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Original Paper

"The Pharmacy of the World": The Rise of India's Pharmaceutical Patent Regime

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Abstract

When India achieved its hard-fought independence, it inherited both a blazing hope for the future and the burdens of its colonial past. These realities converged as the nation embarked on the path toward self-reliance in pharmaceutical and patent law. Beginning with the British patent law imposed in 1856, India grappled with its inadequacies—particularly its susceptibility to foreign monopolies and the stifling of domestic competition. The solution was clear: the establishment of a distinct, resilient, and innovative Indian patent regime to address these challenges. Through a long and arduous journey, starting at independence and culminating in the landmark Patents Act of 2005 and beyond, India struck a balance between safeguarding patent rights and ensuring equitable access to essential medicines. In doing so, the post-colonial nation earned its place as the "pharmacy of the world", dedicated to fostering both innovation and public welfare.

Keywords

indian pharmaceutical industry, patent law evolution, TRIPS compliance, generic medicines, pharmaceutical accessibility, evergreening

1. Introduction

"Believe me, if we impose price controls on the pharmaceutical industry, and if you reduce the research and development that this industry is able to provide, it's going to harm my kids and it's going to harm those millions of other Americans who have life-threatening conditions" (Rousseau, 2023, p. 36).

-Alan Holmer, former president of the U.S. Industry Trade Association

Hailed as the "pharmacy of the world", India's pharmaceutical sector stands as a testament to the profound influence of patent law on the twin pillars of pharmacy: *innovation* and *accessibility*. In the space of a century, India etched radical changes into Intellectual Property (IP) law that would catapult

its nascent pharmaceutical industry into a commercial powerhouse. Present-day India is renowned for its bustling manufacturing of generic medicines and expansive research and development (R&D) initiatives. Boasting a network of some three thousand pharmaceutical companies and fifteen thousand manufacturing units, Indian manufacturing satiates half of worldwide vaccine demand, 40 percent of American demand for generics, and one fourth of all medicines in the UK—a fitting resume for its reputed moniker (India Brand Equity Foundation, 2023). Thus far, the development of India's pharmaceutical patent regime has been well documented, with patent law professor Janice M. Mueller's *The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation* representing a seminal work on the subject (Mueller, 2007, p. 508). More broadly, the tight linkages between patent law and the growth of domestic pharmacy has been the subject of quantitative and qualitative analyses (Dwivedi, Hallihosur, & Rangan, 2010, p. 329; Feldman, 2018, pp. 590-647), some of which are embodied as far back as an 1807 letter from Thomas Jefferson to Oliver Vans:

"Certainly an inventor ought to be allowed a right to the benefit of his invention for some certain time. It is equally certain it ought not be perpetual; for to embarrass society with monopolies for every utensil existing, and in all the details of life, would be more injurious to them than had the supposed inventors never existed" (Jefferson, 1807, pp. 200-202).

A patent regime may only be deemed successful if it remedies the conflict between *accessibility* and *innovation* inherent to commercial pharmacy (Racherla, 2019, pp. 274-275). Giving precedence to *accessibility*, the Indian pharmaceutical system is marked by pervasive government interventionism—the stuff of capitalist nightmares—at odds with its American counterpart, regulated predominantly by the *invisible hand* of the free market (Racherla, 2019, p. 272). In the latter regime, the purported perks of leading in the discovery of new drugs and turning out lucrative financial reports paper over the premium paid by ordinary Americans for essential treatments like epinephrine and Insulin—a microcosm of the nationwide prescription non-adherence epidemic (Kneller, 2010, pp. 867-882; Bosworth et al., 2011, pp. 412-424).

Such motifs are enshrined in Article 41 of the Indian Constitution and Article 12 of the *International Covenant on Economic, Social, and Cultural Rights*, which India became signatory to in 1979, which put it on the state to ameliorate public healthcare outcomes (The Constitution of India, 2022, Article 41, ii; International Covenant on Economic, Social and Cultural Rights, 1966, Article 12). Building upon existing chronological documentation, this paper plots the history of India's patent regime from colonial times to present day *vis-à-vis* the legal recourse available to address monopolistic practices. This paper then argues that over the development of India's patent regime, legal recourse was iteratively expanded to insulate domestic pharmaceutical manufacturers from foreign predation and ensure widespread *accessibility* to essential medicines. The Indian Patents Act of 1970 and its 2005

successor attest to the paper's central claim that India's patent regime was rigged with both anticipatory and responsive legal provisions to combat monopolistic pharmaceutical practices. Moreover, under India's distinct twentieth-century socioeconomic circumstances, this paper posits that the deliberate choice to put *accessibility* above *innovation* maximized social welfare at little detriment to R&D.

