine 425, 449.

[48] ibid 453.

[49] ‘2007 Special 301 Report’ (Office of the United States Trade Representative 2007) 27.

[50] Suwit Wibulpolprasert and others, ‘Government Use Licenses in Thailand: The Power of Evidence, Civil Movement and Political Leadership’ [2011] Globalization and Health 7(32) 1,2.

## 3.2 Concerns about the CGPat's independence

I next turn to examine concerns about the CGPat's independence, demonstrated aptly by the following example. In 2016, the CG reportedly made a private assurance to the U.S India Business Council that it would not invoke CLs, other than for noncommercial purposes.[51] The subsequent denial by the CG was half-hearted.[52] The fact that the CG was able to arrogate to itself the power to adopt a blanket position on a matter within the CGPat's statutory discretion underscores the tenuous basis on which the CGPat's independence rests.

All of this throws into sharp relief the need to develop a clear pathway to address the problems described above, so as to make these PLVs come alive. It is here that the right to health ('RtH') can serve as a prompt for course-correction.

# Conclusion

This chapter has established that patents are a key cause to which the unaffordability of medicines in India can be ascribed. It has also been demonstrated how the use of PLVs,

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[51] '2016 Special 301 Submission' (United States Chamber of Commerce's Global Intellectual Property Center 2016) 94 :'While the Government of India has privately reassured Industry that it would not use Compulsory Licenses for commercial purposes, a public commitment to forego using compulsory licensing for commercial purposes would enhance legal certainty for innovative industries'.

[52] The clarification did not even make an explicit mention of the submission referenced in the previous footnote.

See also Press release, NHRC takes serious view of India restraining production of cheaper versions of generic medicines, as reported in media; calls for reports from Union Ministries (National Human Rights Commission, 1 April, 2016) <http://nhrc.nic.in/dispArchive.asp?fno=238936> accessed 15 July 2020.

amongst the available alternatives, would be the most appropriate way to remedy this problem. The chapter also accounts for why these PLVs have thus far not been operationalised in India.

# CHAPTER 2

## Introduction

In the last chapter, it was established that patents significantly contribute to the unaffordability of medicines in India. It was also demonstrated that the use of PLVs offers the most promising solution to remedy this problem. In this chapter, I will outline the theoretical framework for my argument. To recapitulate, my central argument is that the RtH can serve as a prompt for the operationalization of the PLVs to be spelt out in the next chapter, through judicial intervention.

My normative proposal entails the use of HR law to trigger a change in the working of the IP system. Therefore, I will begin by tracing the academic debate on the relationship between IP and HR law. I will, in particular, analyze two highly influential framings that have clearly emerged in academic literature and contend that neither of these framings provides strong theoretical grounding for the argument I will subsequently develop. I will argue that we should view IP law as being the means by which to attain HR ends.[1] More fundamentally, I will ground my argument in the unique institutional disposition of Indian patent law. In the second part of the chapter, I will flesh out the understanding of the RtH in Indian constitutional law, to contextualize the discussion to follow.

[1] Laurence Helfer, 'Toward a Human Rights Framework for Intellectual Property' [2006] 40 UC Davis L Rev 971, 1018-1020.

# 1. From strangers to fellow travelers: mapping the IP and HR relationship

This segment will proceed as follows. First, I will briefly describe the initial period of non-engagement between IP and HR law. I will then examine their increasing interaction, through the prism of two influential framings. Thereafter, I will draw on the framing that provides the greatest support for my argument. I will then make the case for the need to view this relationship through an institutional lens. I will finally respond to arguments by those who are not sanguine about the project of fostering a linkage between IP and HR law as well as respond to the possibility of a clash of HRs.

## 1.1 Initial non-engagement

At the time of the emergence of IP and HR law, each legal regime addressed a distinct set of questions. The focus of IP law was on expanding the scope and ambit of IP subject matter and rights and on developing a linkage between IP and trade.[2] While the three foundational IP conventions – Berne, Paris and TRIPS – couch the entitlements of authors and inventors in the language of rights, this is rooted in instrumental, as opposed to deontological, considerations.[3] HR law was not seen as having anything meaningful to contribute to this enterprise, either by supporting the grant of IP monopolies or by serving as a check against the expansion of IP.[4]

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[2] Laurence Helfer, 'Human rights and intellectual property: Conflict or coexistence' [2003] 5(I) Minn Intell Prop Rev 47, 51.

[3] ibid 50.

[4] ibid. Also see Agreement on Trade-Related Aspects of Intellectual Property Rights (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 299 (TRIPS Agreement).

See also Audrey Chapman 'A human rights perspective on intellectual property, scientific progress, and access to the benefits of science' (2016) WIPO/OHCHR, 129.

On the other hand, the focus of HR law was on the codification of norms that could protect the new global order sought to be created after the Second World War, in light of the lessons emerging from the war.[5]Therefore, 'historically, there was very little formal interaction between IP and human rights law'.[6] What was true generally of the relationship between IP law and HR law was also true specifically of the relationship between patent law and the RtH.[7]

## 1.2 Emerging engagement

Eventually, a cross-regime engagement began to emerge in the mid-1990s. Two prominent schools of thought to study this engagement are clearly discernable. Under the first approach, IP and HR law were seen as being in conflict with each other.[8] To illustrate, in 2000, the report of the UN Sub-Commission on the Promotion and Protection of Human Rights was fundamentally premised on the idea that there exists a conflict between IP rights and HRs as a general matter. The resolution notes that the TRIPS agreement does not clearly recognize the fundamental nature and indivisibility of all HRs. Therefore, it states that 'there are apparent

<https://www.wipo.int/edocs/mdocs/tk/en/wipo_unhchr_ip_pnl_98/wipo_unhchr_ip_pnl_98_5.pdf> accessed 14 July 2020.

[5] Laurence Helfer, Human rights and intellectual property: Mapping an evolving and contested relationship. in Rochelle Dreyfuss and Justine Pila (eds), *Oxford Handbook of Intellectual Property Law* (OUP 2018) 118.

[6] Ruth Okediji, 'Does Intellectual Property Need Human Rights' [2018] 51(1) NYUJ Int'l L & Pol 1, 10.

[7] Laurence Helfer, Pharmaceutical patents and the human right to health: the contested evolution of the transnational legal order on access to medicines, in Terence Halliday and Gregory Shaffer (ed), *Transnational Legal Orders* (CUP 2015) 320.

[8] Helfer, Conflict or Coexistence (n2) 48.

conflicts between IP rights on the one hand, and international human rights law, on the other'.[9] It asserts the primacy of HR law over economic policies and agreements.[10] The Resolution does not offer a normative articulation of the reason why HRs have primacy over IP rights. However, this finds expression in general Comment ('GC') 17 of the Committee on the International Covenant on Economic, Social and Cultural Rights ('ICESCR') in 2005.[11] It notes that HRs are fundamental as they accrue to human beings by virtue of their humanity. IP rights, on the other hand, serve instrumental purposes, such as fostering creativity and inventiveness.[12]

The second approach proceeds on the presumption that these two bodies of law can coexist. It recognizes that the key question that they both seek to answer is delineating the amplitude of private monopoly power in a way that 'gives authors and inventors a sufficient incentive to create and innovate, while ensuring that the consuming public has adequate access to the fruits of their efforts'.[13] Under this approach, the IP and HR frameworks operate in harmony to arrive at the appropriate balance between these two goals of incentivizing creations while simultaneously promoting access to knowledge goods. HRs are seen as a mechanism

[9] UNCHR 'Sub-Commission on Human Rights resolution 2000/7' (17th August 2000) UN Doc E-CN_4-SUB_2-RES-2000-7 Sub-Commission Resolution [2].

[10] ibid [3].

[11] UN Economic and Social Council 'GC 17: the right of everyone to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he or she is the author (article 15, paragraph 1 (c), of the Covenant)' (January 2006) UN Doc E/C.12/GC/1712. GC 17.

[12] ibid [1]. However, the reasons for according normative primacy to HR law can vary. Illustratively, Christoph Geiger argues that they should serve as a corrective against IP abuse. See Christophe Geiger, 'Fundamental Rights, a Safeguard for the Coherence of Intellectual Property Law?' (2004) 35 International Review of Intellectual Property and Competition Law 268, 278.

[13] Helfer, Conflict or Coexistence (n2) 48.

which call for a recalibration of IP rights, to the extent that this is necessary to ensure their realization.[14] One can find support for this approach in the idea of patents being a social contract between the inventor and society. In lieu of making the invention public, inventors are allowed to enjoy patent rights over them. The (not-unproblematic) orthodoxy posits that this serves as an incentive for further innovation and benefits society. In this way, the DNA of IP and HR law makes it possible for the two to be partners in this shared project.[15] In its report, the UN High-Level Panel on A2M recognizes that access to drugs is an HR. Starting from this premise, it calls on states to use IP law in a way that helps realize appropriate HR outcomes, such as by setting HR-sensitive patentability standards.[16]

## 1.3 Treatment in the case law of the IP and HR relationship

The case law implicating this relationship is not susceptible to clean theoretical categorization. This is because it rarely offers a theoretical account of the approach that it is based on. That said, one can discern from the case law support for either of the above framings.

First, an example of the conflict approach. In Kenya, in 2012, the High Court had to rule on the constitutionality of the Kenyan Anti-Counterfeit Act.[17] The petitioners argued that

[14] ibid.

[15] Susy Frankel and Jessica Lai, 'Recognised and Appropriate Grounds for Compulsory Licences: Reclaiming Patent Law's Social Contract', *Compulsory Licensing* (Springer 2015) 15.

[16] 'Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines. Promoting Innovation and Access to Health Technologies' (United Nations Secretary-General, 2016) 4,5 (UN Report).

[17] P.A. Ochieng, M. Atieno, and J. Munyo v Attorney General, Petition No 409/2009 (Kenyan High Court).

the law did not exclude generic medicines from the definition of counterfeit medicines.[18] This could result, they argued, in the seizure of generic medicines, ultimately translating into a violation of the RtH of Kenyans.[19]

Agreeing with their argument, the Court reasoned as follows. It recognized the key object of the Act as being to 'protect the intellectual property rights of individuals'.[20] It framed the dispute as involving a conflict between two bodies of law notionally at war with each other: IP rights and the RtH. It stated:

'The right to life, dignity and health of the petitioners must take precedence over the IP rights of patent holders'.[21]

In another vein, some cases evince a judicial tendency to achieve harmonious reconciliation between HR and IP law and can therefore be characterized as evidencing the coexistence approach. These cases take into account HR considerations while interpreting the limitations and exceptions already found in IP law. To illustrate, in a 2008 case involving the grant of a preliminary injunction for a life-saving drug (Erloticip), the Delhi High Court took the RtH into account as a background right in its injunction analysis. It held that the grant of

[18] ibid [14].

[19] ibid [1].

[20] ibid [82].

[21] ibid [85].

This summary is drawn from Emmanuel Kolawole Oke, 'Incorporating a Right to Health Perspective into the Resolution of Patent Law Disputes' (2013) 15 Health and Human Rights 97, 103.

the injunction would result in stifling the right to life of those who would otherwise have access to the generic equivalent of Erloticip.[22] Therefore, it refused to grant an injunction.[23]

The Court here uses its discretionary power in a way that helps advance the RtH. By 'weav[ing] respect for the right to health into the preliminary injunction standard'[24], the court achieves a happy synthesis between IP and HR law.

In a trinity of judgments delivered in 2019, the Court of Justice of the European Union ('CJEU') had to determine what role HRs play in the interpretation of the exceptions to the rights of a copyright owner set forth in the Information Society Directive. The position that the court adopted in all three cases was as follows. It held that the legislative exceptions constituted a self-contained code.[25] The court envisaged fundamental rights ('FRs') being used as an interpretive device in the interpretation of these exceptions and limitations in the following terms. It held that FRs are operationalized, inter alia, through their role in influencing the manner in which national courts interpret the Directive. National courts must construe the

[22] *F. Hoffmann-La Roche Ltd. and Ors v. Cipla Limited*, 148 (2008) DLT 598 (Delhi High Court, India) [85].

*Affirmed* - *F. Hoffmann-LA Roche Ltd. and Ors v Cipla Ltd*., 159 (2009) DLT 243 (Delhi High Court, India) [80-82].

[24] Brennan and others (n 5 ch 1) 20.

[25] Case C-467/17 *Pelham GmbH and Others v Ralf Hütter and Florian Schneider-Esleben [*2019] [58];

Case C-516/17 *Spiegel Online GmbH v Volker Beck* [2019] [41] and

Case C-469/17 *Funke Medien NRW GmbH v Bundesrepublik Deutschland* [2019] [56].

Directive, the CJEU held, in consonance with its text, but also consistent with FRs in the Charter.[26]

The conflict and coexistence framings serve a valuable purpose. They throw open the possibility of the functioning of IP law being influenced by HR law. However, much like the conflict framing, the coexistence framing is limited in its scope. It can only help implement change within the existing IP system and therefore is constrained by the limits of the system. Whenever there are conflicts within the IP system, it calls for them to be resolved in a way that is pro-HR, to the extent the IP system allows. However, it does not countenance the possibility of more capacious and impactful interventions, by allowing the court to determine how best the IP system can be leveraged in ways that affirmatively promote HRs.[27]

## 1.4 Achieving HR ends through IP means

In this environment, a more effective way to obtain the desired outcomes, from the standpoint of this project, is the adoption of the approach of achieving HR ends through IP means.[28] This

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[26] ibid *Spiegel Online* [59]. This summary is drawn from Thom Snijders and Stijn van Deursen, 'The Road Not Taken – the CJEU Sheds Light on the Role of Fundamental Rights in the European Copyright Framework – a Case Note on the Pelham, Spiegel Online and Funke Medien Decisions' (2019) 50 IIC 1176, 1182-83.

[27] Helfer, mapping (n5) 130.

[28] Helfer does not propose this approach as an alternative to the conflict or coexistence framings. See Helfer, Towards (n 1) 1015, 1017. (proposing this approach as an alternative to:

A. Using HRs to Expand IP and

B. Using HRs to Impose External Limits on IP).

However, I am self-consciously suggesting it as an alternate framing because it is well-suited for my argument, for the reasons outlined.

approach would require, as the first step, the determination of outcomes that a given right requires, such as the RtH or right to education/ food and then using, inter alia, the IP system as a means to achieve those outcomes. To illustrate, in his 2001 report, the UN High Commissioner adopted this approach in the context of the RtH.[29]

He first identified the key outcomes that states are required to pursue. Drawing on the work of the ICESCR Committee, he drew on the tripartite structure of respecting, protecting and fulfilling rights. One clear outcome that is required by that structure is for states to ensure access to affordable treatments. [30] He then applied this in the context of treatment for AIDS and argued that states must address IP-based restrictions to such access, such as through parallel importation and generic substitution of patented drugs.[31]

The framing discussed above provides strong theoretical support for the approach that I will propose. This approach requires the determination of the outcomes required by the RtH in terms of fostering A2M and determining the role that IP law can play in enabling such access. This framing has a more capacious scope than the conflict and coexistence framings. This is because it examines how the IP system can be leveraged to advance HR ends, rather than giving primacy to HR law or trying to balance the two through existing mechanisms within IP law.

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[29] UNCHR 'Report of the High Commissioner on the Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights' (27 June, 2001) U.N. Doc. E/CN.4/Sub.2/2001/13

[30] ibid [32] and [34].

[31] ibid [46].

## 1.5 Need for an institutional approach

A more fundamental point needs to be made here. The above conceptual framings, and others that explore the IP and HR relationship, are acontextual. This is because they do not account for the institutional context in which disputes implicating IP and HR law are litigated. There is a difference between thinking about/conceptualizing the relationship between IP and HR law in the abstract and litigating a dispute implicating their relationship. The focus of this project is on the latter. Resultantly, it would be more helpful to ground the argument I will make in the unique 'facilitating circumstances and precipitating conditions'[32] that informed the formulation of modern Indian patent law. Being sensitive to these peculiarities can help us arrive at a uniquely Indian understanding of the IP and HR relationship. Such a contextual understanding is also likely to find greater purchase in an Indian court, as opposed to the acontextual conceptual framings discussed above.

In India, the existing patent law was constructed on the premise that it should serve that jurisdiction's unique needs and conditions, as a perusal of the Ayyangar Committee Report makes clear. This Report laid the groundwork for modern Indian patent law. It declared: 'Patent systems are not created in the interest of the inventor but in the interest of national economy'.[33] It went on:

'The precise provisions of the Patent law, however, have to be designed, with special reference to the economic conditions of the country, the state of its scientific and technological

[32] This phrasing is inspired from Helfer, Incorporating (n7) 312.

[33] Rajagopal Ayyangar, 'Report on the Revision of the Patents Law' (1959) 12 (Ayyangar).

advance, its future needs and other relevant factors and so as to minimise if not to eliminate the abuses to which a system of patent monopoly is capable of being put'.[34]

This makes it clear that a public-facing justification was the clear animating force that informed the determination of the extent to which patent protection should be granted.[35] It follows that, when the patent system operates in a way that does not serve the public interest, there is a need for a course-correction. This project will examine how this course correction can precisely take place, using the RtH as a prompt.

