PRIMER ON PUBLIC HEALTH AND INTELLECTUAL PROPERTY RIGHTS (IPR)

PREPARED FOR THE WHO COUNTRY OFFICE, INDIA

AUTHORED BY:

Shamnad Basheer, Swaraj Barooah, Rupali Samuel,

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Table of Contents

Executive Summary

Intellectual property (IP) regimes encapsulate a careful balance between a private monopoly right meant to foster innovation, and an equally compelling public/social interest in accessing the innovation at affordable rates. Nowhere is the issue of this balance thrown up more starkly than in the area of public health. While the infusion of public health concerns into intellectual property debates was relatively rare in the past, it is now widely accepted that public health forms a critical part of the social bargain underlying the grant of intellectual property rights.

The pre-eminence of public health concerns in IP debates is more than amply borne out by global instruments and policies such as the Doha Declaration on the TRIPS Agreement and Public Health, the WHO's Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, and WIPO's Development Agenda. All of these international instruments/policies serve to highlight two essential features:

i) That intellectual property rights are not an end in themselves, but a means to an end, namely the fostering of higher levels of innovation.

ii) That a "one size fits all" framework cannot work and that IP regimes must be carefully calibrated, taking into account the specific socio-economic status of the country in question and its technological trajectory. In other words, the patent regime of the US (a high technology superpower) cannot, and should not, be the same as that of Ethiopia (a least developed country).

A close perusal of the Indian patents regime reveals a number of provisions aimed at fostering greater access to medicines and public health goals, as highlighted below.

Public Health and Patents: Key Provisions

- Section 3(d): This patent provision, which generated controversy like no other, forbids patents on new forms of known substances that do not demonstrate significantly enhanced therapeutic efficacy. It is aimed at curbing 'evergreening', where successive patents are sought on minor variants of a drug, effectively extending the period of monopoly over a drug.
- Section 25(1), 25(2) and 64: In recognition of the fact that a wrongly granted patent could affect the public adversely, India offers three shots at challenging the grant of a patent: pre-grant, post-grant and revocation proceedings.
- Sections 82-94: These provisions encapsulate the compulsory licensing regime in India. The grounds for triggering a compulsory licence (CL) are wide and include instances of patent abuse (such as charging excessive prices) and 'public interest' factors (such as public health emergencies).
- Section 107A: Also known as the *Bolar Exception*, this provision permits a third party to manufacture or use a patented drug for the purpose of obtaining regulatory approval for a generic version. This provision enables generic manufacturers to launch immediately after patent over the drug expires.

Viewed from a public health perspective, these provisions are not mere exceptions to be interpreted restrictively, but embody values predicated on human rights and public interest that must be interpreted broadly. Courts have done so in copyright cases, and there is no reason why the same logic cannot extend to the patent sphere as well.

This report explores the interface between public health and Indian intellectual property law. While most of the focus is on patents, the report also touches upon the interface between public health and other areas of IP, such as copyrights, trademarks and traditional knowledge/biodiversity. The highlights of these sections include:

Public Health and Copyright

- Copyrighted articles dealing with medicine and public health issues are very expensive to access. One-sided enforcement of copyright law can potentially restrict access even further. Therefore, there is a pressing need to interpret copyright exceptions liberally, so as to promote access. There is also a need to promote open access models.
- Section 52(1)(i): This section of the Indian Copyright Act allows the reproduction of any copyrighted material in the course of instruction. A controversial infringement suit against Delhi University now offers the court a chance to interpret the contours of this exception.
- Open Access models have begun to gain popularity, with several governments advocating them, particularly in relation to publicly funded work.

Public Health and Trademarks

- The interface between trademark law and public health is a significant one. Illustratively, brand name confusion and the consequent consumption of wrong drugs can be particularly fatal for patients.
- The use of International Non-proprietary Names (INNs) leaves such names free for public use, thereby promoting the uptake of generic drugs. However, despite efforts by the government, usage of these names is still far from satisfactory.
- Given that the term “counterfeit” has a significant intellectual property connotation (that may have nothing to do with the quality of the drug), it is best to delink this term from other regulatory efforts geared towards weeding out spurious, sub-standard, falsified and falsely labelled drugs. We propose the use the term "illicit" instead to refer to such drugs.

Public Health and Traditional Medicine and Biodiversity

- A majority of the developing world uses Traditional Medicine as part of their primary health care. Developing countries also house a significant part of the world's biodiversity.
- Commercial exploitation of biodiversity and related traditional knowledge (TK) requires a clear regulatory framework that prevents misappropriation, whilst ensuring that any commercial benefits are shared with holders of TK.
- While the Indian regime contains a number of potent provisions in this regard and the TKDL in particular helps protect TK in a defensive manner, much more needs to be done in terms of a positive protection agenda. In particular, we need to find more ways in which this ancient knowledge can be mapped better with modern healing systems so that it can contribute more significantly to public health initiatives.

As this report seeks to serve as a primer for those lacking technical familiarity with the super specialized nuances of intellectual property law, care has been taken to keep the discussion to a fairly basic level. Given space constraints, a wider range of issues have not been discussed. Nor could we explore the current issues in-depth or offer a detailed comparative perspective.

However, it is hoped that this report will serve as a springboard for a deeper investigation into the various issues highlighted.

A. Intellectual Property and Access to Medicines

India houses 1.2 billion people, a significant portion of whom qualify as poor. This, along with the fact that the government spends an abysmal 1.3% of its GDP on public health issues[1] means that the challenges on the public health front are enormous.

Given the multifactorial nature of the challenge, we focus in this report on one of the key areas of concern, namely intellectual property rights. In particular, two main issues deserve mention at the outset, so as to lay the base for what is to follow:

Firstly, owing to rapidly rising drug prices, particularly in the biologics space, a large percentage of the Indian population is unable to access important life saving and life enhancing drugs.[2] Although the problem is complex, and hinges on several issues including insurance, health care delivery mechanisms, government support and public health infrastructure, it is now widely acknowledged that intellectual property plays a significant role in blocking access to affordable medication. A study notes that 'the most immediate gains in

[1] India remains amongst the ten countries with the lowest public health spending levels in the world. *See Health Expenditure, public (% of GDP)*, THE WORLD BANK, available at http://data.worldbank.org/indicator/SH.XPD.PUBL.ZS (last visited on June 1st, 2014). However, the the 12th five year plan indicates that by 2017, the spending would be 2.5%. **please cite**

[2] *See e.g.*, Prashant Reddy, *Dealing with the cost of cancer treatment in India: Are Patents the problem?* SPICYIP, (June 22, 2012) available at http://spicyip.com/2012/06/dealing-with-cost-of-cancer-treatment.html (last visited on June 1st, 2014).

health can be achieved by improving access to existing medicines, as opposed to developing new compounds.'[3]

Secondly, most of the world's R&D is geared towards diseases of the developed world; the amount of investment in neglected diseases and other diseases of concern to the developing world is negligible. It is widely acknowledged that mainstream legal incentives in the form of intellectual property rights do not trigger optimal R&D for cures for developing country diseases.[4]

B. Right to Health

Underlying the Indian legal regime is a strong conception of health as a constitutional right.[5] Recently, in *Mohd Ahmed v. Union of India,*[6] the Delhi High Court while interpreting the fundamental right to life guaranteed under Article 21 of the Constitution of India held:

> *"Although obligations under Article 21 are generally understood to be progressively realizable depending on maximum available resources, yet certain obligations are considered core and non-derogable irrespective*

[3] Mattke S, et al. *Improving access to medicines for non-communicable diseases in the developing world.* RAND CORPORATION, at p.20, (2011) available at http://www.rand.org/pubs/occasional_papers/OP349.html (last visited on June 1st, 2014).

[4] *See* WORLD HEALTH ORGANIZATION, INNOVATION AND PUBLIC HEALTH: REPORT OF THE COMMISSION ON INTELLECTUAL PROPERTY RIGHTS, INNOVATION AND PUBLIC HEALTH 34 (2006) http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf (last visited on June 1st, 2014). (Noting that: "as is the case for diseases affecting millions of poor people in developing countries, patents are not a relevant factor or effective in stimulating R&D and bringing new products to market.").

[5] *See* Swaraj Paul Barooah, *Framing Debates on IP & Health – Part III*, SPICYIP, (September 16, 2013) available at http://spicyip.com/2013/09/framing-debates-on-ip-part-iii.html (last visited on June 1st, 2014). (Arguing that framing IP debates in human rights terms is required to advance the aims of the IP regime as a whole).

[6] *Mohd. Ahmed (Minor) vs Union Of India & Ors*. on 17 April, 2014 available at http://www.indiankanoon.org/doc/77985236/ (last visited on June 1st, 2014).

> *of resource constraints. Providing access to essential medicines at affordable prices is one such core obligation."* (para 87)

This judgment is significant in that, apart from emphatically affirming the right to health under the right to life, it also ventured forth into the constitutionalisation of IP,[7] thus paving the way for potentially limiting the scope of IP rights in instances of conflict with basic human rights.

Similarly, in *Paschim Banga Khet Mazdoor Samity v. State of West Bengal (1996),*[8] the Supreme Court of India held that the state had a constitutional obligation to provide adequate medical services to the public and could not ignore these obligations on account of its financial constraints. In *Parmanand Katara v. Union of India (1989),*[9] the Supreme Court held that the preservation of human life was of paramount importance.

[7] *See generally,* Gautam Bhatia, *Delhi High Court rules on Article 21 and Access to Medicines*, INDIAN CONSTITUTIONAL LAW AND PHILOSOPHY, (April 17, 2014) available at http://indconlawphil.wordpress.com/2014/04/17/delhi-high-court-rules-on-article-21-and-access-to-medicine/ (last visited on June 1st, 2014).
[8] 1996 SCC (4).
[9] 1989 AIR 2039.

Table 1

"In the light of Arts. 22 to 25 of the Universal Declaration of Human Rights, International Convention on Economic, Social and Cultural Rights, and in the light of socio-economic justice assured in our Constitution, right to health is a fundamental human right to workmen. The maintenance of health is a most imperative constitutional goal whose realisation requires interaction by many social and economic factors. Just and favourable condition of work implies to ensure safe and healthy working conditions to the workmen" (para 26)

- C.E.S.C. Ltd v. Subhash Chandra Bose (1991 Supreme Court Decision)[10]

The right to health also draws from several international instruments.[11] Illustratively, Article 25 of the United Declaration of Human Rights (UDHR), 1948 states: "Everyone has the right to a standard of living adequate for the health, and well-being of himself and his family." Similarly, Article 12 of the *International Covenant of Economical, Social and Cultural Rights* (ICESCR) recognizes the right of all human beings to the highest attainable standard of physical and mental health. Further, the *Preamble of the World Health Organization (WHO)'s constitution* declares that it is the fundamental right of every human being to enjoy the highest attainable standard of health."[12]

Table 2: Relevant International Instruments

Instrument	Parties	Provision
Universal Declaration of Human Rights	N/A	Article 25

[10] 1992 AIR 573.
[11] *E.g. see* The People's Movement for Human Right's Education, *The Human Right to Health*, available at http://academic.udayton.edu/health/07humanrights/health.htm (last visited on June 1st, 2014).
[12] Preamble to the Constitution of the World Health Organization as adopted by the International Health Conference, New York, 19 June - 22 July 1946.

(1948)		
International Covenant on Economic, Social and Cultural Rights (1966)	162	Article 7, 11 & 12
Convention on the Elimination of All Forms of Discrimination Against Women (1979)	188	Articles 10, 12 & 14
Convention on the Elimination of All Forms of Racial Discrimination (1979)	177	Article 5
Convention on the Rights of the Child (1989)	194	Article 24

C. Indian Pharmaceutical Industry and TRIPS Flexibilities

India's pharmaceutical industry has played a vital role in ensuring access to affordable medication, earning it the moniker 'pharmacy of the developing world'. Though the TRIPS (Trade Related Aspects of Intellectual Property) Agreement forced India to grant product patent protection for pharmaceuticals in 2005, she made use of a number of creative TRIPS flexibilities to preserve the space for promoting affordable medications.

Illustratively, Table 3 highlights some of the key provisions that deserve mention:[13]

Table 3: India's Use of TRIPS Flexibilities

[13] For a larger discussion on each of these provisions, see Part II of this report.

- Section 3(d): This patent provision, which has generated controversy like no other, forbids patents on new forms of known substances that do not demonstrate significantly enhanced therapeutic efficacy. This section is aimed at curbing 'evergreening', where successive patents are sought on minor variants of a drug, effectively extending the period of monopoly over a drug.[14]
- Section 25(1), 25(2) and 64: In recognition of the fact that a wrongfully granted patent could affect the public adversely, India offers three shots at challenging the grant of a patent: pre-grant, post-grant and revocation proceedings.[15]
- Sections 82-94: These provisions encapsulate the compulsory licensing regime in India. The grounds for triggering a compulsory licence (CL) are wide and include instances of patent abuse (such as charging excessive prices) and 'public interest' factors (such as public health emergencies).[16]
- Section 107A: Also known as the *Bolar Exception*, this provision permits a third party to manufacture or use a patented drug for the purpose of obtaining regulatory approval for their generic version. This provision effectively allows generic manufacturers to launch as soon as the patent over the drug expires.[17]

In the recent past, multinational pharmaceutical companies and their home governments have taken issue with the use of these flexibilities and alleged that the current Indian regime contravenes obligations under WTO/TRIPS.[18] The

[14] *See* Part II B 2.
[15] *See* Part II B 4.
[16] *See* Part II C 4.
[17] *See* Part II C 2.
[18] *See* Shamnad Basheer and Swaraj Barooah, *Patent Error*, Indian Express (February 20, 2014) available at http://indianexpress.com/article/opinion/columns/patent-error/99/ (last visited on June 1st, 2014).

Indian government has however reiterated that its laws comply with its international obligations.[19]

D. Revisiting the Intellectual Property Paradigm

In order to frame this debate through an appropriate conceptual lens, it is essential that we revisit certain assumptions about intellectual property and its role in innovation and development.

For a great number of years, the global intellectual property debates (particularly in the immediate aftermath of TRIPS) suffered from three significant deficits:

i) It was assumed, for the large part that higher levels of intellectual property protection (particularly patent protection) would foster a higher rate of innovation.

ii) It was assumed that a largely uniform intellectual property regime would work optimally for all countries, irrespective of the differences in their socio-economic status.

iii) IP as a discipline was hermetically sealed off from larger societal considerations i.e. it was treated rather narrowly as an instrument of exclusive private rights, sans any consideration of the larger societal goals or public interest.

However, there has been some correction on all three fronts, as explained below:

[19] *See* Nayanima Basu, *India Play's WTO Card Against US*, Business Standard (April 28, 2014), available at http://www.business-standard.com/article/economy-policy/india-plays-wto-card-against-us-114042800008_1.html (last visited on June 1st, 2014).

D.1 IP and Innovation

Patents are often perceived as the primary legal incentive for technological innovation.[20] At its very core, the patent system seeks to foster new and non-obvious inventions by granting a limited legal monopoly.[21] The theories underlying the patent system are many, but the most prevalent is the incentive theory. This theory stipulates that patent rewards (in the form of a limited set of exclusive legal rights) incentivise prospective inventors to accelerate their efforts, more than would be the case without patents.[22] In other words, patents are likely to increase the rate of generation of new and useful ideas for society.