2. The History of India's Patent Regime

The centennial history of India's patent regime can be slotted into its *colonization*, *post-independence*, and *globalization* phases (Racherla, 2019, pp. 275-276). Each period bore witness to radical change in statutory patent law. Nevertheless, one consideration loomed overhead: providing essential medicines at an affordable price. Not formally defined until the World Health Organization (WHO) curated its first *Essential Medicines List* in 1977, the original meaning of *essential medicines* echoes its modern, universally-accepted definition: "medicines… selected based on disease prevalence and public health relevance, evidence of clinical efficacy and safety, and comparative costs and cost-effectiveness" (World Health Organization, 2023a; World Health Organization, 2023b). In what follows, I trace the evolution of India's patent regime from its inauguration in 1856 to the Patents Act of 2005 to understand how it shook off British influence and carved out its own, distinctive pharmaceutical legacy.

2.1 Colonization

The colonial era was a relatively uneventful chapter in the storied history of India's patent regime. For the most part, Britain has no intention of experimenting with India which it saw as the "brightest jewel in the imperial crown" (Judd, 2004, p. 94). It would not be until India's independence in 1947 when drastic measures could be taken to fulfill the goals laid out in its constitution (Mueller, 2007, p. 505). Nevertheless, the *colonization* period established a broad framework for IP protection in India and uncovered structural frictions that would receive significant attention during the *post-independence* and *globalization* periods. While most scholars agree in regard to the three broad classifications of India's patent history—*colonization*, *post-independence*, and *globalization* (Mueller, 2007, p. 504; Racherla, 2019, p. 275)—the commencement of the *colonization* period remains contentious. In her seminal paper on the subject, Mueller contends that British influence on Indian patent law dates back to Queen Elizabeth I's chartering of the "Governor and Company of Merchants of London trading into the East Indies" at the turn of the 17th century (Mueller, 2007, pp. 505–506). However, other reputed scholars such as Dharam Prakash Verma maintain that India had to wait two centuries before Britain officially implemented the first patent statute in 1856 (Verma, 2009, p. 32). Irrelevant of who is correct, much of Indian patent law during the colonial period was inherited directly from the British system (Mueller, 2007, p. 505). Act VI of 1856 is a case in point: the statute provided a 14-year exclusivity period to inventors and manufacturers—the first of its kind—that mimicked the British Patent Law of 1852 (The Patent Office India, 2008, p. 6).

In 1859, the statute was amended to clarify that patents would only be granted to "useful" inventions (The Patent Office India, 2008, p. 7). The seemingly trivial addition was responsible for sweeping legal uncertainties—such as "What qualifies as a useful invention? Should usefulness be judged by practical benefits or potential market value? Who decides if an invention meets the criteria?"—that would be the subject of heated controversy in the *post-independence* and *globalization* eras. These disputes elegantly capture the essence of India's century-long tussle with patent law. Unless statutory law and court precedent are so well-established as to be interpreted singularly, then political rent-seeking and hijacking of the patent system at the hands of pharmaceutical corporations are inescapable.

The Indian Patents and Designs Act of 1911 put patent enforcement under the purview of the Controller of Patents, an individual authorized to oversee patent evaluations, resolve disputes, and set policy guidelines (Verma, 2009, p. 32). In this sense, the Controller of Patents served both a quasi-judicial role and as a figurehead for India's patent regime. That same year, the act was amended, hereinafter referred to as Act II of 1911, to introduce official issuance of *product* and *process* patents (Governor General of India, 1911, pp. 6-7). Cumulatively, the colonial period displayed the broadest scope of patentable subject matter, owing to a liberal interpretation of "usefulness" and the issuance of *process* and *product* patents under Act II of 1911, which allowed companies to garner IP exclusive rights for the end product (*product*) and the method of production (*process*) (Ayyangar, 1959, p. 40). As we will explore in the coming sections, definitions dictating patentability and the issuance of *product* patents blossomed into major points of contention in the Patents Act of 1970 and its 2005 successor.