Further, on conducting a considered evaluation of the desirability of granting patents on pharmaceutical products, the Ayyangar Committee held that such patents should not be granted. Instead, patent protection should only be granted for the underlying process. It noted:

> 'The reason for this state of law [i.e. the laws excluding product claims on pharmaceuticals] is stated to be that the denial of product claims is necessary in order that such important articles of daily use as medicine or food which are vital to the health of the community should be made available to everyone at reasonable prices and that no monopoly should be granted in respect of such articles'.[36]

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[34] ibid 20.

[35] I am grateful to Professor Ruth Okediji, Professor of Law, Harvard Law School (conversation dated 5 February 2020) for suggesting this framing.

[36] Ayyangar (n 33) 39.

See also Indira Gandhi, former Prime Minister of India, at the World Health Assembly (May 6, 1981) (stating that '[m]y idea of a better ordered world is one in which medical discoveries would be free of patents and there would be no profiteering from life or death'), in BK Keayla, *Conquests by Patents. The TRIPS Agreement on Patents Laws: Impact on Pharmaceuticals and Health for All* (1998).

This excerpt shows that the need to ensure A2M was a general policy concern that informed the formulation of modern Indian patent law. In this project, I seek to offer a clear pathway for how that developmental/ policy concern can be transformed into a justiciable HR concern. Pertinently, the Ayyangar Report has been cited by Indian courts as a source of guidance, even in the post-TRIPS era.[37]

This analysis is also consistent with Emmanuel Oke's view that 'intellectual property rights [including patent rights] are instrumental rights that should serve those needs and interests which human rights discourse identifies as fundamental'.[38]

## 1.6 Response to the skeptics

Some scholars, however, are not sanguine about viewing patent law through an HR lens. Siva Thambisetty, for instance, argues that using HR law as a means to correct the deficiencies in patent law comes in the way of the latter being able to incorporate self-correcting mechanisms.[39] While she acknowledges the problem of PBU, she contends that this can be addressed by dealing with the epistemic weaknesses and instrumental reasoning of patent law.[40] She notes: 'The two systems of law are like oil and water; the argument that one should

[37] *Bayer Corporation v Union of India and Ors*., MIPR2013(2)97 (Intellectual Property Appellate Board, India) [20]; Novartis (n 7 ch 1) [36-38].

[38] Peter Drahos, 'Intellectual Property and Human Rights' [1999] 3 Intellectual Property Quarterly 349; Oke (n21) 100.

[39] Siva Thambisetty, 'Improving Access to Patented Medicines: Are Human Rights Getting in the Way?' (2018), LSE Legal Studies Working Paper No. 3/2018, 28 <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3130703> accessed 15 July 2020.

[40] ibid 5.

prevail over the other is intellectually incoherent'.[41] She argues that the RtH merely serves as a placeholder [that points to specific sites of injustice] in A2M debates which detracts us from the larger project of seeking more ambitious patent law reform. These reforms would be overhauling the fashion in which innovation in medicinal products is funded in the first place. In conclusion, therefore, she advocates for the need to make patent law reflexive and equip it to deal with the consequences that it produces.[42]

Thambisetty's concerns are well-founded. However, my point of departure from her argument is the following. Pursuing internal patent law reform and external HR-infused reform are not mutually incompatible. As Peter Yu points out, 'efforts to strengthen and refine the discourse on intellectual property and human rights do not always compete in a zero-sum manner with efforts to undertake reform in the intellectual property area'.[43]

She may be right in suggesting that resources spent on trying to usher in patent law reform through the HR route are resources that could instead be spent on seeking internal patent law reform. However, what she does not countenance is the possibility of patent law reformers and HR law advocates coordinating and working together. As I shall demonstrate subsequently, HR law can provide the nudge for reform which patent law can respond to.

Next, I turn to her claim that HR-oriented thinking thus far has only produced minimal success. She contends that, when compared with the resources invested on influencing IP

[41] ibid.

[42] ibid 29.

[43] Peter Yu, 'Intellectual Property and Human Rights 2.0' [2018] 53 U Rich L Rev 1375, 1442.

thinking through an HR lens, the results have been quite limited. This is a questionable assertion. As Brennan and colleagues document, the use of an RtH approach in patent law disputes, though not uniformly successful and progressing slowly thus far, nonetheless has been gaining momentum. They point out how judicial exposition of the IP and RtH relationship can not only counteract the impact of patents on medicinal access, but also provide a vocabulary to legitimize actions in other fora that deploy RtH based arguments over IP law. Similarly, such exposition can spur legislative and executive action. As an illustration, Brazil issued a CL over Efavirenz. In its notification issuing the CL, the Government rationalized its action by pointing to the 'fundamental human right to health'.[44] Helfer further points out that courts in a large array of countries, such as Argentina, Colombia, Costa Rica, Ecuador, Kenya and Peru have ordered Health Ministries to provide individualized access to patented medicines and to expand national health plans to widen such access., based on the use of the RtH. However, this has been done using the conflict framing, such that courts, while giving precedence to the RtH, have not thought about the consequences of their actions for distributive justice or the IP regime.[45] Therefore, the question is not if the RtH [or HR law] should influence patent law [or IP law]. It already is. The question is how this can be done in a tempered and nuanced fashion. The clear pathway for this that I shall outline in the next chapter can be a valuable response to this question.

[44] Brennan and others (n5 ch 1) 24.

[45] Helfer, mapping (n5) 137.

Third, a parallel can be drawn here with Helfer's insight about the consequences that a change in the IP disputes adjudication regime can produce.[46] In the context of this project, framing a dispute about the non-utilization of IP law levers in RtH-based terms can change the value system with which the court is working, the prioritization of values, and the arguments and evidence to be considered. In sum, my claim is that the RtH can prompt, rather than obstruct, patent law reform.

## 1.7 Clash of rights

The language of HRs, it could be argued, can be deployed by IP owners, just as it is deployed by those seeking answers to the problem of PBU.[47] The Indian Supreme Court ('SC'), for instance, has held that the rights enjoyed by a copyright owner are HRs.[48] As one illustration, patents are property, which is a protected interest under HR law. Space precludes a detailed consideration of this potential clash, but two responses are offered. First, in a case involving a clash between the RtH and the right to privacy, the Indian SC held that the balance had to be struck in a way that furthered public morality and the public interest.[49] Therefore, in the analysis that an Indian court will conduct when confronted with a clash of rights, if a clear

[46] See generally Laurence Helfer, 'Regime Shifting: The TRIPs Agreement and New Dynamics of International Intellectual Property Lawmaking ' [2004] 29 Yale L J Int'l L 1.

[47] Amy Kapczynski, 'The Right to Medicines in an Age of Neoliberalism' [2019] Humanity Journal 79, 95.

[48] *Entertainment Network (India) Ltd. and Ors. v Super Cassette Industries Ltd. and Ors*., 2009(3)ALT23(SC) (Indian SC) [82].

[49] *X v Hospital Z* AIR 1999 SC 495 (Indian SC) [43] . Subsequently partially reversed, but not on this point - see *X v Hospital Z* AIR 2003 SC 664 [Indian SC].

argument is made for why the public interest requires prioritizing the RtH of those demanding affordable access, in the fashion I do here, such a pushback can be persuasively countered.

Second, when evaluating a clash between HRs of natural persons and those of corporations, a court can be urged to attach greater solicitude to the former. Support can be drawn for this claim from the European Court of Human Rights' judgment in *Uj v Hungary*.[50] When evaluating the clash between the reputational interests of a natural person and a corporation, it held that the latter was merely a commercial interest and was devoid of the moral and dignitarian character possessed by the former.[51]

[50] App no. 23954/10 (ECHR, 19 July 2011).

[51] ibid [22].

# Part 2

In this segment, I will establish that there exists an FR to access medicines and that the state must take steps to secure such access. This will then form the basis to subsequently argue that the state must attenuate the barrier posed by patents to accessing medicines. In this regard, I will begin by pointing out, by way of background, how Art. 21 [embodying the right to life and personal liberty under the Indian Constitution] has been interpreted to include the RtH within its ambit.

## 2.1 Recognition of the RtH as an FR in India

The RtH is not a textually guaranteed FR in India. That said, Art. 47 of the Constitution reads, in pertinent part, as follows: 'The State shall regard [...] the improvement of public health as among its primary duties...' This provision is found in the chapter on Directive Principles of State Policy ('DPSPs'). These DPSPs are non-justiciable but nonetheless fundamental in the governance of the country. [52] One of the multiple functions that the DPSPS have served has been to act as a 'framework of values that structure and constrain the interpretation and construction of fundamental rights'.[53] They have helped infuse the dignitarian conception of Art. 21's guarantee of life with substantive content.[54]

[52] Constitution of India 1950, Article 37.

[53] Gautam Bhatia, Directive Principles of State Policy in Sujit Choudhry, Madhav Khosla, and Pratap Bhanu Mehta (ed), *The Oxford Handbook of the Indian Constitution* (Oxford University Press 2016) 644.

[54] ibid 658.

Consistent with this trend, the RtH has been read to be a part of Art. 21, influenced by Art. 47 and other DPSPS on health.[55] In *Bandhua Mukti Morcha v. Union of India*[56], the SC held that Art. 21 must draw its life breath from the DPSPS. And that: 'It must include protection of the health and strength of workers [-] men and women'.[57]

The recognition of the RtH as an FR initially took place in disputes concerning workers, but the SC has gone on to recognize it in more categorical terms. The case of *Devika Biswas v Union of India*[58] was concerned with the existence of unsanitary conditions in sterilization camps. The SC held, in general terms, that the RtH was an integral component of the right to life.[59]

## 2.2 Right to access medicines as part of the RtH under Art. 21

The proposition that the RtH under Art. 21 includes A2M finds its strongest endorsement in the case of *Mohd. Ahmed v. Union of India* decided by the Delhi High Court.[60] The case concerned a boy aged around 7 years with limited means who was suffering from gaucher disease. This is a rare genetic disorder characterized by the body's inability to process fats,

[55] These chiefly include Constitution of India 1950, Art. 39[e], calling on the state to ensure, inter alia, that the health and strength of workers, men and women, are not abused, and Article 41, calling on the state to make provisions for the sick.

[56] (1984) 3 SCC 161 (Indian SC).

[57] ibid [14].

[58] (2016) 10 SCC 726 (Indian SC)

[59] ibid [24].

[60] MANU/DE/0915/2014 (Delhi High Court, India).

resulting in their accumulation. [61] The court had to decide if that child was entitled to free medical treatment, especially considering that the disease had a good prognosis.[62]

This treatment was in the shape of enzyme replacement therapy which has to be administered on a monthly basis. It costs INR 6 lakh per month which was beyond the petitioner's economic capacity.[63] The Court ruled that everyone has the FR to access quality healthcare that is affordable, accessible and compassionate. [64]

On this basis, it pertinently observed: 'The State is under a legal obligation to ensure access to life saving drugs to patients. A reasonable and equitable access to life saving medicines is critical to promoting and protecting the right to health. This means that Government must at the bare minimum ensure that individuals have access to essential medicines even for rare diseases like enzyme replacement for Gaucher disease'. [underlined for emphasis].[65]

Crucially, not only does the judgment situate life-saving drugs within the ambit of the RtH under Art. 21, but it also recognizes the state's obligation to ensure access to such drugs.

[61] ibid [2].

[62] ibid [1].

[63] ibid [3].

[64] ibid [58].

[65] ibid [68].

However, it does not define what life-saving drugs are or how this assessment is to be made. This aspect will be developed in the next chapter.

Next, the SC has recognized, albeit as obiter, that access to life-saving drugs is part of the RtH and that the state must take steps to secure such access. In the 2018 case of *Union of India v. Mool Chand Khairati Ram Trust*[66], the SC had to rule on the constitutionality of a government policy which required hospitals constructed on cheaply procured government land to offer free treatment to the poor.

In upholding the policy, the court noted as follows:

'In the wake of globalisation, we are in a regime of Intellectual Property Rights. Even these rights have to give way to the human rights. It is an obligation of the Government to provide life-saving drugs to have nots at affordable prices so as to save their lives, which is part of Article 21 of the Constitution of India ...'[67]

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[66] AIR 2018 SC 5426 (Indian SC).

[67] ibid [52].

See also TNN, 'SC Forces Govt to Agree to Second-Line ART to All AIDS Patients' (Times of India, 2010) <https://timesofindia.indiatimes.com/india/SC-forces-govt-to-agree-to-second-line-ART-to-all-AIDS-patients/articleshow/7078375.cms>.https://timesofindia.indiatimes.com/india/SC-forces-govt-to-agree-to-second-line-ART-to-all-AIDS-patients/articleshow/7078375.cms> accessed 15 July, 2020.

Also see *Vincent Panikurlangara v. Union of India* (1987) 2 SCC 165 (Indian SC) [20] noting:

'The State's obligation to enforce production of qualitative drugs and elimination of the injurious ones from the market must take within its sweep an obligation to make useful drugs available at reasonable price so as to be within the common man's reach'.

Finally, in the case of *Jeevan Jyoti Health & Welfare Society v Union of India and Ors.*[68], the court assumed [admittedly without expressing a definitive view on the matter] that Art. 21 includes the right to access medicines at affordable prices. [69] Sellin concludes that the SC's capacious interpretation of the right to life and recognition of the centrality of health to a dignified life can be inferred to include an FR to access medicines, Especially life-saving, essential medicines. [70]

To conclude, all the above evidence, cumulatively viewed, indicates that the RtH includes access to life-saving medicines. What kinds of medicines meet this criterion, and what other medicines are covered by the RtH, is not clear from the case law. It is hoped that this project will help infuse some clarity in answering these questions. Since it is clear that every HR is subject to scope-defining limitations, the next question to be discussed is what those are as regards the RtH.

## 2.3 Justifications for limiting the RtH

In the next chapter, I will propose the grant of a deliberative remedy to address the problem of PBU. For such remedies to work, it is necessary to have in place a fixed, constitutionally sanctified, standard of review – currently lacking in India in the area of socioeconomic rights.

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[68] (2008)ILR 1 Delhi 1088, (Delhi High Court, India).

[69] ibid [8].

[70] Jennifer Sellin, 'Justiciablity of the Right to Health-Access to Medicines-The South African and Indian Experience' [2009] 2(1) Erasmus L Rev 445, 463.

[71] Therefore, all I can offer is my best reading of the standard of justification for limiting the RtH.

A good starting point for this discussion is the case of *Paschim Banga Khet Mazdoor Samity and Ors v. State of West Bengal and Ors.*[72] The case was brought by a worker who had fallen from a train and been denied treatment in seven government-run hospitals due to inadequate facilities or absence of beds. The SC recognized that the state is obligated to provide adequate medical facilities to all its people.[73] It issued a set of seven directions to prevent the recurrence of the incident.[74] Illustratively, it held:

- Adequate facilities must be made available in the primary healthcare centres to ensure grant of emergency relief.

- A centralised communication system must be set up to ensure that patients can be sent to hospitals in which beds are readily available.

None of the governments to the proceedings offered any counterarguments against the issuance of these directions. However, the SC drew one clear red line, in assessing any

[71] VG Shreeram, 'Coronavirus and the Constitution – XXV: Socio-Economic Rights and the Shifting Standards of Review' (Indian Constitutional Law and Philosophy, 9 May 2020) <https://indconlawphil.wordpress.com/2020/05/09/coronavirus-and-the-constitution-xxv-socio-economic-rights-and-the-shifting-standards-of-review-guest-post/?fbclid=IwAR31fQNKYmartHQDleY9RjImrZDRk5DIxN9NNqjNgi_mWhKptKZ7Pi9AiA0> accessed 15 July 2020.

[72] AIR 1996 SC 2426 (Indian SC).

[73] ibid [9].

[74] ibid [15].

counterarguments. It recognized that financial resources would be required to comply with this obligation. However, it held that, this being a constitutional obligation: 'Whatever is necessary for this purpose has to be done'.[75] The excerpted portion is vague and imprecise. For by expressing itself in such wide language, the court appears to suggest that no justification whatsoever for limiting the RtH will pass muster. However, since it only dealt explicitly with financial justifications, I suggest that those alone were made impermissible by the court.

In a key subsequent holding, the SC appeared to cabin the width of the above position. *State of Punjab v. Bagga* was concerned with a government policy as per which reimbursement for medical care could be obtained by government servants only if the conditions spelt out in the policy were complied with. [76] The government justified the conditional nature of the policy on the basis that its resources were limited and that the RtH was not absolute. [77] The Court acceded to its plea. It held that the grant of reimbursement on the rate and scale fixed by the government was proper. This was because the state had limited resources which the court had to be cognizant of. [78]

The seemingly conflicting holdings in the above two cases can be reconciled, I submit, by relying on the holding in *Mohd. Ahmed.* The *Mohd. Ahmed* court recognizes that financial constraints are a relevant factor in the justification analysis. It recognizes that it cannot direct that everyone be provided access to free medical care, for there isn't infrastructure or finances

[75] ibid [16].

[76] (1998) 4 SCC 117 (Indian SC) [4].

[77] ibid [7].