However, this theory is yet to find convincing empirical support.[23] Bronwyn H. Hall concludes that although a stronger patent system is likely to result in an increase in patenting, it is not clear if these changes will also simultaneously result in an increase in innovative activity.[24]

Whilst assessing the role of the patent system in fostering innovation, scholars often point to the fact that significant investments and efforts may be required to

[20] *See* Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575 (2003) ("Patent law is our primary policy tool to promote innovation, encourage the development of new technologies, and increase the fund of human knowledge. To accomplish this end, the patent statute creates a general set of legal rules that govern a wide variety of technologies.")

[21] *See* Hall, *Patents and patents policy* 18 (4) OXF. REV. ECON .POLICY at 568 (2007).

[22] The US Supreme Court explained it thus: "The economic philosophy behind the clause empowering Congress to grant patents and copyrights is the conviction that encouragement of individual effort by personal gain is the best way to advance public welfare." Mazer v. Stein, 347 U.S. 201, 219 (1954).

[23] *See* Andrew W. Torrance, & Bill Tomlinson, *Patents and the Regress of Useful Art*s (May, 28 2009); Columbia Science and Technology Law Review, Vol. 10, 2009. ("Despite the economic logic of the conventional view, there exists surprisingly little empirical evidence to support the key assumption that patents do actually spur technological innovation.").

[24] *See* Hall, *supra* note 21, at 574. *See also* Committee on Intellectual Property Rights in the Knowledge Based Economy, NAT'L RESEARCH COUNCIL OF THE NAT'L ACADS., A PATENT SYSTEM FOR THE 21ST CENTURY 81–130 (Stephen A. Merrill et al. eds., 2004), *available at* http://www.nap.edu/catalog.php?record_id=10976 (last visited on June 1st, 2014). It notes: "[t]here are theoretical as well as empirical reasons to question whether patent rights advance innovation in a substantial way in most industries".

translate inventive ideas into commercially useful products.[25] Pharmaceutical drugs are often cited as the poster child for this proposition, where firms may be reluctant to invest in R&D in the absence of some form of legally sanctioned market protection against generic manufacturers who could copy the drugs at a fraction of the cost.[26] The most cited study in this regard (hereinafter "DiMasi study") estimated that it would take approximately U.S. $802 million and 90 months to produce a marketable drug.[27] These estimates have increased, with the most recent figures ranging from approximately U.S. $1.3 billion to over U.S. $1.8 billion and durations of 10 – 15 years.[28] However, given that drug companies have been reluctant to publicly disclose their costs of drug discovery and development, these costs remain a highly contested issue and the Di Masi study has been heavily critiqued.[29]

Regardless of the precise figure, it is acknowledged that pharmaceutical R&D requires considerable investment, when compared with other industries. For this reason, even critical scholars such as Hall,[30] and Bessen and Meurer[31] note that patents provide strong incentives for innovation in the pharmaceutical industry.

However, this does not automatically mean that all countries grant a uniformly high level of patent protection. Rather the level of protection has to be calibrated

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[25] *See* F.M. SCHERER, INDUSTRIAL MARKET STRUCTURE AND ECONOMIC PERFORMANCE, 440–41 (2d ed. 1980). (The traditional economic justification for patents has likely always encompassed the promotion of development and commercialization efforts in addition to inventive activity).
[26] *See* LANDES AND POSNER, THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW, (2003) at p.315.
[27] *See* Joseph A DiMasi, Ronald W Hansen, Henry G Grabowski, *The price of innovation: new estimates of drug development costs,* 22(2) J. OF HEALTH AND ECONOMICS 151-185 (2003).
[28] *See* J. Mestre-Ferrandiz, J. Sussex, and A. Towse, *The R&D Cost of a New Medicine.* London, UK: Office of Health Economics, 2012.
[29] Illustratively, *see* Donald W. Light, *Misleading Congress about Drug Development*, 32(5) J. HEALTH POL., POLICY & LAW 895, 897 (2007).
[30] *See* Hall, *supra* note 21, at 575
[31] *See* James Bessen & Michael J. Meurer, *Of Patents and Property*, 31(4) REGULATION 18, 19 (2008-09); *see also* JAMES BESSEN & MICHAEL J. MEURER, PATENT FAILURE: HOW JUDGES, LAWYERS, AND BUREAUCRATS PUT INNOVATORS AT RISK (2008).

taking into account the social costs of patents, as also the developmental imperatives of the country in question that hinge, in turn, on its technological proficiency and socio-economic status.

The social costs of patents often come in two broad forms:[32]

(i) The costs to innovation, in terms of the potential for patents to decelerate or slow down innovative progress by "blocking" competition, particularly downstream research and improvements.[33]

(ii) The costs to the consumer in terms of excessive pricing,[34] and consequent deadweight losses to society.[35] This is more than amply illustrated in the recent outcry around Gilead's Hepatitis C treatment, Sovaldi. Priced at $84,000 for a 12 week course, it has prompted a furious worldwide debate on how such a price has been reached, and effect that

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[32] *See* Mark A. Lemley, *Rational Ignorance at the Patent Office,* 95 NORTHWESTERN U. L. REV. 1, 20 (2001) (discussing the rational ignorance at the patent office). He argues:

> The patent system intentionally restricts competition in certain technologies to encourage innovation. Doing so imposes a social cost, though the judgment of the patent system is that this cost is outweighed by the benefit to innovation…There is a great deal of literature attempting to assess whether that judgment is accurate or not, usually without success).

[33] This potential for blocking has been documented through specific historical examples in a seminal piece by Merges and Nelson. *See* Robert P. Merges & Richard R. Nelson, *The Complex Economics of Patent Scope*, 90 COLUM. L. REV. 840 (1990). See also Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anti-commons in Biomedical Research*, 280 SCIENCE698, 698–701 (1998).

[34] *For example, see "Drug Prices, Costly Cures"*, THE ECONOMIST, (June 7, 2014) available at http://www.economist.com/news/business/21603453-american-fight-over-expensive-new-treatments-has-global-implications-costly-cures (last visited on June 1st, 2014).

[35] *See* WILLIAM M. LANDES & RICHARD A. POSNER, THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW 17-20 (2003) (explaining that deadweight losses occurs when a seller with market power prices a product higher than the competitive price, which prevents some consumers from purchasing the product who otherwise would have done in a competitive market).

such a high price will have on the patient population who require the treatment.[36]

As noted earlier, patent regimes are to be calibrated taking into account the specific socio-economic needs of the country in question and its technological status. This leads us to the next section on intellectual property and development.

D.2 IP and Development:

Given our mainstream market-based incentive structure, it is no surprise that rich developed countries are often the main markets for most drugs[37] (see Table 4 and 5). These countries are also the primary contributors to pharmaceutical R&D costs with the US, EU and Japan accounting for the largest shares.[38] However, this feedback loop of R&D costs and sales from the same set of developed countries effectively sidelines developing countries. One needs to ask if a strong intellectual property regime would necessarily help these poorer countries or

[36] The heavy price tag has induced bipartisan collaboration amongst US Senators in conducting an investigation. *See* Ron Wyden, Committee of Finance, United States Senate, *letter to* John Martin, Gilead Sciences, Inc, available at http://www.finance.senate.gov/imo/media/doc/Wyden-Grassley%20Document%20Request%20to%20Gilead%207-11-141.pdf (last visited on August 13th, 2014); Interestingly, in India where there is a pre-grant opposition pending to one of the relevant patents, Gilead has priced the drug at around $900 (Rs 54,000) for a 12 week course. *See* Rupali Mukherjee, *New Hepatitis-C drug 99% cheaper in India*, TIMES OF INDIA, August 6, 2014, available at http://timesofindia.indiatimes.com/india/New-Hepatitis-C-drug-99-cheaper-in-India/articleshow/39719323.cms (last visited on August 13th, 2014).

[37] *See* WORLD HEALTH ORGANISATION, INTELLECTUAL PROPERTY RIGHTS, INNOVATION, AND PUBLIC HEALTH, WORLD HEALTH ASSEMBLY RES. WHA56.27 10TH PLEN. MTG. (2003) (reporting that the World Health Assembly estimates that approximately 90% of drug sales are in developed countries).

[38] A study found that of a total of 1400 first-year pharmaceutical patents granted between the years 2000 and 2009, the inventors were concentrated mainly in the US, Europe and Japan *i.e.* "60% of inventors were from the United States and 31.5% of inventors from Europe (United Kingdom, Germany¸ Sweden, France, Switzerland and Belgium) and Japan. *See* Yali Friedman, *Location of Pharmaceutical Innovation: 2000-2009*, NATURE REVIEWS DRUG DISCOVERY 835 (2010).

whether it would detrimentally impact the innovation and public health goals of such countries.

Table 4: Top 5 Pharmaceutical Markets and India in $US (by sales)

Country	1976 Value	2000 Value	% Of World Market (2000)	Population (2000)
1. USA	7.9 billion	149.5 billion	52.9%	282,161,411
2. Japan	4.02 billion	51.5 billion	18.2%	126,870,000
3. France	2.70 billion	16.7 billion	5.9%	60,911,057
4. Germany	3.41 billion	16.2 billion	5.7%	82,211,508
5. UK	1.03 billion	11.1 billion	3.9%	58,892,514
India	N/A	3.4 billion	1.2%	1,042,261,758

Source: Sales data from Essential Medicines and Health Products Portal, WHO.[39]
Population data from World Development Indicators, World Bank.[40]

Table 5: Disease Burden from 1990 – 2000 in top 5 Pharmaceutical Markets and India (by sales).

Country	DALYs (1990)	DALYs (2000)	DALYs (2010)
1. USA	71,906,600	76,038,400	81,834,600
2. Japan	27,812,800	29,990,700	31,231,200
3. France	16,253,000	16,212,600	16,570,500
4. Germany	25,763,800	24,521,200	23,875,100
5. UK	18,220,000	17,096,900	16,820,000
India	568,932,000	555,164,000	518,879,000

Source: Data from GBD 2010.

[39] *Available at http://apps.who.int/medicinedocs/en/d/Js6160e/6.html* (last visited on June 1st, 2014).
[40] *Available at http://data.worldbank.org/indicator/SP.POP.TOTL?page*=2 (last visited on June 1st, 2014).

From the perspective of national innovation policy, a number of scholars suggest that countries that are net importers of technology are better off without strong IP or market exclusivity enhancing regimes.[41] Rather, narrower IP rights leave more scope for technological growth through learning and imitation.[42] This also reduces the prospects of the country remaining dependent on high priced foreign imports.[43] Such dependence is especially problematic for most developing and least developed countries[44] where patients lack elaborate state subsidized insurance schemes.[45]

Therefore, developing countries may be better off with strategically tailoring their intellectual property regimes to leave more space for technological imitation and to reduce their dependence on highly priced imports. The success of such tailoring strategy is borne out by historical evidence, where several

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[41] *See* Shamnad Basheer & Annalisa Primi, *The WIPO Development Agenda: Factoring in the 'Technologically Proficient' Developing Countries* in IMPLEMENTING WIPO'S DEVELOPMENT AGENDA 100 (Jeremy DeBeer, ed., 2009) at 100.

[42] *See* Brian Casey, *Perspectives on the Patent system and its Role in Innovation: A Way Forward?*, 4 OTAGO MANAGEMENT GRADUATE REVIEW 2, 2 (2006), available at http://www.business.otago.ac.nz/mgmt/research/omgr/omgr2006.pdf (last visited on June 1st, 2014). ("One of the more obvious benefits supposed to accrue from the weak protection of intellectual property, especially for developing countries, is claimed to be the cheap acquisition of technology through imitation, and the encouragement this provides to innovation").

[43] *See* KEITH MASKUS, PETERSON INSTITUTE OF INTERNATIONAL ECONOMICS, *Intellectual Property Rights and Economic Development: Patents, Growth and Growing Pains*, *in* INTELLECTUAL PROPERTY RIGHTS IN THE GLOBAL ECONOMY 143, 159 (2000) http://www.piie.com/publications/chapters_preview/99/5iie2822.pdf (last visited on June 1st, 2014). ("A major concern of technology importers is that strong patents ...expand the market power of foreign providers of information and new products, permitting high price mark-ups. In turn, importing countries would experience losses in their terms of trade, while access to new products and key inputs could be diminished.")

[44] *See* Rajat Khosla & Paul Hunt, *Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicines* http://www.popline.org/node/204713 (last accessed 01/06/2014) (estimating that more than 2 billion people are effectively priced out of the market for patented drugs drawing from his experience as a former UN Special Rapporteur on the right to the highest attainable standard of health).

[45] *See* U.S. DEPARTMENT OF COMMERCE, *Pharmaceutical Price Controls in OECD Countries: Implications for U.S. Consumers, Pricing, Research and Development, and Innovation* at 3 (December, 2004) http://www.ita.doc.gov/td/chemicals/drugpricingstudy.pdf (last visited on June 1st, 2014). (Suggesting that in wealthier developed countries, access issues are ameliorated by government-subsidized insurance and other social mechanisms).

countries deliberately instituted weak IP regimes in the past to promote more technological imitation, before moving on to stronger IP regimes.

Table 6: From Imitation to Innovation: A Historical Narrative on Climbing the Technology Ladder

The following countries did not provide for product patent protection for chemicals/pharmaceuticals till very late in their technological development trajectories (dates listed below):
Japan: 1976
Italy: 1978
Spain: 1992
Germany: 1967
Switzerland: 1977
Sweden: 1978

Source: Michelle Boldrin and David K. Levine, The Pharmaceutical Industry, in Against Intellectual Property Monopoly 241, 245 (2008).[46]

The most recent example is that of India which did away with product patent protection for pharmaceuticals in 1970 owing to the findings of a Committee that the patent system was not benefiting India, particularly in relation to food, chemicals and pharmaceuticals.[47] The Committee, therefore, recommended that patents in this sector be granted only to processes and not to products. Owing to this clever legal strategy, India's fledgling chemical industry was able to reverse engineer patented drugs, find alternative processes to make them and slowly

[46] *Available at http://levine.sscnet.ucla.edu/papers/ip.ch.9.m1004.pdf* (last visited on June 1st, 2014).
[47] *See* JUSTICE N. RAJAGOPALA AYYANGAR, REPORT ON THE REVISION OF THE PATENTS LAW (1959) available at http://www.spicyip.com/docs/Rajagopala_Ayyangar_Report/Rajagopala_Ayyangar_Report_1-20.pdf (last visited on June 1st, 2014).

establish itself as a leading supplier of generic medications worldwide, earning the moniker 'pharmacy of the developing world'.[48]

India was then forced to introduce product patents for pharmaceuticals in 2005, owing to the WTO-TRIPS mandate. However, as noted earlier, it did so strategically, by exploiting TRIPS flexibilities and preserving space for affordable generic medications. It also made clear that meritorious incremental innovations would be encouraged.