2.2 Post-Independence

After emerging triumphant from its decades-long battle for independence, India turned its attention towards ridding its pharmaceutical markets of foreign exploitation. Over the next three decades, the government rallied for, experimented with, and instituted a series of *anti-patent* policies that highlighted the corrective effects of patent law on monopolistic practices in the pharmaceutical industry. It was this proliferation of patent regulations that ushered in the "Golden Age" of India's pharmaceutical industry—denoted by mass manufacturing of generic drugs and widespread *accessibility* to *essential* medicines among its impoverished population. The *post-independence* period saw the burgeoning nation draw inspiration from other states in comparable socioeconomic conditions. Lessons learned from other nations led India to focus on pharmaceutical *accessibility*, as opposed to *innovation*, which proved to be a sound decision given the nation's distinctive socioeconomic circumstances. In an attempt to prove that India made the correct choice, this section forwards a relationship between a nation's developmental trajectory and its leaning on the *accessibility-innovation* spectrum.

Shortly after breaking free from British shackles in 1947, India declared a sovereign socialist secular democratic republic (Racherla, 2019, p. 277). The nascent country faced innumerable challenges in

disseminating pharmaceuticals to, what was then, a population of over 400 million people (Racherla, 2019). Central to these struggles lay its dormant patent regime, which facilitated few inducements for drug manufacturing (*accessibility*) and R&D (*innovation*). India resorted to importing *essential medicines* such as penicillin and insulin at exorbitant prices relative to the rest of the world (Racherla, 2019). During Britain's stronghold over India, IP protections were so "inequitably strong" that Multinational Corporations (MNCs) pushed domestic manufacturers out of business (Racherla, 2019). Irrelevant of whether or not a given infringement suit was warranted, courts habitually ruled in favor of MNCs. An infringement lawsuit German company Hoechst Pharmaceuticals brought against Indian manufacturer Unichem Laboratories over the manufacture of anti-diabetic drugs epitomized the preferential nature of contemporary court rulings. Notwithstanding the fact that the defendant utilized an entirely distinct method of production, which should have qualified as a unique *process*, the Bombay High Court ruled in favor of the plaintiff, nonetheless (Bombay High Court, 1968). To remedy this asymmetry, the Indian government instituted an authoritative committee in 1949 with Jurist Bakshi Tek Chand at the helm. In light of the *Farbewerke Hoechst v. Unichem Laboratories* case, the committee recommended:

The main provisions suggested by the committee among others include compulsory licensing, commercial working of patented inventions in India barring importations, setting up of appellate body in the form of an ad-hoc Special Tribunal nominated by the Central Government consisting of a sitting or retired judge of a High Court (as the President), and ensuring that food and medicines are available at cheapest rates to the public commensurate with giving reasonable compensation to the patentee etc. (The Patent Office India, 2008, pp. 8-9).

This recommendation represents the first of many instances in which India would temper patent statutes to protect domestic manufacturers. In advocating for compensation to be only "commensurate" and "reasonable", the recommendation encouraged India to orient patent law towards public welfare. As the committee saw it, optimal patents compensated patentees *sufficiently*, such that it encouraged *innovation*, and no further. None of the Chand Committee's recommendations would end up as statutory law, but another committee headed by retired Indian Supreme Court justice Rajagopala Ayyangar was established to build off its predecessor's findings. The new committee tackled two imprecisions with existing patent law: (1) "the precise… extent of patentability… to inventions"; and (2) "the law determining the patentability of inventions relating to food and medicine" (Ayyangar, 1959, p. 23). Accordingly, the Ayyangar Committee authored the nearly four hundred-page *Report on the Revision of the Patents Law* which touched on topics from safeguards against foreign competition, patent-eligible subject matter, to the necessity of a patent regime at all. For its contribution to the Indian Patents Act of 1970, clause 56 stands out:

As regards inventions relating to chemical products, or products produced by chemical processes, I am clearly of the view that the interests of the country would be best served by confining patentability to the processes by which the products are obtained and to deny patents to the products either per se or in the qualified manner suggested in the Bill (Ayyangar, 1959).