[78] ibid [26].

to make that happen.[79] However, it holds that access to life-saving drugs is part of the state's core and non-derogable obligation and must be provided to everyone, regardless of resource constraints.[80]

As I shall argue in the next chapter, interpreting the RtH as meaning an individual right to access life-saving drugs can have counter-productive consequences from a distributive justice standpoint. Therefore, I will argue that the court's analysis was flawed on this score. For the present, though, *Mohd. Ahmed* provides the most nuanced articulation of the standard of justification in Indian law for limiting the RtH.

The next question that now arises is determining if it is the state's obligation to facilitate A2M, and if it is, what the contours of the obligation are. In order to answer this question, one has to analyze the duties that the RtH imposes on the state. For this purpose, I propose to rely on the typology of duties cast on India under the RtH as a state party to the ICESCR.

## 2.4 Duties of the state under the RtH

This segment will serve 3 functions. First, it will delineate the duties that the ICESCR imposes on India to secure the effective enjoyment of the RtH. Second, it will analyze the bearing of this international commitment on Indian law. Third, it will demonstrate that the tripartite framework to be discussed below has received judicial support in India.

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[79] *Mohd. Ahmed* (n 60) [63].

[80] ibid [68].

### 2.4.1 Tripartite nature of obligations

By now, the formulation of every HR giving rise to a tripartite set of obligations on states is well settled. These are the duties to respect, protect and fulfill.[81] To explicate, the obligation to respect means that the state cannot, directly or indirectly, infringe the right at issue. Under the duty to protect, the state is obligated to ensure that third parties do not violate the concerned right. Under the duty to fulfill, the state is required to take a series of affirmative steps to ensure the effective enjoyment of the right. [82] The ICESCR Committee has also applied the formulation in the context of the RtH. [83]

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[81] The genesis of this formulation is commonly traced to Shue's formulation of every right, irrespective of its character, giving rise to 3 types of duties: the duty to avoid, duty to protect and duty to aid. Henry Shue, *Basic Rights: Subsistence, Affluence, and US Foreign Policy* (Princeton University Press 2020).

Also see A. Eide, 'The International Human Rights System', in A. Eide and others (eds), *Food as a Human Right* (United Nations University Press 1984).

Within the UN human rights system, this formulation was first articulated in the UN Sub-Commission on Prevention of Discrimination and Protection of Minorities, 'The right to adequate food as a human right' (15 August-9 September 1983) UN Doc E/CN.4/Sub.2/1983/25.

Judicial exposition of the formulation can be found in the case of *Social and Economic Rights Action Centre (SERAC)* v *Nigeria* (2001) Communication 155/96, (2001) AHRLR 60 67, 273-4 (African Commission for Human and Peoples' Rights).

[82] Sandra Fredman, *Comparative Human Rights Law* (Oxford University Press 2018) 66.

See also Michael Dennis and David Stewart, ' Justiciability of Economic, Social, and Cultural Rights: Should There Be an International Complaints Mechanism to Adjudicate the Rights to Food, Water, Housing, and Health?' [2004] 98(3) American Journal of International Law 462, 515.

[83] UN Economic and Social Council 'GC 14: The Right to the Highest Attainable Standard of Health (article 12)' (August 2000) UN Doc E/C.12/2000/4. GC 14 para 33.

India is a party to the ICESCR. Article 12 of the instrument embodies the right of everyone to enjoy the highest available standard of physical and mental health.

The Committee has pertinently held that the duty to protect requires states to ensure that privatization does not emerge as a barrier to healthcare being available and accessible.[84] The GC states, in pertinent part:

'This category [the category spelling out the content of the state's duty to protect] includes such omissions as the failure to regulate the activities of individuals, groups or corporations so as to prevent them from violating the right to health of others'.[85] As regulation of private actors is at the heart of this project, the above excerpt provides strong support for the types of interventions I will advocate for subsequently.[86] As Yamin argues, the duty to protect requires that states use competition law measures to prevent patentees from abusing their monopoly. [87] Applying this logic, the use of PLVs, in the manner I advocate, would serve the same goals as her proposal and would therefore be similarly obligated by the duty to protect. Further, Yamin also pertinently notes:

> 'In the event that private commercial pricing practices were shown to be probabilistically related to impaired or reduced access to medications, it would be reasonable to affirm that a failure to grant compulsory licenses or to adopt other protective measures would presumptively constitute a violation of the state's obligations to protect the right to health'.[88]

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[84] ibid [35].

[85] ibid [51].

[86] In this regard, see also statement by the then Chief Justice of India KG Balakrishnan: 'The "right to health" cannot be conceived of as a traditional right enforceable against the state. Instead, it has to be formulated and acknowledged as a positive right at a global level'. Justice K.G. Balakrishnan, 'National Seminar on the "Human Right to Health"' (Madhya Pradesh State Human Rights Commission 2008).

[87] Alicia Yamin, 'Not Just a Tragedy: Access to Medications as a Right under International Law' (2003) 21 B.U. Int'l L.J 325, 355-56.

[88] ibid 356.

As I have already established in the previous chapter that patents are a key cause for lack of access to A2M, a failure of the state to take concerted measures to address these problems would constitute a violation of the duty to protect.

The duty to fulfill also has particular relevance for my project. In this regard, the ICESCR Committee states: 'The obligation to fulfil (facilitate) requires States inter alia to take positive measures that enable and assist individuals and communities to enjoy the right to health. State parties are also obliged to fulfil (provide) a specific right contained in the Covenant when individuals or a group are unable, for reasons beyond their control, to realize that right themselves by the means at their disposal'. [underlined for emphasis]. [89] As a perusal of the emphasized text makes clear, state parties are required to mitigate the hardship of those who do not otherwise have access to healthcare. Applying that to our case, it is clear that state parties must take measures to address the problem of PBU in order to secure the effective enjoyment of the RtH of those who need access to patented drugs but are unable to access them because of the patent barrier.

Finally, as I shall discuss in the next chapter, the GC recognizes a core, non-derogable obligation of states to secure access to essential drugs, as defined by the World Health Organization ('WHO').[90]

[89] GC 14 [37].

[90] ibid [43(d)].

## 2.4.2 Domestication in Indian law

Art. 51 [c] of the Constitution of India obligates the State to 'foster respect for international law and treaty obligations in the dealings of organised peoples with one another'. Indian courts have striven to develop domestic rights and constitutional jurisprudence 'in lockstep with international law'.[91] The ICESCR is an international treaty which has not been specifically domesticated in India, through a Parliamentary enactment. Indian courts have sought to construe domestic law in conformity with commitments embodied in treaties of this nature. Illustratively, in *Peoples' Union for Civil Liberties v. Union of India,* it was held that Art. 21 includes the right to privacy, in light of two important international treaties embodying this right.[92]

Further, Indian courts consider soft law instruments [which GC 14 is] 'in the same expansive and catholic fashion [as] hard law'.[93] Illustratively, the SC, in ruling that transgenders constituted the third gender, inter alia, drew support from the Yogyakarta principles.[94]

Specifically as regards the tripartite framework in GC 14, in the *Mohd. Ahmed* case, the Court affirmed this framework.[95] It held that the right to life clause under the Indian

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[91] Lavanya Rajamani, International Law and the Constitutional Schema (n 53) 143, 156.

[92] (1997) 3 SCC 433 (Indian SC) [13].

Also see ibid 146.

[93] ibid Rajamani 152.

[94] (2014) 5 SCC 438 (Indian SC) [58]–[60].

[95] Mohd. Ahmed (n 60) [53].

Constitution has to be interpreted in conformity with the ICESCR to which India is a signatory.[96] This, inter alia, formed the basis for its holding about the government's obligation to provide life-saving medicines, mentioned earlier. Further, drawing on the tripartite framework in GC 14, in a concurring opinion, Justice Chandrachud of the Indian SC recognized that the RtH gives rise to the duty to respect, protect and fulfill.[97]

Cutting through the vast morass of case law and literature, the following is clear. There is a basis to contend that there is a manifest constitutional obligation on the state to facilitate A2M, at least of a life-saving character, pursuant to the RtH under Art. 21.[98]

## 2.5 Use of RtH to influence patent law thus far

Given that the next chapter will explore the use of the RtH to influence the working of PLVs, it would be instructive to anchor my contribution within the existing thinking of using the RtH to influence Indian patent law. Timothy Bazzle shows that the RtH has suffused India's post-TRIPS patent law jurisprudence.[99] He cites three examples to substantiate this point, only one of which is discussed here due to space constraints. This example is the Madras High Court's judgment in a case challenging the constitutionality of the prohibition of secondary patents.

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[96] ibid [55].

[97] *Navtej Singh Johar and Ors. v Union of India and Ors*., AIR 2018 SC 4321 (Indian SC) [421].

[98] See generally A Grover and B Citro, 'India: Access to Affordable Drugs and the Right to Health' (2011) 377 The Lancet 976.

[99] Timothy Bazzle, 'Pharmacy of the developing world: Reconciling intellectual property rights in India with the right to health: TRIPS, India's patent system and essential medicines' [2010] 42 Geo J Int'l L 785, 814.

Secondary patents are those where the focus of protection switches from the active ingredients to the dosage regime/production methods. In its holding, the High Court upheld the prohibition, *inter alia*, on the following basis. It recognized India's constitutional duty to provide good healthcare to its citizens and viewed the provision as furthering that aim.[100]

Further, the Mohd. Ahmed judgment also laid the groundwork for the development of the patent law and RtH relationship. It is unclear whether the treatment at issue in the case was patented. However, the court's invocation of the RtH as the basis to mandate access to the treatment implies that the Constitution matters, even when patents are the cause for inaccessibility.[101] This has laid the groundwork for limiting IP rights when they conflict with HRs. [102]

The above jurisprudential developments provide an entry point for deepening the patent law and RtH relationship, in the manner I will propose in the next chapter.

## Conclusion

In this chapter, I first analyzed the engagement between IP and HR law in the abstract, to contextualize the argument to follow. Then, I offered a concrete pathway for conceptualizing

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[100] *Novartis AG v Union of India*, 2007 AIR 24759 (Madras High Court, India) [119].

[101] Gautam Bhatia, ' Delhi High Court rules on Article 21 and Access to Medicines' (Indian Constitutional Law and Philosophy, 17 April, 2014) <http://indconlawphil.wordpress.com/2014/04/17/delhi-high-court-rules-on-article-21-and-access-to-medicine/> accessed 15 July 2020.

[102] Shamnad Basheer and others, 'Primer on Public Health and Intellectual Property Rights. Prepared for the WHO Country Office India' (2014) <https://spicyip.com/wp-content/uploads/2014/08/Final-Report.pdf> accessed 14 July 2020 3 (WHO Report).

their relationship in the Indian context. Having established the theoretical foundation for the project, my focus shifted to the task of studying India's RtH jurisprudence. I made the case that there exists a constitutional basis to require the state to facilitate access to patented medicines that are unaffordable. Finally, I analyzed the existing thinking on the relationship between patent law and the RtH in Indian case law. In the next chapter, I will flesh out the contours of my argument, as to how the RtH can be used as a prompt to facilitate the meaningful use of the chosen PLVs.

# CHAPTER 3

## Introduction

To recapitulate, we have seen that the RtH includes A2M and that the state is required to take steps to secure such access. In this chapter, we will see how this constitutional obligation can be deployed to operationalize the PLVs covered in this project ('selected PLVs'). In March 2020, the Delhi High Court was confronted with the case of an 18-month child suffering from gaucher, an inherited metabolic disorder affecting the body's ability to process lipids. Since the child's family could not afford the cost of the treatment of Rs. 3,50,000/- per month, and since their representations to the government had not yielded any results, they came to court. The court, in similar fashion to the *Mohd. Ahmed* case, asked the All India Institute of Medical Sciences to provide free treatment to the petitioner, with the financial consequences to be subsequently determined.[1]

A few days later, the SC was confronted with a plea that COVID 19 tests be made free in private labs for everyone, as opposed to the prevailing rate of Rs. 4500. At first, the Court acceded to this plea, holding that the reimbursement mechanism for this would be worked out later.[2] The decision spawned considerable backlash, with many arguing that the Court had failed to consider the practical feasibility or broader consequences of its decision.[3] Five days later, the court walked back on this determination. It made it mandatory for free testing to be

[1] *Alishba Khan* v *Union of India and Ors*. MANU/DE/0927/2020 (Delhi High Court, India) [5].

[2] *Shashank Deo Sudhi* v *Union Of India & Ors*., MANU/SC/0364/2020 (Indian SC) [8-9].

[3] Krishnadas Rajagopal, 'SC urged to modify order on free COVID-19 testing by private labs' (The Hindu, 11 April, 2020) < https://www.thehindu.com/news/national/coronavirus-supreme-court-urged-to-modify-order-on-free-covid-19-testing-by-private-labs/article31316430.ece> accessed 15 July 2020.

provided to people covered under an existing government scheme and any scheme to be subsequently notified.[4] It further encouraged, but did not mandate, the government to consider widening the reach of financial assistance, to workers in the informal sector, beneficiaries of cash transfer schemes, etc. [5] At the end of the path of judicial intervention in the RtH domain lies the need to balance competing tensions such as those brought to the fore by these two cases. Therefore, this chapter will seek to offer a roadmap for how such interventions can take place, within the framework of the existing IP law, in a tempered fashion.

I will begin by surveying the PLVs embodied in Indian patent law and focus on the selected PLVs. I will then examine the existing thinking on the tensions that need to be negotiated when considering judicial intervention to secure the enjoyment of the RtH. I will finally conclude by offering a roadmap for effective judicial intervention, in light of this analysis.

## Part 1: A discussion of the PLVs

There are broadly two sets of PLVs which seek to balance the grant of patents with the public interest. These PLVs are ex-ante [before the grant of a patent] and ex-post [those after its grant].[6] While my focus is on ex-post measures in this chapter, I will offer some prefatory remarks about the key ex-ante levers, as a reminder of the full range of levers that exist.

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[4] Shashank Deo Sudhi (n2) (13 April 2020) 5-6 (i).

[5] ibid 6 (II).

[6] WHO Report (n 102, ch2) 26.

## 1.1 Key ex-ante levers

These measures can be broadly classified into two types: patent exclusions and patentability criteria.[7] The term Patent exclusions refers to subject matter/inventions beyond the realm of patent protection. Illustratively, Section three of the 1970 Act excludes inventions which seek to artificially extend the temporal protection conferred by a patent, by making minor variations to the invention [i.e. secondary patents], alluded to in chapter two. [8] This is perhaps the most crucial and widely debated exclusion.[9] In the Novartis case, the SC held that the litmus test for ascertaining if an invention fell outside this prohibition was determining if it possessed enhanced efficacy which, in the context of medicines, meant enhanced therapeutic efficacy.[10]

The patentability criteria are in the shape of the requirements of novelty[11], inventive step[12] and industrial application[13] which every invention must meet for it to be patentable. These criteria have achieved a measure of success in ensuring A2M. To illustrate, in *Sankalp*

[7] ibid 18.

[8] 1970 Act, Section 3 (d).

[9] Shamnad Basheer, ' Trumping TRIPS: Indian patent proficiency and the evolution of an evergreening enigma' [2018] 18(1) Oxford University Commonwealth Law Journal 16; Shamnad Basheer and Prashant Reddy, ' The 'Efficacy' of Indian Patent Law: Ironing out the Creases in Section 3(d)' [2008] 5(2) Scripted 232.

[10] *Novartis* (n 7 ch 1) [180].

[11] 1970 Act, Section 2 (1) (l).

[12] ibid Section 2 (1) (ja).

[13] ibid Section 2 (1) (ac).

*Rehabilitation Trust v. Hoffmann-La Roche*[14] the Intellectual Property Appellate Board ('IPAB') invalidated Roche's patent on the Hepatitis C drug, Pegasys.[15]

## 1.2 Focus of the project

The focus of this project is on ex-post levers. While ex-ante levers can serve as a useful safety valve to prevent the monopolization of essential medicines, they have not been designed with the objective of serving as a corrective against exorbitantly priced medicines. Put differently, they are a useful tool to ensure that only inventions which legally meet the parameters for securing patent protection are actually conferred with that status but not to remedy the unaffordability of such inventions.[16]

Within the subset of ex-post measures, my focus is on measures that can be governmentally triggered. This is for two reasons. First, the set of PLVs which can be triggered by private parties, such as filing a petition for the revocation of a patent[17] are not amenable to the kind of analysis I am conducting here. Specifically, it is not legally or practically feasible for a court to nudge a private party to ensure the activation of these PLVs. Second, in HR law, the government is traditionally considered the duty-bearer for securing the effective enjoyment

[14] OA/8/2009/PT/CH (IPAB, India).

[15] ibid [44].

[16] Jain and Darrow (n47 ch1) 455.

[17] Section 85 empowers any person to file an application for the revocation of a patent, two years after a CL is granted for it, on specified grounds.