Much in line with this traditional wisdom, developing countries may wish to implement a similar innovation policy that permits a significant amount of technological learning and imitation prior to adopting a strong IP regime. It is important to appreciate in this context, that rather than viewing 'developing countries' as a single category, it may be more useful to apply a more nuanced mode of categorization based on levels of technological proficiency and socio-economic development.[49]

D. 3. Incentives for Developing Country Drugs

In view of the fact that the primary innovation incentives are geared towards diseases of the rich, how ought we to incentivize diseases of the poor or developing country diseases (mainly Type III and to some extent, Type II diseases)?[50] Global pharmaceutical firms often ignore these diseases, on account

[48] *See* Shamnad Basheer, *India's Tryst with TRIPs: The Patents (Amendment) Act, 2005,* 1 IND. J. LAW & TECH. 18 (2005).
[49] *See* Basheer and Primi, *supra* note 41 at 100.
[50] Type III diseases are those that are predominantly or exclusively prevalent in developing or least developed countries, such as onchocerciasis (river blindness), leishmaniasis (kala-azar), Chagas disease, and African sleeping sickness. Type II diseases are those which affect both rich and poor countries, but have a substantial proportion in developing countries, such as HIV/AIDS and TB.

of the prospect of low returns.[51]

Illustratively, of the 1550 New Chemical Entities marketed worldwide between the years 1975 to 2004, only 3 were for tuberculosis.[52] This, despite the fact that the disease claims an estimated 1.7 million deaths annually. Similarly, notwithstanding the slow ascendancy of differential pricing, for the large part, drugs made for developed country markets (with significantly subsidized state health insurance schemes) are often sold at equivalent prices in developing countries, where patients largely pay out of pocket. Given the limitations of the patent system in incentivizing diseases of the poor, one could think of alternative incentive models such as public funding, prizes, open innovation models and advanced market commitments.[53] These issues are discussed in more detail in Part III of this report.

D. 4. Integrating Public Health into IP

The above discussion provides an over-reaching framework within which to understand the current tension between patents and public health. Indeed, intellectual property regimes are best seen as a balance between a carefully defined private interest (a legally vested monopolistic right) to enhance innovation, and an equally compelling public/social interest, which serves to constrain the extent of the monopoly. Nowhere is the issue of this balance

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[51] *See* Médicins Sans Frontiéres, *Fatal Imbalance: The Crisis in Research and Development for Drugs for Neglected Diseases* (Access to Essential Medicines Campaign & Drugs for Neglected Diseases Working Group, 2001) available at http://www.msf.org/source/access/2001/fatal/fatalshort.pdf (last visited on June 1st, 2014).

[52] *See* Pierre Chirac and Els Torreele, *Global framework on essential health R&D*, 367 (9522) THE LANCET: 1560 (2006); *See also* Ellen t'Hoen et al, *Driving a decade of change: HIV/AIDS, patents and access to medicines for all*, 14 J. INT. AIDS SOC. 15 (2011).

[53] The WHO's Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPA-PHI) points to some of this. *See* Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, WORLD HEALTH ORGANIZATION, available at http://www.who.int/phi/publications/gspa-phi/en/ (last visited on June 1st, 2014).

thrown up more starkly than in the area of public health. While the infusion of public health concerns into the intellectual property debates was relatively rare in the past, it is now widely accepted that public health forms a critical part of the social bargain underlying the grant of intellectual property rights.

It is thus that patent exceptions and limitations are now more amenable to being interpreted in a more meaningful manner to effectuate the public health concerns punctuating them. Significantly, in the developing country context, where countries constitute a very small or insignificant portion of the world's market (by revenues), the 'marginal gains' provided by stronger patent law will likely not outweigh the excessive costs to local consumers.[54] Courts have elevated what were commonly perceived as copyright "exceptions" to full fledged "user rights"[55] and there is no reason why the same logic cannot apply to the patent space as well.

The pre-eminence of public health in intellectual property regimes has also been reiterated in international declarations such as the Doha Declaration on the TRIPS Agreement and Public Health,[56] the WHO's Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property,[57] and WIPO's Development Agenda.[58]

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[54] *See* Carlos A. Primo Braga & Carsten Fink, *The Economic Justification for the Grant of Intellectual Property Rights: Patterns of Convergence and Conflict*, 72 CHI.-KENT L. REV. 439, 442–43 (1996).

[55] In CCH Canadian Ltd. v. Law Society of Upper Canada (2004 SCC 13), the Supreme Court of Canada held: "The fair dealing exception, like other exceptions in the Copyright Act, is a user's right. In order to maintain the proper balance between the rights of a copyright owner and users' interests, it must not be interpreted restrictively."

[56] World Trade Organization, Declaration on the TRIPS Agreement and Public Health, Nov. 20, 2001, WT/MIN(01)/DEC/2, at para. 4, *available at* http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm ['Doha Declaration'] (last visited on June 1st, 2014).

[57] GSPA PHI, *supra* note 53.

[58] WIPO Doc. A/43/16 Annex A. available at http://www.wipo.int/ip-development/en/agenda/recommendations.html (last visited on June 1st, 2014).

Though patents are the main species of intellectual property considered in this report, other branches such as trademarks and copyrights also interface significantly with public health, as discussed briefly below.

D. 4.1. Integrating Copyrights and Public Health

Copyright norms play a strong role in technological capacity building, as they determine the level of access to scientific learning. Restrictive copyright practices and excessive pricing could lead to a severe access crunch,[59] impacting the flow of valuable scientific and medical knowledge to doctors and public health practitioners. The Indian copyright regime houses sufficient safeguards to offset these barriers in some part and improve access to knowledge.[60] Furthermore, Open Access models have begun to gain popularity, with governments encouraging it, especially for publicly funded work.[61]

D. 4.2. Integrating Trademarks and Public Health

The interface between trademark law and public health is a significant one and the discussion is summarized below:

i) Brand name confusion can be very problematic when it comes to pharmaceutical drugs, as a similarity in name could result in the wrong drug being meted out to an unsuspecting patient – more so in developing countries where illiteracy rates are high.

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[59] *See* Keith Wagstaff, *If Harvard Can't Afford Academic Journal Subscriptions, Maybe It's Time for an Open Access Model*, Time, April 26, 2012, available at http://techland.time.com/2012/04/26/if-harvard-cant-afford-academic-journal-subscriptions-maybe-its-time-for-an-open-access-model/ (last visited on June 1st, 2014).

[60] Gavin Yamey, *Open Access to Medical Literature Can Boost Global Public Health*, VIRTUAL MENTOR, July 2009 (Volume 11, Number 7: 546-550).

[61] Research Councils UK, *Policy on Open Access*, available at http://www.rcuk.ac.uk/research/outputs/ (last visited on June 1st, 2014).

ii) The WHO maintains a database of "International Non-Proprietary Names" (INNs)[62] or generic names for drugs. This helps prevent confusion between different drugs, and also leaves such names open for public use without encumbrance, thereby promoting the uptake of generic drugs, wherever possible. However, despite efforts by the government, the reliance on such INNs is still low.

iii) Given that the term "counterfeit" has a significant intellectual property connotation (that may have nothing to do with the quality of the drug), it is best to delink this term from other regulatory efforts geared towards weeding out spurious, sub-standard, falsified and falsely labelled drugs. We propose the use the term "illicit" instead to refer to such drugs

D. 4.3. Integrating Traditional Medicine and Public Health

Owing to a number of factors including culture, costs and accessibility, a vast majority of developing countries use traditional medicines as part of their primary health care.[63] These medicines often comprise bio-resources and associated knowledge.

The Indian legal framework attempts to prevent the misappropriation of such bio-resources/associated knowledge. It also seeks to ensure an equitable benefit sharing mechanism between exploiters of the knowledge and the people that have held and nurtured this knowledge over centuries. The Indian government spearheaded a defensive protection approach by documenting a variety of

[62] WHO, *Guidelines on the Use of International Nonproprietary Names (INNs) for Pharmaceutical Substances*, 2 World Health Organization (1997).
[63] Traditional Medicine, Fact Sheet No. 134, World Health Organization, (2008), available at http://www.who.int/mediacentre/factsheets/2003/fs134/en/ (last visited on June 1st, 2014).

traditional medicinal systems through a mammoth database (TKDL).[64] This database helps prevent third parties from misappropriating this traditional knowledge through patents. However, in terms of a positive protection agenda, much more needs to be done.

E. International Agencies

Given the increasing internationalization of the IP and public health interface, this section highlights the role of three of the largest international institutions that work in this area, namely the WHO, WTO and WIPO.

E. 1. World Health Organization

The World Health Organization (WHO) is the primary health agency within the United Nations system.[65] In 2004, the WHO set up the Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH)[66] to evaluate the impact of IP rights in developing countries. Following a 2006 CIPIH Report and a Members' resolution, the 61st WHA, in 2008 adopted a resolution containing the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPA PHI). The aim of the strategy was to promote new thinking on innovation and access to medicines, with particular reference to diseases that disproportionately affect developing countries.[67]

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[64] Traditional Knowledge Digital Library, available at http://www.tkdl.res.in/tkdl/langdefault/common/Home.asp?GL=Eng (last visited on June 1st, 2014).

[65] It's membership stands at 194 countries, making it larger than WTO's 159 and one of the largest in the world.

[66] The Report of the Commission, Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) available at http://www.who.int/intellectualproperty/en/ (last visited on June 1st, 2014).

[67] *See* WHA 59.24 available at http://apps.who.int/phi/Res59_R24-en.pdf (last visited on June 1st, 2014).

The strategy consists of 8 strategic elements, 25 sub-elements and 108 specific actions.[68] The 8 main elements are listed in the table below:

Table 7: Eight Elements of GSPA PHI

- Element 1: Prioritizing Research and Development needs
- Element 2: Promoting Research and Development
- Element 3: Building and improving innovative capacity
- Element 4: Transfer of Technology
- Element 5: Application and management of intellectual property to contribute to innovation and promote public health
- Element 6: Improving Delivery and Access
- Element 7: Promoting sustainable financing mechanisms
- Element 8: Establishing monitoring and reporting systems

How a country adapts these elements into their national policy depends on their national innovation strategy, which in turn depends on their technological capabilities and socio-economic status. A country like India that is a proficient generic manufacturer, yet houses a significant poor population,[69] can best be described as a 'technologically proficient' developing country[70] - and it is to this status that India must adapt the GSPA PHI.

[68] This primarily refers to Type II and Type III diseases and specific research and development needs of developing countries in relation to Type I diseases.

[69] A 2013 World Bank study reports that as of 2010, India contains one third of the world's extreme poor (living on less than US $ 1.25 a day). THE STATE OF THE POOR: WHERE ARE THE POOR AND WHERE ARE THEY POOREST?, The World Bank, (2013) available at http://www.worldbank.org/content/dam/Worldbank/document/State_of_the_poor_paper_April17.pdf (last visited on June 1st, 2014); *See also* The World Bank's India profile shows that as of 2012, 21.9% of the Indian population was below the national poverty line. Available at http://data.worldbank.org/country/india (last visited on June 1st, 2014).

[70] *See* Basheer and Primi, *supra* n 41.

E. 2. WTO

The World Trade Organization (WTO) is the primary forum for international trade and consists of a variety of trade instruments including the Agreement on Trade Related Aspects of Intellectual Property (TRIPS); a comprehensive agreement mandating minimum standards for intellectual property protection.

TRIPS allows for a considerable amount of implementation flexibility by member states.[71] It has a number of provisions directly relevant to public health,[72] including a mention in its 'Principles,'[73] that "member states may adopt measures necessary to protect public health provided they are consistent with the Agreement." Further, the Doha Declaration preserves the right of member states to use flexibilities necessary to protect public health.

E. 3. WIPO

Established in 1967, the World Intellectual Property Organization aims 'to lead the development of a balanced and effective international intellectual property (IP) system that enables innovation and creativity for the benefit of all.'[74]

In 2007, at the behest of certain developing countries, the WIPO General Assembly adopted the WIPO Development Agenda[75] setting out 45 points of recommendation to guide the work of WIPO. Underlying the agenda was the

[71] Article 1 of TRIPS states that member states are free to determine the appropriate methods of implementing the provisions of TRIPS within their own legal system and practice.
[72] Discussed in more detail in Part II.
[73] Article 8.1 of the TRIPS Agreement states, ". Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement."
[74] http://www.wipo.int/about-wipo/en/ (last visited on June 1st, 2014).
[75] *Supra* note 58.

recognition that a "one size fits all" IP regime will not work and that developing countries must be free to craft their IP regimes based on national interest.

The agenda covers six main areas of activities, including technical assistance and capacity-building; norm-setting, flexibilities, public policy and public knowledge; technology transfer, information and communication technology (ICT) and access to knowledge; assessments, evaluation and impact studies; and institutional matters including mandate and governance.[76]

Further, the 2009 WIPO Global Challenges Program seeks to address global IP issues in sectors such as climate change, public health and food security.[77]

E. 4. Trilateral Cooperation

In recognition of the complex global challenges posed by public health and intellectual property, the three institutions mentioned above began collaborating on a variety of fronts.

In 2013, the three organizations put together a comprehensive report titled "Promoting Access to Medical Technologies and Innovation: Intersections between Public health, Intellectual Property and Trade".[78] The report focuses on an integrated, dynamic approach towards spurring innovation, whilst also emphasizing the importance of access to essential medicines. The highlights include:

[76] *See* recommendation 17, *supra note* 58.
[77] http://www.wipo.int/policy/en/global_health/ (last visited on June 1st, 2014).
[78] Report available at http://www.wto.org/english/res_e/publications_e/who-wipo-wto_2013_e.htm (last visited on June 1st, 2014).

- **Changing disease burden:** Non-communicable diseases such as cancer are increasingly forming a larger part of the disease burden in developing countries. Access to expensive cancer treatments will be a growing challenge in the coming years.
- **Government measures to contain costs:** Governments have several ways of controlling the price of medicines, such as price controls, reference pricing, removal of tariffs and taxes, etc. However, the challenge will be to invoke these measures whilst still ensuring sustainable margins for commercial suppliers.
- **Necessary Regulations:** Regulations ensure quality and safety of medicines, but a higher regulatory threshold increases the cost of innovation. Overall, there is a need to simplify regulation whilst maintaining safety and quality standards.
- **Innovation structures:** Though more money is being spent on R&D, there is no proportional increase in the number of new drugs. Further, the market-based innovation structure of patents does not address developing country diseases. New innovation models are being examined, including open innovation regimes and other push and pull incentives.[79]
- **Central role of IP:** The protection of various forms of IP (patents, trademarks and copyrights) has been central to the debate on innovation and access. Though the TRIPS Agreement sets minimum standards for IP, it also provides for a wide range of flexibilities that can be leveraged to increase access to medicines. IP licensing can also play a crucial role in public health. Public private partnerships and voluntary licensing programs such as the Medicines Patent Pool have evolved creative licensing structures that shift the focus away from profit maximization.

[79] *See* discussion in part III.

F. Objectives of Report and Methodology:

Against the above background, this report seeks to provide policy makers an understanding of the fundamentals of India's IP regime, in so far as it interfaces with public health concerns. The aim will be to discuss the basics of the intellectual property regime in a language that is accessible to a lay audience, and highlight some of the ways in which the Indian parliament and courts have integrated public health concerns into mainstream patent jurisprudence.

Of all the IP regimes, patents have the closest nexus to public health. As such, it will be the main focus of this report. Other IP categories of relevance to public health will also be traversed, such as trademarks, copyrights and traditional knowledge. The report will be largely descriptive in nature, and policy prescriptions kept to the minimum. While some of the references are to primary materials (domestic statutes, international instruments and case law), others are to secondary materials, such as academic articles. Owing to paucity of time and shortage of resources, no empirical study could be conducted for this report.

