



India's IPR Regime: Reconciling Affordable Access with Patent Protection

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Indian Council for Research on International Economic Relations

Strategic Studies Programme

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FOREWORD

Even as India-US trade (in both goods and services) has progressed towards the \$100 billion mark, 2013-14 witnessed the emergence of a number of issues which adversely impacted the climate for bilateral trade and investment. Of these, none has been more contentious than the question of India's IPR regime for pharmaceutical products.

Following up on ICRIER's earlier publications under the "Navigating the Headwinds" series, this report traces the genesis of India's IPR policy in the pharma sector from Independence up to the present.

Given the vast requirement for public health provisions for a large and economically disadvantaged population, India's policymakers have sought to balance incentives for IPRs against the need for greater affordability and wider accessibility of pharma products. With the increasing prevalence of non-communicable diseases, this challenge has only intensified.

We at ICRIER are confident that this report will make an important contribution to the public policy discourse around India's IP regime and provide timely insights for the Indian Government's prospective IPR policy.

I would like to express my appreciation for Prof. H.K. Singh's efforts in directing this research and compliment both him and Aman Raj Khanna for their painstaking effort for a timely, insightful and high quality report.

Rajat Kathuria
Director & Chief Executive
ICRIER, New Delhi

August, 2015

“We are all aware that the text of the TRIPS is a masterpiece of ambiguity, couched in the language of diplomatic compromise, resulting in a verbal tight-rope walk, with a prose remarkably elastic and capable of being stretched all the way to Geneva.”

- **Former Commerce & Industry Minister Murasoli Maran,**
while moving for consideration of the Patents (Second Amendment) Bill in the Rajya Sabha in 2002¹

¹ http://commerce.nic.in/pressrelease/pressrelease_detail.asp?id=880

² http://www.jec.senate.gov/public/index.cfm?a=Files.Serve&File_id=6aaa7e1f-9586-47be-82e7-326f47658320

PART – I:

The Evolution of India's Modern IPR Regime: Tracing the Origins of the Current Contention between India and the US Pharmaceutical Industry

I. INTRODUCTION

Innovation has been a vital component of the American success story. In fact, the Joint Economic Committee of the U.S. Congress estimates that as much as 50% of all economic growth in the US over the past half-century can be attributed to productivity gains resulting from innovation.² Patents have, therefore, been integral to the United States' approach to incentivizing innovation by ensuring that innovators enjoy exclusive rights to the commercial gains from their inventions.

With the impact of globalization over the past three decades, America's competitive advantage has increasingly gravitated towards innovation-intensive, high-technology products as its less competitive sectors have ceded ground to products from lower cost economies.³ Consequently, the protection of intellectual property rights (IPR) accorded by patents have become all the more central to the United States' ability to preserve its competitive edge, particularly over developing economies that have ample human resources and substantial cost advantages, but lack its innovative capacity.

It is against this background that over the past decade, the United States and India have found themselves increasingly locked in conflict over India's IPR regime. In 2013-14, these disagreements were at the forefront of contention, setting an adversarial tone for the entire discourse on bilateral trade and investment and dampening expectations for the future of bilateral economic ties.

This paper seeks to analyse salient aspects of India's approach to intellectual property rights that have been the crux of contention for the US (and Western) pharmaceutical industry.

The first of these is a provision in the Indian patent law, namely, Section 3(d) of the Patents (Amendment) Act of 2005, that sets a unique benchmark for the patentability of inventions, establishing stringent norms with respect to obtaining pharmaceutical patents.

The second involves India's perceived propensity for granting compulsory licences, a provision that enables a country to suspend patent privileges in cases where the best interests of their citizenry are at stake as a result of force majeure or wilful exploitation of patent privileges by the patentee.

Both these aspects of India's IPR regime have accounted for a handful of recent judicial decisions on pharmaceutical patents, resulting in unfavourable outcomes for major global pharmaceutical manufacturers. Finding little favour from Indian courts that have since upheld the constitutionality of Section 3(d) and the grounds for the granting of India's (so far) singular

² http://www.jec.senate.gov/public/index.cfm?a=Files.Serve&File_id=6aaa7e1f-9586-47be-82e7-326f47658320

³ Dai, Lauren. The Comparative Advantage of Nations: How Global Supply Chains Change Our Understanding of Comparative Advantage

compulsory licence, US firms in particular have raised the issue with their own lawmakers in the U.S. Congress. This has opened the floodgates to relentless and scathing criticism of India in response to what the U.S. Chamber of Commerce has termed “India’s attack on innovation”.

Wielding the threat of sanctions accorded by Section 301 of the US Trade Act,⁴ American officials have called upon India to “apply its IP laws in a manner consistent with *recognized global standards*.”⁵

This paper seeks to investigate this matter further, by establishing what exactly are the recognized global standards, and how and why has India, if at all, departed from them. Further, it examines whether India’s unique iteration of patent laws, as seen in its approach to patentability and post-grant measures such as compulsory licensing, is in violation of its TRIPS commitments.

II. THE EVOLUTION OF INDIA’S PATENT LAW

An understanding of the historical context in which India’s patenting laws have evolved is crucial to making sense of the current Indian approach to IPRs. Particularly relevant is the establishing of the historical nature of India’s patent laws and how these were amended in 2005 to comply with its commitments under the TRIPS agreement.

Post-Colonial Era

Upon gaining independence from Great Britain in 1947, India’s 400 million people represented nearly a fifth of the entire world’s population, with the vast majority of them remaining abjectly impoverished.⁶ Even as it struggled to reckon with the staggering welfare needs of its citizens, the fledgling Indian government found itself almost entirely dependent on imports manufactured in the West for basic necessities, including medicine.⁷ As a consequence, even critical drugs such as insulin or penicillin were priced well out of the reach of large sections of the population.⁸ Several scholars have attributed this phenomenon in large part to the Patent Act of 1911 that was configured to distinctly favour the mercantilist interests of the British Empire and was still enforced at the time of India’s independence.⁹ Specifically, it allowed British manufacturers virtual monopolies over the vast Indian market for finished goods, mostly produced from raw materials imported cheaply from India and various other colonies.

⁴ Section 301 of the Trade Act, 1974 authorizes trade sanctions against countries with inadequate intellectual property protection on the pretext that it would impose unjustifiable burdens on its commerce.

⁵<http://www.mondaq.com/india/x/295286/Patent/Compulsory+Licensing+An+Emerging+Trend+Towards+IndianPatent+Regime>

⁶ Janice M. Mueller, *The Tiger Awakens: The Tumultuous Transformation of India’s Patent System and the Rise of Indian Pharmaceutical Innovation*, 68 U. PITT. L. REV. 491, 511 (2006).

⁷ *Ibid.*

⁸ *Ibid.*

⁹ Justice Aftab Alam, “*Novartis v. Union Of India & Ors*” on 1 April 2013

In order to remedy this situation, in 1949 the Government of India sought an intensive review of its existing patent laws from a high-powered committee led by an eminent jurist of the erstwhile Lahore High Court, Bakshi Tek Chand.¹⁰ The Chand Committee's report noted, among other things, that the prevailing patent law offered inequitably strong protections to foreign multinationals while acutely constraining the nascent and as yet uncompetitive domestic manufacturing sector from finding its feet. An injunction won some years later by western manufacturer Hoechst in the Bombay High Court against the home-grown Unichem Laboratories over an infringement of its patent for the manufacture of a highly sought after anti-diabetic drug is among the most notably cited examples of this phenomenon.¹¹

In 1957, a second committee was constituted under another distinguished judge of the Supreme Court of India, N. Rajagopala Ayyangar, with the intent of building upon the Chand committee's findings and crafting legislation "more conducive to national interests".¹²

The Ayyangar committee undertook a detailed study of patent laws and successful public welfare models of several other nations. Its recommendations, released in the Ayyangar Committee Report of 1959, most notably advocated the abolition of "product" patents in favour of "process" patents following the precedent of Germany, Canada and a handful of other European nations.¹³ Together with various other amendments and after much deliberation in the Indian Parliament, these recommendations culminated in the Patents Act, 1970.¹⁴

The adoption of this Act marked a watershed in the history of the domestic pharmaceutical industry as it enabled Indian companies to replicate western drugs, laying the foundations for the flourishing Indian generic drug industry as we know it today.

As western pharmaceutical companies began to exit the Indian market for want of protection for their intellectual property, Indian companies quickly filled the vacuum and acquired increasing competence in reverse engineered generics that sold for a fraction of prices charged by their western counterparts.¹⁵ Consequently, the Indian government was able to broaden access to medicines while simultaneously laying the ground for what has today become among the most prolific drug manufacturing industries, ranking third globally by annual volume.

However, while the near total departure of the western pharmaceutical industry from Indian shores was hardly lamented, there were adverse repercussions. This period was marked by stagnation in R&D in the domestic pharmaceutical manufacturing sector. Several commentators

¹⁰ *Ibid.*

¹¹ *Supra, fn. 6*

¹² *Supra, fn. 9*

¹³ *Ibid.*

¹⁴ *Ibid.*

¹⁵ *Ibid.*

have pointed out that the contraposition of the generic industry's success was the stunting of the innovative capability of the Indian pharmaceutical industry, including limited exposure to clinical trials and other valuable practices the lack of which continues to plague the industry to the present day.

Economic Liberalization and TRIPS

Acute economic problems persuaded India to abandon its four-decade-long self-imposed isolation and pursue the progressive liberalisation of its economy through active participation in the Uruguay Round of international trade negotiations that commenced in 1986.

With the United States' success in ensuring the inclusion of patent and intellectual property rights in the GATT negotiations, India found itself faced with the prospect of what it considered to be a pyrrhic victory for its economy. The benefits of globalization notwithstanding, it believed that the strong patent protections required under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) would once again undermine its nascent domestic industry and public healthcare commitments in favour of western pharmaceutical manufacturers and thus unravel the benefits reaped under the Patents Act of 1970.

Initially India resisted, leading the vanguard of a bloc of some fifty developing nations with similar patent laws that opposed the TRIPS provisions with similar reservations. However, the lure of trade gains or coercion in the form of trade sanctions from the U.S. prevailed upon an increasing number of these nations. Eventually, India found itself increasingly isolated. Unwilling to risk its textile industry to the onslaught of U.S. sanctions or jeopardize prospective IMF loans, India eventually relented and reversed its stance on TRIPS. Nevertheless, it continued to press for balanced provisions that addressed the concerns of developing nations in overhauling their patent laws for TRIPS compliance.

The conclusion of the Uruguay Round in December 1994 culminated in the establishment of the WTO and ratification of GATT. India as a signatory was required to enact IPR legislation in compliance with the requirements set out under the TRIPS agreement. The agreement provided a ten-year grace period intended for developing nations to bring their laws in conformity with TRIPS provisions and allow for adjustments in their judicial system and economies.

Changing India's IP Laws for TRIPS Compliance

For India, amending its laws to be compliant with TRIPS posed a tough but necessary challenge once TRIPS came into force on January 1, 1995. To meet these obligations, India initiated a piecemeal, but nonetheless substantive overhaul of its patent laws to comply with the standards laid down in TRIPS.

Among the first of these, the Government of India enacted the Patents (Amendments) Ordinance of 1994 on December 31, 1994, to buy time while statutory changes to the law were pursued in Parliament.¹⁶ This ordinance, however, expired on March 26, 1995 without a permanent legislative solution from Parliament to meet the TRIPS requirements. The 10th Lok Sabha (the lower house of Parliament) was itself dissolved later in the year, ushering in a period of limbo for India's IPR laws. During this time of political uncertainty, India was twice taken to the WTO dispute settlement panel, once each by the US and EU respectively, that resulted in pronouncements against India.

Under the looming threat of trade sanctions, the Indian Parliament added unprecedented impetus to passing the necessary laws. This culminated in three separate amendment Acts in 1999, 2002 and 2005 that made incremental adjustments to the Patents Act of 1970 to make it fully TRIPS-compliant. The Indian Patents Act 1970 was amended in 2005, reinstating "product" patents and making the reverse-engineering or copying of patented drugs without requisite licensing from the patent holder illegal after January 1, 1995. The Act did, however, allow the manufacture of generic versions of drugs patented prior to 1995. Additionally, it adopted the controversial 20-year period of guaranteed protection to patent holders as mandated under Article 32 of TRIPS, while establishing various other measures to strengthen the overall rights of patentees.

However, amidst growing disquiet from developing and least-developed nations, the Doha Declaration of November 2001 had, meanwhile, reinforced flexibilities under Article 31 of TRIPS allowing member states to mitigate hardships resulting from adjustment of patent laws to TRIPS standards.

¹⁶ Justice Aftab Alam and Justice Ranjana P. Deshai

Box 1: The Doha Declaration

The fourth Ministerial Conference of WTO Member Nations in Doha in November 2001 dwelt on deep reservations among developing and least-developed member nations of the WTO with regard to their obligations under TRIPS. Collectively, these nations had felt that the provisions of the TRIPS agreement, along with the narrow interpretations used by the developed member nations, made this an onerous commitment that jeopardized both their welfare objectives and nascent industries.

To address this dissatisfaction, the Doha Declaration of November 14, 2001 declared that the TRIPS agreement “can and should be interpreted and implemented in a manner supportive of WTO members’ right . . . to promote access to medicines for all.” In brief, the Doha Declaration gave a wider berth to developing and least-developed member states under the provisions of TRIPS, with regard to deadlines for compliance and overall interpretation of the articles vis-à-vis their domestic laws. It reinforced certain remedial mechanisms to make exclusions to the TRIPS patent requirements under certain circumstances.

*The full text of the declaration may be viewed at the WTO’s website at the following link:
https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.htm*

With this reassurance, Indian lawmakers retained sections 84 and 92 of the law through which India reserved the right to invoke compulsory licensing, either as a remedy to abuse of patent privileges by the patentee or in the case of national emergencies, respectively.

Further, it also inserted Section 3(d) into its amended law that set a higher standard for patentability, particularly with regard to incremental innovation, which added the requirement to demonstrate enhanced efficacy to the previously known substance to be considered patentable. This was specifically intended to prevent the possibility of patent layering, a strategy that involves the extension of patent monopolies, most often through frivolous incremental changes to a product, a practice commonly known as ‘evergreening’.

Both these aspects of India’s patent law have formed the locus of recent contention on India’s intellectual property regime, which is examined in the following sections of this paper.

III. REVIEWING INDIA'S APPROACH TO PATENTABILITY STANDARDS

Dissecting Section 3(d)

Central to the criticism of Section 3(d) has been the fact that it sets the invention threshold higher than TRIPS, specifically Article 27 (1) which mandates that patentable inventions, whether products or processes across all fields of technology, must be i) new; ii) involve an inventive step; and iii) must be capable of industrial application.¹⁷ The contention made by Western pharmaceutical manufacturers and the USTR among others is that the prerequisite for 'enhanced efficacy' under Section 3(d) adds a fourth requirement for patentability in excess of the three already prescribed in TRIPS.¹⁸ The USTR's Special 301 report of 2013 made the following observation with regard to the Indian Supreme Court's judgment in the Novartis case on the basis of section 3(d):

*"...the decision appears to confirm that India's law creates a special, additional criterion for select technologies, like pharmaceuticals, which could preclude issuance of a patent even if the applicant demonstrates that the invention is new, involves an inventive step, and is capable of industrial application."*¹⁹

Consequently, India has been exhorted to bring its patentability standards "on par with established international norms". The question that arises is whether the 'established international norms', that presumably refer to a configuration of patentability standards styled after the U.S. model, are the best possible approach, especially for countries with vastly different economic circumstances to those prevailing in the U.S. Further, does India's deviation from this precedent constitute a violation of its commitments under international agreements, namely TRIPS?