Section 64 enables the IPAB or the High Court to revoke a patent on any of the grounds spelt therein, on the filing of a revocation petition or a counterclaim respectively.

of an HR. [18]Consequently, PLVs triggerable by the government are more amenable to being the subject matter of the type of intervention I propose. Out of the available PLVs that meet this criterion, space precludes a consideration of the lever allowing the government to revoke patents in the public interest. [19] Therefore, my focus is on the remaining PLVs: public interest CLs and government use [these will be defined below]. Further, as an exception to the above, I will also focus on the CL lever concerned with the abuse of patent rights. This lever can be activated on an application being filed by a third party and is not unilaterally triggerable by the government. However, it is relevant here because it is joined at the hip with the CL public interest lever. This is for the reason that the efficacy of both these levers to ensure A2M can be enhanced through the implementation of the selfsame systemic reforms that I will propose, using the RtH as a prompt.

I will also discuss the form 27 procedure. While it is qualitatively different from the other PLVs to be discussed, it nonetheless merits consideration. For it represents the practical embodiment of my prescriptions, of judicial intervention to repair dysfunctional elements of the patent system.

[18] For instance, part three of the Indian Constitution, containing FRs, largely applies only against the state. Only three of its provisions are susceptible to application against private parties. For a critique of this approach in HR law, see Quinn Slobodian, ' Human Rights Against Dominium' (Humanity Journal, 4 October, 2019) <http://humanityjournal.org/blog/human-rights-against-dominium/> accessed 16 July 2020.

[19] 1970 Act, Section 66.

## Part 2: A discussion of the relevant ex-post PLVs

This segment will serve two functions. First, I will outline, by way of background, the key features of the selected PLVs. Second, I will then establish the fashion in which they have remained signally underutilized thus far. This will set the stage for the prescriptions to be proposed in the next part.

### 2.1 Compulsory Licenses

In this part, I will demonstrate that the CL regime has been viewed as a key pathway, in the post-independence period, to foster A2M. This underscores the need for it to be made operational. One of the most potent tools to counteract the high pricing of patented drugs is the issuance of a CL. A CL allows a party to access a patented drug at a governmentally determined price without the permission of the patent holder.[20] The raison d'etre for the issuance of such licenses is that the use of the invention in the public interest, in some instances, outweighs the need to preserve the patentee's monopoly and any negative consequences arising from the making of such an inroad into the same. [21]

[20] J Liu, ' Compulsory Licensing and Anti-Evergreening: interpreting the TRIPS flexibilities in sections 84 and 3 (d) of the Indian Patents Act' [2015] 56 Harv Int'l LJ 207, 213; Srividhya Ragavan, ' The Jekyll and Hyde Story of International Trade: The Supreme Court in PhRMA u Walsh and the TRIPS Agreement' [2004] 38 U RICH L REV 777, 782 'Compulsory licenses [are defined] as involuntary contract[s] between a willing buyer and an unwilling seller imposed and enforced by the state'.

[21] ibid Ragavan; Sarah Germano, 'Compulsory Licensing of Pharmaceuticals in Southeast Asia: Paving the Way for Greater Use of the TRIPS Flexibility in Low-and Middle-Income Countries' [2007] 76 UMKC L REV 273, 279-280.

Since India's priorities in the colonial period were different, our discussion starts in the post-independence period.[22] The first important development in this regard was the report of the Tek Chand Committee.[23] In its report, the Committee opined that CLs should be used as a mechanism to safeguard the public interest, in the areas of food and medicine.[24] Its suggestion found reflection in the 1950 amendment of the 1911 Act.

The next significant development was the Ayyangar Committee Report, adverted to in chapter two. The Ayyangar Committee, drawing on the Swan Committee in England, ascribed the inadequate use of the CL regime to four factors, chief amongst which were:

A. The possibility of CLs being granted, resulting in patentees entering into voluntary licenses to avoid CL grants; and

B. CL grants not resulting in the transfer of knowhow.[25]

Therefore, the Committee suggested that the CL regime be reformed. Its proposals found reflection in the 1970 Act, to be discussed below.

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[22] For an assessment of Indian patent law up to this period, see Mueller (n8 ch1) 504 [describing the three phases of Indian patent law i.e. colonial, post-independence and globalization and 504-510 describing the evolution of the law up to the post-independence period].

[24] Rajeev Dhavan, Lindsay Harris and Gopal Jain, 'Whose interest? Independent India's Patent Law and Policy' [1990] 32(1) Journal of Indian Law Institute 429, 433.

[25] Ayyangar (n33 ch2) 59.

### 2.1.1 CL regime under the 1970 Act

Chapter XVI of the 1970 Act envisages the grant of CLs. The two types of CL provisions relevant for the present relate to the abuse of patent rights under Section 84 and in the public interest under Section 92. A discussion of the first regime follows. This regime envisages the grant of CLs in three circumstances, on an application being filed to the CGPat after the expiry of three years from the patent grant. These are when the patented invention:

A. Does not meet the reasonable requirements of the public; or

B. Is not available at a reasonably affordable price; or

C. Has not been worked in India.

A meaningful indication of how these criteria are to be interpreted can be found from the Nexavar case discussed below.

The second statutory scheme envisages the grant of a CL in the public interest, absent the commission of any fault by the patentee. Section 92(1) spells out the 3 circumstances for such a grant: national emergency, extreme urgency and using the patented invention for a public non-commercial use. The CG has to issue a notification to trigger this provision.[26] On the issuance of such a notification, the CGPat shall grant a CL to any person interested filing a CL application. She is empowered to determine the terms of such a license, [27] but has to ensure that the patented invention is made available at the lowest price, while also enabling the

[26] 1970 Act, Section 92 (1).

[27] ibid Section 92(1)(i).

patentee to derive a reasonable advantage from the patent. [28] When the CL relates to HIV AIDS, TB, Malaria or other epidemics, the normal procedure to be followed for granting CLs[29] can be dispensed with.[30] The proviso to this clause states that in such circumstances, the CGPat is to inform the patentee of the grant of the CL 'as soon as is reasonably practicable'.

### 2.1.1.1 Section 84 route

Under the 1970 Act, a solitary CL has been issued thus far[31], involving Bayer's anticancer drug, Nexavar, contested up to the SC. The application was filed by Indian generic Natco, against Bayer's anticancer drug, nexavar. A substantive discussion of the interpretation of the three statutory criteria, spelt out above, follows.

On the first criterion, the CGPat recognized that there were 8842 patients with liver cancer in India. The CGPat reasoned that the Patentee would not have supplied the drug to

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[28] ibid Section 92(1)(ii).

[29] This procedure is set out in the 1970 Act, Section 87. It entails: [a] publication of CL application in the register and its dispatch to the patentee; [b] offering the patentee an opportunity to oppose the grant; and [c] conducting a hearing to make a determination on the objections raised.

[30] 1970 Act, Section 92(3).

This is in marked contrast to the assurance made by the Government in Parliament when the 2005 amendment to the Patents Act was passed. Mr. Kamal Nath, the Commerce and Industry Minister had stated:

'[O]ur compulsory licensing is very tight. With the alertness of our Members who are interacting with the people, in the event of any increase in prices, I think, the Government would have enormous ability to act on that'. Lok Sabha debate (n40 ch1).

See also

[31] Mueller (n8 ch1) 581:

'fewer than half a dozen compulsory licenses have been granted in the history of India's patent system'.

more than 200 patients in India in 2011. This amounted to less than 2% of the concerned patient population.[32] On the second criterion, the CGPat pertinently held that the reason why such a small portion of the public was able to access the drug was because of its price. This showed that it was not reasonably affordable. [33] On the third criterion, he held that a combined reading of the 1970 Act and the Paris and TRIPS Convention meant that working could not be satisfied by mere imports. He particularly relied on provisions in the 1970 Act supporting the proposition that working meant local working and not imports. [34]

The matter was then appealed in three fora. A brief description of these proceedings is provided here, in light of the fact that they shed light on all the obstacles and factors that need to be considered when evaluating a CL grant. First, Bayer filed an interlocutory application for the grant of an injunction which was rejected by the IPAB.[35] The CGPat's decision was appealed in the IPAB on procedural as well as substantive grounds. Procedurally, the IPAB rejected all of Bayer's arguments which are not being discussed here due to space constraints.

Substantively, the IPAB, in large part, upheld the CGPat's ruling. It held that the price at which Bayer was selling the drug was the sole determinant to assess its affordability, and the price clearly indicated that the drug was not reasonably affordable.[36] The IPAB disagreed with the CGPat on meeting the working requirement, in that the former held that it could be

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[32] *Natco Pharma Limited v Bayer Corporation*, CLA No 1 of 2011 (CGPat, India) 20.

[33] ibid 36.

[34] ibid 37.

[35] *Bayer Corporation v Union of India and Ors*., M.P.Nos.74 to 76 of 2012 & 108 of 2012 in OA/35/2012/PT/MUM (IPAB, India).

[36] *Bayer* (n 37 ch2) [45].

met by mere imports as well.[37] In the case at hand, however, it held that Bayer had failed to show why it had not manufactured the drug in India, despite having a manufacturing facility in India.[38] However, the IPAB did accept Bayer's plea for the enhancement of royalty and raised it from 6 to 7%. [39] The matter was then appealed to the Bombay High Court which dismissed Bayer's appeal. [40] Bayer then appealed the decision in the SC which rejected it at the threshold stage. [41]

This case is a vivid illustration of the manner in which the CL regime contained in Indian law can be practically operationalized. The reason why the above analysis is relevant for my project is this. The thoroughness with which each of Bayer's arguments were considered evidences the balanced nature of India's CL regime. The prescriptions that I am going to propose will not disturb this balance. This case study demonstrates that PLVs can be operationalized in a way that takes account of all arguments by a patentee against their operationalization.

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[37] ibid [51].

[38] ibid.

[39] ibid [53].

See also Madhavi Chopra, 'Of the Big Daddy, the Underdog, the Mother Hen, and the Scapegoats: Balancing Pharmaceutical Innovation and Access to Healthcare in the Enforcement of Compulsory Patent Licensing in India, Its Compliance with TRIPS, and Bayer v. Natco' (2015) 13 Santa Clara Journal of International Law 333, 364-365.

See also generally: Jodie Liu (n20) 210; Mansi Sood, 'NATCO Pharma Ltd v Bayer Corporation and the Compulsory Licensing Regime in India' [2013] 6 Nujs L Rev 99.

[40] *Bayer Corporation v Union of India*, AIR2014Bom178 (Bombay High Court, India).

[41] *Bayer Corp. v Union of India,* Petition for Special Leave to Appeal No 30145 / 2014 (Indian SC).

In two subsequent cases, applications for the grant of CLs filed by generic manufacturers were rejected. The first relates to BDR Pharmaceutical's application relating to Bristol Myers Squibb('BMS') anticancer drug, Dasatinib, used to treat patients with Chronic Myeloid Leukemia. The applicant undertook to sell a tablet of the drug for Rs. 135 each day, as opposed to the patentee's price of Rs. 2761.[42] The application was rejected. This was because the applicant had not complied with the statutorily prescribed procedural requirement of voluntarily negotiating with the patentee for six months before making the CL application.[43]

The second case involved an application being filed by Lee Pharma for the grant of a CL over Saxagliptin – a drug used to manage Type II Diabetes Mellitus. As opposed to the patentee's price of Rs. 42-52 per tablet, the applicant offered to sell it for Rs. 11-16 per tablet.[44] This application was also unsuccessful. The principal reason for the rejection was as follows. The CGPat held that there did not exist adequate authentic data, on the basis of which to establish that Saxagliptin, in particular, was unaffordable. He held as follows:

'In the absence of exact quantum of Saxagliptin required and the number of patients vis-a vis doctors prescriptions as against the other options existing in the market, the question of accessibility and affordability cannot be determined'.[45]

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[42] *BDR Pharmaceuticals International Pvt. Ltd v Bristol Myers Squibb Company* CLA No 1 of 2013 (CGPat, India) [2].

[43] ibid [22].

[44] *Lee Pharma Ltd. v AstraZeneca* AB CLA No 1 of 2015 (CGPat, India) [30].

[45] ibid [31].

At present, there does not exist a clear mechanism by which to monitor the unaffordability of patented medicines – a prerequisite for making successful CL applications. Lee Pharma's failure to furnish such data is not a surprise in light of this reality. This case underscores the necessity of developing such a mechanism – more on this later. In both the above cases, no appeal was pursued by the applicants. [46]

After the Nexavar CL grant, India faced considerable backlash, such as by being designated a notorious market by the US.[47] Also recall that India reportedly made a private assurance to the US in 2016 that it would not use its CL provisions. It is believed that this fact prompted Lee Pharma and BDR's decision not to appeal the rejection of their CL applications. [48]

The above demonstrates the need for constructive judicial involvement to help create an environment in which CL applications are considered with an eye to the RtH consequences at stake. And it is to this end that I will propose a set of prescriptions in part 3 below.

### 2.1.1.2: Section 92 route

Section 92 of the 1970 Act, to reiterate, allows for the grant of a CL in 3 circumstances: national emergency, extreme urgency and for a public non-commercial use. Further, when the

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[46] Kiran George, 'BDR, Lee Pharma decide not to pursue CL appeals' (SpicyIP, 13 April, 2016) <https://spicyip.com/2016/04/bdr-lee-pharma-decide-not-to-pursue-cl-appeals.html> accessed 16 July 2020.

[47] Srividhya Ragavan, ' Drugs, Drugs Everywhere but Just Not for the Poor' [2016] 8 WIPO J 41, 49.

[48] Devika Agarwal and Radhika Agarwal ' The Dismal History of Compulsory Licenses in India' (Cluwer Patent Blog, 21 April 2016) < http://kluwerpatentblog.com/2016/04/21/the-dismal-history-of-compulsory-licences-in-india/> accessed 16 July 2020.

CL relates to HIV AIDS, TB, Malaria or other epidemics, the procedure of hearing the parties prior to the grant of a CL can be dispensed with.[49] An important point here is that the section is couched in directory terms, stating that the government 'may' authorize a CL issuance under this provision. This point will assume significance when our focus will switch to considering the shape of the intervention I will propose. India has not fared much better through this route, compared with the Section 84 route, for the grant of CLs. In January, 2013, the Ministry of Health ('MoH') recommended the invocation of this lever as regards three anti-cancer medicines: dasatinib; trastuzumab (originator: Roche); and ixabepilone (originator: BMS) to the Department of Industry and Policy Promotion ('DIPP') – whose mandate it is to consider triggering this PLV.[50] In response to a question in Parliament, the Minister for Commerce and Industry stated that the Herceptin proposal was dropped due to the patent not being renewed and Ixabepilone was considered unsafe. Consequently, the only drug remaining was Dasatinib, for which requisite data was awaited from the MoH.[51] the DIPP issued a series of questions to the MoH, to gauge the need to utilize this PLV. A perusal of a series of Right to Information ('RTI') replies reveals that the MoH was unable to furnish the information sought from it. This led to the proposal getting stalled.[52]

[49] For a summary of this procedure, see n 29.

[50]E Hoen, *Private patents and public health: changing intellectual property rules for access to medicines (*Health Action International 2016) 67.

[51] Nirmala Seetharaman, 'Compulsory Licensing on Patented Drugs' (Question in Lok Sabha, 19 December 2014).

[52] The last RTI reply is dated 16 August, 2016. It indicates that there was no reply after 6 May, 2015, from the MoH [on file with author].

This incident brings to light our inability to maintain an appropriate data-gathering mechanism, on the scale and scope of the problem of the PBU of drugs. This data is in the custody of private parties.[53] Absent such information, it is well-nigh impossible to make out a robust, evidence-based case, for the triggering of this PLV. Another reason for the non-grant of the Dasatinib CL appears to be US pressure on the government not to issue CLs. [54] The bearing that the government's decision not to issue the CL had on the RtH of the concerned patients becomes clear from the fact that Dasatinib costs USD108 per day, with India's per capita income at the time being USD1570 per year. Further, generics agreed to supply the drug for USD four a day. [55] In this environment, the right kind of judicial intervention can play a crucial role in helping reverse the existing state of affairs in which the transition from paper to practice has not taken place as regards this PLV. This point will be developed more fully in part 3 of this chapter.

## 2.2 Government use provisions

At the outset, it bears mention that these government use provisions can be divided into two categories, and the critical difference between them is the following. Under the first one, the patentee has to be paid adequate remuneration for the use of their patent, while no such

[53] Shamnad Basheer, 'Patents over Patients' (Indian Express, 14 March, 2016) <https://indianexpress.com/article/opinion/columns/patents-over-patients/> accessed 16 July 2020.

[54] WHO report (n 102 ch2) 25.

[55] Union for affordable cancer treatment, ' Indian compulsory licenses on dasatinib patents' (Union for Affordable Cancer Treatment, 29 October 2014) <https://cancerunion.org/files/UACT-Froman-dasatinib.txt> accessed 16 July 2020.

financial compensation has to be paid under the second regime.[56] The first scheme contemplates both governmental use of patented invention and outright governmental acquisition. As regards the former, on the filing or grant of a patent, the government or any person authorized by it *may* use the patent 'for the purposes of government'.[57] This must be accompanied by the payment of adequate remuneration to the patentee. The terms of such use are to be determined by the CG and the patentee.[58] Adequate remuneration is to be assessed in light of the economic value of the use of the patent. [59] Again, critically, like Section 92, the invocation of this PLV is within the CG's discretion and is not mandatory. The phrase 'for the purpose of government' has been defined in the following manner:

'an invention is said to be used for the purposes of Government if it is made, used, exercised or vended for the purposes of the Central Government, a State Government or a Government undertaking.'[60] What uses would qualify as government use has not thus far fallen for judicial

[56] Section 47 (4) allows the government to import a patented product into India, either for its own use or for use in a government hospital/dispensary, notified by it, that provides public service. Space precludes a consideration of this scheme.