In the following clauses (57 to 61), Ayyangar justifies this recommendation (that is, to confine patent issuance to only processes) by analyzing the patent regimes of Europe and nations similarly-situated to India, as well as the theoretical disadvantages of permitting *product* patents in a developing economy (Ayyangar, 1959, pp. 23-26). In observing Germany's patent regime, which exclusively issued *process* patents, Ayyangar noted that such an approach engendered healthy competition wherein companies patented more and more efficient methods of production to gain a comparative advantage—reducing production overhead, making the pharmaceutical supply chain more resilient, and driving down consumer prices (Ayyangar, 1959). These findings were echoed in Dr. Van Ing's 1935 award-winning publication, *A Survey of the Principal National Patent Systems*: "The fact that in Germany henceforth chemical process only, not however chemical products as such, were patentable, thus leaving an open field for the search for new methods of manufacturing known chemicals, was of great advantage to the chemical industry" (Vojáček, 1936, p. 145). Scientists working for generic firms partook in the "reverse engineering" of *processes* for brand-named drugs. If *product* patents had been instituted instead, Ayyangar theorized that German industry would have been afflicted by a "deadening" effect that would have "precluded attempts to arrive at the same product by other alternative processes" (Ayyangar, 1959, pp. 23-24). However, much of Ayyangar's analysis reflected the lax scientific practices of his time. His findings about *process* patents were merely correlatory. For instance, he cited how industrially-advanced countries had implemented *process* patents when they were underdeveloped as proof of his theory (Ayyangar, 1959, pp. 24-26). In addition, he posited that India ought to adopt *process* patents, arguing that virtually all nations—bar certain developed countries including the United States, United Kingdom, and others in the Commonwealth—had analogous patent regimes and comparable socioeconomic conditions with India (Ayyangar, 1959).

For what it set out to accomplish, however, the Ayyangar Committee was a resounding success. The Indian Patents Act of 1970, a landmark statute that would define India's patent landscape for the following three decades, inherited directly from the report. This novel statute repealed the Patents Act of 1911 (except for designs) and contained a few outstanding declarations. (1) The Indian Patent Office terminated the issuance of *product* patents for *process* patents (Intellectual Property India, 2017, p. 9). This change had complicated and varying effects on *innovation*. Pharmaceutical companies pursue precarious and costly R&D to attain exclusive IP rights of their drug that would allow them to establish a temporary monopoly. The termination of *product* patents, thus, nullified the ability for patents to command high prices, putting the discovery of new drugs in jeopardy. Consequently, there is merit

backing the inverse of Ayyangar's initial observation that *process* patents stunted the discovery of new drugs post-1970 (Damodaran, 2008, pp. 414-423). By the 1979 fiscal year, data retrieved from the Indian Patent Office's annual report revealed that foreign patent applications were filed at less than a quarter of their pre-1970 levels, although domestic patent applications remained steady (around a thousand annually) (Bagchi, Banerjee, & Bhattacharya, 1984, p. 293). While the precise innovative implications of the Indian Patents Act of 1970 are difficult to ascertain, it is likely the case that *innovation* existed to a similar degree in the aftermath of *process* patents, but the goalpost had shifted from novel drugs to novel methods of production.

Nevertheless, the transition to *process* patents had a definitive and overwhelmingly positive effect on pharmaceutical *accessibility*. *Process* patents were the ultimate hedge against absurd drug prices since they exterminated monopolies on popular drugs and with it the ability for pharmaceutical companies to set prices. Over the next three decades, India gained global notoriety as a manufacturer of generics—and so began the "Golden Age" of Indian pharmacy. Citizens benefited from prices that were cheaper than their *product* patent counterparts by a factor of five up to thirty (Sundaram, 2018, pp. 139-140). As a case in point, the Indian equivalent of ranitidine, the active ingredient in anti-ulcer medicine, was over a hundred times cheaper than its American counterpart. For better or for worse, India was so proficient at reverse engineering that it gained a reputation as a "pirate" nation that manufactured *copycat* versions of drugs innovated and patented in foreign countries (this claim is legally inaccurate, however, as it ignores that patents are only enforceable within their respective jurisdictions) (Foster, 1998, pp. 306-307).

The expansion of pharmaceutical *accessibility* confers distinct advantages to developing nations such as India—marred by sparse insurance coverage and low healthcare expenditure. In such settings, a significant segment of the population stands to benefit from reduced drug prices. Conversely, in developed nations like the United States or the United Kingdom—where the majority of the population can afford essential medicines—the prioritization of pharmaceutical *innovation* reigns supreme. Hence, under India's unique twentieth-century socioeconomic circumstances, the actionable choice to put *accessibility* over *innovation* was logically sound, despite the suppressive effects of *process* patents on the discovery of new drugs.

Not only did the Patents Act of 1970 confirm that the Indian government sought to leverage patents to advance public welfare, but it also expressed vehement distaste for monopolistic practices. In Article 83 of Chapter XVI, the Indian government unequivocally voiced these sentiments across seven clauses:

(a) that patents are granted to encourage inventions and to secure that the inventions are worked in India on a commercial scale and to the fullest extent that is reasonably practicable without undue delay;

(b) that they are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article;

(c) that the protection and enforcement of patent rights contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations;

(d) that patents granted do not impede protection of public health and nutrition and should act as instrument to promote public interest specially in sectors of vital importance for socio-economic and technological development of India;

(e) that patents granted do not in any way prohibit Central Government in taking measures to protect public health;

(f) that the patent right is not abused by the patentee or person deriving title or interest on patent from the patentee, and the patentee or a person deriving title or interest on patent from the patentee does not resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology; and

(g) that patents are granted to make the benefit of the patented invention available at reasonably affordable prices to the public (Intellectual Property India, 1970, p. 64).