These salient issues are considered in the following segments.

Assessing the TRIPS Compatibility of Section 3(d)

At the time it was first enforced in 2005, the amended Section 3(d) of India's patent law was indeed both unprecedented and unique among the world's existing patent regimes.²⁰ However, that did not necessarily imply it was non-compliant with TRIPS. In marked contrast to the

¹⁷ Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, THE LEGAL TEXTS: THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS 320 (1999), 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [TRIPS].

¹⁸ Roy Waldron, Chief Counsel for Pfizer Inc. Testimony to US Congress, House Ways and Means Committee

¹⁹ "2013 Special 301 Report", Office of the United States Trade Representative, May 2013
<http://www.ustr.gov/about-us/press-office/reports-and-publications/2013/2013-special-301-report>

²⁰ *Supra*, fn. 6

criticism noted above, a significant number of scholars and legal experts (including those from leading US institutions) conducting unbiased independent assessments of the Indian patent law have found Section 3(d) to indeed be compatible with TRIPS.²¹ In the corresponding literature, it is widely noted that both the intent and language of TRIPS is geared towards creating a broad framework of minimum standards rather than specifically defining the concepts of novelty, inventive step and industrial applicability.²² This is particularly true for Article 27 of the agreement that addresses patentable subject matter.

Paragraphs 2 and 3 of Article 27 of TRIPS go on to further delineate the broad conditions under which nations may exclude inventions from patentability. Significantly, para 2 accords nations the ability to exclude the grant of patents to inventions - “...*the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment...*”²³

It is quite clear, therefore, that the TRIPS agreement affords its member nations a substantial degree of flexibility to tailor their patentability standards to best suit national conditions, as long as they remain within these stipulated boundaries, and provided they are enforced “without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.”²⁴

In this regard, the requirement of ‘enhanced efficacy’ stipulated by Section 3(d) of the Indian Patents Act is interpreted as a refinement (albeit a more restrictive one) of the ‘inventive step’ and ‘industrial applicability’ guidelines rather than a separate and additional requirement altogether.

Writing in the Harvard International Law Journal, R. Banerjee observes: “*Viewed this way, it is by no means the only provision in the world to deny patents to insubstantial derivatives of known substances. In American patent law, an invention may not be patentable if it is obvious to an ordinary person skilled in the relevant art, in light of prior inventions and references.*”²⁵

²¹ See 1) Basheer, Shamnad and Reddy, Prashant, “‘Ducking’ TRIPS in India: A Saga Involving Novartis and the Legality of Section 3(d)” National Law School of India Review, Vol. 20, No. 2, pp. 131-155, 2008, January 2009 and ii) Banerjee, Rajarshi, “The Success of, and Response to, India’s Law against Patent Layering” Harvard Law Journal

²² *Supra*, fn. 21

²³ “Agreement on Trade-Related Aspects of Intellectual Property Rights”. WTO Analytical Index. Available at: https://www.wto.org/english/res_e/booksp_e/analytic_index_e/trips_02_e.htm

²⁴ Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, THE LEGAL TEXTS: THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS 320 (1999), 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [hereinafter TRIPS].

²⁵ *Supra*, fn. 21

In fact, the U.S. Patent Office's Manual for Patent Examination Procedures mandates under Chapter 7.16 that the claimed invention must demonstrate evidence of *unexpected results* when compared to prior art in order to fulfil the requirement of 'non-obviousness' referred to by Banerjee above.²⁶

The application of this requirement within the context of our discussion is best demonstrated by the case of *Pfizer vs Apotex (Fed. Cir. 2007)*. In its ruling in favour of Apotex, the Court of Appeals for the Federal Circuit invalidated Pfizer's patent on the *bessylate salt* of the compound *amlodipine* (the active ingredient in the blockbuster hypertension drug Norvasc), decreeing that it failed to demonstrate "*unexpected superior results*" over the base compound to satisfy the requirement of non-obviousness and thereby did not merit a patent.²⁷

It is the opinion of several scholars that this ruling demonstrates patentability requirements within U.S. law that are analogous to the 'enhanced efficacy' condition of section 3(d) of the Indian patent law used to assess patentability of inventions.²⁸ Therefore, the logic and motive behind Section 3(d) to disallow 'evergreening' by requiring a demonstrable advancement in utility is not entirely without precedent, including in the U.S. where attitudes towards this issue are in a state of flux.

Further, there is indication that the U.S. authorities are becoming increasingly aware of the potentially adverse impact of lower standards of patentability and are gravitating towards defining higher standards of non-obviousness for awarding patents to derivatives of known substances.

For instance, the U.S. Federal Trade Commission's Deputy General Counsel for Policy Studies, in a hearing before the Antitrust Modernization Commission (AMC) on Patent Law Reform in November, 2005 had stated that "*the prevalence of poor quality patents (in the United States) is an impediment to competition, and it is an impediment that, by definition, is governmentally created and, like private business restraints, harms consumer welfare*".²⁹

The experience of the United States with secondary, poor quality patents including for medicines resulting from the configuration of its patentability requirements, may very likely have served as

²⁶ USPTO, Manual for Patent Examination Procedure, Section 716 (8th ed., rev. 2012)
<http://www.uspto.gov/web/offices/pac/mpep/s716.html>

²⁷ Zuhn, Donald, "Pfizer, Inc. vs. Apotex, Inc. (Fed. Cir. 2007).PatentDocs. March 25, 2007,
http://www.patentdocs.org/2007/03/pfizer_inc_v_ap.html

²⁸ 2014 Special 301 Review: Post-Hearing Comments filed by Professor(s) Srividhya Ragavan, Sean Flynn and Brook Baker. 2014 special 301 review: identification of countries under section 182 of the trade act of 1974: request for public comment and announcement of public hearing. Docket #USTR-2013-0040

²⁹ Remarks of Susan S. DeSanti, FTC Deputy General Counsel for Policy Studies Before the Antitrust Modernization Commission Hearing on Patent Law Reform, November 8,2005 available at
<http://www.docstoc.com/docs/5730413/Remarks-of-Susan-S-DeSanti-FTC-Deputy-General-Counsel> as quoted in

an inspiration to India in the crafting of its own patent laws enacted in 2005, including section 3(d).³⁰

The fundamental difference remains that despite sharing an increasingly unfavourable view of frivolous innovation, the U.S. retains relatively low patentability standards with the intent of incentivizing innovation that do little to inhibit the granting of secondary patents. The burden of distinguishing cases of exploitation or ‘evergreening’ has been effectively shifted to the judiciary.³¹

Instead of following the tried and tested but evidently problematic U.S. approach to patent laws, India has elected to integrate the ‘enhanced efficacy’ benchmark into its pre-grant phase as a standard for patentability. Thereby, it has chosen to implement a higher threshold for discerning true innovation, yet this remains well within its rights and obligations accorded by TRIPS. In fact, India’s amendment of its patent law has been hailed for avoiding retroactive measures that entail needless private and public expenditure and the burden on the judicial system that is inherent in the U.S. model for addressing evergreening of patents.³²

Therefore, the generally prevailing opinion among experts is that not only is Section 3(d) of India’s law likely to withstand any legal challenge on TRIPS-compatibility raised at the WTO’s Dispute Settlement Board (DSB), but it is also an effective and successful model for finding common ground between the dual intents of discouraging the practice of evergreening on one hand and achieving compatibility with TRIPS on the other.

The greatest testament to the success of this unprecedented approach set by India in global patent law is that it has since served as a model for other TRIPS signatories, notably the Philippines and Argentina, whose legislatures have each enacted amendments to their law modelled on section 3(d), after careful consideration.³³

Section 3(d) and its Impact on Innovation

Another aspect of criticism of Section 3(d) stems from the contention that by setting an extremely high bar for patentability, it discourages incremental innovation and adversely impacts the environment for innovation on the whole.³⁴

³⁰ United States International Trade Commission Investigation No. 332-543, “Trade, Investment, and Industrial Policies in India: Effects on the U.S. Economy.” Filing by Professor(s) Srividhya Ragavan, Brook Baker and Sean Flynn

³¹ Ibid.

³² Ibid.

³³ *Supra*, fn. 21

³⁴ See:

India made the decision to rely on the criteria for ‘enhanced efficacy’ as the sole and primary basis for distinguishing between ‘true’ incremental innovation and more frivolous modifications to existing inventions. In the case of pharmaceuticals, this definition of efficacy is limited to imply “enhanced *therapeutic* efficacy” as reaffirmed by the Novartis judgment and subsequent guidelines published by the Indian Patent Office providing clarifications on the matter.³⁵

In its Special 301 report of 2014, the USTR expressed consternation over this issue in the following manner: “*The United States is concerned that section 3(d), as interpreted, may have the effect of limiting the patentability of potentially beneficial innovations. Such innovations would include drugs with fewer side effects, decreased toxicity, improved delivery systems, or temperature or storage stability.*”³⁶

Indeed the USTR does have a significant point, that the narrow definition applied by the Indian law for inventiveness disregards some important and beneficial dimensions of improvement when considered with respect to the pharmaceutical sector where breakthrough discoveries, especially those involving entirely new chemical entities (NCEs), are relatively rare.³⁷

This is a view subtly echoed by the Mashelkar Committee, which in its report on Indian patent law in 2009 recommended *inter alia* that: “*incremental innovations involving new forms, analogs, etc. but which have significantly better **safety** and efficacy standards, need to be encouraged*”(emphasis added).³⁸

The noteworthy aspect of this observation is that it suggested “better safety” standards as an aspect of inventions worthy of consideration to be rewarded, in addition to “better efficacy” provisions which are already extant in the Indian law. The relevance of this observation needs to be further examined in the context of the shifting nature of patent applications that can be expected in the coming years.

“A Dangerous Prescription”. Economist Intelligence Unit. April 15, 2014.

<http://www.eiu.com/industry/article/41724988/a-dangerous-prescription/2014-04-15>

“Supreme Court denial of Glivec patent clarifies limited intellectual property protection and discourages future innovation in India”. Novartis Media Release. April 1, 2013. <http://www.novartis.com/newsroom/media-releases/en/2013/1689290.shtml>

³⁵ C.H. Unnikrishnan, “Patent Office issues draft pharma norms”, Live Mint, March 7, 2014.

<http://www.livemint.com/Industry/PoJQRr06SMppCP55iscaM/Patent-office-issues-draft-pharma-norms.html>

³⁶ “2014 Special 301 Report”, Office of the United States Trade Representative, April 2014

<http://www.ustr.gov/sites/default/files/USTR%202014%20Special%20301%20Report%20to%20Congress%20FINAL.pdf>

³⁷ Basheer, Shamnad, “The “Mashelkar Committee Report” on Pharma Patenting Resurfaces!” Spicy IP. April 18, 2009 <http://spicyip.com/2009/04/mashelkar-committee-report-on-pharma.html>

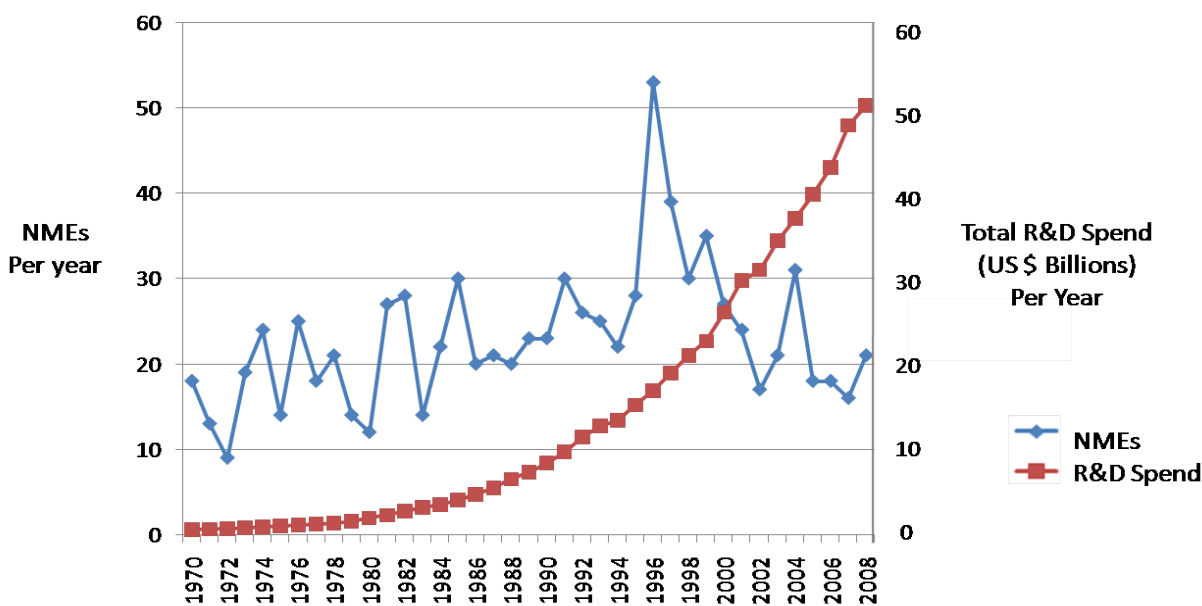
³⁸ Report of the Mashelkar Committee

Declining Discoveries of NCEs

New Chemical Entities (NCEs), by way of their unique molecular structure and properties, present a far simpler test for patent eligibility as compared to derivatives which fall under the ambit of Section 3(d).³⁹ However, discoveries of NCEs are increasingly hard to come by, being the exception to the rule rather than the norm, and with most instances likely qualifying as ‘breakthroughs’ in the pharmaceutical research industry.⁴⁰ Data from the U.S. FDA suggests that despite a spike in the past two years, the discovery of NCEs approved by the regulator has been on the decline on the whole since the TRIPS agreement was enacted.⁴¹ This has occurred even as the total number of pharmaceutical patent applications and awards by the U.S. Patent Office annually has continued to rise (Figure 1).

This suggests that in the future, an increasing percentage of pharmaceutical patent applications considered by the Indian Patent Office will be for derivatives or repurposed drugs, often presenting subtle incremental improvements over existing chemical entities. However, the limiting scope of the Indian law discussed earlier may preclude an entire class of genuinely innovative and substantial improvements in pharmaceutical therapies as they fall outside the current purview of what is regarded as genuine incremental innovation.

Figure 1: Discovery of NCEs vs. R&D Spend (1970-2008)⁴²



³⁹ “The Changing Role of Chemistry in Drug Discovery” Thomson Reuters
<http://thomsonreuters.com/content/dam/openweb/documents/pdf/pharma-life-sciences/report/international-year-of-chemistry-report-drug-discovery.pdf>

⁴⁰ Ibid.