Also see WHO Report (n 102 ch2) 59.

A discussion of the difference between these two statutory schemes can be found in *Garware Wall Ropes Ltd. v AI Chopra,* 2009(3)BomCR896, (Bombay High Court, India) [21-22].

[57] 1970 Act, Section 100(1).

[58] ibid Section 100(3).

[59] ibid Section 100(3), proviso.

[60] ibid Section 99(1).

consideration. In the sole case involving this PLV, the question that had to be answered was the form in which the government could authorize a third party to use an invention.[61]

In sharp contrast with India's marked underutilization of this PLV, several other countries have made ample use of this PLV. Indonesia, for instance, used this lever thrice, in 2004, 2007 and 2012. [62] Similarly, Thailand has used the government use CL provisions for seven drugs.[63] A study assessing the impact of Thailand's aforesaid use of this PLV found that this measure significantly facilitated greater affordability of the drug at issue. Illustratively, the number of users of EFV increased by 17,959 and of LPV/r by 3,421.[64] Further, the use of this PLV did not adversely impact Thailand's exports or foreign investment inflows.[65] As this example shows, this PLV can be put to good use in ways that foster A2M, while not producing the consequences feared by its opponents.

## 2.3 Response to objections about using PLVs

Some scholars are not sanguine about the possibility of using CLs as a policy instrument to foster greater A2M. Illustratively, Christopher Catropia argues that the grant of CLs runs

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[61] *Garware* (n 56) [24].

[62] B Stirner and H Thangaraj, 'Learning from practice: compulsory licensing cases and access to medicines' [2013] 2(2) Pharmaceutical Patent Analyst 195, 207.

[63] Hoen, Private patents (N 50) 54.

[64] Inthira Yamabhai and others, 'Government Use Licenses in Thailand: An Assessment of the Health and Economic Impacts' (2011) 7.1 Globalization and Health 1, 5.

[65] Hoen, Private patents (n 50) 67.

counter to basic patent law principles. Given that inventors face the prospect of their patents being punctured at any time, he argues, this can 'erode' the incentive to invest. To quote him: 'A would-be inventor can no longer depend on patent exclusivity as a means of recouping costs because of the uncertainty of such exclusivity'.[66]

He contends that there has to exist a countervailing interest, a 'political or social objective', in order for CLs to be issued legitimately.[67] In response, building on Frankel and Lai's intervention, it is submitted that the real question to be asked is not if we need to have exceptions such as CLS, but how those should be operationalized. For, as they point out, an exception, by definition, is designed to run counter to the default position.[68] Catropia's intervention can best be understood as calling for clarity in how CLs are operationalized.[69]

An effective response to his intervention would entail a clear delineation of the circumstances in which CLs can be invoked, in a manner that exhibits certainty and overall balance.[70] The prescriptions to be proposed meet this criterion. This is because they will ensure the use of CLs (and the government use PLV) in a meaningful, structured and accountable manner. They will not disturb the delicate balance that these PLVs have already created, to adequately safeguard the interests of patentees.

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[66] Cristopher Cotropia, Compulsory licensing under TRIPS and the Supreme Court of the United States' decision in eBay v MercExchange. in T Takenaka (ed), *Patent law and theory: a handbook of contemporary research* (Edward Elgar, Cheltenham 2008) 557, 560.

[67] ibid.

[68] Frankel and Lai (n 15 ch 2) 160

[69] ibid.

[70] ibid.

Further, to Cotropia's point as to the grant of CLs disincentivizing investments, as an empirical matter, this is a questionable proposition. This is made clear by the Thai example shared above. In addition, as Reichman' points out, the impact of the issuance of CLs on the patentee depends on the importance of that market to the patentee's overall business operations.[71]

The Indian market is likely to be a small part of the revenues of big pharma, because they earn, and are likely to continue earning, sizable revenues from elsewhere. [72] Further, the need to develop cures for diseases of the developing world presently receives hardly any attention from big pharma. [73] As an illustration, out of the 1550 new chemical entities developed between 1975 and 2004, only three were for TB [74], a disease that predominantly affects the developing world and causes 1.7 million deaths each year. [75] As a result, even

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[71] JH Reichman, Compulsory licensing of patented pharmaceutical inventions: evaluating the options. in CM Correa (ed), *Research handbook on the protection of intellectual property under WTO rules: intellectual property in the WTO* (Edward Elgar, Cheltenham 2010) 589, 614-18.

[72] In this regard, see M Mikulic, 'Global Pharmaceutical Industry - Statistics & Facts' (Statista, 13 August, 2019) <https://www.statista.com/topics/1764/global-pharmaceutical-industry/> accessed 16 July 2020.

[noting that global growth in terms of spending on medicines will primarily be driven by developed markets, till 2023, and that China alone will be a significant contributor amongst emerging markets]. Also see the statement by Bayer's CEO on the grant of a CL for Nexavar. He noted that the decision would not have a meaningful impact on Bayer's business, as the drug was primarily developed for the developed world anyway. Claire Cassedy, 'Transcript of Bayer CEO Marjin Dekkers quote at the December 3, 2013 FT Event, regarding India compulsory license of Nexavar' (Knowledge Ecology International, 7 Feb 2014) <https://www.keionline.org/22414> accessed 16 July 2020.

[73] See 'Public Health, Innovation and Intellectual Property Rights, Report of the Commission on Intellectual Property Rights, Innovation and Public Health' (WHO 2006).

[Noting that, as regards diseases afflicting developing countries, 'patents are not a relevant factor or effective in stimulating R&D and bringing new products to market'.]

[74] P Chirac and E Torreele 'Global framework on essential health R&D' [2006] 367(9522) Lancet 1560.

[75] This illustration is taken from WHO Report (n 102 ch 2) 16.

accepting at face value the contested assumption that patents incentivize R and D investments[76], it is clear that that rationale does not hold good for diseases predominantly affecting developing countries like India. Therefore, the utilization of these PLVs, on balance, has the potential to move the needle in a positive direction, in fostering A2M.

## 2.4 Form 27 procedure

In this segment, I will analyze the litigation surrounding the form 27 procedure. This will be with a view to underscoring the importance of adopting the rights route when seeking patent law reform. The lessons emerging from this case study will feed into the prescriptions I will subsequently propose. This procedure was designed to offer an empirical basis to determine how far a patented invention has been worked in India. Section 146(2) of the 1970 Act, in pertinent part, states as follows:

> 'Every patentee and every licensee (whether exclusive or otherwise) shall furnish in such manner and form and at such intervals (not being less than six months) as may be prescribed statements as to the extent to which the patented invention has been worked on a commercial scale in India'.

In a 2015 petition, Basheer and colleagues provide a detailed account of the deficiencies in the effective functioning of the Form 27 procedure. They principally point out that the form's filing rates were abysmally low and that the government did not take steps to

[76] It is incorrect to view patent protection as being a precondition to R and D investments. The absence of a vaccine for infectious diseases like COVID clearly demonstrates the failure of over-reliance on the IP system as a means to incentivize R and D investments. In this regard, see Ana Rutchman, 'The Intellectual Property of Vaccines: Takeaways From Recent Infectious Disease Outbreaks' [2020] 118 Mich L Rev 170, 177.

See also generally Ana Rutschman, 'IP Preparedness for Outbreak Diseases ' [2018] 5 UCLA L Rev 1212.

reverse this state of affairs.[77] The petition demonstrates the facilitative role that these filings can play in the activation of public health PLVs and, conversely, the fashion in which its improper functioning can translate into denial of access to life-saving medicines.[78] In response, the court asked the government to address the deficiencies pointed out by the petitioner.[79] The government undertook to consult stakeholders and do the needful in a time-bound way. The Court disposed of the matter, asking the Government to report to it once this exercise was completed and the revised form notified. [80]

The revised iteration of the form, however, contains several deficiencies and is a diluted version of the previous form. It does not require the patentee to disclose the steps being taken to work the invention; all it requires is a justification for non-working. [81] It also excludes some vital information necessary for CL applications to be meaningfully examined, such as total units of the invention manufactured in, and imported into, India. [82]

What is surprising, however, is that the original petition does not make any mention of the RtH as a resource in crafting its arguments. The petition doubtless underscores the

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[77] Shamnad Basheer, 'Writ Petition (c) No 5590 of 2015' (21 May, 2015, Delhi High Court, India) 5, 9 (Basheer Writ).

[78] ibid 25-26.

[79] *Shamnad Basheer v Union of India and ors*., MANU/DE/0736/2018 (Delhi High Court, India) [4].

[80] ibid [7].

[81] Shamnad Basheer and others, *'Comments on Proposed Amendment to FORM-27'* (2019) 3 (Basheer comments).

[82] ibid 4.

importance of making sure that life-saving drugs are made available on an affordable basis.[83] However, it does not frame the dispute as being one implicating the duties of the state to citizens pursuant to their RtH. An alternative framing was possible. As an editorial points out, the local working information, solicited through the form, is necessary for the state to fulfill its duty under Article 21 to citizens [of ensuring affordable A2M]. [84]

Two additional features of the litigation merit emphasis. First, the timelines that the government provided to the court for the completion of the exercise were not adhered to. Till January 2019, the Respondent did not take any steps to start the form revision exercise[85], even though it had undertaken to finalize the form for inter-ministerial consultation by 06.12.2018. [86] Second, the consultation meeting held by the government, to discuss revisions to the form, were only attended by industry representatives and lawyers. Absent from the discussion were any NGOs and academics – why this was so is unclear.[87]

The form 27 litigation is an indicator of the promises and pitfalls of judicial intervention as an instrument to usher in patent law reform. On the positive side, the court was able to set in motion a dialogic process for the revision of a vital mechanism.

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[83] Basheer Writ (n 77) ibid.

[84] Srividhya Ragavan and Prabha Sridevan, 'Patents and Protecting Public Health' (The Hindu, 9th April 2018) < https://www.thehindu.com/opinion/op-ed/patents-and-protecting-public-health/article23484302.ece> accessed 16 July 2020.

[85] Basheer Comments (n81) 5.

[86] Shamnad Basheer, 'Writ Petition (c) No 5590 of 2015' (Application for directions, 7 January 2019, Delhi High Court, India) 10, 11.

[87] Personal correspondence with an attendee at the consultation meetings; details on record with the author.

However, on the negative side, some argue that the litigation offered the government an opportunity to dilute the Form's requirements rather than strengthening it.[88] This case illustrates the need for more thoughtful judicial intervention, not for none at all. More narrowly, the Court asked the government to submit a report to it, on the completion of the form 27 revision and notification exercise. [89] However, if it had monitored the exercise more closely, it would have been able to help effectuate the laudable objective underpinning this litigation. It did not outline the terms of the consultation exercise that was to be conducted or ask the government to report to it about the completion of the exercise regularly.

Further, if the litigation had been framed in RtH terms, the dilution of the form could have also potentially been prevented. Specifically, the Indian SC has recognized the doctrine of non-retrogression. This doctrine prevents the state from taking any steps that result in the deliberate retrogression/regression of constitutional rights.[90] As stated earlier, the information obtained through form 27 is critical for the activation of levers which can help promote access to life-saving drugs and vindicate the RtH of those involved. Its dilution, therefore, arguably violates this right.

[88] This insight was shared with the author by Ms. Leena Menghaney, Regional Head, South Asia - Access Campaign, Medecins Sans Frontieres, in a conversation dated 17 April, 2020.

[89] Shamnad Basheer (n 79), order dated 23 April, 2018 [7].

[90] Navtej (n 97 ch 2) [188].

## Part 3:[91]

It has clearly been established above that the CL and government use levers have remained signally underutilized in India. The potential of judicial intervention to reverse this state of affairs has also been examined, through the form 27 example. This section seeks to provide a roadmap for how courts can ensure that the selected PLVs do not remain mere parchment barriers against unaffordable pricing by patentees. At this stage, it might be asked why rights litigation is the right answer to the problem of PBU and if its benefits outweigh its costs.

### 3.1 Why rights-based litigation

It might be contended that, if the issue here is of the non-utilization of the PLVs which are statutorily embodied, why can that problem not be remedied through seeking a writ of mandamus, as was done in the form 27 case above? Why should the matter be framed in RtH terms? I will offer three reasons for choosing the rights route.

First, as mentioned earlier, the provisions embodying the selected PLVs vest the executive with the discretion to determine if they should be activated. In administrative law, it is a general rule that a mandamus is to be issued when: 'there is a clear and specific legal right to be enforced or a duty which ought to be and can be performed'.[92]

[91] How far issues of access to health should be justiciable remains a contested issue. For instance, see generally Aryah Neier, ' Social and Economic Rights: A Critique ' [2006] 13(2) Human Rights Brief 1. Due to space constraints, I am operating in this project on the prevailing positive law position of the RtH being an enforceable FR in India.

[92] BP Banerjee, *Writ Remedies- Remediable Rights under Public Law* (7th edn, LexisNexis 2016).

As regards discretionary powers, such as the ones conferred on the CG to activate these PLVs, the scope of a mandamus is very limited. It can only be used to set in motion the exercise of the discretionary power and to demand that the authority exercises discretion on all matters entrusted to it. The court does not interfere with their discretion or control the manner in which it is exercised, unless such exercise is mala fide or arbitrary.[93] It is here that Fredman's bounded deliberative ('BD') approach, to be discussed subsequently, becomes useful. The CG's obligation to ensure access to patented medicines can be the end point around which the deliberation can be structured. More on this below.

Second, as the Form 27 litigation mentioned above makes clear, the framing of a dispute in rights terms activates the principle of non-retrogression. Therefore, couching the use of these PLVs in the language of rights can serve as a basis to ensure that they are not subsequently diluted, as opposed to being bolstered, as happened in the form 27 litigation. Third, I have clearly established (in part 2 of the first chapter) that the use of these PLVs is the most efficacious pathway to vindicate the RtH of those who need access to unaffordable patented drugs. Therefore, an RtH-based framing provides a constitutional basis for the court to propose systemic reforms for their meaningful operationalization.

The appropriateness of rights-based litigation having been established, I will now discuss the key concerns that scholars have voiced against the intervention of courts to secure the enjoyment of the RtH. I will divide my analysis into institutional concerns i.e. those that relate to the legitimacy and competence of courts to intervene and framing concerns i.e. those that relate to the fashion in which cases are brought, arguments raised and remedies sought.

[93] ibid §9.2.5.1. Also see *TG Goakar v RN Shukla*, AIR 1968 SC 1050 (Indian SC).

These are not watertight categories, and there may be some overlap between these two. In the second part, I will offer a schematic exposition of the interventions I propose, following the above division.

## 3.2 Institutional concerns

The concerns I will discuss under this head are: polycentricity and the proper role of courts.

The first concern is of polycentricity, of which Lon Fuller is the main exponent.[94] The concern is rooted in the inability of courts to anticipate and appropriately account for all the repercussions their judgments might produce. For instance, let's assume a court is tasked with fixing prices and wages in a socialist regime of the prescribed commodities. A determination of the price of one commodity, say, aluminum, will implicate the prices of different units of steel, plastic, wood, etc.[95] The problem is not one that is remediable by hearing all parties implicated, even if they could be identified. The quantum of the price fixed for any given commodity is likely to have a different set of repercussions and require a redefinition of parties affected.[96]

He metaphorically describes the problem as a spiderweb. He notes: 'A pull on one strand will distribute tensions after a complicated pattern throughout the web as a whole.

[94] L Fuller, 'The Forms and Limits of Adjudication' [1978] 92 Harv L Rev 353.

[95] ibid 394.

[96] ibid 395.

Doubling the original pull will, in all likelihood, not simply double each of the resulting tensions but will rather create a different complicated pattern of tensions'.[97] He further observes:

'In lesser measure, concealed polycentric elements are probably present in almost all problems resolved by adjudication. It is not, then, a question of distinguishing black from white. It is a question of knowing when the polycentric elements have become so significant and predominant that the proper limits of adjudication have been reached'. [98] Fredman points out how the adversarial system especially lends itself to this problem. The court can only hear the parties before it, without being able to access all the relevant information. It has to choose one party as the victor and cannot deliver a satisfactory solution that accounts for all the consequences of its decision. [99]

The concern of polycentricity is also closely tied to another concern, about judicial intervention undermining the democratic process. Specifically, questions best left to the political process, the argument runs, might be answered by unelected judges by drawing on their ideological dispositions. [100] Attached to this, though distinct, is the competence concern about courts being ill-equipped to make allocative decisions with budgetary and other financial

[97] ibid.

[98] ibid 398.

[99] Sandra Fredman (n82 ch 2) 95.

[100] ibid 64.

consequences.[101] These concerns can become particularly pronounced in the context of RtH litigation, as the critiques by Ferraz, Yamin and Flood and Gross below will show.