A. Introduction

As noted in the introduction, the key challenge for most countries is in evolving an optimal patent regime that appropriately balances competing and often conflicting concerns i.e. a regime that fosters innovation on the one hand through the grant of private monopoly rights, whilst ensuring that important social values such as public health are not compromised on the other.[80]

A number of provisions in the Indian patent regime aim to effectuate this balance and ensure that public health goals are not compromised. These include ex-ante measures (limiting the scope of patentability in order to foster greater access to affordable generics) and ex-post mechanisms (where the use of the patent monopoly is regulated through tools such as compulsory licensing).[81] These measures will be discussed in some detail below.

B. Ex-Ante Measures: Patent Exclusions and Patentability Standards

The Indian patent regime aims to encourage genuine pharmaceutical innovation by formulating a rather strict patent threshold and ensuring that trivial advances do not make it past the patent filter. It does so through clearly defined "patent

[80] *See generally* Holger Hestermeyer, *Human Rights and the WTO: The case of Patents and Access to Medicines*, 14(6) INT. TRADE LAW & REG 122 (2008).
[81] Carlos Correa, *Integrating Public Health Concerns into Patent Legislations in Developing Countries* 93-109 (2000), available at http://www.who.int/medicinedocs/fr/d/Jh2963e/6.html. (last visited on May 25, 2014).

exclusions" (such as excluding mere discoveries from patentability) as well as through a strict application of the traditional "patentability criteria" such as novelty and inventive step.

B.1. Patent Exclusions

Section 3 of the Indian Patents Act excludes several categories of subject matter from the purview of the term "invention". Some of the exclusions that have a bearing on public health are listed in Table 8 below:

Table 8: Indian Patent Exclusions

Section 3. What are not inventions: The following are not inventions within the meaning of this Act:

(b) An invention the primary or intended use or commercial exploitation of which could be contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment;

(c) The mere discovery of a scientific principle or the formulation of an abstract theory or discovery of any living thing or non-living substance occurring in nature;

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

***Explanation.*—**For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to

efficacy;

(e) A substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance;

(i) Any process for the medicinal, surgical, curative, prophylactic diagnostic, therapeutic or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products;

(j) Plants and animals in whole or any part thereof other than micro organisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals;

(p) An invention which in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components.

Source: The Patents Act (India), 1970 (as amended upto 2005).

A careful evaluation of these various exclusions reveals a diversity of rationales underlying them:[82]

i) Exclusions based on "policy" considerations: Section 3(i) [excluding all methods of medical treatment from patentability] and section 3 (j) [excluding plants and animals from patentability] are good examples of this.

[82] *See* Shamnad Basheer, Intervenor cum Amicus, Summary of Arguments in *Novartis v. Union of India*, (2013) 6 SCC 1, at p. 17, available at https://docs.google.com/file/d/0Bxi2TzVXul5ZRTVPcXdaQUNyWFU/edit (last visited on May 25, 2014). See also Prashant Reddy, *A Successful Academic Intervention Before the Supreme Court in Novartis- Glivec Patent Case,* SPICYIP (available at http://spicyip.com/2012/11/a-successful-academic-intervention.html (last visited on June 1st, 2014).

ii) Exclusions that in some way derive from the meaning of the term "invention": Section 3(c), which excludes "discoveries" from patentability, is a good example of this.

iii) Exclusions that encompass a heightened patentability standard or encapsulate a bright line patentability rule: Section 3(e) [excluding combinations of existing substances with no synergistic effect] and section 3(p) [excluding inventions that essentially aggregate existing traditional knowledge] are good examples of this.

The first 2 exclusions are more easily categorised as patent eligibility exclusions. However the last category is more of a regular patentability criterion (bright line patentability rule) than a patent eligibility one. In other words, even absent section 3(p), one might have still held that any invention based on existing traditional knowledge is not "new" and therefore not deserving of a patent.

Here again, these are not sharply defined categories but admit of crossovers, particularly categories (ii) and (iii). This conceptual crossover also stems from the Indian definition of the term 'invention' which encapsulates patentability criteria (such as novelty and inventive step) within its fold. [83]

As noted earlier, some of these exclusions have a bearing on public health and are elaborated upon below:

B.1.1 Discovery [Section 3(c)]

[83] Section 2 (j) of the Indian Patents Act, 1970: "invention" means a new product or process involving an inventive step and capable of industrial application. However, it bears noting that not all countries subscribe to this framework. Indeed, TRIPS itself treats the term "invention" as separate and distinct from patentability criteria such as novelty and inventive step. See Article 27 in Box 36 in Appendix A.

Section 3(c) excludes from the ambit of invention, the "discovery of any living thing or non-living substance occurring in nature." Since a number of medicinal discoveries have their roots in plants, animals, microorganisms and human body parts, this is an important exclusion for public health, as illustrated by a recent US Supreme Court case discussed below:[84]

Table 9: The BRCA Case (Assn. for Molecular Pathology v. Myriad Genetics, Inc)

A leading biotech company, Myriad Genetics, owned patents to BRCA1 and BRCA2 genes, mutations of which dramatically increase the susceptibility to breast and ovarian cancer. These patents granted Myriad a monopoly over the isolation and sequencing of these genes, and consequently over any diagnostic kits for cancer risk detection based on these genes.[85] Given the excessive prices charged by Myriad for their diagnostic tests, several patients, advocacy groups, and doctors challenged the validity of Myriad's patents. The key ground was that, being a naturally occurring gene sequence and therefore a mere "discovery" of a product of nature, the alleged invention was not patent eligible.[86] Holding that naturally occurring isolated DNA could not be patented, the Supreme Court noted:

> "Phenomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work. Monopolization of those tools

[84] *Ass'n for Molecular Pathology v. Myriad Genetics, Inc* 133 S. Ct. 2107.
[85] *Id* at p. 2111. The patent also granted a near monopoly on any further scientific research on these mutations, and it was alleged that Myriad did attempt to block follow on research efforts by others.
[86] *Supra* note 84, at p. 2118.

through the grant of a patent might tend to impede innovation more than it would tend to promote it."[87]

The Indian patent office (hereafter "IPO") has had occasion to consider the contours of section 3(c). A patent application claiming a "tissue system with self generating stem cells", [88] was rejected *inter alia* on the ground that it was a mere discovery, since it pertained to cells already existing in the adult body, which were then isolated and cultured by the applicant for transplant and regeneration purposes.[89] The office held that the mere extraction of cells from their natural habitat and the consequent tissue culture did not change the fact that the alleged invention was essentially a discovery of a product of nature.[90]

B.1.2. Method of Medical Treatment [Section 3(i)]

[87] However, the court held that synthetic DNA or complementary DNA (cDNA) could be patented as these were not a "product of nature." *Supra* note 84, at p. 2120.

[88] Reliance Life Sciences Private Limited filed Patent Application No. 4/MUM-WTO/2004 claiming a "cultured tissue system comprising isolated limbal stem cells from the adult corneoscleral limbus tissue in which at least 30 - 90% of the limbal stem cells are undifferentiated stem cells". This decision was rendered on September 17, 2009.

[89] The Guidelines for Examination of Biotechnology Applications for Patent (March 2013), available at http://nopr.niscair.res.in/bitstream/123456789/20283/1/JIPR%2018%284%29%20323-329.pdf (last visited on May 25, 2014). They expressly state that sequences isolated directly from nature are not patentable subject matter. However, it is pertinent to note that the guidelines do not have the force of law. For a list of patents granted on modified genes, *see* Bhavishyavani Ravi, *Gene Patents in India: Gauging Policy by an Analysis of the Grants made by the Indian Patent Office*, 18 JO. OF INTELL. PROP R. 323 (2013)

[90] *See supra* note 88 at 24. "The claimed tissue system comprising undifferentiated limbal stem cells is a discovery of living entity occurring in a nature (here the human body), since it was already existing in adult corneoscleral limbus tissues of the human eye. ….the invention probably resides…in a process of producing or culturing the stem cell outside the body, but not resides in the cells as such and therefore, the claimed invention is excluded from the patentability as per section 3(c) of the Act."

Section 3(i) excludes from patentability, "any process for the medicinal, surgical, curative, prophylactic diagnostic, therapeutic or other treatment." Such an exception is found in the patent regimes many other countries as well. While some of them do so through direct patent eligibility exclusions, others do so by exempting the activities of doctors from patent infringement.[91] An examination of recent IPO decisions indicates that the exception is not interpreted as narrowly as is done by the European Patent Office (EPO) and UK patent office/courts.[92] Illustratively, in a patent application[93] claiming a "kit for the treatment of infertility in women comprising multiple doses of FSH …", the Controller held that although the invention was dressed up as a kit, it really pertained to a method of treatment, and was therefore excluded under section 3(i).

B.1.3. Plants and Animals [Section 3(j)]

Unlike the US[94] and EU,[95] India excludes all plants, animals and their parts from patentability. This patent exclusion is particularly relevant to two areas of public health – traditional medicine and biotechnology.[96] Medicinal plants and their extracts form an important component of traditional medicine.[97] Since the interface between traditional medicine and public health and the issue of

[91] Section 287(c)(1) of the US Omnibus Consolidated Appropriations Act of 1997, Pub. L. No. 104 208, 110 Stat. 3009 (1996) exempts the use of patented medical methods by doctors or health practioners.

[92] Shamnad Basheer, Shashwat Purohit and Prashant Reddy, *Patent Exclusions that Promote Public Health Objectives*, WIPO Doc No. SCP/15/3 Annex IV, at p. 35 available at http://www.wipo.int/edocs/mdocs/scp/en/scp_15/scp_15_3-annex4.pdf (last visited on June 1, 2014).

[93] *Applied Research Systems Ars Holding, Netherland's* Patent Application No. 404/MUMNP/2005 decided on 28.09.2007.

[94] *Ex parte Allen,* 2 USPQ2d 1425 (Bd. Pat. App. & Inter. 1987).

[95] *Onco-Mouse*, Case number T 0019/90 decided on 3.10.1990.

[96] This is especially so in the case of development of genetically modified plant varieties and seeds.

[97] Ripu M Kunwar, et. al, *Medicinal plants, Traditional Medicine, Markets and Management In Far-west Nepal* 9 JOURNAL OF ETHNOBIOLOGY AND ETHNOMEDICINE 24 (2013).

biopiracy has been discussed elaborately in the Part VI titled 'Traditional Medicine, Biodiversity and Public Health', it will not be dealt with here.

The IPO and courts have had occasion to consider the ambit of this exclusion. In *Reliance Life Science Pvt. Ltd's* patent application referred to earlier,[98] the Controller found that the invention (a type of stem cell culture) fell within the exclusionary ambit of section 3(j), as the claimed cells constitute a part of the animal/human body and "are basic structural and functional units (i.e. parts) of higher form of the life."[99] In *Speaking Roses International Inc. v. Controller-General Of Patents And Anr.*,[100] the Mumbai High Court held that section 3(j) does not prevent a patent on the mechanical process of providing an image on a plant (or any organic product).

In *Monsanto v. the Controller*,[101] India's specialized IP tribunal, the IPAB (Intellectual Property Appellate Tribunal) held that the process of developing a transgenic plant resistant to extreme cold, heat, salt and drought conditions, was not 'an essentially biological process' defeated by section 3(j). However, the patent was still denied on the ground that the claimed process, though patent eligible, was "obvious" to a person skilled in the art, [102] a requirement that will be dealt with more elaborately later in this report.

The IPO *Guidelines for Examination of Biotechnology Applications for Patent* provides that although microorganisms are patentable under section 3(j), a conjoint reading with section 3(c) of the Act (excluding mere discoveries) implies that

[98] *Supra* note 88.
[99] *Id.*
[100] 2007 (109) Bom L R 630.
[101] OA/02/2012/PT/DEL, available at http://www.ipab.tn.nic.in/146-2013.htm (last visited on May 25, 2013).
[102] Monsanto also voluntarily dropped all of its product claims (claims relating to recombinant DNA, plant cell, progeny, plant, crop plant, propagule and seed). *Id.*

only modified microorganisms (distinct from microorganisms found in nature) are patentable subject matter under the Act.[103] This interpretation has the effect of preserving a high standard for patentability and ensures that products of nature are free for all to use and are not the subject of an exclusive patent monopoly.

As discussed in Appendix A, the section 3(j) exclusion finds legitimacy in Article Article 27 of TRIPS.

B.1.4. Immoral Inventions [Section 3(b)]

Apart from the discussion above, the patenting of plants and animals, in particular, genetically modified plants and animals raises complex ethical questions.[104] This in turn triggers another exclusion, namely section 3(b), which provides that immoral inventions are not patentable.

Section 3(b) of the Patents Act, 1970 states that "an invention, the primary or intended use or commercial exploitation of which could be contrary [to] public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment" is not an invention under the Act.

This exception was invoked by the IPAB in the famous case involving anticancer drug Glivec over which Novartis was denied a patent. The board found that the high price of Glivec could "create a havoc to the lives of poor people" and "create public disorder" and was hence proscribed by Section 3(b). However, this reasoning is flawed since it conflates standards of patentability, which are determined ex ante (before the invention typically converts to a product), with

[103] *Supra* note 89, at p. 15.
[104] Eileen Morin, *Of Mice and Men: The Ethics of Patenting Animals*, 5 HEALTH L.J. 147, 153 (1997).

the issue of regulating abuse of a patent after it has been granted (ex post stage) through the use of instruments such as compulsory licensing and price control.[105]

Secondly, such a ruling could potentially fall foul of TRIPS. The Article 27.2 exclusion under TRIPS (which is largely similar to the exclusion in section 3(b) of the Indian Patents Act) applies only if a prohibition against the commercial exploitation of the invention is necessary to protect *ordre public* or morality and only if the exclusion from patentability will likewise contribute to the protection of that *ordre public* or morality.[106] Under such an interpretation, unless India bans the sale of Novarti's drug Glivec or shows that Glivec is otherwise harmful, it cannot exclude a patent covering it on the grounds of public order or morality.[107] However, is to be noted that although the Supreme Court appeared to disagree with the IPAB's finding on this count during the course of hearings, it did not expressly address this issue in its final written decision.

Apart from the above, there appears to be only one earlier instance (albeit unreported) of the use of this exception by the IPO. The invention in this case related to medicinal powder prepared from skeletal remains of dead bodies dug up within a week of burial. Digging up graves for profit-oriented purposes was seen as highly objectionable by the patent office.[108]

B.1.4 Traditional Knowledge [Section 3(p)]

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[105] *Supra* note 82, at p. 33.

[106] Charles R. McManis, *Patenting Genetic Products and Processes: A TRIPS Perspective,* available at <http://law.wustl.edu/faculty_profiles/documents/Kieff/HGPIP/Final/GEN_50_CH5.pdf> (citing Nuno Pires de Carvalho, The TRIPS Regime of Patent Rights 170-173 (2003)).

[107] *See supra* note 82, at p. 33.

[108] Shamnad Basheer, *Grave Diggers, "Immoral" Patents and the NBRA*, SpicyIP (July 30, 2008) available at http://spicyipindia.blogspot.com/2008/07/grave-diggers-immoral-patents-and-nbra.html (last visited on May 25, 2013).