⁴¹ US FDA

⁴² <http://www.slideshare.net/MentLife/mentlife-drug-discovery-development-trends-nov-6-2013>

While India is under no compulsion under the TRIPS agreement to expand the scope of its law, the concern that this limitation may ultimately create disincentives among pharmaceutical manufacturers to pursue the development of drug improvements is genuine. It has been further noted that despite the affinity of Indian drug manufacturers for developing similar refinements to existing drugs, their expertise remains yet unproven in the relatively new and highly complex category of drugs known as *biologics* that constitute the most advanced treatments of diseases such as cancer and so forth.⁴³ Whether Indian manufacturers are able to fill this emerging void by acquiring the necessary expertise and deploying the very considerable resources required for such research, in the absence of adequate patent protection, remains an open question. This scenario can adversely impact Indian consumers and manufacturers alike, and should foster an informed debate.

Impact of Section 3(d) on the Awarding of Patents

Despite concerns on the limiting scope of Section 3(d) in the context of future drug discovery trends, what can be established with certainty is that in the nine years since its inception, Section 3(d) has not resulted in discrimination against western manufacturers as is often claimed. In the three fiscal years between April 2010 and March 2013 alone, India's Controller General of Patents, Designs and Trade Marks awarded as many as 1001 pharmaceutical patents, of which 771 (a staggering 77 per cent) were granted to foreign firms from the US and Europe.⁴⁴ In fact, the two greatest beneficiaries during this period were US-based pharma giants Eli Lilly and Pfizer, who between them secured a total of 68 patents.⁴⁵

Further, allegations that Section 3(d) effectively bars all forms of incremental innovation altogether (thus limiting patentability exclusively to NCEs) are also inaccurate. A report prepared by the Indian Pharmaceutical Alliance details a list of 86 drugs that entailed relatively minor variations over pre-existing compounds, yet upon successfully demonstrating enhanced efficacy over the base formulation, had been awarded patents in India up to the year 2010. While an updated study of this nature needs to be replicated, it is a fair assumption that this number is likely to have risen in the four years since this study was last undertaken.⁴⁶

In conclusion, Section 3(d) has functioned just as the Indian legislature had intended when it was included in amendments to India's patent law after much deliberation. India's novel approach to

⁴³ USPTO Deputy Director Teresa Rea before House Judiciary subcommittee for Intellectual Property <http://keionline.org/node/1447>

⁴⁴ Hemant Krishan Singh & Aman Raj Khanna, "India's IPR regime - Moving beyond the myths of US pharma" Business Standard, October 2013

⁴⁵ Ibid.

⁴⁶ James, T.C., "Patent Protection and Innovation: Section 3(d) of the Patents Act and Indian Pharmaceutical Industry" Department of Industrial Policy and Promotion (DIPP), November 2009

patent law has allowed it to successfully strike a balance between its obligations to TRIPS and its desire to discourage patent evergreening in the best interests of its citizens. While the resulting higher standard for patentability has caused much consternation among western pharmaceutical innovators, there is little evidence that it serves as a discriminatory measure or precludes incremental innovations that do demonstrate enhanced efficacy, a parameter that is being increasingly relied upon globally, including in the US Justice system, to distinguish between ‘true’ and ‘frivolous’ innovation. There is indeed room for broadening its definitions (as suggested by the Mashelkar Committee in 2009) in view of future trends in drug discoveries and keeping in mind the overall best interest of patients as well as innovators.

With legal opinion increasingly acknowledging Section 3(d)’s intent and compatibility with TRIPS, it is unlikely that a legal challenge will be raised successfully against India’s patents law. For the time being, Section 3(d) can be expected to remain an integral aspect of the Indian IPR regime, and risk planning involving patentable subject matter must continue to be framed around this assumption.

IV. COMPULSORY LICENSING

In addition to India’s higher standards of patentability, another contentious aspect of India’s patent regime is its purported propensity to employ the compulsory licensing provision against (usually foreign) innovators in the Pharma sector.

To begin with, one must be clear that compulsory licensing is neither an Indian construct nor a new phenomenon to global patent regimes.

The Paris Convention of 1883, under Article 5A.(2) reads: "*Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work.*"

In an extension of the Paris Convention of 1883, the TRIPS agreement reaffirmed the right of member nations to grant compulsory licences and freedom to determine the grounds upon which such licences are granted.

The TRIPS agreement states that, for public health reasons, countries may suspend patent protection over drugs. The primary provision for compulsory licensing under Article 31 provides for “Other Use without Authorization of the Right Holder.” This provision permits WTO member countries to authorize compulsory licences for use by the government or third parties subject to certain restrictions.

In the context of India's IPR regime, this issue came into the global spotlight in March 2012, when India's Controller General of Patents awarded Indian generic manufacturer NATCO a compulsory licence for producing Bayer's blockbuster kidney cancer treatment *Sorafenib tosylate*, widely marketed under the name Nexavar.⁴⁷

The proceedings were initiated by NATCO's application for a compulsory licence under the provisions of Section 84 of the Indian patent law, after it unsuccessfully approached the patentee for a voluntary licence of the product.

The Controller General had found that the patentee's misuse of its privileges satisfied the requirements under Section 84 for a compulsory licence for manufacture of the patented product. Observing that Bayer charged the equivalent of \$5,000 for a month's dose of the medication (well beyond the affordability of the vast majority of the Indian public) and imported stock only sufficient for a tiny fraction of the total patient population treatable by the drug, the Controller ruled that the patentee had failed to satisfy the reasonable requirements of the public in terms of the supply of the patented product and that it had further failed to provide this at a reasonably affordable price to the public.⁴⁸

However, in addition, the Controller also controversially observed that by relying exclusively on imports as opposed to manufacturing locally, the patentee had "*failed to work the patent in the territory of India*". This additional rationale employed by the Controller immediately became the focal point of international criticism, entirely shifting attention away from other crucial aspects of the case such as the excessive pricing or failure to ensure reasonable access for the public of what is essentially a life-saving therapy, all of which had been central to the public debate and legal proceedings in India.⁴⁹ Instead, the ruling gave rise to the allegation that the compulsory licence was a part and parcel of a state-sponsored policy for meeting domestic welfare and commercial objectives through the systematic forced localisation of drug manufacturing.⁵⁰

⁴⁷ Maulik Vyas, "Bayer challenges IPAB's compulsory licence order to Natco Pharma on cancer drug Nexavar". Economic Times, October 12, 2013
http://articles.economictimes.indiatimes.com/2013-10-12/news/42968576_1_natco-pharma-nexavar-compulsory-licence

⁴⁸ http://www.ipindia.nic.in/iponew/compulsory_license_12032012.pdf
http://www.nujslawreview.org/pdf/articles/2013_1/mansi.pdf
<file:///C:/Users/AKhanna/Downloads/IAM%20Magazine%20issue%202013%20-%20The%20pitfalls%20of%20compulsory%20licensing%20in%20India.pdf>
<http://www.managingip.com/Blog/3273950/India-rejects-another-compulsory-licence.html>
<http://www.livemint.com/Companies/feivYXISXb6XBMhELJD6LJ/Bombay-HC-upholds-Nexavar-compulsory-licensing-decision.html>

⁴⁹ <http://keionline.org/node/1447>

⁵⁰ Rep. Robert Goodlatte, in testimony by USPTO Deputy Director Teresa Rea before House Judiciary Subcommittee for Intellectual Property
<http://keionline.org/node/1447>

Bayer proceeded to appeal the Controller's decision with the Intellectual Property Appellate Board (IPAB), while seeking an injunction against NATCO for the manufacture of a generic version of Nexavar. In March 2013, however, the IPAB upheld the Controller General's decision, while also making a crucial clarification with regard to the application of Section 84 (1)(c) concerning *the working of patents*. The IPAB opined that the lack of local manufacturing alone did not constitute a failure to work the patent.⁵¹ Nonetheless, Bayer's failure to ensure affordability and accessibility to the public constituted a failure to work the licence and was sufficient in itself to justify the compulsory licence under the Indian patent law.⁵²

Some observers are of the view that the requirement of local manufacturing to satisfy the 'working of the patent' stipulated by the Controller was incompatible with the TRIPS agreement.⁵³ In particular, they believe that this consideration breaches Article 27(1) which states that "*patents shall be available and patent rights enjoyable without discrimination as to [...] whether the products are imported or locally produced*".⁵⁴

The IPAB's subtle modification of the Controller General's interpretation was significant in this regard, as it ensured that the government avoided any transgressions of TRIPS requirements as a result of the ruling against Bayer.

Subsequently, Bayer had sought relief against the IPAB's decision through an appeal before the Bombay High Court. However, Bayer's challenge was dismissed on July 15, 2014 with the presiding Justice Sanklecha stating that "*We don't see a reason to interfere with the order passed by IPAB and, therefore, the case is dismissed.*"⁵⁵ As of May, 2015, Bayer had indicated it may pursue an appeal against the High Court's decision by moving the Indian Supreme Court.⁵⁶

⁵¹ Indian Patent Act 1970 (Amended 2005) http://ipindia.nic.in/ipr/patent/patent_Act_1970_28012013_book.pdf

⁵² *Ibid.*

⁵³ <http://spicyip.com/2012/10/guest-post-bayer-natco-decision-trips.html>

⁵⁴ *Supra*, fn. 23

⁵⁵ <http://spicyip.com/2014/07/spicyip-tidbit-bombay-hc-dismisses-challenge-to-nexavar-compulsory-license.html>

⁵⁶ <http://www.livemint.com/Companies/feivYXISXb6XBMhELJD6LJ/Bombay-HC-upholds-Nexavar-compulsory-licensing-decision.html>

V. PATENT LINKAGE AND DATA EXCLUSIVITY

‘Patent Linkage’ refers to the regulatory practice of linking the marketing approval of a pharmaceutical product to the patent status of the original drug in order to ensure that for on-patent drugs, marketing approval to a third party of a generic imitation is only granted upon patent expiry or with the consent and acquiescence of the patent owner.⁵⁷

‘Data exclusivity’, on the other hand, refers to a policy measure that prevents public access to proprietary clinical testing data that innovator firms present to a regulator to demonstrate drug safety and obtain marketing approvals. Many regulatory regimes in India, the US and elsewhere permit generic companies, who subsequently wish to gain their own approval for the same drug substance, to rely on trial data filed by the innovator company that made the first application in order to avoid a wasteful duplication of efforts and thus decrease the costs and delay in market entry for generics. The generic company must simply demonstrate that their product has the same qualitative and quantitative composition as that product and that it is bioequivalent. The rationale for granting data exclusivity is to compensate the innovator company for the significant risk and cost it assumes in generating the clinical trial data required to obtain a marketing authorization.⁵⁸ While it may not necessarily add any new advantages to the market exclusivity enjoyed by approved innovator drugs, the delay in proliferation of clinical data does hand innovator firms a decisive strategic advantage over generic manufacturers.

Patent linkage and data exclusivity, though distinct aspects of the IP regime, are associated in that they both contribute to preservation of the originator’s market monopoly for the drug in question. India has so far declined to incorporate provisions for either patent linkage or data exclusivity into its amended Patents Act of 2005. As such, these practices have been a matter of serious contention between innovators and the authorities, rivalling only that caused by Section 3(d) and Compulsory Licensing policies.

In order to examine and appreciate the contrasting positions and rationales on the issue of patent linkage and data exclusivity, it is helpful to understand the background of these policy measures that both found their way into U.S. law with the Hatch-Waxman Act, well before the advent of TRIPS.

Hatch-Waxman and the Advent of Patent Linkage in the U.S.

Some experts of IP law trace the history of rigorous clinical trials to the ‘thalidomide tragedy’ in Europe where a largely untested ‘wonder drug’ resulted in grave health consequences for its

⁵⁷ Mittal, Anshul. “Patent Linkage in India: Current Scenario and Need for Deliberation” CSIR. May 2010.

⁵⁸ http://www.taylorwessing.com/synapse/regulatory_dataexclusivity.html

users.⁵⁹ Consequently, the U.S. implemented an onerous system that required separate clinical trials for every drug seeking market approval, including generics.⁶⁰ Furthermore, during this period, innovator companies in the U.S. had complete and perpetual control of ‘clinical trial’ data for the duration of the patent.⁶¹

Subsequently, however, the case of *Roche Products Inc. vs. Bolar Pharmaceutical Co.* heard in the U.S. Court of Appeals Federal Circuit in 1984 was an inflection point with regard to patent linkage and data exclusivity in the U.S. and its subsequent proliferation across some global IP regimes.⁶²

Bolar Pharmaceuticals, a manufacturer of generics, had been experimenting with Valium, the active ingredient used in Roche’s patented drug Dalmane. Its objective was to ascertain the bio-equivalency of its own generic product against Dalmane for future FDA approval for marketing upon expiry of the original drug’s patent, somewhat abridging the usual duplicative clinical trial process for generics. In its defence, Bolar had argued that its use of the patented product did not constitute infringement based upon an exception for experimental use pre-existent in US patent law.

The Court rejected Bolar’s argument drawing upon the ‘experimental use exception’ on the grounds that Bolar had intended to sell its generic product in competition with Roche’s Dalmane after patent expiration and, therefore, its experiments had a business purpose.

The Court also found no merit in Bolar’s contention on grounds of public welfare where it stated that the need to ensure availability of generic drugs immediately upon patent expiration justified the experimental use of the patented drug, which would otherwise result in an extension of Roche’s monopoly beyond the patent expiry date.

Although Bolar Pharmaceutical Co. lost the case, the arguments presented in the course of the proceedings initiated a policy debate in the US Congress resulting in the landmark *Drug Price Competition and Patent Term Restoration Act*, also known as the Hatch-Waxman Act of 1984.⁶³ This Act sought to implement a compromise between incentivizing innovative drug originators and ensuring the speedier introduction of generics. Among other things, the Act permitted use of patented products in experiments for the purpose of obtaining FDA approval. Furthermore, it also eliminated the need for duplication of costly and time-consuming clinical trials. Under its provisions, generic manufacturers were able to use the data generated by drug originators in seeking approval, thereby vastly easing the market entry of generics following expiry of patents.

⁵⁹ <http://spicyip.com/2011/02/attempt-to-balance-data-exclusivity.html>

⁶⁰ *Ibid.*

⁶¹ *Ibid.*

⁶² <http://nopr.niscair.res.in/bitstream/123456789/9066/1/JIPR%2015%283%29%20187-196.pdf>

⁶³ *Ibid.*

However, in order to reassure and placate originator firms, the Act also introduced some important concessions. Under “Patent Term Restoration” the Hatch-Waxman Act awards drugs containing a new chemical entity a period of five years of data exclusivity to compensate for the portion of the patent term lost due to the regulatory approval process.⁶⁴ Therefore, during this period, generic competitors are prevented from relying on the clinical data submitted by the original pharmaceutical manufacturer for a competing generic product.⁶⁵

Additionally, the Act also introduced a system of patent linkage that essentially places an onus on the applicant to prove to the regulator that the drug for which it seeks approval will not be infringing a preexisting patent.