Yamin shows how the concern of lack of competence is well-founded in the health context. Judges are ill-equipped to assess the clinical and cost-efficacy of medicines being sought. Illustratively, in Costa Rica, as much as 70% of successful health cases focused on low priority medicines, and out of the 37 medicines to which access was judicially granted, only three are listed in the WHO list of essential medicines.[102]

Second, whether judicial orders produce positive effects remains contested. A study by Pratap Bhanu Mehta and Shailashri Shankar points out that the impact of courts on government policies in India was low, that courts were unwilling to penalize errant government authorities and that this resulted in NGOs not relying on litigation as a strategy to obtain improved outcomes. [103] They conclude that all that Indian courts can do is to declare a right in strong terms.[104]

## 3.3 Framing concerns

The concerns that I will outline here are of individual-centric litigation, the myopic scope of judicial intervention and the possibility of elite capture of the judicial process.

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[101] ibid 65.

[102] Alicia Ely Yamin, Promoting Equity in Health: What Role for Courts? (2014) 16(2) Health and HRJ 1, 3.

[103] Shylashri Shankar and Pratap Mehta, 'Courts and Socioeconomic Rights in India', in Varun Gauri and Daniel Brinks (eds) *Courting Social Justice: Judicial Enforcement of Social and Economic Rights in the Developing World* (Cambridge University Press 2009) 177.

[104] ibid 179.

First, individual-centric litigation. Octavio Ferraz shows how the existing Brazilian jurisprudence on the RtH prioritizes individualized A2M and that courts order such access, without regard to financial implications.[105] In 1993, Brazil enacted a law, law 9.908/93. It provided for 'exceptional medication' for individuals 'unable to afford such medication without jeopardising their subsistence and that of their family'. Exceptional medication was defined as medicines 'which needs to be used often and permanently, and which is essential to sustain the life of the patient.'[106] In the first two cases that came before it under this law, Brazil's Federal Supreme Court saw its task as ensuring that access to the drug was provided, as this was its legislative mandate. It opined that there was a dilemma between the RtH on one hand and budgetary considerations, on the other. It held that that the former should prevail in the following terms:

> 'I believe that - once this dilemma occurs - ethical-juridical reasons compel the judge to only one possible solution: that which furthers the respect of life and human health. The interpretation of a programmatic norm cannot transform it into a toothless constitutional promise'.[107]

This thinking has been deployed in 146 subsequent cases.[108] Consequently, there has been a flood of health litigation in Brazil.[109]

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[105] Octavio Luiz Motta Ferraz, 'Moving the Debate Forward in Right to Health Litigation' (2016) 16 Health and Human Rights 265.

[106] O Ferraz, 'Between Usurpation and Abdication? The Right to Health in the Courts of Brazil and South Africa' in Oscar Vilhena Vieira, Upendra Baxi, Frans Viljoen (eds), *Transformative Constitutionalism: Comparing the Apex Courts of Brazil, India and South Africa* (PULP, Pretoria 2013) 375, 393.

[107] ibid 395.

[108] ibid 392.

[109] ibid 391.

Second, elite capture. Judicial intervention in the healthcare domain is unlikely to be pro-poor in circumstances in which there are significant inequities in the social determinants of healthcare. This is because litigation becomes an avenue for the middle and upper classes to seek curative treatments and expensive medicines.[110] Further, in Colombia, Brazil and Argentina, Yamin finds that some amount of healthcare litigation is driven by pharmaceutical companies and pharmaceutical regulation impacts the budgetary and equity-based consequences of healthcare litigation. [111]Ferraz similarly notes that the courts are generally accessed only by individuals who possess rights consciousness, organizational capacity and the ability to mobilize.[112]

Third, myopic scope. Kapczynski problematizes the use of litigation to ensure A2M. She notes that patents enable exorbitant medicinal pricing.[113] And so judicially granting access to such medicines at the extremely high rates charged by patentees makes them richer even as it makes governments significantly poorer. [114] Courts, she argues, are unable to question the underlying logics and structures that help sustain this system. Further, she draws on cases from Brazil, Colombia, South America and India concerning A2M. She notes that the litigation

[110] Yamin (n 102) 6.

[111] ibid 7

[112] O Ferraz, 'The Right to Health in the Courts of Brazil: Worsening Health Inequities?' (2009) 11 Health and Human Rights 33, 39.

[113] Kapczynski, The Right to Medicines (n 47 ch2) 8.

[114] ibid 3.

concerning the medicines does not explain why these medicines are so profoundly expensive. [115]

## Key lesson

To conclude, the implication of the above critiques for my project is this. They point to the need for some circumspection when proposing judicial intervention, using the RtH. It is unclear how legitimate and competent courts are to intervene and how far their interventions improve the situation. The litigation route is also susceptible to manipulation and capture and may not address the underlying structural problem. Cumulatively viewed, these challenges have the potential to make any solution predicated on judicial intervention worse than the problem. In calling for such a solution, therefore, we would do well to ensure that we do not burn a house to roast a pig. [116] As I shall demonstrate in the next part, the arguments against judicial intervention just outlined are not conclusory. I will argue that courtrooms can serve as agents for positive and meaningful change, if used appropriately.

As Justice Cameron noted in his conversation with me, the key question is really the 'how question' in these matters. This includes who the litigating agent is, how the litigation is framed [i.e. the arguments raised] and the relief that is sought. Litigation that is conducted by an isolated person, without any clear public interest in mind, must be distinguished from litigation that is well-focused and narrowly tailored. To explicate, by well-focused, I mean litigation that is based on strong evidence and arguments that form the basis for seeking the

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[115] ibid 8.

[116] *Sable Communications of Cal., Inc*. v *FCC*, 492 US 115, 127 (1989).

most appropriate relief in the given case. Models such as the Brazilian one have had a counterproductive impact and have been rightly decried. That does not mean, however, that productive interventions cannot take place. A court can respond most positively, when it is acting in the passive voice. This entails playing a facilitative role in ensuring that the RtH is effectively secured, as opposed to making the allocative decisions itself. Based on his insight, I will offer a schematic exposition, in this part, of the shape of intervention I propose. To this end, I will evaluate the lessons on the forms of intervention considered positive. I will then deploy these lessons to outline the contours of the model of intervention I advocate.

## 3.4 Response to institutional concerns

In this part, I will first respond to the polycentricity concern. Second, to concerns about the proper role of courts and the limits of their powers.

First, courts achieve positive results when they ensure the implementation of existing laws and policies, rather than going off on their own to create new obligations for the government. This counters the polycentricity challenge directly. This is because of the critical factor of the government having already made a law.

This general normative insight also appears to be supported by the approach hitherto deployed by Indian courts. More concretely, in their analysis of Indian case law on the RtH and education, Shankar and Mehta divide their analysis into 3 types of cases. Cases (a) involving issues on which there is no law in the books; (b) involving the enforcement of an existing law; and (c) involving the need for the law to keep pace with changes, like in IP law

or drug prices. They find that judicial intervention in India largely falls in category b.[117] They give the example of cases involving a failure by municipal authorities to provide potable water, pursuant to their statutory obligation. In a number of cases, high courts across India held them to this obligation.[118] This needs to be contrasted with their critique about the ground-level impact of judicial intervention mentioned earlier. That applied to circumstances in which there did not exist any statute or policy and the court sought to intervene without much success.

Madhav Khosla's 'conditional social rights' thesis similarly tracks the model of courts intervening to enforce existing commitments. Under this model, courts seek to ascertain if the government has made a statutory or policy commitment. If it has, they hold the government to that commitment. A majority of RtH cases that he studies fit this model. Illustratively, in *Rakesh Chandra Narayan*[119], the Court ruled on the conditions obtaining in mental hospitals. It appointed a management committee to monitor their functioning and outlined its mandate.[120] This supports his thesis, in that the Court held that, given that the government had undertaken to construct hospitals, they had to be suitably maintained.[121]

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[117] Mehta and Shankar (n 103) 177.

[118] Illustratively, see *KC Malhotra v State of M.P. and Ors*. AIR 1994 MP 48 (Madhya Pradesh High Court, India).

[119] *Rakesh Chandra Narayan v State of Bihar*, AIR 1989 SC 348 (Indian SC).

[120] Madhav Khosla, 'Making Social Rights Conditional: Lessons from India' (2010) 8 International Journal of Constitutional Law 739, 753.

[121] ibid.

In *Consumer Education and Research Centre*[122] ('CERC'), the Court focused on the conditions of workers in asbestos industries. It held that the existing statutory framework was inadequate to protect them. The framework anticipated compensation being granted only for injuries sustained during the course of employment. This was inadequate, for the consequences of asbestos exposure typically surfaced after retirement. As a result, the Court incorporated the ILO rules on this score and held that all industries had to comply with them.[123] It further asked the government to set up an institutional framework to ensure the maintenance of safe working conditions. [124] This case also supports the conditional social rights model, for the court sought to augment the existing statutory framework, pursuant to the government's commitment of looking after workers sustaining health hazards during employment.[125]

It is beyond this project's remit to determine if Khosla's model fairly characterizes India's socio-economic rights jurisprudence. Suffice it to state that the model of intervention I propose draws on his insight. The executive has undertaken a statutory commitment to ensure affordable A2M, and the Court will meaningfully hold it to that commitment. More on this in the section on the proposed intervention below.

Second, to concerns about the proper role of courts. In socio-economic rights cases generally, courts are believed to contribute constructively when they act in coordination with other governmental organs. The two tasks that they can perform well are helping in the resolution

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[122] *Consumer Education & Research Centre v Union of India*, (1995) 3 SCC 42 (Indian SC).

[123] Khosla (n 120) 755.

[124] ibid.

[125] ibid.

of incomplete commitments [undertaken by the government but not discharged] and fire alarm-monitoring [i.e. soliciting information and fostering transparency in the way decisions are made].[126] This also finds significant support in the RtH context. In India, in their analysis of RtH litigation, Parmar and Wahi note that courts have helped create a discursive space and given voice to the concerns of the marginalized which would otherwise be ignored. [127] Indeed, the dialogic mode of intervention is not an anathema in India. The Supreme Court most famously adopted a dialogic solution of working with the government to ensure implementation of existing schemes on access to food in the famous right to food case.[128] The approach has also been adopted by the Gujarat, Karnataka and Bombay High Courts to monitor the government's COVID response.[129]

Under dialogic models of adjudication, it is unclear where the dialogue has to end, and what is the framework within which it must be conducted. It is here that Fredman's BD

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[126] D Brinks and V Gauri, A New Policy Landscape: Legalizing Social and Economic Rights in the Developing World (n 103) 346.

[127] Sharanjeet Parmar and Namita Wahi, 'India - Citizens, Courts and the Right to Health. Between Promise and Progress?' in Alicia E. Yamin and Siri Gloppen (eds), *Litigating health rights. Can courts bring more justice to health?* (Harvard University Press 2011) 155, 180.

[128] *PUCL v Union of India* WP (C) No. 196/2001 (Indian SC).

[129] 'Coronavirus and the Constitution – XXVIII: Dialogic Judicial Review in the Gujarat and Karnataka High Courts' (Indian Constitutional Law and Philosophy, 24 May 2020) <https://indconlawphil.wordpress.com/2020/05/24/coronavirus-and-the-constitution-xxviii-dialogic-judicial-review-in-the-gujarat-and-karnataka-high-courts/> last accessed 22 July 2020.

'Coronavirus and the Constitution – XXXIII: N-95 Masks and the Bombay High Court's Dialogic Judicial Review [Guest Post]' (28 June 2020) <https://indconlawphil.wordpress.com/2020/06/28/coronavirus-and-the-constitution-xxxiii-n-95-masks-and-the-bombay-high-courts-dialogic-judicial-review-guest-post/> last accessed 22 July 2020.

approach becomes important. This framework can also furnish a response to the concern of court decisions not being able to produce ground-level impact. This is because the framework provides a clear structure, and a set of deliverable outcomes, for the litigation, which can ensure more impactful judicial interventions. What the bounds of the deliberation must be in this context are set out in section 3.8.1 and 3.8.2 below.

A second lesson emerging from the above segment is that it is problematic for courts to intervene without a firm recognition of their limitations. An explication of such limits is found in the Soobramoney case from South Africa.[130]

The case concerned a 41-year-old man who was diabetic and suffered from multiple other health conditions, including chronic renal failure. The appellant sought judicial intervention to access dialysis under a government scheme which envisaged such access only to those whose condition was reversible, unlike him.[131] The court rejected his claim in the following terms.

'The state', the court observed, 'has to manage its limited resources in order to address all these claims. There will be times when this requires it to adopt a holistic approach to the larger needs of society rather than to focus on the specific needs of particular individuals within society'.[132] An awareness of the court's limits is also evident from the concurrence of Sachs, J. As he perceptively observed, 'The inescapable fact is that if governments were unable to

[130] *Soobramoney* v *Minister of Health* [1997] ZACC 17 (South African Constitutional Court).

[131] ibid [5].

[132] ibid [31].

confer any benefit on any person unless it conferred an identical benefit on all, the only viable option would be to confer no benefit on anybody'.[133]

In relying on the above case, I am conscious of the textual differences between the Indian and South African Constitutions. In India, unlike South Africa, the Constitution does not contain a caveat that the RtH is progressively realizable, within the state's available resources. However, Soobramoney is relevant, insofar as it provides a robust conceptual justification for why the RtH cannot be interpreted as an individual right to access medicines.

To sum up, then, the model of intervention I will propose takes account of the institutional concerns set out earlier, for two key reasons. First, the solution that I advocate is that courts should reach for the statutorily embodied PLVs to ensure A2M. Second, to the extent that this does not yield the desired result, and to address the problem at the systemic level, I argue for the adoption of the BD model, to ensure that the state's action is constitutionally compliant but that the court nonetheless does not hijack the conversation.

## 3.5 Response to Framing concerns

In this segment, I will, in chronological order, respond to concerns about individual-centric litigation, the myopic scope of judicial intervention and elite capture.

[133] ibid [53].

On the first point. Ferraz highlights the need to eschew the simplistic interpretation of the RtH as being a right to everything, irrespective of its cost. [134] The Soobramoney decision discussed above also counsels against the interpretation of the RtH as meaning an individual right to access any medicines. Therefore, in the model of intervention that I will propose, I will lay down some indicative criteria to ensure that the RtH is triggered only when lack of access to the patented medicine at issue becomes a widespread problem.

On the second point, the model of intervention I will propose below also takes account of the gravamen of Kapczynski's concern. To recapitulate, Kapczynski's principal concern is that litigation to seek medicinal access does not interrogate or help dismantle the background fact-situation in which such access is sought. Instead, it reaffirms and exacerbates neoliberal structures. At the core of her intervention lies a distinction between the use of HRs in a way that helps sustain neoliberal logics and structures and in a way that helps interrogate and dismantle them. In the latter category, she cites the Ochieng case from Kenya and the Roche case from India, discussed in chapter 2. In both these cases, the court used the RtH as a means to challenge the monopoly conferred by patents.[135]

My prescriptions fit in the latter category. Specifically, instead of granting access to patented medicines on prevailing market rates, I am arguing that courts should be involved in the project of challenging the insularity conferred by patents. This will be through the use of the PLVs that can break down the insularity conferred by patents. Therefore, the intervention

[134] O Ferraz, 'The Right to Health in the Courts of Brazil: Still Worsening Health Inequities?' [2017] Revista del Centro de Estudios Constitucionales 195, 220

[135] Kapczynski (n47 ch 2) 92.

I propose addresses her concerns, both at the level of the use of the RtH within my analysis and at the level of challenging the monopoly conferred by patents.

As to the elite capture concern, I will propose below a two-track model of intervention, at the individual and systemic level. So even assuming that the claim to seek affordable access to patented medicines is brought by well-resourced litigants, the litigation can serve as a launching point for the Court to suggest systemic reforms. This will ensure that the benefits of such litigation do not just redound to the litigants.

## 3.6 Example of positive judicial intervention using the RtH

An example of thoughtful and carefully calibrated judicial intervention in the health domain would be instructive. This will feed into the model of intervention I will propose. This is the South African case of *Minister of Health versus Treatment Action Campaign*.[136] At issue was the Government's policy of making a drug called Niverapine available, to thwart mother-to-child HIV transmission, only at a few pilot sites. The court held that the circumscribed scope of the rollout only to research and training sites was unreasonable.[137] It rejected the reasons

[136] (2002) 5 SA 721 (CC) (South African Constitutional Court)

[137] ibid [80].

advanced by the government to support the limited rollout – of efficacy[138], resistance[139], safety[140] and capacity.[141]

Three learnings from the judgment are relevant for my project. First, the judgment is a testament to how a court can intervene, on a consideration of the arguments and evidence raised, to assess the justifications offered by a government for limiting the RtH. The textual differences between the language of the RtH in the Indian and South African Constitutions notwithstanding, the judgment demonstrates the possibility of thoughtful judicial intervention. Second, the Court recognized that it could grant a mandamus, coupled with continued judicial supervision through an injunction[142] in the face of governmental recalcitrance. [143] In the instant case, however, it did not retain such supervision. If the TAC had furnished evidence to enable the Court to recognize the political blockages that the judgment would confront, it could have decided differently. [144] Note how this insight parallels that on the form 27 litigation in India, where, as argued earlier, continued judicial supervision could have facilitated smoother implementation.