Section 3(p) excludes from patentability any invention that is "in effect, traditional knowledge" or an "aggregation" of "known properties of traditionally known component or components." Since this provision has been elaborately discussed in the Part titled 'Traditional Medicine, Biodiversity and Public Health', it will not be discussed here.

B.1.5 Mere Admixtures [Section 3(e)]

Section 3(e) excludes from patentability any "substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance."

By excluding 'mere admixtures', section 3(e) suggests that only synergistic combinations (where the combination exhibits a property that is beyond the sum total of the properties of its individual components) merit patent protection.[109] In *Kibow Biotech v. The Controller of Patents,* the IPAB ruled that a synergistic effect is an 'enhanced' effect or a new function that reflects more than just the qualities or functions, or aggregation of the properties of its individual components.[110] Applicants must produce data before the patent office demonstrating such synergetic effect by way of comparison at the time of application itself.[111]

This subsection complements section 3(d) in preventing evergreening, and ensures that only genuine innovations receive patent protection. It is also important in terms of protecting traditional knowledge from misappropriation, since patents are often sought for combinations of medicinal plants, such

[109] Other countries with a similar provision are Argentina, Chile, Costa Rica, Mexico, and Panama.
[110] *Kibow Biotech v. The Controller of Patents*, ORA/29/2011/PT/MUM, at ¶ 27, available at http://www.ipab.tn.nic.in/262-2013.htm (last visited on May 25, 2014).
[111] Failure to produce such information was a ground for refusal of Novartis Ag's Patent Application no. 3725/CHENP/2006 decided on 9.10.2012 and Tibotech Pharmaceuticals Ltd's Patent Application No. 687/DELNP/2006 decided on 24.09.2012.

combinations being nothing more than obvious aggregations of the properties of individual constituents.[112]

B.1.6. Non Efficacious Derivatives [Section 3(d)]

Section 3(d) excludes from patentability structurally similar pharmaceutical derivatives that demonstrate no significant therapeutic efficacy over and above what existed earlier. This is an excellent example of a cross over between a rigorous patentability filter and a patent eligibility exclusion. This nuanced provision and its conceptual basis can be better appreciated only after a discussion of traditional patentability criteria.

B.2. Patentability

The Patents Act 1970 lists 3 essential criteria for patentability. These are novelty, non-obviousness (or inventive step) and utility, as elaborated upon below:

B.2.1. Novelty

In order to be patentable, a product or process must be new or novel. A 'new invention' is defined in section 2(l) as *"any invention or technology which has not been anticipated by publication in any document or used in the country or elsewhere in the world before the date of filing of patent application with complete specification, i.e., the subject matter has not fallen in public domain or that it does not form part of the state of the art."*

[112] See *Natural Remedies Private Limited v. India Herbs Research and Supply Co.* MANU/KA/2739/2011 and Central Council for Research in Unani Medicine's Patent Application no. 1576/DEL/2006/ decided on 27.12.2012.

Effectively, this provision requires that the product or process must not be *anticipated* or disclosed by any prior art.[113]

In keeping with the philosophy that a patent monopoly is to be suffered only when the claimed invention is truly meritorious, the Indian patent regime endorses an "absolute" novelty standard, where prior art found in any part of the world will anticipate the patent, as opposed to a "relative" novelty standard, where only prior art found in India will be taken into consideration.[114]

The regime also makes clear that even oral knowledge[115] and common general knowledge[116] falls within the ambit of anticipatory prior art.

B.2.2 Inventive Step/Non-obviousness

Although a claimed invention may be "new", it might still fail the test of patentability if it is found that the invention was "obvious" to a person skilled in the art. This "inventive step" or "non-obviousness" criterion effectively lies at the heart of the patent filter and ensures that trivial advances are not granted a patent monopoly. However, this test is very difficult to apply, for the distance

[113] *Novartis v. Union of India* (2013) 6 SCC 1 at para 88 [hereinafter referred to as 'Novartis'].

[114] As per the absolute novelty standard, if the invention already exists in the public domain anywhere in the world in one form or another, it can no longer qualify as a new invention for the purpose of acquiring patent rights. Relative novelty, on the other hand, is usually restricted to within the country (or any other geographical region), where only local knowledge comprises prior art for the purpose of assessing novelty. *See*, CARLOS CORREA, A GUIDE TO PHARMACEUTICAL PATENTS 2 (VOL. I, 2008).

[115] *See* section 64(1)(q) of the Patents Act, 1970: "anticipation having regard to the knowledge, oral or otherwise, available within any local or indigenous community in India or elsewhere" as a ground for revocation of a patent.

[116] *See Monsanto v. Corommandal* AIR 1986 SC 712, at p. 717: 'Publicly known does not mean that it must be published in a document; although not found in a book, it may form a part of the common knowledge among the public concerned. It also does not mean that it should be widely used to the knowledge of the consumer. It is sufficient if it is known to persons who are engaged in the pursuit of knowledge of the patented product or process, either as men of science or men of commerce or as consumers.'

between prior art and the claimed invention is usually a matter of degree and prone to some amount of subjective assessment.[117] This is particularly so in the context of pharmaceutical and biotechnology inventions, where the element of uncertainty is higher than in other technological domains.[118]

Inventive step is defined under the Indian patents regime as below:[119]

1. A feature of an invention that involves a technical advance as compared to existing knowledge *or* having economic significance *or* both, and,
2. That makes the invention not obvious to a person skilled in the art.

An inventive step determination begins with an ascertainment of the 'state of the art' before the relevant date of the patent application. Then, having regard to the state of the art, one needs to ask whether the claimed invention (1) involves a technical advance or economic significance, and, (2) would have been obvious to a person skilled in the art.[120]

In *Sankalp Rehabilitation Trust v. Hoffmann-La Roche,*[121] a post grant opposition proceeding, the IPAB invalidated Roche's patent on 'Pegasys', a drug for Hepatitis C on the ground that it used conventional methods with predictable

[117] *See* John Barton, *Non-Obviousness*, 43 IDEA 475 (2003) ("The non-obviousness principle….asks whether the invention is an adequate distance beyond or above that state of the art; it clearly and unavoidably, therefore, involves a judgment call.").
[118] *See* Timo Minssen, *Meanwhile on The Other Side of The Pond: Why Biopharmaceutical Inventions That Were "Obvious To Try" Still Might Be Non-Obvious – Part I*, 9 CHI.-KENT J. INTELL. PROP. 60 (2010).
[119] Section 2(ja) of the Patents Act, 1970: "inventive step" means a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art.
[120] Novartis, *supra* note 112, at ¶ 190. This test was first laid down in *Biswanath Prasad Radhey Shyam v. Hindustan Metal Industries* AIR 1982 SC 1444 as follows: "Was it for practical purposes obvious to a skilled worker, in the field concerned, in the state of knowledge existing at the date of the patent to be found in the literature then available to him, that he would or should make the invention the subject of the claim concerned?"
[121] OA/8/2009/PT/CH available at http://www.ipab.tn.nic.in/250-2012.htm (last visited on May 25, 2014).

results and therefore failed the non-obviousness test.[122] This decision drew on an American case, *KSR v. Teleflex*[123] which held that a person skilled in the art is a person with "ordinary creativity" and thus "the combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results."[124]

Similarly, in *Monsanto v. the Controller*,[125] a patent application claiming a method of producing a cold stress tolerant plant by inserting a known cold shock protein encoding gene into a plant through genetic engineering techniques was held to be obvious. Endorsing a "reasonable expectation of success" standard, the IPAB held:

"There had been ample suggestion in [the prior art] that the claimed method would work for plants with reasonable success. It is sufficient that a person of ordinary skill would have found a degree of predictability which is reasonable. …..The appellant's argument of unpredictability will not stand as absolute predictability is not a condicio sine qua non to a case of obviousness."[126]

This indicates that Indian decision makers have adopted a fairly rigorous conception of the inventive step standard.

Who is a person skilled in the art?

[122] *Id*. at ¶ 44.
[123] 550 US 398 (2006).
[124] *Supra* note 120, at ¶ 42.
[125] *Supra* note 101.
[126] At ¶ 22. tThe IPAB also held at ¶ 23: "When the structure and function of cold shock protein was already known in cited prior art and it is obvious to person skilled in plant to make transgenic plant which is heat or drought tolerance by inserting the recombinant DNA molecule [into] its genome."

The inventive step determination is always done from the vantage point of a "person skilled in the art". In *Sankalp Rehabilitation Trust v. Hoffmann-La Roche*[127] the IPAB held that this person is not an automaton or a dullard, but vested with ordinary creativity and imagination *and* not ignorant of the basics of his/her field or the activities of that field.[128]

B.2.3. Industrial Application

The Patents Act defines 'industrial application' as follows:

> *Section 2 (ac): "capable of industrial application", in relation to an invention, means that the invention is capable of being made or used in an industry.*

This is an easy criterion to fulfill for most technological innovations.

B.3. Evergreening and Section 3(d)

The pharmaceutical industry is often accused of engaging in a practice commonly known as "evergreening".

Although the term does not have a precise definition as yet,[129] it is understood to mean the stacking up of several patents over minor/trivial variants of an existing drug/active ingredient in order to extend the patent monopoly over such

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[127] *Supra* note 120.

[128] *Supra* note 120. "We must remember that this ordinary man has skill in this art. He is not ignorant of its basics, nor is he ignorant of the activities in the particular field. He is also not ignorant of the demand on this art."

[129] 'Evergreening' is not a formal concept of patent law. It is best understood as a social idea used to refer to the myriad ways in which pharmaceutical patent owners utilise the law and related regulatory processes to extend their high rent-earning intellectual monopoly privileges, particularly over highly profitable (either in total sales volume or price per unit) 'blockbuster' drugs. *See* T. A. Faunce & J. Lexchin, '*Linkage*' *pharmaceutical evergreening in Canada and Australia*, available at http://law.anu.edu.au/StaffUploads/236-Art%20ANZHP%20Linkage%20Evergreening.pdf (last visited on May 25, 2014).

drug/active ingredient.[130] A study of 2803 patent applications made via the Patent Cooperation Treaty (an international patent filing system) from 1st July, 2000 to 1st July, 2005 found that nearly 60% of the applications claimed mere new forms[131] and were susceptible to a section 3(d) attack.

In many ways, patent evergreening is facilitated by the lack of rigorous scrutiny during the patent examination process and/or liberal patent grant standards.[132] Although traditional patentability criteria could potentially nip evergreening in the bud, its rather nebulous contours often leave space for minor variants with no real patient benefit to make it past the patent filter. It is thus that India consciously brought in a separate provision to address the scourge of evergreening.[133]

Section 3(d) states in pertinent part that the following will not be considered an '*invention*' within the meaning of the Act: "*The mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance.*"

This provision is followed by an explanation that states: "*For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers,*

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[130] Put another way, the classic evergreening strategy consists of "acquiring patents on minor, often trivial, modifications of existing pharmaceutical products or processes in order to indirectly extend the period of patent protection over previously patented compounds." *See* Carlos Correa, *Guidelines for Examination of Pharmaceutical Patents*, available at http://www.iprsonline.org/resources/docs/Correa_Patentability%20Guidelines.pdf (last visited on May 25, 2014).

[131] They included changes in formulations, dosage forms, polymorphs, salts, etc. Bhaven Sampat & Tahir Amin, *How Do Public Health Safeguards in Indian Patent Law Affect Pharmaceutical Patenting in Practice?* 38(4) J HEALTH POLIT POLICY LAW. 735 (2013).

[132] Aaron S. Kesselheim, *Think Globally, Prescribe Locally: How Rational Pharmaceutical Policy in the U.S. Can Improve Global Access to Essential Medicines*, 34 AM. J. OF LAW AND MEDICINE 125 (2008).

[133] *See* the statement by Minister Kamal Nath excerpted in the *Novartis, supra* note 112, at ¶ 84. "In regard to evergreening, I just want to read out section 3(d) which says that a mere discovery of a new property or a new use for a known substance or the mere use of a known process in a new product [is not patentable]…. There is no question of evergreening."

mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy."[134]

In short, this section requires that in order to merit a patent, a pharmaceutical derivative that is structurally similar to a known chemical compound must demonstrate significantly enhanced efficacy over and above that known compound. But for such demonstration, the law assumes that new forms of an old substance confer the same or a similar kind of efficacy.

B.3.1. Meaning of Efficacy

In *Novartis AG v. Union of India*,[135] the Supreme Court of India held that not all advantageous or beneficial properties were relevant for section 3(d), but only those properties that directly related to efficacy. The court held in pertinent part that in so far as medicines were concerned, efficacy meant '*therapeutic efficacy*'.[136] The scope of therapeutic efficacy and whether or not it includes reduced toxicity[137] was left open by the court.

B.3.2. Section 3(d) and Inventive Step

[134] Section 3(d) of the Patent Act, 1970.
[135] *Supra* note 112..
[136] *Id* at ¶ 180: "What is evident, therefore, is that not all advantageous or beneficial properties are relevant, but only such properties that directly relate to efficacy, which in case of medicine, as seen above, is its therapeutic efficacy." In an earlier writ petition before the Madras High court challenging the constitutional validity of section 3(d), the court had come to a similar finding. *Novartis AG vs Union of India* **(**2007) 4 MLJ 1153.
[137] Shamnad Basheer, the lead author to this report had, in his submissions to the court as intervenor cum amicus, argued that therapeutic efficacy must not be understood in a purely drug regulatory sense, but rather must include (1) greater effectiveness; (2) greater safety; or, (3) demonstration that the drug makes a major contribution to patient care in "unusual cases. See *supra* note 82.

As explained earlier, section 3(d) is a cross-over between a strict patent eligibility threshold (a patent "exclusion") and a refined patentability criterion (novelty, non-obviousness, etc).

In many ways, section 3(d) is largely similar to the US/EU test for determining inventive step or non-obviousness in the chemical arts.[138] Courts have held that structural similarities between a pharmaceutical substance sought to be patented and an earlier known substance triggered a presumption of prima facie obviousness.[139] This presumption could however be dislodged if the patent applicant demonstrated that the claimed substance exhibited "unexpected or surprising results."[140]

The key difference however is that unlike the term "efficacy" in section 3(d), the term "unexpected results" is ordinarily not limited to "therapeutic" advantages alone. However, it bears noting that some courts have discounted mere "physical" advantages. Illustratively, in *Pfizer v Apotex*[141], the CAFC (Court of Appeals for the Federal Circuit) struck a distinction between therapeutic properties and other properties (physical properties such as process-ability) of a pharmaceutical substance and appeared to indicate that the latter would be seen as the result or routine experimentation and not an "unexpected result" meriting a patent.[142]

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[138] *Id.*

[139] *See In Re Diane M. Dillon,* 919 F.2d 688 (Fed. Cir. 1990).

[140] *See In re Deuel* (51 F.3d 1552, 1558 (Fed. Cir. 1995), where the court held that "A known compound may suggest its homolog, analog, or isomer because such compounds often have similar properties and therefore chemists of ordinary skill would ordinarily contemplate making them to try to obtain compounds with improved properties."

[141] 480 F.3d 1348 (2007).

[142] Shamnad Basheer & Prashant Reddy, *The "Efficacy" of Indian Patent Law: Ironing out the Creases in Section 3(d)*, 5(2) SCRIPTED 251 (2008).