Emblematically, all seven clauses touched on pharmaceutical *accessibility* in some way, stating that patents "encourage inventions… to the fullest extent that is reasonably practicable without undue delay"; "are not granted merely to enable patentees to enjoy a monopoly"; "contribute to… innovation… dissemination"; "act as instrument to promote public interest"; "do not… prohibit Central Government in taking measures to protect public health"; and "make the benefit of the patented invention available at reasonably affordable prices to the public". Cumulatively, these clauses laid a legal foundation for potential litigants—the state, other patentees, generic manufacturers, civil society organizations, and licensees—to litigate and even win against monopolies. Even more, the 1970 statute included a series of safety-net provisions the government could defer to if preliminary measures faltered. Notably, clause (e) flexed the Central Government's authority to bypass patent protection "to protect public health" and Article 97 sanctioned the Controller to grant compulsory licenses to applicants, defined as *any interested person*, to manufacture patented articles at the lowest prices for the general public. It states:

(1) If the Central Government is satisfied in respect of any patent or class of patents in force that it is necessary or expedient in the public interest that compulsory licences should be granted at any time after the sealing thereof to work the invention or inventions, it may make a declaration to that effect in the Official Gazette, and thereupon the following provisions shall have effect, that is to say–

(a) the Controller shall on application made at any time after the notification by any person interested grant to the applicant a licence under the patent on such terms as he thinks fit;

(b) in settling the terms of a licence granted under this section, the Controller shall endeavour to

secure that the articles manufactured under the patent shall be available to the public at the lowest prices consistent with the patentees deriving a reasonable advantage from their patent rights (Intellectual Property India, 1970, p. 73).

Ultimately, the Indian Patents Act of 1970 cements the tight linkage between patent law and pharmacy. The era-defining enactment constructed a harmonious apparatus of checks and balances that legally reinterpreted, and thus suppressed, the generous privileges patents offered under British rule. The transition between *colonization* and *post-independence* bore witness to a role-reversal: India's patent regime positioned *accessibility* and public welfare above all other considerations, shedding its foreign-first mantra from the colonial era. By establishing legal bounds (although still somewhat ambiguous) and litigatory procedures, the landmark statute opened the pharmaceutical domain to new actors who juggled the burden of enforcing fair pharmaceutical practices. After all, a burden shared is a burden halved.

2.3 Globalization

The Golden Age of Indian pharmacy subsided as the *globalization* period disrupted established norms and systems. Until this point, India had erected national industry on the back of domestic and economic reform (Cohen, 2001, p. 95). Then prime minister Jawaharlal Nehru was the poster boy of India's liberal economic standing and a firm proponent of "social engineering and economic regulation" (Cohen, 2001). As the twentieth century came to a close, India found itself on the precipice of integration into the global economy (Mueller, 2007, p. 516). The country, which was not yet independent only several decades prior, was about to springboard into the increasingly international, interconnected, and interdependent global economy. While the fruits of liberalization were ready to be picked, *globalization* was nonetheless a daunting prospect (Cohen, 2001, p. 95).

The *globalization* period backgrounded the final comprehensive revision of India's patent regime through the Patents Act of 2005. Even so, the momentum for the statute and the *globalization* era in general lay in a movement that took off in the 1990s (Cohen, 2001, p. 96). India's initial foray into market liberalization was met with the 1991 Balance of Payment crisis wherein its foreign expenditures exceeded its earnings. This blemish catalyzed a series of sweeping reforms under Finance Minister Manmohan Singh that devalued the rupee, undermined protectionist policies, and liberalized capital markets (Cohen, 2001, p. 101). Howbeit, even as the movement gained traction, India's stance on the General Agreement on Tariffs and Trade (GATT) remained unwavering. For the first three years of the Uruguay Round, famously deemed "the largest negotiation of any kind in history" by the World Trade Organization (WTO), India headed opposition against the inclusion of patent and IP protection (World Trade Organization, 2023). From the perspective of many developing countries, the GATT was an elaborate attempt at glorified economic coercion—the *quid pro quo* being the imposition of taut patent law that would allow MNCs to run-over developing markets (akin to British rule) for access to western

markets (Cohen, 2001, pp. 97-99). Most countries could not pass up the privilege to export to and import from foreign markets. And so, despite their initial resistance, the unified frontier of developing countries thawed as nations reversed their positions in negotiations: first Mexico, then Brazil, followed by Argentina (Cohen, 2001).