In accordance with the provisions of the Hatch-Waxman Act, the FDA maintains a list of all pharmaceutical products and uses currently under patent, widely referred to as the ‘Orange Book’.⁶⁶ Any new applicant seeking marketing approval for a product must indicate in a legally binding manner one of four options with regard to the patent status for its proposed product:⁶⁷

1. There is no existing patent related to the applicant’s drug
2. The relevant patent has expired
3. Marketing approval is sought after the existing patent expires
4. The applicant is contesting the validity of the patent

Subsequently, the patentee has a period of 45 days upon notice to bring action for infringement, upon which the approval of the generic drug is automatically delayed by a period of 30 months. Generic firms that are able to prove the invalidity of an existing patent are awarded a 180-day (6-month) period of exclusive marketing rights.⁶⁸

There are significant drawbacks to this provision that is widely seen as affording originator firms far too much leeway to delay generic entry and prolonging monopolies through litigation and strategic patenting. In fact, as a result of this concern, the US Federal Trade Commission undertook a study that concluded, among other things, that this provision led to a proliferation of litigation and disadvantaged smaller firms that were all too often unable to summon the resources to mount a legal challenge to invalidate a patent.⁶⁹

⁶⁴ <http://www.lexology.com/library/detail.aspx?g=0a295b70-e577-461b-99e5-48e0eeec512>

⁶⁵ Ibid.

⁶⁶ Ravikant Bhardwaj. *The Impact of Patent Linkage on Marketing of Generic Drugs..* Journal of Intellectual Property Rights. Vol 18, July 2013, pp 316-322.

⁶⁷ Ibid.

⁶⁸ Ibid.

⁶⁹ Luke M. Olson, Brett W. Wendling. Estimating the Effect of Entry on Generic Drug Prices Using Hatch-Waxman Exclusivity. U.S. Federal Trade Commission, Bureau of Economics. April 2013

Rather often, generic firms had to resort to out-of-court settlements in the face of the tremendous cost of litigation against originator firms. Ultimately this adversely impacted the consumer by delaying access to generics or increasing the overall cost of the drug as a result of litigation costs.⁷⁰

The EU's Centrist Approach

The European Union has introduced a pharmaceutical policy that harmonizes drug regulation in all of its member countries. Significantly, the EU has taken an approach to finding common ground between innovation and public access that altogether rejects patent linkage in the belief that it delays generic entry and adversely impacts access.

The EU, however, compensates originator firms in this arrangement with some of the longest periods of data exclusivity extant globally. The EU grants full data exclusivity during the initial eight years. Any applications for marketing rights may only be entertained after this eight-year period, but granted only after an additional two-year window, hence a total of 10 years. In some cases, regarding 'new therapeutic indications' of a drug, an additional one year of exclusivity is granted to the originator. Due to this unique staggered arrangement for preserving data exclusivity, the EU data policy is often referred to as the '8 + 2 + 1' system.

The Indian Perspective

India's policy on patent linkage and data exclusivity can be said to still be in a formative state. The legislature and separately the courts, through a handful of rulings, have nevertheless contributed to the delineation of some crucial contours of the policy.

To begin with, in the process of overhauling India's IP regime to comply with TRIPS, the Indian legislature took the first step in defining India's policy on this aspect of the IP regime.

With respect to framing the minimum rights conferred on a patentee, Article 28.1 of the TRIPS agreement reads:

"A patent shall confer on its owner the following exclusive rights:

- (a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing (6) for these purposes that product;*
- (b) where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using,*

⁷⁰ Ibid.

offering for sale, selling, or importing for these purposes at least the product obtained directly by that process."⁷¹

However, under its interpretation of Article 27, read along with Article 39 that deals with the disclosure of proprietary data, the Indian legislature did not feel compelled, in spite of lengthy deliberations, to include any provision for a period of data exclusivity to the originator. Remaining consistent in its disfavor towards provisions that could encourage unwarranted prolonging of patents, the Indian legislature also chose not to include a patent linkage clause, following the same path as the European Union in this regard.

Even so, with the language of TRIPS on this issue being vaguely worded and without an expressly worded statutory policy or directive towards this end, a sense of ambiguity and disharmony prevailed in the initial years following the implementation of the Indian Patents Act of 1970 (Amended 2005). For example, the application form issued by the DCGI to applicants seeking marketing approvals contained a question which required the disclosure of the patent status of the original product, implying patent linkage despite the legislature never having adopted such a clause.⁷²

Capitalizing on this ambiguity, multinational corporations were able to initially gain some legal ground towards a system of patent linkage, along the lines of the US system governed by the Hatch-Waxman Act.

Most notably among these, in a ruling by the Delhi High Court in 2008 in the case of *Bristol Myers Squibb vs. Hetero Drugs Ltd.*, Bristol Myers Squibb (BMS) secured an ex-parte injunction against Hetero Drugs which had sought marketing approval for its drug 'Dasatanib' which was a generic version of the drug *Sprycel* marketed by the former for the treatment of Chronic Myeloid Leukemia.⁷³

The Court added that *"It is expected that the DCGI while performing statutory functions will not allow any party to infringe any laws and if the drug for which the approval has been sought by Hetero Drugs is in breach of the patent of BMS, the approval ought not to be granted to Hetero,"* thereby creating a link between the regulatory approval and patent status of a drug that was unprecedented in the Indian IP regime. As such, the ruling implied that it was also DCGI's mandate to identify a possible infringement of an existing patent prior to granting marketing approval to any drug.

⁷¹ "Agreement on Trade-Related Aspects of Intellectual Property Rights". WTO Analytical Index. Available at: https://www.wto.org/english/res_e/booksp_e/analytic_index_e/trips_02_e.htm

⁷² <http://spicyip.com/2010/09/spicy-ip-tidbit-health-ministry-set-to.html>

⁷³ http://articles.economictimes.indiatimes.com/2009-01-08/news/28479352_1_patent-linkage-dcgi-shamnad-basheer

The decision was, expectedly, widely welcomed by multinational pharmaceutical corporations. However, experts on Indian intellectual property law such as Shamnad Basheer have noted that the Delhi High Court's decision transgressed existing laws and regulations, particularly in giving legal mandate to the DCGI to link marketing approval with patents.⁷⁴

A subsequent landmark judgment from the Delhi High Court in the case of *Bayer Corporation and Ors vs. the Union of India (UOI) and Ors* on August 18, 2009 finally brought much needed clarity to the issue. Bayer had in this case initially sought an injunction (somewhat similar to the one obtained by BMS in 2008) against Cipla to restrain the granting of a license to manufacture, sell and distribute its drug 'Soranim', which was a generic version of the anti-cancer drug Nexavar marketed by Bayer. In its arguments, Bayer argued *inter alia* for the establishment of a patent linkage policy through its reading of the Drugs Act in conjunction with the Patents Act.⁷⁵

In this instance, however, the Court did not find merit in the petitioner's argument, ruling first and foremost that the mandate of the DCGI as the country's drug regulator is limited to examining the safety and efficacy of drugs, for which it was expertly qualified. The Court opined that DCGI is not competent to adjudge cases pertaining to patent law, particularly regarding questions of patent validity or infringement. Therefore, the performance of this role was beyond the drug regulator's mandate.

Furthermore, the Court also ruled that the enactment of an entirely new policy, such as the enforcement of a system for patent linkage, was the exclusive preserve of the legislature, which the court noted had made the conscious decision to omit such a provision for patent linkage in the law. It added that while it was the Court's function from time to time through interpretation of legislation to fill in statutory gaps, to effect such a substantive change in policy would constitute a case of overreach. Therefore, such a policy could only be enacted by the Parliament.⁷⁶

The Delhi High Court's judgment in this case marked a watershed in the modern Indian IP regime and was a definitive veto against the incorporation of elements of patent linkage in the Indian system. Furthermore, the decision upheld the so-called 'Bolar provision' of the Indian Patents Act that allowed generic manufacturers access to clinical data for the development of generic alternatives that could be introduced with minimal delay following patent expiry.

The decision, however, like others before it, invited scathing criticism and an overall miscasting of the Indian patent regime as anti innovative.

⁷⁴ Ibid.

⁷⁵ <http://nopr.niscair.res.in/bitstream/123456789/9066/1/JIPR%2015%283%29%20187-196.pdf>

⁷⁶ <http://nopr.niscair.res.in/bitstream/123456789/9066/1/JIPR%2015%283%29%20187-196.pdf>

Is Market Exclusivity Impossible in the Absence of Patent Linkage?

A leading consultant on the global IP regime, discussing India's approach to IP policies in a popular IP blog, has written: "*In effect, without patent linkage, the grant of patents for pharmaceutical products cannot assure any exclusivity in the market, and so advanced developing and developed countries with well-functioning patent systems have also made an effort to implement patent linkage.*"⁷⁷ This observation in many ways reflects the misconception among critics of the Indian IP regime who fear that patents are unenforceable in the absence of a patent linkage provision.

Towards this end, the Delhi High Court, in the *Bayer vs. Union of India* case, made a most crucial observation in emphasizing that patent rights are 'private rights' and contingent upon the patent holder's desire to enforce them rather than an obligation of public institutions such as the DCGI.⁷⁸ This places the onus of defending a patent against infringement through legal recourse squarely on the patentee and thereby underscores the fundamental difference in approach towards patent linkage followed by the United States and other nations that have adopted such a policy.

Further, the patentee is provided sufficient legal recourse under the Indian Patents Act of 1970, which elaborately provides for the procedure for patent opposition and revocation under Sections 25 and 64 respectively.⁷⁹ Section 104 of the Patent Act also mandates that no court lesser than a District Court should have jurisdiction over matters of patent infringement. This only validates the DCGI's lack of jurisdiction over the matter.

This dispensation clearly requires a far more proactive approach from a patentee, without the convenience of the 'firewall' against patent infringement of sorts created under the Hatch-Waxman Act. However, it also limits opportunities for strategic litigation that, as noted by the US FTC, could otherwise forestall the entry of generics into the market. Prolonged delays in generic entry could have major consequences for Indian patients, the vast majority of whom tend to be precluded from accessing the benefits of on-patent drugs due to their significantly higher prices.

On the other hand, it also necessitates a greater level of transparency and access to information from the drug controller in order to allow the patentee to remain abreast of any new applications that may potentially infringe upon an existing patent and take remedial action in a timely manner. These scenarios are highly time-sensitive, as can be seen from Pfizer's experience with

⁷⁷ <http://www.biotechblog.com/2013/10/22/miscasting-data-linkage/>

⁷⁸ <http://nopr.niscair.res.in/bitstream/123456789/9066/1/JIPR%2015%283%29%20187-196.pdf>

⁷⁹ <http://nopr.niscair.res.in/bitstream/123456789/9066/1/JIPR%2015%283%29%20187-196.pdf>

Sutent, where a delay in the legal process was sufficient to flood the market with generic supply to the detriment of Pfizer, which ultimately won its appeal.⁸⁰

The Controller General of Patents, Designs and Trademarks has made important strides to address concerns in this regard. The “Indian Patent Advanced Search System (InPASS)” launched on February 27, 2015 enables digital access to both granted patents and pending applications for the benefit of all stakeholders.

Does India’s Stance on Data Exclusivity make it a Global Outlier?

On the matter of protection of undisclosed information and trade secrets, Article 39 of TRIPS provides the requisite guidelines for member nations. The relevant paragraph (3) of Article 39 reads as follows:

“3. Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.”

In order to inform and evolve India’s legal framework in accordance with the data protection requirements of Article 39.3 of TRIPS, the Government of India had convened an inter-ministerial Committee in 2004 under Satwant Reddy, then Secretary in the Ministry of Chemicals and Fertilizers. The Committee examined the implications of Article 39 and proposed various approaches to address India’s commitments in this regard.⁸¹ In its report dated May 21, 2007, the Committee found that Article 39.3 did not obligate signatories to offer data exclusivity and that the ‘Trade Secrecy’ provision already extant in Indian law was sufficient in providing protection against unauthorized use or disclosure of confidential data.

Second, current literature advocating the implementation of these policies often invokes comparisons with OECD countries such as Canada, Australia and Singapore, all of which have implemented patent linkage and data exclusivity measures, but also have vastly more advanced economies than India.⁸² Curiously enough, this is a context where even China is touted as a role model, having made the unusual commitment to enact both a patent linkage system as well as a six-year period of data exclusivity, absent any binding treaty obligations, and in a noteworthy reversal of its usually protectionist trade policy.

⁸⁰ [http://democrats.energycommerce.house.gov/sites/default/files/documents/Testimony-Waldron-CMT-Trade-
Barriers-India-US-2013-6-27.pdf](http://democrats.energycommerce.house.gov/sites/default/files/documents/Testimony-Waldron-CMT-Trade-Barriers-India-US-2013-6-27.pdf)

⁸¹ <http://chemicals.nic.in/DPBooklet.pdf>

⁸² <http://infojustice.org/wp-content/uploads/2012/08/Patents-TPP-vs-Canada-Mexico-NAFTA-08162012.pdf>

However, as the table below indicates, India’s stance on patent linkage is quite consistent with economies of a similar developmental status such as Brazil and Indonesia.

Table 1: Patent Linkage Practices

Country	Patent Linkage	Data Exclusivity
Brazil	No	No
Russia	No	Yes – 6 years
China	Yes	Yes – 6 years
South Africa	No	No
Thailand	No	Yes - 5 years
Indonesia	No	No
Philippines	No	No
Singapore	Yes	Yes - 5 years
Vietnam	No	Yes - 5 years
Brunei	No	No

Sources in footnotes⁸³

On the issue of data exclusivity as well, India can hardly be termed an “outlier”.

Divergent economic circumstances that prevent the extemporaneous adoption of policies followed by developed nations has been recognised by none other than U.S. Rep. Henry Waxman, the co-author of the Hatch-Waxman Act, who has observed that “(data exclusivity) works in this country because most people in the U.S. have health insurance that pays for essential drugs and because we have a health care safety net to assure that the poorest in our society are not left without medical care and treatment.”⁸⁴ “But to impose such a system on a country without a safety net, depriving millions of people of life-saving drugs, is irresponsible and even unethical. In developing countries, we must do everything in our power to make affordable drugs for life-threatening diseases available now”⁸⁵.

⁸³ <http://www.mirandah.com/pressroom/item/340-patent-linkage-in-asian-countries-compared-to-the-us> and <https://bricwallblog.files.wordpress.com/2014/06/table4.pdf>

<http://www.lexology.com/library/detail.aspx?g=0a295b70-e577-461b-99e5-48e0eeeac512>

⁸⁴ <http://www.law360.com/articles/4061/india-mulls-data-exclusivity-for-drug-patents>

⁸⁵ Ibid.

The Policy on Data Exclusivity Remains in Flux

So far we have demonstrated that India's stance on patent linkage and data security, though a source of distress to western trade negotiators and MNCs, is neither in violation of its TRIPS commitments nor does it make India an outlier among similar developing economies across the globe. Following the Delhi High Court's definitive ruling in this regard, this policy is unlikely to be reversed by the Parliament.

However, Indian policy is far from mature with respect to data exclusivity, where the debate has in fact remained alive and vibrant.