The Supreme Court did not definitively pronounce whether or not section 3(d) was a patent eligibility (exclusion) threshold or a regular patentability test. Rather it held that:

> *"Thus, in whichever way section 3(d) may be viewed, whether as setting up the standards of "patentability" or as an extension of the definition of "invention",*[143] *it must be held that on the basis of the materials brought before this Court, the subject product, that is, the beta crystalline form of Imatinib Mesylate, fails the test of section 3(d), too, of the Act."*[144]

The court was however careful enough to "*leave the door open for true and genuine inventions but, at the same time, to check any attempt at repetitive patenting or extension of the patent term on spurious grounds*."[145]

This strict requirement of inventive step in Section 2(ja) as well as the patent bar under Section 3(d) ensures that trivial medical advances are not granted a patent. As such, these provisions promote further competition in the market, and foster access to affordable medication.

C. Ex-post Measures:

C.1. Compulsory Licensing

The implementation of broad patent exclusions, strict patentability criteria, and a potent opposition regime enabling third parties to challenge patents goes a long

[143] It must be noted here that the court does not use the terms "patent eligibility", "patent exclusion" or "patentability". Rather it appears to use the term "patentability" to refer to patent eligibility/exclusions and the term "invention" to refer to the standard patentability tests of novelty, non obviousness and utility.
[144] Novartis, *supra* note 112, at ¶ 190.
[145] Novartis, *supra* note 112, at ¶ 103.

way towards ensuring that only genuine innovations are granted exclusionary patent rights.

But once granted, there is a likelihood of the patentee abusing the monopoly in a manner detrimental to public interest and/or the cause of innovation. It is thus that patent regimes provide for a slew of ex-post measures aimed at curbing the extent of patent monopoly.

Of the various ex-post measures, compulsory licensing is the most prominent. As the name suggests, a compulsory licence is a legal instrument designed to force intellectual property owners to license out their statutorily granted patent rights to interested third parties capable of fulfilling the reasonable requirements of the public in a better manner by, *interalia,* manufacturing the patented product at cheaper prices.

It typically issues in cases where the intellectual property owner stands accused of abusing her monopoly by engaging in prohibitive pricing (where a patented drug is priced out of the reach of the average consumer) or by failing to supply adequate quantities of the IP good to the public.

Apart from the actual grant of a compulsory licence, the threat of its issuance could play an important role in driving down drug prices.[146]

The Indian compulsory licensing regime is contained in Chapter XVI of the Patents Act 1970, comprising of sections 82 to 94. Broadly speaking, the grounds

[146] *Bayer v. Union of India, the Controller and Natco* MIPR 2013 (2) 97 [hereinafter referred to as 'Bayer v. Natco'] at ¶ 43. Illustratively, in 2001, the US government forced Bayer to slash the price of its anti anthrax drug ciprofloxacin to under $1 a tablet by threatening it with a compulsory license *See*, James Love, *Recent Examples of the Use of Compulsory License on Patents*, available at http://keionline.org/content/view/41/1 (last visited on May 25, 2014).

for a compulsory licence can be sub-divided into two main categories: patent abuse (as found in section 84), and public interest (as found in Section 92).[147]

C.1.1. Patent Abuse (Section 84)

Under section 84 of the Patents Act, after three years have lapsed from the date of grant of the patent, '*any person interested*' may make an application for the grant of a compulsory licence to the Controller General of Patents, Designs and Trademarks (hereafter CG), on the following grounds:

(a) That the reasonable requirements of the public with respect to the patented invention have not been satisfied, *or*

(b) That the patented invention is not available to the public at a reasonably affordable price, *or*

(c) That the patented invention is not worked in the territory of India.

All of these grounds were found to be satisfied in *Bayer v. Union of India & Ors*[148] a landmark compulsory licensing case outlined in the table below:

[147] Shamnad Basheer and Mrinalini Kochupillai, *The 'Compulsory Licence' Regime In India: Past, Present And Future,* p. 15, available at http://ssrn.com/abstract=1685129 (last visited on May 25, 2014).

[148] *Bayer v. Natco*, *supra* note 146.

Table 10: Bayer v. Natco

In August 2011, Natco, an Indian generic manufacturer applied for a compulsory licence in respect of Bayer's patent covering an anticancer drug, Sorefanib Tosylate. Constituting what many regard as a classic text-book case for compulsory licensing, the CG found that all the grounds prescribed in section 84 of the Indian Patents Act for the issuance of a compulsory licence had been met, namely:

1. Bayer supplied the drug to only 2% of the patient population (approximately 8000 odd patients required the drug). It was therefore held that the reasonable requirements of the public with respect to the patented drug (Nexavar) were not met.

2. Bayer's price was not "reasonably affordable". It charged Rs 2.8 lakhs for a month's supply of the drug, whereas Natco was willing to supply the same at Rs 8800 per month.

3. Since Bayer did not manufacture the drug in India, but merely imported it, the Controller held that the patent had not been "worked in the territory of India."

The CG then proceeded to issue India's first post TRIPS compulsory licence on March 9, 2012, stating that Natco ought to pay 6% of its net sales to Bayer as royalty.

The IPAB Appeal

On March 14, 2013, the IPAB upheld the grant of a compulsory licence, upon appeal from Bayer. The IPAB confirmed all three grounds of the IPO. In particular, it agreed that a determination of whether a price was "reasonably affordable" to the public did not hinge on the R&D costs of the drug. Rather, affordability had to be examined from the perspective of the patients.[149] It also held that the issue of affordability co-related strongly with whether or not the reasonable requirements of the public were being met under Section 84(1)(a).[150]

However, it also differed with the IPO in important particulars:

i) It held that the 'working' requirement under the Patents Act did not automatically preclude "imports", but was to be decided on a case by case basis.[151]

ii) It increased the rate of royalty from 6% to 7%.[152]

Efforts to obtain a licence

Article 31 (b) of TRIPS requires that prior to the application for a compulsory licence, the applicant should have "made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time." The Patents Act

[149] *Bayer v. Natco, supra* note 146, at ¶ 40: "The reasonably affordable price necessarily has to be fixed from the view point of the public and the word, 'afford' itself indicates whether the public can afford to buy the drug and therefore, we must consider this question from the view point of whether Rs.280,000/- per month is reasonably affordable price to the public. All the evidence filed by the appellant; the affidavits, the reports, etc. relating to the cost are not relevant to decide what the public can reasonably afford."

[150] *Bayer v. Natco, supra* note 146, at ¶ 38.

[151] *Bayer v. Natco*, *supra* note 146, at ¶ 52.

[152] *Bayer v. Natco*, *supra* note 146, at ¶ 54.

incorporates this requirement and mandates that the CG shall first determine whether "the applicant has made efforts to obtain a licence from the patentee on reasonable terms and conditions and such efforts have not been successful within a reasonable period as the Controller may deem fit."[153] An explanation to this clause states "for the purposes of clause (iv), 'reasonable period' shall be construed as a period not ordinarily exceeding a period of six months." In *BDR v. Bristol-Myers Squibb*[154] **(**the second CL application to be considered under section 84), the CG rejected the application on the ground that the applicant had not made sufficient efforts to voluntarily negotiate with the patentee. This case illustrates the balanced tone of India's compulsory licensing regime. Even as the importance of public health is reflected in the presence of multiple grounds for the grant of a compulsory licence, the rights of the patentee are also protected through adequate procedural safeguards.

Table 11: BDR v. Bristol-Myers Squibb[155]

On 4th March, 2013, BDR filed a compulsory licence application for 'Dasatinib', an anticancer drug patented by Bristol-Myers Squib. On 4th May, 2013, the Controller issued a notice to BDR stating that it had failed to make out a prima facie case for the grant of compulsory licence on two grounds: the failure to obtain regulatory clearance for the drug and the failure to make efforts to obtain a licence from the patentee. Rule 97 of the Patent Rules, 2003 provides that if the Controller is satisfied that a prima facie case is not made out, she is to notify the applicant accordingly. The applicant can then request

[153] Section 84(6)(iv) of the Patents Act, 1970.
[154] C.L.A. No. 1 of 2013, available at ipindia.nic.in/iponew/Order_30October2013.pdf (last visited on May 25, 2014).
[155] *Id*.

to be heard in the matter within a period of one month, failing which, the IPO 'shall refuse the application.'[156] It was found that BDR did not make any reasonable efforts to voluntarily negotiate with the patentee. It first sent a letter to BMS seeking a voluntary licence on 2nd February, 2012. BMS responded on 13th March, 2012, setting forth a list of queries in relation to BDR's ability to work the patent. BDR failed to reply to these queries for over a year. It then filed a CL application. The IPO found that this amounted to a failure to make reasonable efforts towards obtaining a licence from the patentee.

C.1.2 'Public Interest' (Section 92)

Section 92 stipulates that the government may declare, by notification in the Official Gazette, that a compulsory licence be granted in respect of any patent, at any time after the grant of the patent, on the ground that the same is necessary in the light of:

a) National emergency
b) Extreme urgency
c) Public non-commercial use

Consequent to such notification, the Controller of Patents *shall*, on an application by 'any party interested', grant a licence 'on such terms and conditions as he thinks fit.'[157] In particular, the Controller shall endeavour to secure that the articles manufactured under the patent shall be available to the public at the

[156] Rule 97(1) of the Patent Rules, 2003.
[157] Section 92(1) of the Patents Act, 1970.

lowest prices consistent with the patentees deriving a reasonable advantage from their patent rights.'[158]

The principle difference between sections 84 and 92 is that while the former requires some notion of "abuse" on the part of the patentee (e.g., not making the patented invention available at reasonable prices to the public), the latter can be triggered even absent any fault on the part of the patentee. In many ways, section 92 encapsulates a "public interest" ground for compulsory licensing. In fact, the predecessor to section 92 (section 97 of the un-amended Patents Act 1970) explicitly used the term 'public interest'. This provision was later amended, presumably to align it more closely with Article 31 of TRIPS.

It bears noting that while section 84 requires the lapse of three years from the date of grant of a patent before a CL application can be made, section 92 can be triggered immediately after the patent grant. Further, in appropriate cases such as a "public health crises relating to Acquired Immuno Deficiency Syndrome, Human Immuno Deficiency Virus, tuberculosis, malaria or other epidemics", the Controller is exempted from adhering to the procedural prerequisites spelt out in section 87.

The meaning of the phrase 'public non-commercial use' has not been defined, but commentators have suggested that it would broadly connote instances where drugs are handed out to patients for free or at cost.[159]

The government is currently considering invoking Section 92 for three drugs – Bristol-Myers Squibb's 'Dasatinib' and 'Ixabepilone' (used for treatment of breast

[158] Section 92(2) of the Patents Act, 1970.
[159] *Supra* note 142; Resource Book on TRIPS and Development, *ICTSD-UNCTAD Capacity Building Project on IPRs and Sustainable Development*, 471 (2004), available at www.iprsonline.org (last visited at May 25, 2014).

cancer) and Roche's Herceptin (used for treatment of breast cancer).[160] However, the formal notification has not yet been issued, as the government appears to be treading cautiously.

C.1.3 Doha Licence for Export (Section 92A)

The TRIPS agreement offers considerable flexibility to member states to institute a wide range of grounds upon which a compulsory licence could be granted, subject, of course, to the fulfillment of the procedural prerequisites spelt out in Article 31. In particular, TRIPS offers significant leeway when it comes to compulsory licensing of pharmaceutical drugs. However, what of countries that are unable to deploy these flexibilities owing to the lack of a technological base sufficient enough to enable manufacture of drugs under a compulsory license?

It is thus that member states agreed through the Doha Declaration (see box below) and the Para 6 Decision[161] to permit technologically proficient countries with manufacturing capability to grant a compulsory license (hereafter "Doha licence") so as to enable drug exports to those countries with little or no manufacturing capability. To this extent, the Para 6 decision makes an exception to the general TRIPS rule that compulsory licenses are to be granted predominantly for domestic manufacture.[162]

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[160] *Health Ministry recommends compulsory licensing of three anti-cancer drugs*, PHARMABIZ.COM (May 3, 2013), *available at:* http://www.pharmabiz.com/NewsDetails.aspx?aid=75138&sid=1 (last visited May 25, 2014).

[161] WTO General Council, 'The Implementation of Paragraph 6 of the Doha Declaration the TRIPS Agreement and Public Health', WT/L/540 30 August 2003, available at http://docsonline.wto.org/DDFDocuments/t/WT/L/540.doc. (last visted on June 1, 2014).

[162] Following the meeting on 6 December 2005 between WTO members, paragraph 6 of the Doha Declaration and the text of the TRIPS General Council Decision of 30 August 2003 were permanently inserted into the text of TRIPS Agreement as Art 31bis. This article effectively modifies Art 31(f) which states that production under compulsory licence should predominantly be for the domestic market.

Table 12: Doha Declaration (Para 6)

"6. We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002."[163]

The Doha licence is subject to a number of conditions to be satisfied by both the importing and the exporting member state, as detailed below[164]

The importing member state must:

i) Confirm that it has insufficient or no manufacturing capacity, unless it is a least developed country (LDC), in which case it will receive automatic confirmation.

ii) Inform the WTO's Council for TRIPS of the name and expected quantity of the drug to be imported.

ii) Confirm that it has granted/intends to grant a compulsory license if the product is patented in its territory.[165]

iv) Take reasonable measures to prevent re-export of products that have been imported under the licence.[166]

The exporting member state must ensure that:

i) The quantum of products manufactured under the licence does not exceed what it is strictly necessary to meet the needs of the importing country.

ii) Products under the license are distinguished through special labeling/packaging/shaping.

[163] *Supra* note 56.
[164] *Id*.
[165] *Supra* note 56.
[166] *Id*.

iii) Information relating to exports under the licence is posted on a website prior to shipment of the products.
iv) It notifies the TRIPS council of the grant of the licence, including the conditions attached to it.

Further, as per Art. 31*bis,* the patentee's remuneration must be fixed after "*taking into account the economic value to the importing Member of the use that has been authorized in the exporting Member*" state[167].

The first 'Doha' compulsory licence was issued by Canada in 2007 for the export of HIV drug TriAvir to Rwanda, a least developed country (LDC).[168]

Indian Provision:

In order to implement the Para 6 Decision, India amended its patent law in 2005 and introduced Section 92A, as below:[169]

Table 13: Section 92A, Indian Patents Act

(1) Compulsory licence shall be available for manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems, provided compulsory licence has been granted by such country or such country has, by notification or otherwise, allowed importation of the patented pharmaceutical

[167] Article 31bis, TRIPS.
[168] Holger P. Hestermeyer, *Canadian-made Drugs for Rwanda: The First Application of the WTO Waiver on Patents and Medicines*, Volume: 11 Issue: 28, December 10, 2007, available at http://www.asil.org/insights/volume/11/issue/28/canadian-made-drugs-rwanda-first-application-wto-waiver-patents-and.
[169] *See also,* Shamnad Basheer, *Roche vs NATCO: India's First "Doha Style" Compulsory License?*, SpicyIP, January 16, 2008, available at http://spicyip.com/2008/01/roche-vs-natco-indias-first-doha-style.html.

products from India.

(2) The Controller, shall on receipt of an application in the prescribed manner, grant a compulsory license solely for the manufacture and export of the concerned pharmaceutical product to such country under such terms and conditions as may be specified and published by him.