Although India held strong for nearly a decade, its conformity with GATT, too, was merely a matter of time (Cohen, 2001). Confronting the daunting prospect of losing vital textile tariff concessions, severing economic aid ties with the International Monetary Fund, and succumbing to economic sanctions imposed by the United States and European Union, India, alongside 116 other nations, officially signed onto the Uruguay Round Agreements on April 15, 1994 in Marrakesh (Foster, 1998, pp. 315–317; Andrade, Shah, & Chandra, 2007, pp. 56-59; Department of Trade and Industry, 1994, p. 1). Not eight months later, India became a member of the WTO and therefore legally obligated to amend its patent regime to comply with Trade-Related Aspects of International Property Rights (TRIPS) (Mueller, 2007, p. 518). Certain obligations were compulsory immediately while others could be postponed for the duration of the transition period (World Trade Organization, 1994, pp. 1125, 1208-1211). For the pharmaceutical industry, TRIPS allowed India until January 1, 2005 (a decade) to comply (World Trade Organization, 1994, Art. 65).

Full compliance with TRIPS was a considerable undertaking. After amending the Patents Act of 1970 on three separate occasions—1999, 2002, and 2005, the final year permitted for the transition—India unveiled the culmination of its efforts: the Indian Patents Act of 2005 (Andrade, Shah, & Chandra, 2007, p. 56). In retrospect, this decade-long struggle paid off. India's timely implementation quelled the rigorous demands of TRIPS without letting go its twentieth-century objective to maximize public welfare. As we will see, the latter feat can be accredited to meticulous anticipatory and responsive legal drafting from India.

At implementation, the Patents Act of 2005 stoked fears that the colonial version of India's patent regime, which benefited MNCs to the demise of home-grown manufacturers, would awaken from dormancy where it had been since 1970. This concern arose from provisions in the 2005 amendment that mirrored the Patents and Designs Act of 1911. Most notably, TRIPS coerced India into bringing back *product* patents, spurring a gold rush that saw domestic and foreign pharmaceutical companies flock to attain patents for popular drugs (Mueller, 2007, p. 519). To hold off the processing of patent applications during the transition period, a mailbox facility was established (as mandated by Article 70 of TRIPS) to serve as a quasi patent application pipeline between January 1, 1995, to December 31, 2004, not to be examined by the Patent Office (Mueller, 2007, pp. 519-521). By 2005, upwards of ten thousand mailbox patent applications had accumulated (Andrade, Shah, & Chandra, 2007, p. 56). However, India's second *rendezvous* with *product* patents did not succumb to the same fate as the first. On this occasion, India was equipped with the wisdom to curate a balanced patent regime that could

hold its own against monopolistic practices. In contrast to its previous patent regimes—the Patents and Designs Act of 1911 and the Patents Act of 1970—India sought to identify a *goldilocks* zone with the newest iteration of their patent regime: it ought not forward IP protection too inept it disincentives R&D and drives a foreign exodus nor too rigid it hampers domestic manufacturing and drives up the prices of essential medicines.

India's initial stint with *product* patents was plagued by exploitation of IP law and pharmaceutical price-gouging. Taut patent law under British rule insulated MNCs from domestic generic opposition, allowing them to run-over large swathes of the market. More broadly, the Patent Act of 1911 gave rise to "evergreening": the exploitation of legal loopholes and engagement in under-the-table deals to prolong the IP protections on a sought-after pharmaceutical. Prominent examples of evergreening include trivially modifying a drug's molecular compound, bribing generic companies to stall the entrance of *copycat* drugs, and abusing a host of legal loopholes (Dwivedi et al., 2010, p. 329; Canedy, 2014; I-MAK, 2021; Dwivedi et al., 2010, p. 326). These practices are antithetical to *accessibility* because they artificially hold up generic entrance into the market that may significantly reduce prices. That is not to say that this version of India's patent regime was wholly defenseless. Rather, provisions could not keep pace with the elusive tactics of well-resourced pharmaceutical companies. For example, Section 26 of the Patents and Designs Act of 1911 implicitly laid out patentability criteria when addressing grounds on which an entity may petition for revocation of a patent: "invention [must] involve an inventive step, having regard to what was known or used prior to the date of the patent" (Governor General of India, 1911, p. 22). On paper, this provision should have hampered evergreening, but the criteria dictating novelty and the degree required to qualify as an "incentive step" remained suspect. Ultimately, the Achilles heel of India's colonial-era patent regime lay in its loose patentability definitions which left pharmaceutical firms just enough wiggle room to advance meticulously-crafted legal, chemical, and biological justifications for patentability.