The Satwant Reddy Committee report⁸⁶ stirred the pot by recommending a provision granting three years of data exclusivity for firms registering new agro chemicals. While these recommendations were incorporated into the proposed Pesticide Management Bill, 2008, the bill was never passed due to contention over a number of other provisions.

The issue has reportedly remained a crucial sticking point in the India-EU Free Trade Agreement (BTIA) negotiations, preventing progress.

At the same time, a significant section of the Indian pharma industry, comprising domestic research-based firms, had demanded stronger data protection laws to protect their investments in global clinical trials.⁸⁷ Breaking ranks with industry associations and patient groups, homegrown firms such as Biocon, Glenmark, Dr Reddy's, Lupin, Bharat Biotech and others have stressed the need for regulatory data protection (RDP) in order to promote innovation and investment in the development of new medicines and clinical research.⁸⁸

Indian Policymakers must take cognizance of this demand as it signals a paradigm shift towards innovation by India's pharma industry.

The three most compelling arguments in favour of a provision of data exclusivity, from the perspective of India's domestic interests, are provided below.

a) To Promote Domestic Innovation

⁸⁶ Satwant Reddy and Gurdial Sandhu, Report on Steps to be taken by Government of India in the context of Data Protection Provisions of Article 39.3 of TRIPS Agreement". Ministry of Chemicals and Fertilizers. May 31, 2007. Available at: <http://chemicals.nic.in/DPBooklet.pdf>

⁸⁷ <http://archive.financialexpress.com/news/pharma-firms-call-for-data-protection-laws/758645/0>

⁸⁸ <http://spicyip.com/2011/03/domestic-pharma-firms-say-yes-to-data.html>

The absence of “an ecosystem conducive to R&D” in India has been widely recognised. As Basheer and others⁸⁹ have noted, the provision of an abbreviated pathway for approval of generics has been beneficial both in terms of speedier access for patients and keeping costs low. However, it has also created a sense of complacency by enabling domestic generic manufacturers to ‘free-ride’ on the clinical data generated by innovator firms abroad. As a consequence, Indian firms remain stunted in terms of their clinical testing and associated innovative capabilities. Reddy points out how this free rider effect has created a disincentive in the realm of Ayurveda ever since clinical trials were mandated.⁹⁰

The pattern of increasing innovative output among domestic industries, despite the prevailing incentive to free-ride, must be encouraged. Awarding a period of data exclusivity would certainly add impetus to this important but nascent trend towards innovation among homegrown firms.

b) To Foster Beneficial Improvements to Drugs

Drug regulatory policy operates independently from patent law, even more so in the case of India following the Delhi High Court’s express directive in this regard. Therefore, the marketing approval of any new drug is subject to regulatory requirements, irrespective of the patent status.

Reddy and other eminent IP experts have pointed out that Rule 122E of the Drugs and Cosmetics Rules 1945 utilizes a definition of a ‘New Drug’ that differs significantly from the definition of a ‘new invention’ as enforced by Section 3(d) of the Patents Act.^[1] The definition used by Rule 122E includes *inter alia* new forms or claims of existing drugs namely ‘new indications, dosage, dosage form and route of administration’, all of which are precluded from patentability under Section 3(d) as discussed in previous sections.^[2] Many of these have considerable medical utility, particularly in instances where vastly improved safety or fewer side effects are demonstrated. Even though they may not be eligible for a patent, by virtue of their classification as ‘New Drugs’ per the Drug Rules 1945, they would require extensive clinical testing to obtain marketing approvals. In those cases where clinical trial data from other countries is not available, the nascent prospects of such potentially beneficial new drugs may be left dead in the water as it is unlikely that manufacturers would be willing to assume the risk and investment on clinical trials only to have their data exploited via a rampant ‘free-riding’ trend along with the absence of legal recourse available to on-patent drugs. With a steadily declining trend in NCE discoveries and a growing propensity for innovation among domestic firms, such cases are likely to occur

⁸⁹ Basheer, Shamnad and Reddy, Prashant, The 'Experimental Use' Exception through a Developmental Lens (2010). IDEA: The IP Law Review, Vol. 50, No. 4, 2010. Available at SSRN: <http://ssrn.com/abstract=2216850>

⁹⁰ <http://spicyip.com/2011/03/domestic-pharma-firms-say-yes-to-data.html>

^[1] <http://spicyip.com/2011/02/attempt-to-balance-data-exclusivity.html>

^[2] <http://spicyip.com/2011/02/attempt-to-balance-data-exclusivity.html>

with increasing frequency. A limited period of data exclusivity would serve as a balance to Section 3(d) in creating an incentive for firms to undertake the requisite investment in clinical trials in cases where patent protection does not apply.

c) To Address the Capability Gaps of the Generic Industry

India possesses a thriving generic industry that has demonstrated an advanced ability to reverse engineer drugs developed elsewhere, thereby providing generic equivalents at vastly lower prices. However, even to date the Indian generic industry's expertise extends by and large only to conventional 'small-molecule' drugs that are fairly straightforward to replicate.

The latest range of biologic medicines, however, are derived from far more complex procedures involving the genetic engineering of living cells rather than through chemical synthesis as in the case of small molecule drugs.⁹¹ With a handful of exceptions, the Indian industry's capabilities in innovating or even replicating biologics remains highly limited. Also, the significant R&D into replication, if at all, can only commence once data exclusivity periods expire in the originator country and the clinical trial data is released to the public. In many cases, there are no alternative sources of such therapies besides the original innovators. A period of data exclusivity would go a long way in providing foreign firms a level of reassurance to make their drugs available in India with minimal delay.

⁹¹ <http://www.ipwatchdog.com/2013/11/10/protecting-data-exclusivity-protecting-the-future-of-medicine/id=46136/>

PART – II:
Charting a Way Forward

VI. THE DISTINCTION IN PHARMA ECONOMICS IN THE DEVELOPED AND DEVELOPING WORLDS

To mitigate contention on IPR issues, the underlying economics of pharmaceutical patents that influence both firms and governments needs to be examined and understood. What drives the pricing strategies of pharmaceutical firms, or motivates government policies such as compulsory licensing?

In its simplest form, a patent is an exclusive right conferred by a government on an inventor to preclude others from the sale, use or import of an invention for a limited period of time. It is understood that this exclusive right awards the inventor the ability to charge a monopolistic price for the invention that exceeds what would be charged in a perfectly competitive market with several suppliers. This price allows inventors to recoup their investment of time and capital devoted to the research and development of an invention and prospectively also accumulate profit, arguably creating an economic incentive for innovation. There is a resulting burden borne by consumers in the form of higher prices and a deadweight loss incurred by society as a whole for the duration of the patent. However, this transfer of wealth from the consumer to the innovator and the foregone benefits to society is seen as a necessary short-term trade-off for a long-term welfare gain achieved through the future proliferation of the said invention once the patent expires and the overall promotion of innovation.

The case of pharmaceutical patents, however, is distinct in that the costs borne by society in the form of restricted access to a newly invented drug due to higher prices is denominated not in terms of reduced productivity, utility or income, but a direct, negative impact on human health and longevity. Nor is the magnitude of this societal cost uniform across different economies. It is influenced in large part by pre-existing conditions including income levels, inequality, prevalence of disease and the relative pricing of the new drug, among others. As we will demonstrate, this creates a relatively far more difficult and complex public policy issue in least developed and developing economies as opposed to the first world.

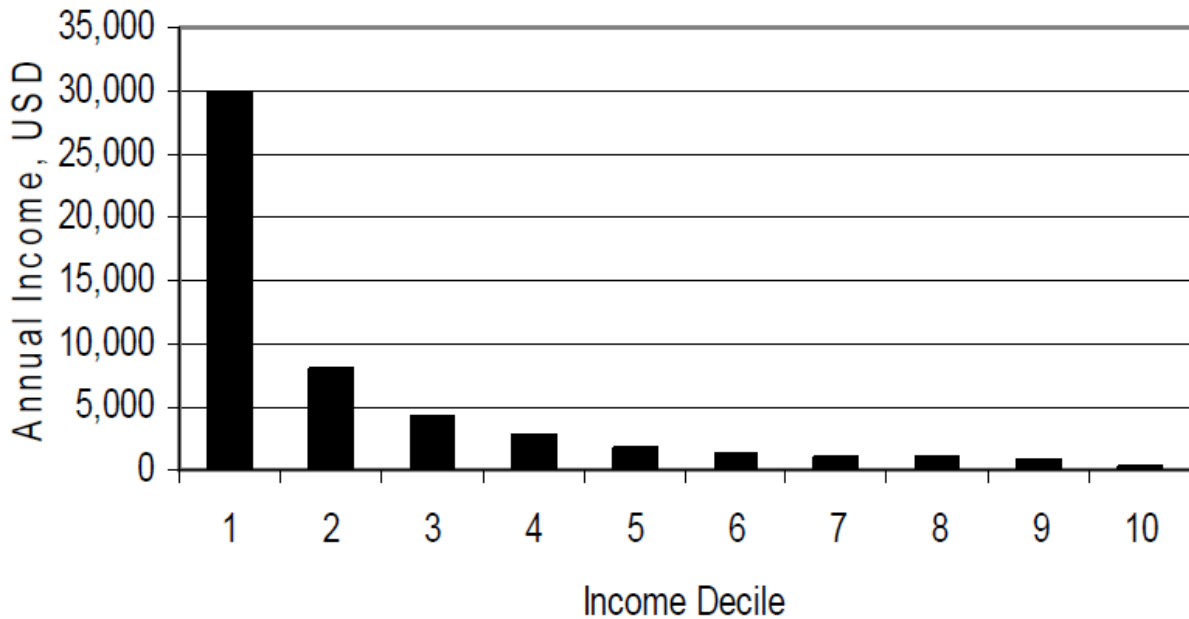
In their seminal work published in 2009 on patent drug pricing and the associated costs to society, Flynn, Hollis and Palmedo proposed that these developing economies characterized by high levels of income inequality demonstrate “highly convex demand curves” for essential medicines with no substitutes, signifying highly variable sensitivity to the unit drug price.⁹²

The illustrative example below depicts the extremely uneven income distribution in South Africa, a typical developing nation. Among the five lowest deciles representing half the population, no one earns more than \$1,500 a year on average. In contrast, the top 10% of the

⁹² S. Flynn, A. Hollis, and M. Palmedo, “An Economic Justification for Open Access to Essential Medicine Patents in Developing Countries,” *Journal of Law, Medicine & Ethics* 37, no. 2 (2009): 184–209. Available at: <http://www.wcl.american.edu/pijip/documents/flynn05222008.pdf>

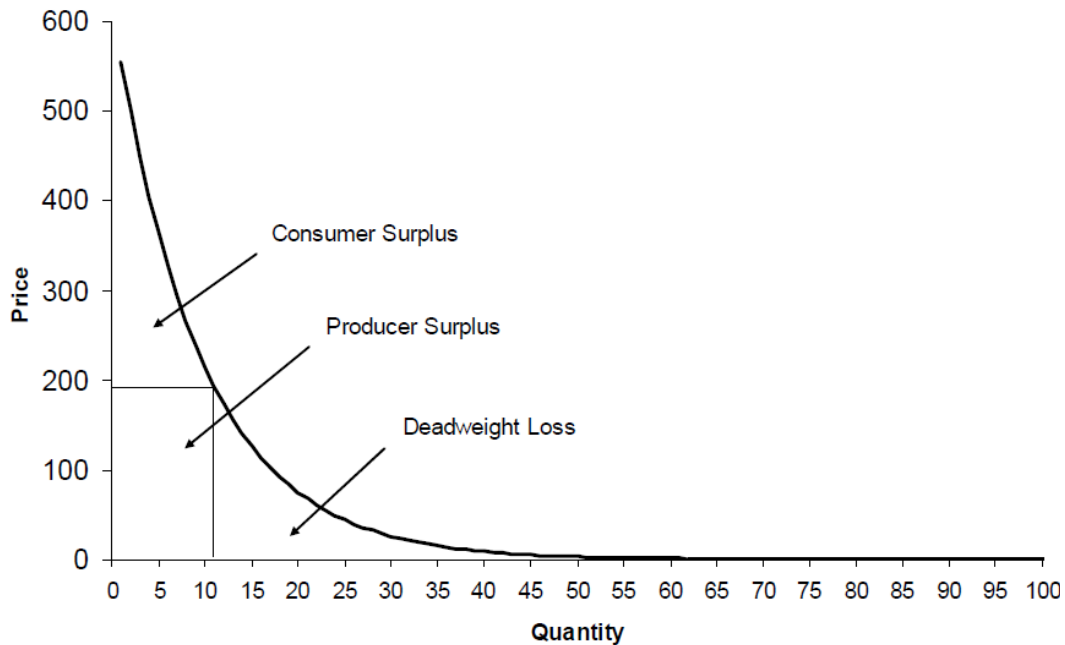
population earns nearly \$30,000 a year, some 20 times the lowest decile of society, and alone accounts for 56% of all income earned by the entire population of the country.

Figure 2: Income by Decile



This wide disparity in the income, and hence ability to pay of each section of society, manifests itself as a highly varying demand curve for life-saving drugs. At a very low price, close to the marginal cost of production, the drug is affordable to most of the patient population. However, every incremental rise in price renders the drug unaffordable to a disproportionately large number of consumers from among the poorest sections of society, resulting in a relatively flat curve towards the right, depicting highly elastic demand. However, as the wealthiest consumers in the economy have considerably higher incomes, they are able to afford the drug even at relatively high prices, resulting in a gradual steepening of the curve towards a vertical line, depicting somewhat inelastic demand for the same drug in question.

Figure 3: Convex Demand Curve



In such scenarios, rationally acting firms invariably achieve revenue maximization (the most lucrative combination of price and volume) by marketing the drug at relatively higher prices, well above the marginal cost of production, which in turn prices out a substantial part of the population constituted by the lower income groups and makes it affordable only to the wealthiest sections of society. Flynn et al. have used several examples from a number of developing economies with high income disparity from across the world including Brazil, Uganda and so forth, to demonstrate this phenomenon.⁹³

Consequently, the deadweight loss incurred by society is also disproportionately large in comparison to the private gains of the firm and a small number of consumers. In South Africa, for example, a patented brand of anti-retrovirals (ARVs) were priced at a level that made them unaffordable to 90% of society. It may be interesting to note here that Bayer's Nexavar that was discussed in previous sections of this paper was accessible to only 2% of the Indian patient population.

Using this analysis, a marked contrast was observed between the characteristics of markets for essential medications in the developing world and those of the affluent economies, such as those of Western Europe and North America. The demand curves for life-saving medication in the latter were distinct in that they tended not to depict the exaggerated convex shape characteristic of the developing world, rather tending to be relatively closer to a 45-degree, right-downward sloping demand curve seen in foundational economics text books. This is in part due to relatively

⁹³ Ibid.

higher and more equally distributed incomes, as well as the prevalence of health insurance and other effective social welfare mechanisms that ameliorate the costs of drugs and help make them affordable to the sections of society covered by these schemes.⁹⁴

Consequently, in contrast to the developing economies, the optimum revenue-maximizing point of output is thus achieved at relatively higher volumes, by making the drug available to much larger sections of the patient population. The social trade-off in terms of deadweight loss is far smaller and creating a mutually convenient scenario for all involved (pharmaceutical firms, the consumers and the government) is far more likely and achievable.