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[138] ibid [58].

[139] ibid [59].

[140] ibid [60].

[141] ibid [66].

[142] ibid [106].

[143] ibid [112].

[144] Jonathan Berger and Amy Kapczynski, 'The Story of the TAC Case: The Potential and Limits of Socio-Economic Rights Litigation in South Africa', in Deena R. Hurwitz & Margaret L. Satterthwaite (eds) *Human Rights Advocacy Stories* (2009) 28.

Third, the case also demonstrates how RtH litigation must be nested within a broader strategy of public advocacy and mobilization, in order to produce an overall positive effect. As Kapczynski and Burger note, the case helped shine the spotlight on TAC's work and paved the way for the rollout of subsequent governmental measures, concerned with HIV-AIDS, in a consultative way.[145]

## 3.7 Shape of proposed intervention

The intervention I propose will operate at two levels: individual and systemic. As regards the former, to recapitulate, the starting point of the court's intervention has to be the issuance of a mandamus, directing the CG to consider exercising its discretion to activate either Section 92 or 100/102. If that does not result in the PLV being triggered, the court should resort to the BD approach, using the RtH as the basis for the same. This framework can also be deployed by the court at the systemic level, to ensure that the government comes up with a constitutionally compliant action plan to ensure the affordable supply of patented medicines. Without being prescriptive in this regard, the Court can outline some factors and reforms for the government to consider.

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[145] ibid 30.

To similar effect, in a land rights context, see *Mwelase and Others* v *Director-General for the Department of Rural Development and Land Reform and Another* 2019 ZACC 30 (South African Constitutional Court) (justifying the appointment of an officer to monitor compliance with a statute in the need to correct deficiencies in government delivery rather than a wish to exercise judicial power [48]).

In spelling out the grant of remedies at two levels, I am drawing on the two-track approach proposed by Roach. This entails combining individual relief to the claimant before the court and a systemic remedy that would allow for the remedying of the broader problem of which the case before the court is but a manifestation. The systemic remedy can be crafted in such a fashion as to enable other governmental organs to ensure that the violation of rights is not repeated. [146] In South Africa, for instance, in housing cases, courts have coupled the grant of individual relief such as stopping evictions from taking place with systemic remedies such as declarations and engagement orders, to achieve larger-scale solutions. [147] As he notes, this approach also accommodates Fuller's concerns. A nuanced reading of Fuller's contribution suggests that he endorsed the creation of social orderings to resolve systemic problems. Roach suggests that courts should retain supervision and facilitate broad participation. [148]

Pertinently, Chatterjee and Ram show that the Delhi High Court has deployed this two-track model in 3 cases involving socioeconomic rights.[149] In the RtH context specifically, in the *Paschim Banga* case discussed in chapter two, at the individual level, it was held that compensation had to be granted to the workman who had sustained injuries. At the systemic level, the Court issued a set of seven directions to address the deficiencies owing to which he could not access prompt treatment.

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[146] Kent Roach, 'Polycentricity and Queue Jumping in Public Law Remedies: A Two-Track Response' (2016) 66 University of Toronto Law Journal 46,47.

[147] ibid 48.

[148] ibid 51-52.

[149] Vasujith Ram and Sohini Chatterjee, 'Delhi High Court's Socio-Economic Rights Adjudication: Some Insights' (2016) 28 National Law School of India Review 74, 84.

### 3.7.1 Contours of individual intervention

In order for the RtH to be used as the basis to trigger the levers being discussed, litigants will have to bring to the SC or a High Court a writ petition that establishes three things. First, that they have a right to access the medicine at issue, pursuant to the RtH. Second, that the medicines being sought by them are unaffordable. This gives rise to the question of the burden of proof that the claimant must discharge. Must she only prove the factum of unaffordability, with the burden then shifting to the CG to rebut the claim, or must she also establish that the unaffordability is because of the existence of a patent on the concerned drug? Space precludes a detailed consideration of how this question should be answered. For the present, I will operate on the assumption that the claimant must show that the causal factor for the unaffordability is the patent barrier. This can be shown, for instance, by putting forth data as to the price at which the drug is being sold in other countries which have issued a CL. Such data can clearly establish that using a PLV will help make the drug affordable. Third, that the fact situation in the case meets either of the statutory criteria prescribed in Section 92 or 100/102 and that triggering either of them would be the most appropriate solution to address this problem. The court can then serve as a forum for deliberation, to arrive at a constitutionally compliant decision.

Now, to the BD approach. The main deficiency of the dialogic model is the fact that it does not offer a clear pathway for how the dialogue can be brought to a closure or provide a framework within which the dialogue can take place. [150] Drawing on Mureinik's idea of a culture of justification, therefore, Fredman argues that courts can use the BD approach as a

[150] Fredman Comparative Human Rights (n 82 ch 2) 89.

structuring framework to seek justifications from the government for how it acts.[151] Let's apply that insight to this project. The bounds of the deliberation here would be the government's obligation to facilitate affordable access to patented medicines, using the RtH. Under this framing, the court would not compel the government to trigger either of these PLVs, but it can require the government to furnish a constitutionally tenable justification for why they are not being triggered. The model accommodates the possibility of reasonable disagreement, as long as the right is vindicated. To illustrate, if the government comes up with a plan to use PC measures instead of PLVs as the means by which to ensure affordability, the court will have to defer to it on that score. However, if the government refuses to trigger a PLV due to fear of US retaliation, that will not pass muster, it not being a constitutionally cognizable concern. This way, citizens needing access will not be left in the lurch.

In order to feed into the deliberation, the Court can delineate its best understanding of what the RtH requires from the government, in terms of ensuring A2M. It can provide a typology of medicines, in order to enable the government to understand what the RtH requires of it as regards each of them. The RtH should be understood as clearly requiring access to life-saving medicines. This is not only supported by the case law[152] but is also normatively appropriate, given that such access self-evidently most directly impacts the RtH. As regards the standard of justification for a failure to comply with this obligation, as the Mohd. Ahmed judgment and the ICESCR Committee make clear, access to such medicines should be

[151] ibid 90-91.

[152] n 65 and 67 ch 2.

considered a core, non-derogable obligation. [153] Therefore, while the state can come up with alternative avenues [apart from PLVs] to provide such access], arguments such as those on resource constraints should not be considered a permissible justification.

A caveat is apposite here. Building on the earlier insight that the RtH cannot be interpreted as an individual right to access medicines, the non-derogable obligation should arise only as regards the widespread unaffordability of the drug. Put differently, the RtH should be interpreted as meaning that the government has to ensure general affordability of life-saving drugs. The court can outline such factors as virulence, rate of mortality and number of people affected as the basis for widespread unaffordability to be determined and for this core obligation to kick in. While the court and the executive can deliberate as to how access to the drug can be progressively realized for every single person who needs it, the non-derogable obligation must only be to ensure general affordability. In determining what medicines are of a life-saving character, the WHO Model list of essential Medicines can serve as a valuable guide.[154] Until 2015, this list did not cover highly priced patented drugs. Since then, however, a range of patented drugs used for cancer, hepatitis c and TB have been part of the list.[155]

As regards life-enhancing medicines, how far the RtH requires access to them, and when the government can hold the state to account for a failure to provide them will turn on

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[153] GC 14, Para 43(D). *Mohd. Ahmed*(n60 ch2) [68].

[154] In Merck Sharp and Dome Corporation, the Court used the WHO list as a guide in holding that the absence of the drug at issue from the list favoured a grant of injunction against its generic version.

See *Merck Sharp and Dohme Corporation and Ors. v Glenmark Pharmaceuticals*, 2015 (63) PTC 257 (Del) (Delhi High Court, India) [83]

[155] Hoen, Private Patents (n 50 ch2) 101.

the facts of each case. The distinction between the relationship of these two categories with the RtH is rooted in the case law. In *Roche*, in which the Delhi High Court allowed the RtH to inform its interpretation of the standard of injunction, the drug at issue was a life-saving cancer drug. [156] On the other hand, in the *Merck Sharp and Dome Corporation* case, in which the RtH was not considered by the Court, the drug at issue was Sitagliptin, used to lower blood sugar levels in Type 2 Diabetes Mellitus ('T2DM') patients.[157] The court, in the latter case, held that, since the drug at issue was used to manage diabetes, a lifestyle disorder, the grant of an injunction would not have the startling consequences due to unaffordability as might have materialized in case of the cancer drug. [158]

A determination on how far the RtH comes into play for life-enhancing medicines will have to be made, I submit, on a case-by-case basis, based on a range of factors. These include the prognosis, the ease in administering the drug and the significance that it will have for enhancing the quality of life. Once the court determines that the medicine is one covered by the RtH, it must ensure that the government comes up with a constitutionally compliant way to provide access to it. Normatively, the Court, in assessing governmental justifications, can distinguish between inability and unwillingness.[159] If a justification for not providing affordable access is based on the former, the court must accept it, subject of course, to a showing being made that the government has made an effort to use the available resources to

[156] *Merck Sharp and Dome* (n154) [2].

[157] ibid [1].

[158] ibid [83].

[159] This is drawn from GC 14, [47].

the extent possible and is genuinely unable to meet the obligation. if the justification falls in the latter category, it should not. Space precludes a more detailed consideration of these standards.

The third type of drugs are lifestyle drugs. Examples of this kind include drugs used to deal with balding or skincare drugs like Botox. An argument could be made, for instance, that access to Botox is essential to deal with societal prejudice and improve one's access to job or other personal opportunities. However, the linkage of such drugs with the RtH would be far too attenuated to merit judicial intervention.[160]

### 3.7.2 Systemic intervention

At the systemic level, the court can provide some suggestions to the government to create an environment in which the selected PLVs can be operationalized. These reforms can help imbue generics with greater confidence in triggering these PLVs and create a more conducive policy environment for their use. Some suggestions in this regard are set out below:

- One of the key irritants in the Nexavar case was the rate at which royalty should be paid. Recall that, while the figure fixed by the CGPat was 6%, the IPAB raised it to 7%. While fixing a flat rate would be problematic from a TRIPS compatibility standpoint, a clear enunciation of the criteria subject to which royalty is to be paid

[160] This segment has benefited from conversations with Justice Ravindra Bhat, Judge Supreme Court of India (conversation dated 5 June 2020); Justice Kate O'Regan, Director, Bonavero Institute of Human Rights (conversation dated 18 April 2020) and Professor Srividhya Ragavan, Texas A and M University (conversation dated 5 April 2020).

[codified in government guidelines] would be valuable in helping avoid litigation on this score.

- The CG could be urged to consider shifting the administration of CL and government use PLVs to the MoH.[161] This Ministry would be far better equipped to evaluate CL applications and the wisdom of triggering these PLVs through an RtH standpoint. Arguments concerning the implications of decisions entailing the invocation of these PLVs for the RtH might find greater purchase in the MoH. Pertinently, the DIPP is also tasked with the responsibility of managing 'Direct foreign and non-resident investment in industrial and service projects.' [162] Therefore, the possibility of any decision as to the triggering of the PLVs having a fallout for India's FDI inflows is likely to exercise a stronger gravitational pull on it. At the same time, in order to ensure that the DIPP's concerns are duly accounted for, the Court could urge the government to develop a mechanism for such concerns to be voiced and considered by the MoH.

- In addition to the second suggestion, or as an alternative, the Court could urge the CG to usher in reforms to vest the CGPat with greater independence and competence. This

[161] At present, the Allocation of Business Rules framed by the Government of India place the administration of the 1970 Act within the Control of the DIPP

Government of India allocation of business rules 1961, Department of Industry and Policy Promotion, Item 31.

[162] ibid Item 21.

could be in the shape of norms to govern the manner of appointment, requirement of legal training, etc.[163]

The court can also ask the CG to develop a monitoring and evaluation mechanism to determine how far patented drugs are affordable and to periodically evaluate such data to determine if the selected PLVs ought to be invoked. This will help arm generics with the information needed to craft better quality CL applications and create a more conducive environment for the activation of PLVs.

Again, consistent with the BD approach sketched above, the Court cannot have the last word on the implementation of these suggestions. All that it can do is to hold that the RtH requires affordable access to patented drugs, especially those of a life-saving character. It can further hold that the PLVs to foster such access, viewed by Parliament as the best solution to solve this problem, have thus far only remained on paper. It can therefore require the government to develop a constitutionally compliant way to make these PLVs come alive and offer the above suggestions for its consideration. If the government is able to come up with other systemic solutions to solve the problem of PBU especially of life-saving medicines, that comply with the requirements of the RtH, the court must, consistent with the BD approach, defer to it.

[163] For a list of proposed reforms in this regard, see Bajaj and Basheer, Who Am I? Of patent independence and 'adjudicative regulators' [2018] Kritika: Essays on Intellectual Property 72, 91-92.

### 3.7.3 Not relitigating need for PLVs

It might be argued that it would be inappropriate for a court to intervene to undercut the rights of patentees. Accepting this characterization for argument's sake, this would be an apposite course of action for two reasons. First, parliament anticipated the use of these PLVs as safety valves against exorbitantly priced patented medicines. Therefore, it would be wrong for patentees to relitigate their justification when they are actually deployed in the manner anticipated. Second, because of the theoretical justification provided in the first part of the second chapter, making the interests of the patentees subservient to the public interest is appropriate.

## 3.8 Summary

I have proposed above a two-track model of intervention, combining access to a widely unaffordable patented drug through the use of the selected PLVs in a given case, coupled with the use of such litigation as a launching point for the court to propose systemic reforms. In light of the concerns with judicial intervention outlined, I have proposed the deployment of the BD model. I have also articulated the terms of the deliberation and the stakeholders between whom it should take place. Importantly, I have argued that the RtH must kick in only when there is widespread unaffordability and furnished some tentative criteria to make this determination. I have also provided a typology of medicines and explained their linkage with the RtH and furnished the standard of justification that ought to inform the deliberation.

## Conclusion

The selected PLVs in the 1970 Act should be assessed for their ability to actually make medicines affordable to the masses. This has clearly not happened. As a result, these PLVs have remained as empty promises. It is also clear that judicial involvement in the RtH domain, when done right, can produce positive consequences. Specifically, I have demonstrated how such intervention can take place in this context in a way that is both strategically optimal [from the standpoint of solving the problem of essential patented drugs being unaffordable] and also doctrinally sound [from the standpoint of the role of courts]. If executed effectively, these prescriptions can help us realize the vision of having a finely balanced patent law regime that the 1970 Act is premised on. I will next turn to consider the fashion in which India can persuasively counter any repercussions it might face against implementing my proposal.

# CHAPTER 4

## Introduction

In the previous chapter, I outlined a clear roadmap for the triggering of the selected PLVs and for their transition from paper to practice at the systemic level to take place. The aim of this chapter will be to assess the possible repercussions that India might face if my suggestions are carried into effect and outline the fashion in which each of these can be effectively negotiated. Two such avenues will be discussed: TRIPS and the USTR's 301 process. The first challenge might come from countries that are opposed to the meaningful deployment of TRIPS flexibilities, led by the US. The second could come from the US Government.

## Part 1: TRIPS compatibility of proposed prescriptions

I first turn to TRIPS, for the prescriptions I propose must be within the outer bounds delineated by it. The repercussion India might face here would be a possible claim under the World Trade Organization ('WTO')'s Dispute Settlement Mechanism ('DSM') for the operationalization of its PLVs.[1] To date, the WTO's Dispute Settlement Body ('DSB') has not adjudicated on any claims relating to the TRIPS compatibility of the use of the three PLVs I am dealing with: CLs, government use provisions and the form 27 procedure. Therefore, it is difficult to predict with precision what provisions of the TRIPS agreement a country might rely on in support of its claims against India. The closest parallel is the U.S. – Brazil dispute.

[1] See generally, Knowledge Ecology International, 'WTO TRIPS Council: Brazil, China, Fiji, India, and South Africa Table Agenda Item on IP and the Public Interest' (2017) <https://www.keionline.org/23368> accessed 19 July 2020.

In 2000, the U.S. brought a claim against Brazil in the WTO DSM. Brazil's 'local working' requirement states that a patent shall be subject to a CL if the underlying subject matter is not locally worked in Brazil. This, the US argued, was violative of Articles 27 and 28 of TRIPS. [2] Article 27 states that patent protection shall be granted for inventions that meet the criteria of novelty, inventive step and industrial application. Article 28 enables patentees to commercially exploit the patented invention. [3] In case of a TRIPS violation being found, parties are given a reasonable time period to determine the amount of compensation. Failing this, a country can seek the DSB's permission to impose trade sanctions on the erring nation as per Article 22.2 of the Dispute Settlement Understanding.

In light of the above, I will outline potential arguments that India can raise to persuasively counter a claim in the above format. The Vienna Convention on the Law of Treaties ('VCLT') furnishes the kinds of evidence that can be relied on, for the interpretation of any treaty, such as TRIPS. The key sources, for the present, are:

- The context, object and purpose of its terms[4]
- Any subsequent agreement between the parties, as regards the interpretation or application of the treaty.[5]

[2] DS199: Brazil — Measures Affecting Patent Protection' (WTO, 2001) <https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds199_e.htm> accessed 19 July 2020.