Although TRIPS was intended to strengthen IP protections for the rights-holder, India exploited definitional openings to sidestep certain mandates. Article 27 of TRIPS mandated that "patents shall be available for any invention... provided that they are new, involve an inventive step, and are capable of industrial application". However, TRIPS forwarded the quintessential law dictating patentable subject matter without even offering the faintest of definitions for keywords and phrases "new" and "inventive step", leaving considerable discretion in the hands of states to modify requirements to suit national objectives. For India, the textual gray area was clarified in Section 2 of the Indian Patents Act of 2005, hereinafter referred to as the "Principal Act" (to reflect its significance), which clarifies:

(ja) "inventive step" means a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the an;

(1) "new invention" means any invention or technology which has not been anticipated by publication in any document or used in the country or elsewhere in the world before the date of filing of patent application with complete specification, i.e. the subject matter has not fallen in public domain or that it does not form part of the state of the art (The Gazette of India, 2005, pp. 1-2);

The stringent definitions in Section 2 set a high threshold for patentability and served as the novel patent regime's primary front against evergreening. In reference to the first provision defining "inventive step", the former criterion concerning "technical" significance is scientifically-complex and creates leeway for pharmaceutical companies to devise nuanced arguments for evergreening. Cheating the latter section about economic significance is less so an opening for evergreening as there is no opportunity for price fluctuations if the drug remains virtually identical (bar some trivial change). Section 2 (1) would institute even more hurdles confronting evergreening. Inventions were only considered "new" provided they were *absolute novelties*, or as the statute put it, if "the subject matter has not fallen in public domain or that it does not form part of the state of the art". This high legal bar undermined evergreening attempts which, at the core, rely on minute, trivial, and insignificant changes to a drug's previous formulation which had already fallen into the public domain. India's streak did not stop there. Provision (d) in Section 3 presented perhaps the strongest bulwark against evergreening. It states:

(d) the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant (The Gazette of India, 2005, p. 2).

With the passage of Section 3 (d), it became apparent that *evergreening* would succumb to the unrelenting barrage of Indian patent amendments. The landmark provision would now reject patent extensions unless they categorically improved efficacy—at least, that was the theory. Unsurprisingly, foreign pharmaceutical companies fell back on their signature tactic of prodding loose legal definitions. This time, they set their sights on "efficacy". Since the term was not legally bound in Section 3(d), pharmaceutical companies could forward a plethora of plausible technical proofs—bioavailability, flow ability, disintegration property, dosage optimization, enhancements in pharmacokinetics and pharmacodynamics, and so on—to demonstrate an "enhancement in efficacy" (The Gazette of India, 2005). In the absence of judicial precedent, ambiguities arose surrounding the type of data and the degree of change required to establish "efficacy" (The Gazette of India, 2005). Other areas of patent law failed to provide additional clarity. India's Patent Rules and the Indian Manual of Patent Office Practice and Procedure contained no guidance on navigating Section 3(d), leaving inventors and practitioners uncertain how much they should invest in R&D (Mueller, 2007, p. 554; The Office of Controller General of Patents, Designs & Trademarks, 2011).

The competing interpretations came to a head in court with the *Novartis AG v. Union of India* case (Du, 2014, p. 225). Heads clashed over the Indian Patent Office's rejection of Gleevec, a medication for chronic myeloid leukemia, in 2005 on the grounds of not meeting the "efficacy" requirement in Section 3(d) (Indian Patent Office, 2005). Imatinib, the chemical compound later brought to market as Gleevec, was first patented in the United States in 1993 (Du, 2014, p. 226). Later, in its 1998 Indian patent application, Novartis argued that Imatinib Mesylate, the crystalline form of Imatinib, did, in fact, qualify as a *new invention* exhibiting better beneficial flow, thermodynamic stability, and lower hygroscopicity (Du, 2014). Afraid that the Patent Act of 2005 would usher in a return to the monopoly-controlled pharmaceutical industry characteristic of the colonial era, the Supreme Court of India ruled that merely demonstrating enhanced bioavailability and better processing and storage properties proved insufficient to satisfy the "efficacy" parameter in Section 3(d) (Davar, 2023). The *Novartis AG v. Union of India* case set a sweeping precedent that "efficacy" was based on the function of a product (Davar, 2023). Therefore, the function of a pharmaceutical being to cure disease, a pharmaceutical company must present experimental data that substantiates that the *therapeutic efficacy* of a new drug differs significantly from that of its predecessor to qualify as patentable subject matter (Davar, 2023).