It is these broad distinctions, both in terms of the pre-existing economic conditions as well as the severity of the adverse social impact of pharmaceutical patents between the developed and developing worlds that must be appreciated by policymakers in the West when approaching this issue. Most importantly, it shows why an indiscriminate replication of the U.S. approach to patents without due consideration of these vastly different economic circumstances is simply unfeasible in many economies of the developing world, including India. J.H. Reichmann, a noted professor of law at Duke University, has observed in a commentary that in reference to life-saving drugs with no adequate substitutes, “deadweight-loss over time tends to become dead bodies”.⁹⁵

Further, as the magnitude of this loss is also a function of the patent duration, it explains to a great extent the initial resistance to the proposed 20-year patent monopoly from India and other developing nations during the Uruguay Round. It also goes to show why preventing evergreening of trivial incremental innovations is such a great imperative in some of these developing nations. Many incremental inventions, besides failing the legal novelty test for a true invention as discussed in previous sections, simply do not warrant the social cost that they impose on society. How does one weigh the benefits of ‘better bioavailability’ or the ‘lower likelihood of an upset stomach’ against the value of the thousands of lives of patients who would be once again priced out of the market should a drug receive a secondary patent over trivial improvements? Enforcing a stringent threshold for patentable innovation seems the natural recourse to this dilemma, as forty years of “dead bodies” is a cost simply no developing-world government can afford.

⁹⁴ K. Outterson, “Disease-Based Limitations on Compulsory Licenses under Articles 31 and 31bis,” in C. Correa, ed., *Research Handbook on Intellectual Property Law and the WTO*. May 2009. Available at: <http://www.bu.edu/law/faculty/scholarship/workingpapers/documents/OuttersonK052009.pdf>

⁹⁵ Reichman, J. H. (2009), Comment: Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options. *The Journal of Law, Medicine & Ethics*, 37: 247–263. doi: 10.1111/j.1748-720X.2009.00369.x

VII. EMERGING CHALLENGES

After two years of intense trade contention in 2013 and 2014, stemming in large part from disagreements on IPRs that appeared to cloud even the broader India-US relationship, there seems to be an upswing in the discourse. This is in no small part due to diplomatic efforts and the personal rapport shared by Prime Minister Narendra Modi and President Barack Obama, a point underscored by the US Trade Representative himself in an address at an India-US Trade Policy Forum meeting in November, 2014.⁹⁶

The USTR's Special 301 Out of Cycle Review (OCR) of India's intellectual property regime released a few weeks later in December, 2014 resonated these sentiments, lauding India's efforts for having a "meaningful, sustained and effective" dialogue on IPRs.⁹⁷ Cementing this significant turnaround of stance, the USTR's report also recognized "India's efforts to institutionalize high level engagement on IP issues and to pursue a specific work programme and to deepen cooperation and information exchange with the United States on IP-related issues under the US-India Trade Policy Forum".⁹⁸

Beyond this renewed sense of engagement between the two governments, the fundamental issues on IPRs and their underlying causes still remain unresolved. Many Western stakeholders in the pharma industry retain a strong sense of discontentment with India's IP regime, finding signs of progress severely inadequate. Some industry representatives are particularly concerned about the USTR's change of tune with regard to India, and have gone on record suspecting a secret compromise involving concessions from India in order to earn this respite from the so far relentless heat it has had to face.⁹⁹

What is evident from these reactions is that the pharma industry is unwilling to alter its fundamental approach towards doing business in India. Among its expectations on regulatory reforms, its wish-list continues to include a carte-blanche for setting price and quantities of drugs sold in the Indian market, with any subsidies or rebates at its own discretion.

In the meanwhile, the economics of the Indian market that dictate the compulsions of policymakers and concerned authorities also remain unchanged. A vast section of the population remains mired in crippling poverty, with income inequality worsening by all indications.

⁹⁶ http://www.business-standard.com/article/economy-policy/wto-breakthrough-due-to-modi-obama-involvement-us-trade-rep-114112400819_1.html

⁹⁷ http://www.business-standard.com/article/economy-policy/us-does-a-u-turn-lauds-india-s-ipr-114121500053_1.html

⁹⁸ Ibid.

⁹⁹ Ibid.

Hence any singular profit-maximizing price set by the pharma manufacturers on patented drugs, without substitutes or generics, will likely price out most of the population and draw the adverse attention of the Indian public health authorities.

In the near future, the three factors outlined below will work to aggravate this conflict of interests.

1) The Growing Convergence in Disease Profiles of the Developed and Developing World

Much of the literature on public health in the developing world has been devoted to the issue of tropical diseases predominant only in the developing world. The recent global Ebola outbreak in West Africa and Dengue fever epidemic in India are just two examples of the all too frequent outbreaks of tropical diseases that largely originate in and most gravely impact the developing world. Further, these epidemics have been stark reminders of how diseases exclusive to the developing world all too often find themselves on the back burner of research priorities of most pharmaceutical companies.

However, several analyses of global healthcare trends suggest that the disease profiles of the developed and developing world demonstrate increasingly converging characteristics. Hence these ‘orphan’ or ‘neglected’ tropical diseases are accounting for an ever smaller share of the developing world’s disease burden. Instead, non-communicable diseases (NCDs) such as cancer and cardio-vascular disorders, for example, once disproportionately found in the developed world, are increasingly affecting low income countries significantly.

A report published by WEF and the Harvard School of Public Health indicates that over 60% of all deaths in India are already due to non-communicable diseases. Alarming, the report further predicts that India stands to lose \$4.58 trillion between 2012 and 2030 as a result of non-communicable diseases, an amount well over twice India’s current GDP. Cardio-vascular disorders alone will account for \$2.17 trillion of this loss.¹⁰⁰

In fact, four NCDs alone caused nearly 50% of all disease-related deaths in India in 2014.¹⁰¹ These are cardiovascular disease (26 per cent), chronic respiratory disease (13 per cent), cancer (7 per cent) and diabetes (2 per cent).¹⁰²

Commenting on these findings, David Bloom, Clarence James Gamble Professor of Economics and Demography at the Harvard School of Public Health, attributed the increasing global burden of NCDs to two related demographic phenomena: global population growth and an increasing

¹⁰⁰ <http://www.weforum.org/news/india-stands-lose-more-458-trillion-non-communicable-diseases>

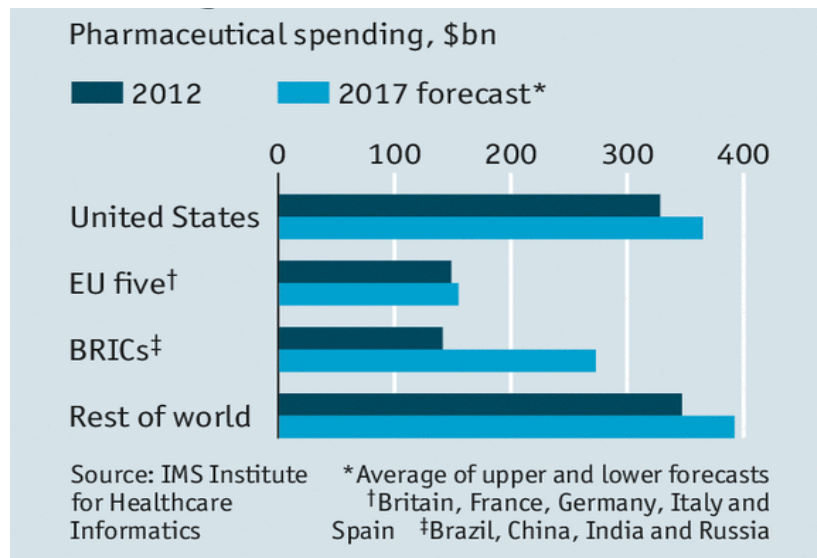
¹⁰¹ *Ibid.*

¹⁰² *Ibid.*

older population.¹⁰³ "Unhealthy diets, physical inactivity, harmful use of alcohol and tobacco consumption also drive the development of NCDs. In India, this is no exception, and NCDs are a large and growing challenge for its continued development. But solutions are available to improve the prognosis, reduce costs and create a healthier population," Bloom has added.¹⁰⁴

These emerging trends have a two-fold impact. First, as a consequence, developing markets will become increasingly important to the pharmaceutical industry. The shifting disease burden in conjunction with an increasing ability to pay due to economic growth will drive a significant component of global demand growth for breakthrough therapies for NCDs. *The Economist* has reported that established markets in North America, Europe and Japan are expected to see between 1-4% growth in drug spending between 2012 to 2017.¹⁰⁵ In contrast, drug spending in emerging markets is likely to grow between 10-13% over the same period, with patented drugs being a significant component¹⁰⁶.

Figure 4: Growth in Drug Spending



Source: *The Economist*

Simultaneously, these trends will almost certainly effect a recalibration of public healthcare priorities for the Indian authorities. Ensuring access to effective treatments for the four leading NCDs mentioned above will become a growing imperative for health departments that have historically focused on tropical diseases and vaccinations.

¹⁰³ http://articles.economictimes.indiatimes.com/2014-11-05/news/55798315_1_ncds-non-communicable-diseases-double-india

¹⁰⁴ Ibid.

¹⁰⁵ <http://www.economist.com/news/international/21592655-drug-firms-have-new-medicines-and-patients-are-desperate-them-arguments-over>

¹⁰⁶ Ibid.

Box 2: Cancer: An Emerging Threat to Indians

Cancer, yet another disease once thought to be largely confined to the developed world, has become a leading cause of deaths in the developing world, according to the World Health Organization (WHO). In 2008, 13% of deaths globally were caused by one of the many manifestations of the disease. Of these, 70% occurred in low and middle-income countries, which largely lack access to innovative treatments. Consequently, cancer has become among the top four leading causes of death in 10 out of 11 key emerging economies.

Though cancer currently ranks sixth among diseases in terms of fatalities in India, it nonetheless accounts for roughly 650,000 deaths annually. This trend is only set to grow in the coming years, with cancer incidences increasing with the expanding and ageing of the Indian population. Healthcare consultants estimate that by 2030, there could be an estimated increase ranging from 72 to 82 percent in cancer incidences in India, compared with 40% in higher income countries (Figure 5). Without adequate treatment, the mortality rate may rise to as much as five times that found in developed countries, representing a serious burden on the healthcare system.

Figure 5: Annual Cancer Deaths in Key Emerging Economies

Therefore, as a leading killer in developing nations such as India, cancer may come to be increasingly considered as a 'national emergency', according to some interpretations.

2) India's IP Policy Response to its Evolving Public Health Needs

These shifting considerations already appear to manifest themselves in India's access and affordability priorities, and possibly explain recent trends in the Indian authorities' approach to IP and their willingness to exercise flexibilities afforded by TRIPS to ensure access to advanced drugs.

Pharmaceutical innovators have been contending with IP threats in the form of compulsory licenses, patent denials and revocations in the developing world for several years now. However, as the table below summarizing some of the significant instances globally since 2001 shows, each of the actions taken against privately held intellectual property preceding those by India against Novartis and then Bayer was either for HIV/AIDS or another communicable disease. Further, these were often invoked under the circumstances of a serious threat of a pandemic, as in the case of widespread prevalence of HIV/ AIDS virus in Africa or the later outbreak of the H1N1 Avian influenza ("Bird flu") in East Asia in 2005.

Table 2: Timeline of Compulsory Licences, IP threats and losses since 2001¹⁰⁷

Year	Market	TA	Products	Outcome
2001	Brazil	HIV/AIDS	Stocrin, Viracept, Crixavan	Discount
2001-2003	South Africa	HIV/AIDS	8 ARVs	VL/Discount/None
2002	Egypt	ED	Viagra	CL
2004	Malaysia	HIV/AIDS	Videx, Retrovir, Combivir	CL
2002-2003	Zimbabwe	HIV/AIDS	All ARVs	CL
2004	Mozambique	HIV/AIDS	Epivir, Viramune, Zerit	CL
2004	Zambia	HIV/AIDS	Epivir, Zerit, Viramune	CL
2005	Argentina	Pandemic Flu	Tamiflu	VL
2005	Brazil	HIV/AIDS	Kaletra, Viread	Discount
2005	Ghana	HIV/AIDS	All ARVs	CL
2004	Indonesia	HIV/AIDS	Epivir, Viramune	CL
2005	Taiwan	Pandemic Flu	Tamiflu	CL
2005	China	Pandemic Flu	Tamiflu	VL
2005	Korea	Pandemic Flu	Tamiflu	CL
2006	India	Oncology	Glivec	Patent rejected
2006-2007	Thailand	HIV/AIDS	Stocrin, Kaletra	CL

¹⁰⁷ http://www.imshealth.com/deployedfiles/imshealth/Global/Content/Home%20Page%20Content/High-Growth%20Markets/Securing_IP_and_Access_to_Medicine_in_Emerging%20Markets.pdf

Year	Market	TA	Products	Outcome
2007	Brazil	HIV/AIDS	Stocrin	CL
2007	Thailand	CVD	Plavix	CL
2007	Canada/Rwanda	HIV/AIDS	Apo-TriAvir	CL
2007-2008	Thailand	Oncology	Glivec	Discount
2007-2008	Thailand	Oncology	Taxotere, Femara, Tarceva	CL
2010	Ecuador	HIV/AIDS	Kaletra	CL
2010	India	HIV/AIDS	Valcyte	Patent revocation
2012	India	Oncology	Nexavar	CL
2012	India	HCV/HBV	Pegasys	Patent revocation
2012	India	Oncology	Sutent	Patent revocation
2012	India	Oncology	Tarceva	Ruling allows generic
2012	Ecuador	HIV/AIDS	Kivexa	CL
2012	Indonesia	HIV/HBV	7 ARVs	CL
2013	India	Oncology	Herceptin, Sprycel, Ixempra	CL initiated, (declined eventually)

In spite of initial alarm, most global pharmaceutical manufacturers were coming to terms with the fact that the loss of revenues from such occasional, but drastic, outbreaks of infectious diseases would constitute a cost of business, and were gradually factoring these into their risk models.

In India's case, however, the flurry of patent opposition against Oncology and Hepatology treatments signals a marked departure from the erstwhile prevailing trend towards non-communicable diseases. With cancer and other NCDs posing an increasing burden on the health of its population, ensuring access to drug treatments for these diseases is taking center stage in India's public healthcare policy.

Traditionally, the newest and most effective 'breakthrough' treatments for cancer and various other NCDs have been priced at restrictively high prices, determined in part by the market dynamics discussed in the previous chapter.

Even so, the concerned Indian authorities have shown remarkable restraint and so far issued only a single compulsory license for Nexavar. However, the perception has been perpetuated that India is willing to exercise the ability to issue compulsory licenses to ensure that these treatments are made affordable to Indian patient populations, including the predominant economically disadvantaged segments.

In addition, this will become a growing concern at the patent application stage, where applications for innovative NCD drugs will face increasing scrutiny from the regulatory authorities and opposition from various patient and domestic interest groups such as has been seen in a growing number of cases, from Novartis's Glivec to Gilead's Sovaldi.