[3]The claim was also based on Article 3 of GATT 1994, but space precludes its consideration here.

[4] Vienna Convention on the Law of Treaties (adopted 23 May 1969, entered into force 27 January 1980) 1155 UNTS 331 (VCLT) Art 31(1).

[5] VCLT, Article 31(3)(a).

- Any subsequent practice in the Treaty's application, evidencing an agreement between parties as to its interpretation. [6]

## 1.1 An assessment of the regime created by TRIPS

Even as TRIPS obliges countries to ensure a minimum level of patent protection, it creates a permissive regime for the carving out of exceptions and limitations that further public health objectives.[7] This is most clearly evident from a conjoint reading of Articles 7, 8, 30 and 31. Article 7 outlines the objectives of the TRIPS agreement as being to ensure the effective enforcement of IP in a way that, inter alia, is: 'conducive to social and economic welfare'. Article 8 gives member countries the freedom to take measures that protect public health and nutrition. Article 8(2) allows for the taking of TRIPS-compatible measures aimed at preventing the abuse of IP rights.

Articles 30 and 31 deal with exceptions to the rights of patent owners. Article 31, being on point here, is being discussed. It allows for the grant of CLs. It leaves countries with significant breathing space to determine how the CL or government use levers can be triggered. All it does is to prescribe some conditions that any such grant must comply with. These have already been embodied in Indian law. They include the condition that such determinations must be made on the individual merits of each case.[8] Attempts to obtain prior authorization of the patentee must have been made on reasonable conditions and within a reasonable time period,

[6] VCLT, Article 31(3)(b).

[7] UN Report (n 16 ch2) 16.

[8] Article 31 (A).

except in three circumstances. These are when the CL grant is for national emergency, extreme urgency or public non-commercial use. [9] As regards the first two of these conditions, the patentee has to be given information of the grant with reasonable expedition. As regards the third condition, when the government or a contractor has reasonable grounds to believe that a valid patent will be used by the government, they must inform the patentee promptly.[10] The scope and duration of the use has to be limited to the authorized purpose [11]. The authorization has to be predominantly for the domestic market. [12] The use must terminate when the circumstances giving rise to the need for it cease and are unlikely to recur. Lastly, the right holder has to be paid adequate remuneration, based on the economic value of the invention. [13] Pertinently, the TRIPS agreement does not outline any procedures for how the CL lever is to be triggered by countries. [14]

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[9] Article 31(b).

[10] ibid.

[11] Article 31(c).

[12] Article 31(f). But see WTO - 'Decision of the General Council, Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health' – General Council (30 August 2003) WT/L/540.

See also Bryan Mercurio, 'TRIPs, Patents, and Access To Life-Saving Drugs In The Developing World' [2004] Marq. Intellectual Property L. Rev. 211, 213, 214.

'Paragraph 6 [of the Implementation Decision]... by creating an exception to [a]rticle 31(f) of the TRIPS Agreement ... allows nations with insufficient or no manufacturing capabilities to override intellectual property protection and import generic copies of patented drugs to combat public health crisis'.

[13] TRIPS Agreement, Article 31(h).

[14] *'Discussion Paper: Compulsory Licencing'* (Department of Industrial Policy and Promotion 2010) 3.

When developing countries sought to use TRIPS flexibilities, they faced considerable backlash. [15] This brought into sharp relief the need to situate TRIPS flexibilities on firmer moorings. This resulted in the signing of the 2001 Doha Declaration.

## 1.2 Salient features of the Doha Declaration

It clarifies that the TRIPS agreement should be interpreted in a manner supportive of the right of members to protect public health and to promote A2M.[16] It recognizes the right of WTO members to use TRIPS flexibilities to the full, to secure this objective. [17]

Para 5[b] is on point and states:

'b. Each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted'.[18] Para 5[c] is also important. It leaves it for

[15] Frederick Abbott, 'The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO' (2002) 5 Journal of International Economic Law 471, 472. Also see Carlos M Correa and Germán Velásquez, 'Access to Medicines: Experiences with Compulsory Licenses and Government Use-The Case of Hepatitis C' (2019) 85 South Centre Research Paper 9 [describing a lawsuit filed by 39 pharmaceutical companies against the South African Government to challenge the use of parallel imports and compulsory licenses. The pharma companies were forced to withdraw their demands].

[16] World Trade Organization, 'Ministerial Declaration of 14 November 2001' (November 2001) WT/MIN(01)/DEC/1, 41 ILM 746. Doha Declaration [4].

ibid Abbott 488: [noting the use of such permissive and wide language, as opposed to an alternative formulation whose scope would have been confined to public health crises and pandemics. And further noting the replacement of the original formulation: 'Nothing in the TRIPS Agreement shall prevent to 'the TRIPS Agreement does not and should not prevent', as being indicative of a desire to create a more exception-friendly regime].

[17] ibid Doha Declaration.

[18] Abbott (n15) 494.

the state parties to decide what constitutes a national emergency or extreme urgency.[19] Further, the three grounds contained in Section 92 map onto the conditions spelt out in Article 31[b] of the TRIPS Agreement.[20] Pertinently, Section 92[3] tracks the grounds spelt out in Article 5[c] of the Doha Declaration. Both clearly recognize that a national emergency can be represented by circumstances related to HIV/AIDS, tuberculosis, malaria and other epidemics. Therefore, a conjoint reading of the above makes clear that countries are given sufficient elbowroom to determine how the selected PLVs are to be applied, substantively and procedurally. The PLVs under discussion comfortably fit within this permissive regime, as they contain a range of safeguards to protect the interest of patentees. As the Doha Declaration calls for the increased utilization of the selected PLVs, this fact can become the defensible ground for India to counter any arguments against the prescriptions I propose.

[19] In this regard, also see generally, Lionel Bently and Brad Sherman, 'Limiting Patents', in *Compulsory Licensing Practical Experiences and Ways Forward* (Springer 2015) 326.

'While there has been a growth in international norms limiting exclusions from patentability, there are much fewer provisions that restrict the exceptions that countries can use in their patent laws. As a result, Member States still have considerable room in terms of the exceptions to patentee's rights that they wish to implement in their patent laws'.

[20] Madhavi Chopra, Big Daddy (n 39 ch 3) 353.

## 1.3 Tobacco plain packaging decision

In the Tobacco Plain Packaging decision ('Tobacco Decision'), the WTO DSB recognized that the Doha Declaration must inform the interpretation of TRIPS. This is rooted in the fact that it is a subsequent agreement, within the meaning of Article 31[3][a] of the VCLT. [21]

After the coming into force of the Doha Declaration, the WTO DSB has not found a single TRIPS violation for the use of TRIPS flexibilities. This is a 'proof of the importance of the legitimation of these flexibilities to the developing countries by means of the Doha Declaration'.[22]

The Tobacco Decision further stated as follows:

> 'As described above, Articles 7 and 8 have central relevance in establishing the objectives and principles that, according to the Doha Declaration, express the object and purpose of the TRIPS Agreement relevant to its interpretation'.[23]

[21] WTO, Australia — Certain Measures Concerning Trademarks, Geographical Indications and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging – Dispute Settlement Body (30 August 2018) WT/DS467/23 [7.2409].

This was upheld by the Appellate Body. It affirmed the use of the Doha Declaration as an instrument to confirm that Articles 7 and 8 of the TRIPS agreement provide useful contextual guidance for its interpretation. See

WTO, Australia — Certain Measures Concerning Trademarks, Geographical Indications and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging – Dispute Settlement Appellate Body (9 June 2020) WT/DS435/441 [6.657 and 6.658].

[22] Correa and Velásquez (n 15) 11.

[23] Tobacco DSB Decision (n 21) [7.2408].

It noted that public health has unquestionably been recognized as a societal interest that needs to be balanced with the rights of patentees.[24] Consequently, it can be confidently asserted that any arguments India might make to defend the implementation of my prescriptions, based on the need to further public health objectives, are likely to find purchase in the DSB. India can also draw on the UN High-Level Panel report. It calls on WTO members to safeguard the rights of other members to 'adopt and implement flexibilities in the TRIPS Agreement as reaffirmed by the Doha Declaration'.[25]

## 1.4 Statutorization and grant of CLs: a ubiquitous practice

Finally, the VCLT allows for the consideration of any subsequent practice between state parties, as mentioned above. India can argue that the CL lever has been embodied in the laws of many member nations. This shows that its operationalization will not be problematic from the standpoint of TRIPS. 84 countries allow for the grant of CLs.[26] Further, 15 American statutes allow for the issuance of nonvoluntary licenses and the US grants such licenses very actively. [27] The form 27 procedure is nothing but the means by which these PLVs can be

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[24] ibid [7.2406].

The importance of Article 8 was reaffirmed by the Appellate Body, [6.649].

[25] UN Report (n 16 ch2) 25.

[26] WIPO, 'Exceptions and Limitations to Patent Rights: Compulsory Licenses and/or Government Use (Part 1)' (Standing Committee on the Law of Patents, 2014).

[27] Knowledge Ecology International, 'KEI Testimony at March 8, 2018 USTR Special 301 Hearing, Focusing on US Compulsory Licensing of Patents' (Knowledge Ecology International, 2018) https://www.keionline.org/27147> accessed 14 July, 2020.

operationalized. As a sovereign nation, India can contend that it is well within her rights to seek the information that is the sine qua non to work the PLVs that help further public health.

## Part 2: Potential US Backlash

A second area of challenge could be the USTR's 301 process, discussed in the second chapter. To recapitulate, a country can be put by the US on the watchlist or the priority watchlist. The consequences of this designation are unclear, except for the fact that it translates into the country being subjected to heightened scrutiny and put on the path to being on the receiving end of sanctions.[28] If a country is subsequently designated as a priority country, an investigation must be conducted and the US has the option of imposing sanctions on it on its conclusion.

This can be in the shape of tariffs, import restrictions or withdrawal of preferential treatment.[29] Recall that, when Thailand used its CL provisions, the US withdrew duty-free access on three Thai products. India can deploy the following strategies to resist any US pressure through this route.

### 2.1 Tenuous legal basis of the 301 process

[28] Kapczynski, Harmonzation (n44 ch1) 1630.

[29] ibid 1628.

First, as Shaun Flynn notes, the 301 process is itself vulnerable under international law. In a challenge lodged against the process, a WTO DSB noted as follows:

'The threat of unilateral action, especially when it emanates from an economically powerful Member [may] disrupt the very stability and equilibrium which multilateral dispute resolution was meant to foster'. The DSB upheld the programme on the narrow basis that the U.S. issued a 'Statement of Administrative Action' to the effect that it would raise a complaint in the WTO DSB in case it identified any violation, rather than acting unilaterally. However, as he points out, the continued use of the programme to unilaterally threaten the withdrawal of GSP benefits, in the teeth of this declaration, makes it legally vulnerable.[30]

The DSB observed that the mere threat of unilateral action by the US, contrary to DSU rules, could exercise a chilling effect on countries contemplating the use of TRIPS flexibilities. [31] As Bluesky concludes, developing countries must use their increased influence to challenge, at different levels, efforts to constrain their ability to use TRIPS flexibilities and widen A2M.[32]

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[30] Sean Flynn, 'Special 301 and Global Administrative Law', in *Balancing Wealth and Health The Battle over Intellectual Property and Access to Medicines in Latin America* (Oxford University Press 2014) 225, 228.

For a blueprint of what a challenge against the process could look like, see Melissa Bluesky, 'Developing Countries and Intellectual Property Enforcement Measure: Improving Access to Medicines through WTO Dispute Settlement' [2011] Trade L. & Dev 407, 432-33., [arguing that the challenge could be two-pronged:

A. Administrative adjudication through the watch-lists, pursuant to Section 301, constitutes a 'determination to the effect that a violation has occurred' which has been clearly understood by the Panel as constituting impermissible unilateral action.

B. Inclusion of countries in the list, and the threat of action based on that, constitutes violations of the DSU].

[31] WTO - United States—Sections 301–10 of the Trade Act of 1974 – DSB (December 22, 1999) WT/DS152/R [7.88]

[32] Bluesky (n 30) 440.

It bears mention that India has, in the past, expressed a wish to take the US to the WTO if any unilateral action is taken against it for working its patent law. [33]

## 2.2 Successful examples of resisting the process

Second, India can seek strength from other countries which have successfully resisted US pressure imposed through the 301 process. Illustratively, in 2007, Canada noted that it would no longer pay any attention to the list as it lacked '"reliable and objective" analysis and was entirely driven by U.S industry'.[34] In 2013, Chile concluded that the list 'lacks clear criteria for categorizing the different countries, but is rather a reflection of the interests of American industry selectively applying their intellectual property standards to other countries'.[35]

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See also Liberal Law Professor Files at UN Formal Allegations Against US Government's 'Special 301Program' Claiming US Laws Protecting IP Violate 'International Human Right' to Access to Medicines' (ITSSD Journal on Intellectual Property Rights, 2010) http://itssdinternationaliprights.blogspot.com/2010/10/liberal-law-professor-files-at-un.html accessed 25 July 2020.

[calling on the U.N. special rapporteur on the RtH to urge the US to, inter alia, halt the use of the 301 programme as a means to prevent developing countries from using TRIPS flexibilities to foster access to medicines].

[33] Nayanima Basu, 'India Plays WTO Card against US' (Business Standard, 2014) <https://www.business-standard.com/article/economy-policy/india-plays-wto-card-against-us-114042800008_1.html> accessed 25 July 2020.

[34] Standing Committee on Public Safety and National Security, 'SECU Committee Meeting' (Parliament of Canada, 2007) <https://www.ourcommons.ca/DocumentViewer/en/39-1/SECU/meeting-35/evidence#T1150>. accessed 14 July 2020.

[35] 'Chile No Reconoce Validez de 'Lista Negra' de Piratería de EE.UU' (Emol, 2013) https://www.emol.com/noticias/nacional/2013/05/01/596379/chile-no-reconoce-la-validez-de-la-lista-negra-de-pirateria-de-eeuu.html accessed 21 July 2020.

## 2.3 Influence of the COVID Pandemic

Lastly, responses to the COVID outbreak have made the possibility of this mechanism being used against India even more remote. Specifically, several countries have loosened their CL mechanisms as part of the pandemic response. To illustrate, Canada has passed a law which allows the Minister of Health to apply to the Commissioner for the grant of a CL. The Commissioner must authorize the government or any specified person to use the patented invention, to the extent necessary to respond to 'a public health emergency that is a matter of national concern.' Similarly, in Germany, the patent law has been amended in light of the outbreak. The amended law states that a patent shall have no effect if the Federal Government states that it is to be used in the interest of public welfare.[36] Admittedly these are extreme measures, necessitated by a global pandemic. However, they have helped create a generally hospitable culture for the use of the selected PLVs.

# Conclusion

As Abbott points out, the Doha Declaration will be of enduring importance only to the extent that it is able to help alter the TRIPS implementation environment.[37] In order for this to be done meaningfully, India will have to find a way to counter any repercussions it faces against

[36] 'COVID-19 IP Policy Tracker' (WIPO, 16 July 2020) <https://www.wipo.int/covid19-policy-tracker/#/covid19-policy-tracker/access> accessed 23 July 2020.

[37] Abbott, Dark Corner (n 15) 504.

its utilization of the selected PLVs. Therefore, I have explained what the key potential sources of repercussions that India might face are and how these can be effectively tackled. Therefore, India should feel uninhibited in using the selected PLVs, safe in the knowledge that any challenge against such use can be effectively repelled.

# THESIS CONCLUSION

Let us briefly summarize the core claims made in this thesis. I began by drawing on existing empirical research to outline the core problem that the project seeks to address: that of PBU. Then, I demonstrated why the use of PLVs appears to be the most promising solution to this problem. Then, I assessed why these PLVs have not thus far seen the light of day.

Then, my focus switched to outlining the contours of my argument for how it can be addressed. While doing so, I consistently sought to convincingly respond to potential concerns against the argument. Specifically, after fleshing out the theoretical framework of the argument and responding to potential criticisms, I established that the RtH includes within its ambit access to patented medicines and that the state must attenuate the barriers preventing such access. Thereafter, I provided a rationale for focusing on the selected PLVs amongst the available menu of options and highlighted the factum of their underutilization. Then, I moved on to making the signature contribution of the project, of outlining a nuanced, carefully considered model of judicial intervention which carries the promise of addressing the problem of PBU. Finally, I provided an account of potential blockages against my proposal being implemented and offered a roadmap to address them.

Some avenues of further research, not explored in the thesis, are the following:

- The need to create opportunity structures and incentivizing mechanisms to encourage the Indian generic industry to collaborate with the government to utilize the selected PLVs.
- A more rigorous and expanded analysis of balancing the individual and systemic dimensions of the RtH. Further, exploring how the concept of a core and non-derogable obligation under the RtH, traditionally applied to individuals, can be applied on a larger scale, as I propose.
- How judicial intervention of the kind I propose can catalyze NGOs and political action to ensure A2M.

It is hoped that this contribution will serve as the seedbed not only for litigation in an Indian court on the terms I propose but also for research in some of the above areas.

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