Given that a number of least developed countries do not have manufacturing capabilities of their own and look to Indian generic manufacturers for their domestic drug requirements, this is a very useful provision.[170]

The first 'Doha licence' case in India arose in 2008 when Natco, a leading Indian manufacturer of generic drugs, requested permission under section 92A to export two patented anti-cancer drugs to Nepal.[171] In order to fulfil the criteria laid down by section 92A, Natco argued in its application that Nepal was facing a public health crisis owing to the increasing number of patients affected by lung cancer, as also the fact that Nepal lacked the manufacturing capabilities to produce these anti-cancer drugs in requisite numbers. The patentees, Roche and Pfizer demanded to be heard before any order was passed. Natco contended that the Patent Act did not provide for any right to be heard in such circumstances and that any such hearing would unduly delay the proceedings and detrimentally impact the patients in Nepal. The Patent Office however ruled that in view of principles of natural justice, a patentee did have a right to be heard.[172]

[170] This provision applies to even developed countries with insufficient manufacturing capacity, provided of course that they have not 'opted out' as importers. *See* TRIPS Council Decision, WT/L/641, 6 December 2005, at < http://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm>

[171] The drugs in respect of which the CL was sought was Roche's "erlotinib" and Pfizer's "sunitinib" and Natco offered to pay a 5% royalty.C. H. Unnikrishnan, *Drug cos seek compulsory licensing*, THE MINT, Jan. 29 2008 available at http://www.livemint.com/2008/01/29000742/Drug-cos-seek-compulsory-licen.html (last visited on June 1, 2014).

[172] Joe C. Matthew, *Patent Office to hear drug firms' views before granting license*, BUSINESS STANDARD, (July 7, 2008) available *at* http://www.business-standard.com/common/news_article.php?autono=328026&leftnm=3&subLeft=0&chkFlg=

In that very same decision, it also outlined several weaknesses in Natco's application, namely:

i) The absence of a notification by Nepal to the TRIPS Council of its requirement for drug imports.
ii) The letter issued by Nepal seeking imports was not in a language recognized by the Indian Patents Act.

Shortly thereafter, Natco withdrew its application, presumably to avoid an adverse ruling on the merits. [173]

C.1.4 Use of Compulsory Licensing

Despite the existence of a large number of grounds for the issue of a compulsory licence, the mechanism has been successfully invoked in India only once in the post TRIPS era. For reasons that are unclear, there has not been any CL application after Natco's victory[174] (barring the failed CL application by BDR).[175]

Even so, the CL machinery in India has come under severe attack in the form of USTR hearings,[176] letters from congressmen,[177] placing India on an IP priority

[173] Shamnad Basheer, *Breaking News: Natco Withdraws "Doha" Compulsory Licence Application*, SpicyIP, September 28, 2008, available at http://spicyip.com/2008/09/breaking-news-natco-withdraws-doha.html.
[174] *Bayer v. Natco*, *supra* note 146.
[175] Shamnad Basheer, *Breaking News: India Rejects Compulsory License Application at Threshold,* SPICYIP, available at http://spicyip.com/2013/10/breaking-news-india-rejects-compulsory-licensing-application-at-threshold.html (last visited on May 25, 2014).
[176] K M Gopakumar, *Intellectual property issues dominate the USITC public hearing on India,* THIRD WORLD NETWORK (February 13, 2014), available at http://www.twnside.org.sg/title2/health.info/2014/hi140201.htm (last visited on May 25, 2014).
[177] On 18 June 2013, 170 Members of Congress (lower house) encapsulated concerns regarding India's patent regime in a letter to President Obama's office. On 20 June 2013, 40 US Senators (upper house) voiced similar concerns in a letter to John Kerry, Secretary, US Department of State. *See* William New, *Members Of US Congress Seek Pressure On India Over IP Rights,* IP Watch

watch list,[178] public statements by Big Pharma,[179] and various reports[180] decrying India's intellectual property environment. This pressure may be one of the reasons behind the Indian government's hesitation to notify Bristol-Myers Squibb's 'Dasatinib' under Section 92.[181] This seriously undermines the ability of compulsory licences to act as effective policy tools to ensure widespread and equitable access to medicines and health care.

C.2 Government Use (Chapter XVII and Section 47(4))

Apart from the compulsory licensing of patented inventions outlined in Chapter XVI of the Patents Act, the regime envisages another variety of non-voluntary licensing i.e. government use of inventions/patents. Chapter XVII and section 47 of the Patents Act expressly provide that in certain cases, the government could use a patented invention without running the risk of infringement. Historically, most nations permitted some form of 'Government use'.

Under Chapter XVII (sections 99 to 103) titled "*Use of inventions for purposes of Government and acquisition of inventions by Central Government*", the Central

(June 20, 2013) available at http://www.ip-watch.org/2013/06/20/170-members-of-us-congress-pressure-india-on-ip-rights/ (last visited on May 25, 2014).

[178] Office of the United States Trade Representative, *2014 Special 301 Report,* available at http://www.ustr.gov/sites/default/files/USTR%202014%20Special%20301%20Report%20to%20Congress%20FINAL.pdf (last visited on May 25, 2014).

[179] TESTIMONY BEFORE THE HOUSE COMMITTEE ON WAYS AND MEANS, SUBCOMMITTEE ON TRADE, March 13, 2013, *available at:* http://waysandmeans.house.gov/uploadedfiles/pfizer_testimony31313.pdf (last visited on May 25, 2014).

[180] US Chamber of Commerce's GIPC IP Index 2014, the Report of the Commission on the Theft of American Intellectual Property, etc. For more on these reports, *see* Swaraj Paul Barooah, *Part II: Pfizer's Testimony leads the way as US pressure on India increases*, SPICYIP (June 27, 2013), *available at:* http://spicyipindia.blogspot.in/2013/06/part-ii-pfizers-testimonyleads-way-as.html (last visited on May 25, 2014).

[181] Anubha Sinha, *Health Ministry's Plan to Issue Compulsory License for Dasatinib hits DIPP roadblock,* SPICYIP, available at http://spicyip.com/2014/04/health-ministrys-plans-to-compulsorily-licence-dasatinib-hits-dipp-roadblock.html (last visited on May 25, 2014).

Government or anyone authorised by it may use an invention or acquire an invention for the purpose of the Central Government, a State Government or a Government Undertaking on payment of adequate remuneration or compensation. Unlike compulsory licensing, government use can be availed of even at the stage of the patent application (prior to it being granted). However, for any such use, the government has to necessarily compensate the patentee through a reasonable royalty.[182]

Section 47(4) envisages another kind of government use and permits the import of any patented medicine or drug by the Government "for the purpose merely of its own use or for distribution in any dispensary, hospital or other medical institution maintained by or on behalf of the Government or any other dispensary, hospital or other medical institution" having regard to the "public service" rendered by such institution and accordingly notified by the government.

It bears noting that when compared with other government use provisions outlined earlier, the government can invoke section 47(4) only after the grant of the patent.

C.3. The Experimental Use Exception

The experimental use exception shields from infringement any act of experimentation on a patented invention. The exception is a natural corollary to the "disclosure" requirement under patent law, which provides that a patent applicant must sufficiently and adequately disclose her alleged invention in

[182] *See supra* note 147.

order to merit the patent.[183] Needless to state, such disclosure enables a member of the public to test the invention and work it as per the prescribed mode in the patent specification. The law therefore exempts a *de minimus* use of the patented invention to examine/study the patented invention.[184] This is the narrow conception of the exception. It has since evolved to cover a much broader range of experimental activities.

The Indian exception is much broader than analogous provisions in other jurisdictions, and is important from a public health perspective.[185] Section 47(3) provides that 'any person' may make or use any patented product or process "for the purpose merely of experiment or research including the imparting of instructions to pupils."[186]

A broad interpretation of the exception would permit the "use" of a patented invention to:

1) develop follow-on inventions and improvements, and
2) invent around or design around the patented invention.[187]

As discussed in Appendix A, this provision is compatible with Article 30 of TRIPS.

C.4. Bolar exception

[183] Illustratively, *see Section 10(4) which stipulates that every complete specification shall –*
(a) fully and particularly describe the invention and its operation or use and the method by which it is to be performed;
(b) disclose the best method of performing the invention which is known to the applicant and for which he is entitled to claim protection; and

[184] Janice Mueller, *No "Dilettante Affair": Rethinking The Experimental Use Exception To Patent Infringement For Biomedical Research Tools*, 76(1) WASHINGTON L. REV. 1,5 (2001).

[185] Shamnad Basheer & Prashant Reddy, *The "Experimental Use" Exception Through a Developmental Lens*, 50 INTELL. PROP. L. REV. 831, 832 (2010).

[186] Section 47(3) of the Patents Act, 1970.

[187] Shamnad Basheer & Prashant Reddy, *supra* note 185 , at 832.

The *Bolar* exception[188] permits a third party to manufacture and use a patented drug for the purpose of obtaining information necessary to procure regulatory approval for a generic or similar product by such third party.[189] As such, it is an important patent exception for the Indian generic industry. The exception is reproduced below.

> ***Section 107A. Certain acts not to be considered as infringement.*** *– For the purposes of this Act, –*
> *(a) any act of making, constructing, using, selling or importing a patented invention solely for uses reasonably related to the development and submission of information required under any law for the time being in force, in India, or in a country other than India, that regulates the manufacture, construction, use, sale or import of any product;*

Given that the procurement of regulatory clearances for generic drugs takes considerable time, effectively extending the patentee's monopoly and delaying the entry of affordable generics, this is an important public health exception. In an acknowledgement of the increasing export focus of India's generic sector, the exception also extends to acts done with an intent to gaining regulatory approval in countries outside India.

In the *Canada Pharmaceuticals case*,[190] a WTO panel ruled that the Bolar exception was compatible with TRIPS (Articles 27.1 and 28.1). One may however argue that, in permitting generic manufacturers to even "sell" and "import" the

[188] Taking its name from *Roche Products Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir. 1984).
[189] Shamnad Basheer & Prashant Reddy, *supra* note 185 , at 832.
[190] Canada - Patent Protection of Pharmaceutical Products, WT/DS114 /R (17 March 2000), p. 174.

patented drug, section 107A(a) extends beyond the scope of the narrow exception that was validated in the Canada Pharmaceuticals case.[191]

C.5. Parallel imports

The doctrine of "first sale" or the principle of "exhaustion" imposes certain limits on the ability of an IP owner to control the distribution of an IP good, once sold. Consequently, a purchaser of a patented invention (eg. an ipad) is free to do what she wishes with it, including reselling it without fear of being sued for patent infringement.

The rationale underlying the principle of 'exhaustion' and the doctrine of first sale is that a patent holder has been adequately rewarded through the first sale of an IP good and ought not to be permitted to repeatedly profit by controlling the resale and distribution of that very same good.

Depending on the territory in question, exhaustion can either be national (confined to a single state) or international (applicable to all countries around the world). Parallel imports are a natural corollary of the doctrine of international exhaustion and envisage the following:

(i) The export of a patented good (e.g. ipad) from country X (e.g. Bangladesh).

(ii) Import of such patented good into country Y (e.g. India).

A parallel importer essentially engages in price arbitrage and exploits the price difference between the exporting country (Bangladesh) and the importing country (India). Parallel importers may also bring in IP goods that are not otherwise available in the importing country. Several countries therefore encourage such imports. Given that such a provision permits the import of lower

[191] Shamnad Basheer & Prashant Reddy, *supra* note 185, at 871.

priced affordable versions of drugs, it is enormously beneficial from a public health perspective.

The Indian regime endorses international exhaustion. Section 107A(b) of the Patent Acts exempts from patent infringement the "importation of patented products by any person from a person who is duly authorised under the law to produce and sell or distribute the product."
All that the section requires is that the "import" be from a person *duly authorized under law* to produce and sell or distribute the product. It does not require that the person be authorized by the patentee, but merely that the person be authorized by law.

On a plain reading, this provision appears to go beyond our traditional understanding of "international exhaustion" i.e. importing a patented product from country X, provided the said product had already been sold once in Country X by or under the authorization of the patentee. However, under section 107A, the purchase could, on a literal reading, be made from a third party who bears no relation to the patentee and independently produces the patented good (either because there is no patent in Country X or because the country's law permits the third party manufacture of such goods). In short, assuming that X is a least developed country with no pharmaceutical patent regime, an Indian pharmaceutical company could set up a manufacturing unit in X, produce drugs (that were patented in other countries by the drug originator) and then import them into India without running the risk of patent infringement. While such a reading is plausible from the literal structure of section 107A (b), it runs the risk of contravening TRIPS.[192]

[192] For an alternative TRIPS compliant reading/interpretation of this provision, *see* Shamnad Basheer & Mrinalini Kochupillai, *TRIPS, Patents and Parallel Imports in India: A Proposal for Amendment,* 2 INDIAN J. INTELL. PROP. L. 63 (2009).

D. Challenging Patents: Oppositions/ Revocation

In view of the fact that a resource-constrained patent office is often amenable to error, the Indian Patents Act provides three modes of challenging a patent application/patent:

i) pre-grant opposition proceedings;
ii) post-grant oppositions proceedings; and
iii) a revocation application before the IPAB or before the High Court on a counter-claim in a suit for infringement of that patent.[193]

Each of these mechanisms complements the work of the patent office in ensuring that patent applications are strictly scrutinized.

The number of patent applications received each year by the IPO is quite small (just over 40,000),[194] when compared with the US Patent and Trademark Office (565,406).[195] However, given that the IPO is vastly deficient when it comes to an adequate number of specialized examiners and access to key databases[196], it is near impossible for the IPO to ensure a strict scrutiny in accordance with the

[193] Section 64(1) of the Patents Act, 1970.
[194] In the year 2012-13, the IPO received 43,674 patent applications. OFFICE OF THE CONTROLLER GEN. OF PATENT DESIGNS & TRADEMARKS, GOV'T OF INDIA, ANNUAL REPORT 2012–2013, at 24 (2013), available at http://ipindia.nic.in/ipr/patent/patents.htm (last visited on May 25, 2014).
[195] UNITED STATES PATENT & TRADEMARKS OFFICE, GOV'T OF USA, PERFORMANCE AND ACCOUNTABILITY REPORT FY 2013, at 188 (2013), available at http://www.uspto.gov/about/stratplan/ar/USPTOFY2013PAR.pdf#page=191 (last visited on May 25, 2014).
[196] A writ petition filed by Nitto Denko Corporation, questioning the delay by the Patent Office in issuing first examination report (FER) as well as seeking an expedited patent prosecution process resulted in the government filing a response outlining the serious shoratge of examiners at the office. The Delhi High court appointed a specialised committee to make suggestions for clearing the huge backlog of cases before the Patent Office. *See* order dated 16th December, 2013 in *Nitto Denko Corporation v. Union of India* W.P.(C) 3742/2013 and W.P.(C) 3756/2013, available at http://delhihighcourt.nic.in/dhcqrydisp_o.asp?pn=246917&yr=2013 (last visited on May 25, 2014).

Act.[197] Therefore, opposition proceedings are extremely helpful in that they invite third party knowledge and expertise into the examination process and foster better scrutiny. In the Indian context, oppositions and in particular section 3(d) have played a significant role in felling undesirable patents.[198]

D.1. Pre-grant opposition

As the name suggests, a pre-grant opposition is one that is filed by a third party prior to the grant of a patent, challenging the alleged invention contained in the patent application and arguing that it should not be granted a patent.