As such, to the innovative pharmaceutical industry, this perceptibly emerging trend presents a serious and growing threat to an entirely different, and extremely lucrative, dimension of pharmaceutical intellectual property assets. Not only has this IP contributed to the lion's share of industry profits in the post TRIPS era (as the next section will discuss), but so far it has also been considered 'safe' by all accounts.

Box 3: Are Poor Patients Entitled to the Latest and Best Treatments?

In theory, the expiry of a patent should mark an inflection point with regard to treatment accessibility for developing world patients, whereupon the patentee's monopoly ceases, and the proprietary knowledge enters the public domain so that generic manufacturers are able to manufacture and offer imitations at significantly lower prices. To be fair, there have been a number of such examples from the OECD nations where this has occurred in an ideal manner. However there are also a large number of instances from the developed world that suggest this transition will not be nearly as seamless nor entirely as beneficial as envisioned among the TRIPS signatories of the developing world, many of whom would have incurred crippling hardships to public welfare during the life of the patent.

The first case that must be considered is that of the exhaustible lifespan of certain types of pharmaceuticals. A vast number of diseases exhibit the ability to continually mutate and develop resistance to existing treatments. This phenomenon is observed not just in tropical infectious diseases such as malaria and tuberculosis but also global diseases such as AIDS and some forms of cancer. As such, by the time the patent expires and is made available to the poorest patients, many treatments may already be rendered ineffective for treating the prevalent strains of a disease.

A report by the American Enterprise Institute highlights the widespread practice of global donors distributing anti-malaria treatments to the poor that were off-patent, hence cheap, yet entirely ineffective even as a more recently developed effective and patented treatment was available.

To compound the problem further, in certain cases, if OECD country patients are no more at risk, there is a low likelihood that there is a new, effective drug in the research pipeline to treat the poor patients who remain at the mercy of the new, resistant strains of the disease.

In such instances, there is a clear failure in the 'trade-off' contract between the temporary monopoly awarded by a patent and the promised technology transfer and incentivization of further innovation, at great loss to the public welfare of the developing world.

Therefore, there is little wonder that developing country governments in many cases expect the latest and most effective treatments to be made available to even the poorest patients as their preferred option.

3) The Patent Cliff

Over the past decade, innovative drug companies have become increasingly dependent on ‘blockbuster drugs’ – the term used to refer to patented specialty drugs that generate more than \$1 billion in sales annually, with many generating revenues as high as over \$5 billion in the US alone.¹⁰⁸

As such, these drugs have played a central role within the pharma ecosystem, accounting for a significant portion of annual revenue and profits and thereby also making a significant impact on share prices. Therefore, research and development as well as the protection of IP pertaining to such ‘breakthrough’ drugs has been a principal aspect of the success strategy of several pharma firms.

However, a disproportionately large number of patented drugs that have formed the mainstay of pharma profits will see their patents expire in quick succession in the period between October 2011 and December 2016, a phenomenon widely termed as the ‘Patent Cliff.’ The table below shows that over these five years, patents on at least 18 blockbuster drugs are set to expire. Altogether, these accounted for a whopping \$64 billion in revenues in the year 2011.

Table 3: Patents on Blockbuster Drugs expiring between 2012- 2017

No.	Drug	Manufacturer	Disease	US Sales in 2011-2012	Patent Expiry
1	Lipitor	Pfizer	Cardio Vascular	\$7.7 billion	November 2011
2	Plavix	Bristol-Myers Squibb/ Sanofi Aventis	Cardio Vascular	\$6.8 billion	May 2012
3	Nexium	AstraZeneca	Acid Reflux	\$6.2 billion	May 2014
4	Abilify	Otsuka, Bristol-Myers Squibb	Anti depressant	\$5.2 billion	October 2014
5	Advair	GlaxoSmithKline	Asthma	\$4.6 billion	March 2012
6	Seroquel	AstraZeneca	antipsychotic, antidepressant	\$4.6 billion	September 2011
7	Singulair	Merck	asthma and seasonal allergies	\$4.6 billion	August 2012
8	Crestor	Shionogi, AstraZeneca	Cardio Vascular	\$4.3billion	July 2016
9	Cymbalta	Eli Lilly	Anti depressant, anti- anxiety	\$3.7 billion	June 2013
10	Copaxone	Teva	Multiple Sclerosis	\$3.6 billion	May 2014

¹⁰⁸ Chandra Mohan, SP Puranik, Prasanna Sagar, Swamy Sreenivasa and Madhu Chakrapani Rao, “Research and Reviews: Journal of Pharmaceutics and Nanotechnology” <http://www.rroij.com/open-access/patents-an-important-tool-for-pharmaceutical-industry-12-16.pdf>

No.	Drug	Manufacturer	Disease	US Sales in 2011-2012	Patent Expiry
11	Humira	Abbott Labs	Rheumatoid arthritis and Crohn's disease	\$3.5 billion	December 2016
12	Zyprexa	Eli Lilly	antipsychotic, antidepressant	\$2.9 billion	October 2011
13	Diovan	Novartis	hypertension	\$2.0 billion	September 2012
14	Sandostatin	Novartis	endocrine disorder	\$1.5 billion	June 2014
15	Exforge	Novartis	hypertension	\$1.35 billion	October 2014
16	TriCor	Abbott Labs	hypertension	\$1.2 billion	July 2012
17	Evista	Eli Lilly	Osteoporosis	\$1.1 billion	March 2014
18	Provigil	Teva	sleep apnea and narcolepsy	\$1.1 billion	April 2012

The loss of exclusivity will throw the doors open for generic manufacture of these drugs from competitors and almost certainly diminish revenues substantially for many firms unless they are able to introduce new blockbuster drugs. So far, this does not bode well for an industry that in 2012 alone lost over \$35 billion in global revenue.¹⁰⁹ The fallout in 2015 is expected to be nearly as bad, at some \$33 billion in lost sales.¹¹⁰

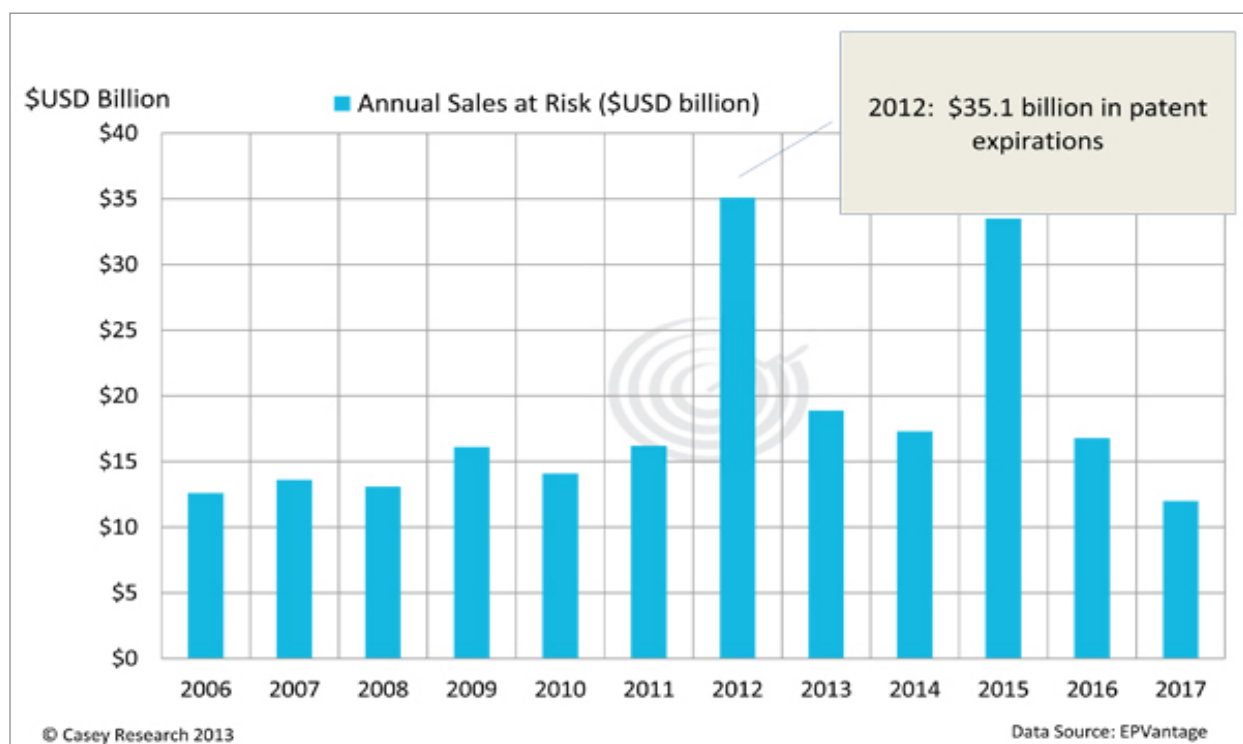
Worryingly for the pharma industry, the pipeline for novel drugs appears nowhere as prolific as it was in the early 2000s. As the New York Times has reported, there has been a marked decline in the discovery of breakthrough drugs, making them relatively fewer and far in between, even though individually a few of these may indeed be just as lucrative as others have been in the past.¹¹¹

¹⁰⁹ Thomas, Katie. "Generic Drug Makers See a Drought Ahead" New York Times. December 3, 2014.

¹¹⁰ Thomas, Katie. "Generic Drug Makers See a Drought Ahead" New York Times. December 3, 2014.

¹¹¹ http://www.nytimes.com/2014/11/16/magazine/why-are-there-so-few-new-drugs-invented-today.html?_r=0

Figure 6: Sales at Risk from Patent Expiration¹¹²



The table below shows some of the forthcoming breakthrough drugs predicted by analysts. Not only is it clear that pharma profits in the future will be sustained by a smaller pool of blockbuster drugs, but also many of these continue to be treatments for NCDs that are becoming increasingly crucial for healthcare needs of the developing world.

Table 4: Forthcoming Blockbuster Drugs Predicted by Analysts

Drug	Manufacturer	Disease	Projected Annual Revenue	Total Market Forecast for Similar Therapies
GA101	Roche	Leukemia	\$ 1.4 billion by 2018	-
Lemtrada	Sanofi	Multiple Sclerosis	-	\$ 13.8 - \$19.6 billion by 2022
Ibrutinib	Johnson & Johnson and Pharmacyclics	Blood Cancer	\$ 5 billion by 2018	-
Anoro	GSK and Theravance	Emphysema and Chronic Bronchitis	1.2 billion by 2018	-
Sofosbuvir	Gilead Sciences	Hepatitis C	\$ 6 billion by 2018	-

¹¹² <http://www.caseyresearch.com/cdd/is-the-patent-cliff-a-lethal-blow-to-big-pharma>

Consequently, on the one hand, the pharma industry may be expected to protect the ever-shrinking pool of IP with only greater ferocity than ever before. On the other, these trends are likely to fall squarely in the line of fire from health authorities and interest groups in the developing world, especially if they continue to be priced at restrictively high levels as before. With the stakes heightened for all parties, the conflict of interests is set to only intensify further in the coming years.

VIII. ADDITIONAL CHALLENGES PRESENTED BY A TRIPS-PLUS DRIVEN IP LANDSCAPE

From the preceding discussion, it is apparent that the need for a new paradigm in the industry has never been greater in order to avert a serious collision between the innovative pharma industry and governments in the developing world, including India. Any new approach must ensure that the healthcare needs of the economically disadvantaged patients within developing countries are met, without unduly compromising the interests of the pharma industry, in particular their incentive to innovate.

A sustained dialogue, with the objective of a gradual fostering of mutual trust and a willingness to collaborate between industry and governments, both in the developed and developing world, is necessary to transform the current contentious state of affairs.

However, rather than resign itself solely to accepting some form of compromise towards a resolution, the pharma industry has sought to hedge its options instead by vigorously seeking to rewrite the rules of intellectual property enforcement. This trend is aimed at effecting a broad proliferation of IP policies that set the privileges and standards for patent protection far above those mandated by TRIPS. This approach is most evident in the IP standards pursued through the prospective Trans-Pacific Partnership (TPP), a comprehensive trade agreement between the US and several nations in the Asia-Pacific that could have a transformative impact on trade regimes in the entire world.

The TPP's Approach to IPRs

The language of the TRIPS agreement expressly conveys that the provisions contained within merely present a set of minimum standards that all signatories must meet. The intent was to bring uniformity to intellectual property regimes of members in the light of increased globalization and trans-national trade facilitated by the newly formed WTO. Member nations retained the prerogative to impose higher standards as per their own considerations within the overall framework set by the agreement.

As the case of India has demonstrated, compliance with TRIPS has been no cakewalk for the developing world. Even the minimum standards mandated by the agreement set the bar far higher than pre-existing regimes in most developing nations. Further, compliance has entailed a substantive recalibration of laws and institutions, sometimes overhauling decades-old norms and approaches to IP issues. As such, many of the developing country members are still in the process of finding their feet and maturing their patent regimes along the requirements of TRIPS while mitigating the adverse near-term welfare impact on their citizens.

However, the US and other OECD nations have increasingly found the TRIPS provisions inadequate towards serving their economic interests, particularly with the welfare-friendly interpretation reinforced by the Doha Declaration that has allowed the introduction of novel legislative countermeasures such as Section 3(d) or the liberal use of compulsory licensing to facilitate access.

Consequently, some nations within the TPP have reportedly sought to advance a number of relatively higher ‘TRIPS-plus’ IPR standards that substantially expand the rights of the patent holder, as revealed by various leaked drafts of the treaty which is being negotiated in secret.¹¹³

Provisions that elicit the most concern in the purported text with regard to pharma patents include:

- Limiting the ability of countries to exercise rights confirmed in the 2001 Doha Declaration, by restricting those rights to a specific list of diseases and situations.
- Limiting the capacity that countries have to restrict secondary patenting and evergreening by requiring patents on “new uses or methods of using a known product”.
- Restricting countries’ ability to include important public health flexibilities in their own national laws, for example India’s Section 3(d) patent law which requires evidence of “enhanced efficacy”, before additional patents can be granted on existing products.
- Restricting countries’ ability to use to the full the public health flexibilities recognized in the TRIPS agreement, including compulsory licenses and patent exceptions.
- Mandating that countries include TRIPS-plus measures in their national laws, including patent linkage, patent term extensions and new monopolies based on clinical data exclusivity, including for biological vaccines and medicines, which have never before been included in a US-led trade agreement.

Cumulatively, these provisions appear to be edging the IPR norms for developing nations, even those not directly associated with the respective agreements, ever higher even before the dust has settled on compliance processes with the baseline TRIPS requirements.

How India can be Impacted by the TPP

The question arises that if India is not a party to the TPP negotiations, should it be concerned by the provisions of the treaty?