The court's denial of Novartis' patent bid epitomized how India's deliberate efforts to fill-in statutory ambiguities, in accordance with TRIPS, positioned its legal system to fend off evergreening. While Novartis' appeal to field-specific technicalities may have qualified as an "inventive step" under the Patents and Designs Act of 1911, the new system established narrow(er) boundaries for patentable subject matter that sidestepped the brunt of *evergreening* efforts which relied on scrupulous legal and technical strategizing. By centering the determination of "efficacy" on functionality, an objective and easily-discernible metric, the Indian Supreme Court had overhauled the knowledge asymmetries that enabled pharmaceutical companies to engage in anti-competitive behaviors.

With the new evaluatory standard came intense commotion, trepidation, and lobbying among MNCs and domestic pharmaceutical companies (Andrade, Shah, & Chandra, 2007, p. 56). They contended that absent a concrete threshold for what constituted a "significant" improvement in therapeutic efficacy, circuit judges, who lacked the know-how and expertise of industry persons, ought not be entrusted with the authority to make final judgements on patentability (Andrade, Shah, & Chandra, 2007). While such rationale appears to be well-reasoned and of good-faith, it is consistent with big pharma's broader project of rhetorical "blackmail" wherein they fund exaggerated studies calculating average R&D costs, endorse "expert" testimonies, and hand blank checks to high-ranking government officials. As a case in point, when Alan Holmer, the former President of the US industry trade association, was faced with growing calls for price controls, he stated, "Believe me, if we impose price controls on the pharmaceutical industry, and if you reduce the R&D that this industry is able to provide,

it's going to harm my kids and it's going to harm those millions of other Americans who have life-threatening conditions" (Rousseau, 2023, p. 36). A 2013 study by esteemed professor Donald W. Light confirmed suspicions that the United States' strong intellectual property rights failed to foster prosocial innovations: "90 percent of all new drugs approved by the FDA over the past 30 years are little or no more effective for patients than existing drugs" (Light, 2013). Thus, while the Indian Supreme Court's ruling left an objective determination of "significant enhancement" to be desired, the judicial precedent left by the Novartis case adhered to India's constitutionally-enshrined goal of ensuring *accessibility* at little or no cost to *bona fide*, altruistic *innovation*.

3. Conclusion

In 1947, India had at last broken free from British rule. It was only then, following 89 years of grueling resistance, that the nascent state began to script its own legacy governing 400 million citizens—few of whom were covered by insurance or had the means to purchase essential medicines out-of-pocket. Against all odds, India turned its fortunes around in the twentieth century. No longer prey to foreign predation, India has, itself, become a leading exporter of generic medicines and disseminates pharmaceuticals to its citizenry of over 1.4 billion persons at as low as a-thirtieth the price charged in developed nations. At the crux of this metamorphosis was the Indian patent regime.

The linkage between patent law and pharmaceutical prices has been the subject of extensive scholarly research. For the most part, the claim is logically sound, and verified by rigorous quantitative and qualitative analyses. It holds that the stronger the IP protections covering the rights-holder, the more efficiently they can recoup development costs and the longer they can profit-maximize. Thus, a strong IP regime may induce *innovation*. However, lucrative returns are accrued through prolonged monopolistic pricing that impedes *access* to essential medicines. Amending statutory patent law invariably runs into this tradeoff.

To this end, twenty-first century India is an outlier. Although it conforms to TRIPS guidelines that mandate the adoption of *product* patents, it has subverted the monopolistic impulses evident in other nations, drawing on a century's worth of errors and experiences. On the heels of the Patents Act of 2005, India has patched the legal loopholes responsible for anti-competitive practices, namely evergreening, and installed various safeguards in case such provisions falter. In this sense, India's modern patent regime has staked out the middle ground. In offering a 20-year exclusivity period for *product* patents, in line with other signatories to TRIPS, and a burgeoning citizenry, India has preserved innovative inducements while discarding the accompanying economic and social baggage. The Indian case study suggests that it is, in fact, possible to strike a delicate balance between *accessibility* and *innovation*, and partake in the best of both worlds.

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