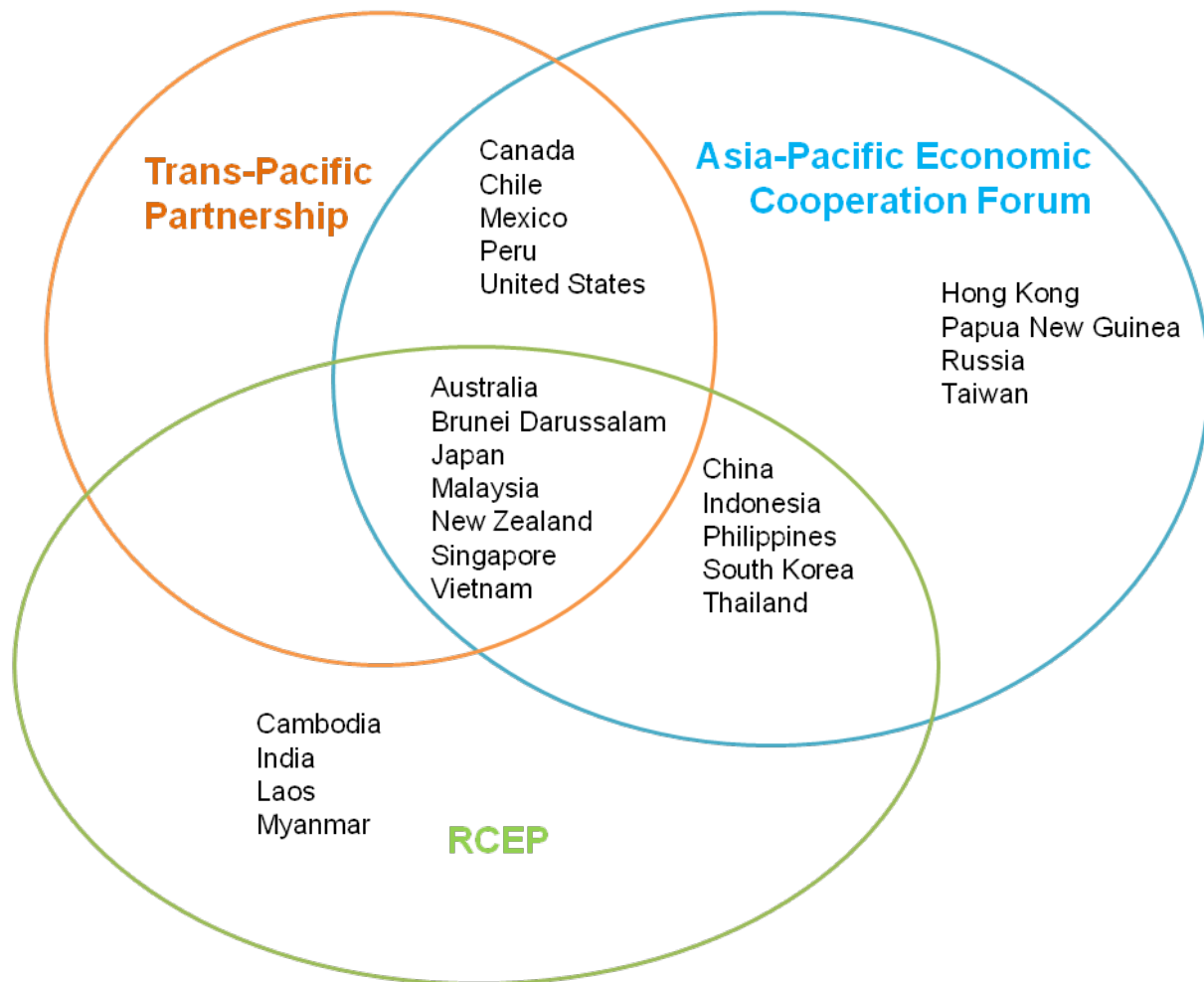
¹¹³ Lew, William; “Leaked TPP Draft Reveals Extreme Rights Holder Position of US, Japan, Outraged Observers Say”. Intellectual Property Watch. 17 October, 2014
<http://www.ip-watch.org/2014/10/17/leaked-tpp-draft-reveals-extreme-rights-holder-position-of-us-japan-outraged-observers-say/>

The answer is a definite “Yes.” Various nations have from time to time engaged in bilateral agreements (more often than not with at least one of two parties being a nation of the OECD) that have included various measures over and above those stipulated in the TRIPS agreement. These include the introduction of patent linkages and data security or export restrictions and anti-counterfeiting measures.¹¹⁴ The Most Favoured Nation (MFN) clause in TRIPS ensures that a country that has been accorded MFN status may not be treated less advantageously than any other country with MFN status by the promising country. Thus, every new broken ground in terms of higher IP standards in a bilateral agreement effectively becomes the new standard for the concerned nation’s IP regime for every other MFN trading partner as well.

Owing to either the promise of greater economic benefits or even geostrategic considerations, plurilateral free trade agreements on the regional level such as NAFTA, CAFTA, RCEP, TPP and TTIP have found increasing favor in recent years. Many of these include nations at vastly differing levels of development. The RCEP, for example, counts among its sixteen members ten states belonging to ASEAN along with six states with which ASEAN has existing FTAs. At one end there are the advanced economies of Japan, Australia, Korea, New Zealand and Singapore and at the other end of the spectrum, developing economies like Myanmar, Cambodia and Laos. Ideally, negotiations would seek a common ground incorporating the divergent considerations of each negotiating party.

¹¹⁴ <http://www.thehindubusinessline.com/todays-paper/tp-economy/india-against-tripsplus-clauses-in-bilateral-trade-pacts/article1001590.ece>

Figure 7: The Interlinked Nature of Regional Trade Agreements¹¹⁵



However, at least seven RCEP members, namely Australia, Brunei, Japan, Malaysia, New Zealand, Singapore and Vietnam, have also entered into the separate negotiations for the TPP, a far more comprehensive and exhaustive agreement entailing a slew of potentially TRIPS plus measures outlined above. Consequently, a brief published by the National University of Singapore argues that “*the RCEP members that have already made specific commitments on these issues at the TPP might consider lower commitments on same issues at the RCEP an economically suboptimal exercise and could urge the RCEP to get closer to the TPP.*”¹¹⁶

¹¹⁵ Kathuria, Rajat et al. “The Mega Regional Trade Agreements: TPP and RCEP” ICRIER. December 2014

¹¹⁶ http://www.google.co.in/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=0CCAQFjAA&url=http://www.isas.nus.edu.sg/Attachments/PublisherAttachment/ISAS_Brief_334_-

In late June of 2014, Japan reportedly confirmed these concerns by presenting a distinctively ‘TRIPS Plus’ negotiating text at the Singapore round of RCEP negotiations.¹¹⁷

Therefore, it is clear that the TPP, due to its vast scope and the inclusion of key nodal trading countries such as Japan, will indirectly impact even non-members due to the interlinking nature of regional free trade agreements. As such, it will have the effect of setting a new normative standard with regard to domestic IP laws that could render the TRIPS agreement obsolete and have a detrimental effect on developing nations by triggering a dramatic reversal of the Doha Declaration of 2002.

It is clear that the ‘TRIPS plus’ measures that could well be propagated by the TPP, at least in their presently known form, will have an immediate and adverse impact on the interests of India and possibly a significant portion of the developing world as well. As a “high quality” instrument enforcing an array of “behind the border rules”, it might also end up skewing the benefits of globalisation in favour of advanced industrialised economies. What is not clear is whether the US will succeed in securing acceptance of its maximalist positions on IP standards among the countries participating in TPP negotiations.

Meanwhile, India can try and ensure that its interests are safeguarded in terms of IPR commitments during ongoing negotiations for RCEP, even if this alone may not be sufficient to counter possible adverse impact from ‘TRIPS’ plus elements that end up being incorporated in the TPP. Ultimately, India’s reliance on and support of multilateral instruments and fora will provide the best way forward.

_The_RCEP_Negotiations_and_India_24062014102624.pdf&ei=MNwLVP64JsWTuATw04LwCw&usg=AFQjCNEjb585xgHg1xgFSauWJmJ0Bav9AA&sig2=EA3SN35zgRTbzl7KpvQrgA&bvm=bv.74649129,d.c2E&cad=rjt
Cited In <http://spicyip.com/2014/09/japan-pushes-for-trips-plus-provisions-in-a-regional-fta-medecins-sans-frontieres-raises-alarm.html>

¹¹⁷ <http://spicyip.com/2014/09/japan-pushes-for-trips-plus-provisions-in-a-regional-fta-medecins-sans-frontieres-raises-alarm.html>

IX. THE ROAD AHEAD

There can be no denying the fact that a transparent and predictable regulatory framework for IPRs backed by better IPR enforcement would benefit India's business environment and also advance public interest. That appears to be the intention behind the Indian Government's decision to set up a Think Tank comprising eminent experts to propose a comprehensive IPR Policy based on extensive consultations with stakeholders, both domestic and foreign. Indeed, the draft IPR policy posted for public comments by this expert body acknowledges the significant role of IPRs as a driver of innovation, trade and economic growth.

That said, there can also be no question that broader public interest will continue to remain the paramount consideration for Indian policymakers as they balance public health needs with safeguards and incentives for innovation.

This report finds that section 3(d) of India's patents law and compulsory licensing provisions are TRIPS compliant and in the national interest. Section 3(d) establishes a new threshold for discerning true innovation and has gained acceptance outside India. Compulsory licensing has been used only once and the case in question has stood the test of judicial scrutiny right up to the Supreme Court of India. Given India's prevailing socio-economic conditions, these provisions balance the objectives of promoting innovation, preventing "evergreening" on insubstantial grounds, and ensuring affordable access to essential medicines.

However, there is need to also recognize the evolutionary nature of IP law and practice. The Mashelkar Committee's recommendation on expanding the interpretation of novelty to include incremental innovations and drug improvements that have significantly better safety and efficacy standards need to be considered. Streamlined drug approval channels must be part of India's modernized IP regime.

It is well known that India has not been in favour of Patent Linkage or Data Exclusivity. Neither aspect is mandated by the TRIPS agreement. That said, it will be in the overall interest of India's expanding pharma industry if the government were to design and put in place an efficient system for data protection. Perhaps another Expert Committee needs to look into this area afresh in consultation with relevant stakeholders.

While the focus of this report has primarily been the Indian IP regime for pharma, much needs to be done by Pharma MNCs in the areas of establishing or expanding R&D, working of patents in India, improving delivery mechanisms and adopting appropriate pricing and licensing policies. It can only be hoped that innovative pharmaceutical companies will look to develop new paradigms for the pricing of life saving drugs for the Indian market better attuned to the economic status of its consumer base. Their future strategies should seek to leverage scale with low-margin high-volumes that have proved so successful for other mass consumption goods.

Drugs with smaller patient populations will require various differential pricing strategies to maximise availability, though government support will also be crucial for the success of such initiatives.

American biotech giant Gilead Sciences has shown the way forward in this regard, offering deep discounts in conjunction with voluntary licenses to Indian generic firms for a number of its breakthrough treatments for HIV and Hepatitis C. Such initiatives will go a long way in bridging the trust deficit between pharma and biotech majors and the Indian authorities, while mitigating threats to the drug innovators' IP.

Ideally, India's business environment should incentivise innovators to conduct an increasing portion of their R&D and drug manufacturing in low cost hubs within India, thereby decreasing the overall cost of drug discovery and development to the benefit of consumers worldwide. A regulatory framework conducive to such a scenario requires serious attention from Indian policy makers.

Finally, while both India and the US have stepped back from the often bitter confrontation of 2013-14 and resumed a measured dialogue on IP, it would be a mistake to accord pharma a central or dominant place in this dialogue. The tendency to focus on one sector alone circumscribes the discussion and does not allow for a constructive and collaborative engagement between the two sides on other important IP issues that foster trade and investment. Significant sectors of US industry are supportive of the IP regime in India. Equally, there are a number of areas of IP congruence and cooperation which are not adequately addressed because of over attention to pharma related issues. This imbalance needs to be remedied.

Even as India moves towards a 21st century IP regime that incentivizes domestic inventions and rewards innovation from all corners of the globe, a balanced and sustained India-US dialogue on IPR issues remains vital to the public and private interests of both nations. Their promising economic partnership will certainly stand to gain if the recent cycle of contention over pharma IPRs can be successfully contained and eventually overcome.

X. ACRONYMS AND ABBREVIATIONS

AMC	Antitrust Modernization Commission
APEC	Asia-Pacific Economic Cooperation
ARV	Anti Retroviral
BTIA	Broad-based Trade and Investment Agreement
CAFTA	Central American Free Trade Agreement
CGPDTM	Controller General of Patents, Designs and Trade Marks
DCGI	Drugs Controller General of India
DSB	Dispute Settlement Board
EU	European Union
GATT	General Agreement on Tariffs and Trade
IMF	International Monetary Fund
IPAB	Intellectual Property Appellate Board
IPO	Indian Patent Office
IPR	Intellectual Property Rights
MFN	Most Favoured Nation
MNC	Multi National Company
NAFTA	North American Free Trade Agreement
NCD	Non-communicable Disease
NCE	New Chemical Entity
OCR	Out of Cycle Review
OECD	Organisation for Economic Co-operation and Development
R&D	Research and Development
RCEP	Regional Comprehensive Economic Partnership
TPP	Trans Pacific Partnership
TRIPS	The Agreement on Trade-Related Aspects of Intellectual Property Rights
TTIP	Transatlantic Trade and Investment Partnership
USFDA	United States Food and Drug Administration
USFTC	United States Federal Trade Commission
USPTO	United States Patent and Trademark Office
USTR	United States Trade Representative
WHO	World Health Organization
WTO	World Trade Organization

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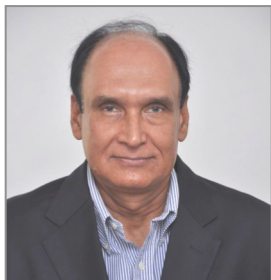
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XII. ABOUT THE AUTHORS



Aman Raj Khanna has been a Research Associate and Programme Coordinator with the Strategic Studies Programme at ICRIER. In this role he has analyzed a wide array of issues of strategic relevance to bilateral economic relations between India and the U.S. He holds a bachelor's degree in economics and geosciences from Denison University in Ohio.



Ambassador Hemant Krishan Singh holds a Masters Degree from Delhi University where he attended and later taught at St. Stephen's College before joining the Indian Foreign Service in 1974. Between 1976-1991, he served in various capacities at Indian Missions in Lisbon, Maputo, Washington D.C., Kathmandu and Belgrade. At the Ministry of External Affairs in New Delhi, he has held assignments of Under Secretary (Americas), Director (Iran, Pakistan and Afghanistan) and Joint Secretary (West Europe). He was Deputy Permanent Representative of India to the UN in Geneva from 1995-99, covering the areas of human rights, humanitarian and refugee law, labour, health and intellectual property. Between 1999-2002, he was the Ambassador of India to Colombia with concurrent accreditation to Ecuador and Costa Rica, playing an active role in promoting economic and commercial relations with Latin America. As Ambassador to Indonesia with concurrent accreditation to Timor Leste from 2003-2006, he was closely associated with the intensification of relations with Indonesia as well as ASEAN. He served as India's Ambassador to Japan from June 2006 to December 2010, contributing extensively to the forging of the India-Japan Strategic and Global Partnership through six Bilateral Summits. Ambassador Singh is Professor for Strategic Studies at ICRIER, New Delhi, since September, 2011.



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