From a global perspective, pre–grant opposition mechanisms are not very common.[199] As such, the pre-grant regime in India, with its wide locus standi provision enabling almost "any person" (with or without a specific interest in the patented invention) to participate in the patent grant process by challenging a

[197] Bhaven Sampat argues that the Indian patent office does not strictly apply its own law, but largely follows EPOs patent grant patterns. Bhaven Sampat, *Institutional Innovation or Institutional limitation? The Impact of TRIPS on India's Patent Law & Practice* , WIPO 29 (July 2010) http://www.wipo.int/edocs/mdocs/mdocs/en/wipo_ip_econ_ge_6_10/wipo_ip_econ_ge_6_10_ref_sampat.pdf (last visited on May 25, 2014). Other studies report the rubber-stamping of decisions of international authorities such as the various Patent Cooperation Treaty (PCT) offices by the IPO without any independent patentability assessment. *See* Peter Drahos, *Trust Me: Patent Offices in Developing Countries*, Centre for Governance of Knowledge and Development Working Paper (Nov. 2008) available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1028676 (last visited on May 25, 2014).

[198] *See* Shamnad Basheer, *Patent Oppositions in India: The "Efficacy" of Section 3(d)*, available at http://spicyip.com/2009/09/patent-oppositions-in-india-efficacy-of.html (last visited on May 25, 2014). Noting that of all the pharmaceutical patent applications that were opposed, 73.5% were rejected.

[199] Only few countries such as Australia, Brazil and Jordan have pre grant opposition regimes. *See* Amy Kapczynski, *Harmonization and its Discontents: A Case Study of TRIPS Implementation in India's Pharmaceutical Sector*, 97 CALIF. L. REV. 1571 (2009). Europe has a third party observation mechanism, which is a diluted version of a pre grant regime (Article 115 of the European Patent Convention). It is to be noted that unlike opposition proceedings, such third observations do not include the observer as a party to the proceeding. The United States had no pre-grant opposition process till 2011 when the Leahy-Smith America Invents Act, introduced pre-issuance third party submissions prior to the grant of a patent.

patent application on several enumerated grounds (see table 12 below), stands out.

This regime enables not only generic competitors, but also patient groups and other members of the public to challenge pharmaceutical patent applications.[200]

Table 12: Grounds of Opposition (Section 25)

1) That the product/process was not novel.[201]
2) That the product/process did not involve an inventive step.[202]
3) That the complete specification does not disclose or wrongly mentions the source or geographical origin of biological material used for the invention.[203]
4) That the invention so far as claimed in any claim of the complete specification is anticipated having regard to the knowledge, oral or otherwise, available within any local or indigenous community in India or elsewhere.[204]
5) That the subject of any claim of the complete specification is not an invention within the meaning of this Act, or is not patentable under this Act.[205]
6) That the complete specification does not sufficiently and clearly describe

[200] For example, patients groups Delhi Network of Positive People (DNP+) and Initiative for Medicine and Access to Knowledge (I-MAK) recently filed pre grant oppositions challenging Gilead's application claiming Sofosbuvir, a crucial Hepatitis C antiviral. *See Indian public opposition to Hepatitis C medicine patent claim,* THIRD WORLD NETWORK (March 25, 2014), available at http://www.twnside.org.sg/title2/health.info/2014/hi140303.htm (last visited on May 25, 2014).
[201] Section 25(1)(b)(c)(d) of the Patents Act, 1970.
[202] Section 25(1)(e) of the Patents Act, 1970.
[203] Section 25(1)(j) of the Patents Act, 1970.
[204] Section 25(1)(k) of the Patents Act, 1970.
[205] Section 25(1)(f) of the Patents Act, 1970.

the invention or the method by which it is to be performed.[206]

7) Failure to disclose information regarding foreign applications for the same or substantially similar patent.[207]

Pre-grant oppositions have been largely successful[208] with a few companies abandoning patent applications in the face of an opposition.[209] It is easier for an application to be challenged prior to the grant of a patent, since the application is still in process and the patent office has not yet locked itself to a decision.

D.2. Post-grant opposition

Unlike pre-grants, a post-grant opposition can be filed only after the grant of a patent, but no later than a year after such grant. As for locus standi, it provides for a narrower set of parties ("any person interested") who are eligible to challenge the granted patent.[210] Although the phrase 'any person interested' is narrower than 'any person' (as used in the pre-grant provision),[211] in *Sankalp*

[206] Section 25(1)(g) of the Patents Act, 1970.
[207] Section 8 of the Patents Act, 1970.
[208] The Novartis case began with a pre grant opposition filed by Alternative Law Forum, Bangalore and Cancer Patients Aid Association, two civil society groups. A collation of the pre-grant opposition decisions is available here http://www.i-mak.org/pharma-patent-decisions/ (last visited on May 25, 2014).
[209] GlaxoSmithKline abandoned applications on two of its HIV drugs, Combivir and Abacavir. *See* Priti Radhakrishnan, *Access to Anti-Retrovirals (ARVs) in India: Patents and the Way Forward*, INFOCHANGE (Sept. 2008) available at http://www.hivaidsonline.in/index.php/Response/access-to-anti-retrovirals-arvs-in-india-patents-and-the-way-forward.html. (last visited on May 25, 2014).
[210] Section 25(2) of the Patents Act, 1970.
[211] *F. Hoffmann-La Roche AG v. Wockhardt Ltd.*, Chennai Patent Office (2009), at 20–21, *available at* http://www.i-mak.org/pharma-patentdecisions (last visited on May 25, 2014). Amy Kapczynski, *supra* note 199, at p. 1600.

Rehabilitation Trust v. Hoffmann-La Roche[212] the IPAB held that patient groups would qualify as "persons interested". This potentially paves the way for any person who is interested in the outcome of the patent to mount a post-grant opposition. The grounds listed in section 25(2) largely mirror that of the pre-grant opposition grounds.[213]

A post-grant opposition entails more careful scrutiny from the patent office, as it involves a two-step procedure, with the parties first presenting their case before an opposition board (consisting of 3 members) and the board issuing a recommendation to the Controller. The Controller then hears the parties and is free to either follow the recommendation of the Board or come to a different conclusion. It was only recently that the Supreme Court held that the Board's recommendations have to necessarily be made available to the parties.[214]

Table 13: Details of the pendency of opposition proceedings u/s 25(1) and 25(2)

Year	Pre-grant Oppositions		Post-grant Oppositions		
	No. of applications filed	No. disposed of	No. of applications filed	No. disposed of	No. pending
2012-2013	262	34	14	7	162
2011-2012	193	11	26	16	155
2010-2011	294	19	29	30	145
2009-2010	103	32	28	4	146
2008-2009	153	39	71	7	122
2007-2008	64	17	34	6	150
2006-2007	44	19	27	-	

[212] *Supra* note 120.
[213] *See* Section 25(2) of the Patents Act, 1970.
[214] *Cipla v. Union of India*, 2012 (11) SCALE 584.

2005-2006	**155**	**100**	**6**	**4**	

Source: OFFICE OF THE CONTROLLER GEN. OF PATENT DESIGNS & TRADEMARKS, GOV'T OF INDIA, ANNUAL REPORT 2005–2013, available at http://ipindia.nic.in/ipr/patent/patents.htm (Last visited on May 25, 2014).

D. 3. Revocation

Section 64 of the Patents Act, 1970 provides for two separate mechanisms for revoking/invalidating a patent - (i) Revocation proceedings before the IPAB by "any person interested" or by the Central government *or* (ii) A counter-claim by a defendant in a suit for patent infringement before the High Court.[215]

The grounds for revocation of a patent are very extensive and largely similar to those listed in section 25 (see table 12 above listing out these grounds).

In a recent case, the Supreme Court[216] held that these two mechanisms were disjunctive and a potential patent challenger had to choose between them. If the challenger opted to file a revocation petition before the IPAB first, then she could not later file a counterclaim challenging the patent in a subsequent infringement proceeding against her by the patentee. Similarly, if she first filed a counterclaim in an infringement proceeding against her, she could not then file a revocation petition before the IPAB.

The court also held that since a revocation proceeding (before the IPAB) is very similar to a post-grant proceeding a potential patent challenger had to choose between these two options as well.

[215] Section 64 reads thus: "*Revocation of patents. – (1) Subject to the provisions contained in this Act, a patent, whether granted before or after the commencement of this Act, may, be revoked on a petition of any person interested or of the Central Government by the Appellate Board or on a counter-claim in a suit for infringement of the patent by the High Court on any of the following grounds…*"
[216] *Dr. Aloys Wobben v. Yogesh Mehra* MANU/SC/0519/2014.

D.4 Revocation in Public Interest

Apart from the above framework for challenging a patent application/grant, the statute also provides a special power to the Central Government to invalidate any patent on the ground of "public interest". The provision reads as below:

"Where the Central Government is of opinion that a patent or the mode in which it is exercised is mischievous to the State or generally prejudicial to the public, it may, after giving the patentee an opportunity to be heard, make a declaration to that effect in the Official Gazette and thereupon the patent shall be deemed to be revoked."

This power has been invoked twice earlier. In 1994, US based Agracetus's patent titled 'a method of producing transformed Cotton Cells by tissue culture', was revoked by the central government under section 66 due to its allegedly far reaching implications for India's cotton economy.[217] Though it is believed that no reasons were recorded for this decision, the show cause notice preceding the revocation of the patent describes it as prejudicial to farmers' rights and having the potential to detrimentally impact the Indian economy.[218] Later that year, the US patent office also revoked Agracetus' patent on the basis of prior art.[219]

Section 66 was again invoked in 2012 when the central government revoked Avesthagen's patent (Patent No. 252093) over an anti-diabetic composition,

[217] Indian Patent No 168950, granted in 1991. Anumita Roychowdhury, *Revoked*!, DOWN TO EARTH, March 31, 1994 available at http://www.downtoearth.org.in/node/29643 (last visited June 20, 2014).
[218] Pravin Anand, *India: Patent: Revocation of Patent in Public Interest,* 17(2) E.I.P.R. D 38 (1995).
[219] Teresa Riordan, *US Revokes Cotton Patents after Outcry from Industry*, THE NEW YORK TIMES, (December 8, 1994) available at http://www.nytimes.com/1994/12/08/business/us-revokes-cotton-patents-after-outcry-from-industry.html (last visited June 20, 2014); *See also,* IIPRD, *Central Government's power of Revocation of Patent in Public Interest,* IIPRD Blog – Intellectual Property Discussions, January 2, 2014, available at http://iiprd.wordpress.com/2014/01/02/central-governments-power-of-revocation-of-patent-in-public-interest/ (last visited June 20, 2014)

comprising *jamun, lavangpatti* and *chundun*.[220] The government revoked the patent on the ground that it was generally prejudicial to the public.[221] The use of *jamun* for the treatment of diabetes has long been known in India. Avesthegen had also applied for a patent for this treatment at the European Patent Office (EPO), which they later abandoned after an adverse search report from the EPO, part of which was based on TKDL references.[222]

E. Patent Enforcement

Apart from the ex-post measures considered above, the grant or non-grant of an injunction in a patent infringement proceeding could have serious repercussions for access to medicines, as discussed below.

One of the most important tools of patent enforcement is the remedy of an injunction or restraining order. These can be either temporary or interim (granted at the beginning of the case and valid during the subsistence of the trial) or permanent (after the conclusion of the trial). Interim injunctions, which involve less tenuous evidentiary standards,[223] are largely dispositive of a case and account for a significant proportion of patent related decisions.[224] The law on

[220] Prashant Reddy, *Govt of India follows up on SpicyIP reporting – revokes Avesthagen patent – First Indian victory for TKDL*, SPICYIP, October 27, 2012, available at http://spicyip.com/2012/10/govt-of-india-follows-up-on-spicyip.html (last visited June 20, 2014).
[221] http://www.ipindia.nic.in/iponew/notification_07November2012.pdf (last visited June 20, 2014).
[222] European Patent Register, Patent Application No. EP2152284 available at https://register.epo.org/application?number=EP07805634&lng=en&tab=doclist (last visited on May 25, 2014).

[223] *See Cordis Corp. v. Medtronic, Inc*. 835 F.2d 859, 859 (Fed. Cir. 1987); *see also Univ. of Tex. v. Camenisch*, 451 U.S. 390, 395 (1981).
[224] Out of a total of 85 patent infringement cases decided by courts up until July 2012, ninety five percent are interim decisions. *See* Shamnad Basheer et. al., *Pharmaceutical Patent Enforcement: A*

interim injunctions is largely based on principles of equity.[225] The grant of an interim injunction is predicated on four criteria:

1. That there is a prima facie case in favour of the plaintiff;
2. That the plaintiff is likely to suffer an irreparable injury if the defendant is not restrained;
3. That the balance of convenience lies in favour of the plaintiff;[226] and
4. That public interest would not be dis-serviced by the grant of the injunction.[227]

Of the above factors, public *interest* is an important one from the vantage point of public health.[228] In *Hoffman-La Roche Ltd. v. Cipla*, a case involving Cipla's manufacture of Roche's patented anti-cancer drug 'Erlocip', both the single judge and division bench denied a temporary injunction on the ground that it would effectively foreclose the public from accessing Cipla's cheaper version of an important anti cancer drug.

Developmental Perspective in PATENT LAW IN GLOBAL PERSPECTIVE 603 (Ruth L. Okediji & Margo A. Bagley eds., 2014).

[225] *See N.R. Dongre v. Whirlpool Corp*., (1996) 5 S.C.C 714, 716 ("Injunction is a relief in equity and is based on equitable principles.")

[226] *Wander Limited v. Antox India Private Limited* 1990 Supp (1) SCC 727; *National Research Development Corporation of India v. The Delhi Cloth & General Mills Co. Limited* AIR 1980 Delhi 132

[227] The UK only follows a tripartite test that does not include a separate public interest standard [McDermott, et. al., EUR. IP BULL. July 2006, available at http://www.mwe.com/info/news/euroip0706.pdf (last visited on May 25, 2014)]. US courts, however, include an independent public interest assessment to the other 3 criteria of prima facie case, irreparable injury and balance of convenience [*eBay, Inc. v. MercExchange*, LLC, 547 US 388, 392 (2006)].

[228] Indian courts have recognized public interest as a separate factor to be considered (*Novartis AG v. Mehar Pharma*, (2005) 3 Bom. C.R. 191, 201), and have also read it into the 'balance of convenience' test. (*Hoffman-La Roche Ltd. v. Cipla Ltd*., (2008) 37 P.T.C. 71 (Delhi H.C.).

Table 14 Roche v. Cipla

Roche, the patentee of the anti–cancer drug– Tarceva, sought an injunction against Cipla, an Indian generic manufacturer, for allegedly infringing its patented product.[229] While denying the interim injunction, the Delhi High Court considered the implications an injunction would have on 'public interest'.[230]

Applying this test to the present case, the court noted the stark difference in pricing by the patentee and the generic manufacturer – Roche was selling Tarceva at Rs. 4,800 a tablet and Cipla at Rs. 1,600 a tablet.[231] Moreover, clinical trial data showed that Tarveca demonstrated a striking survival benefit (42.5%) in advanced, non-small cell lung cancer.[232] In light of these factors, the court refused to grant an interim injunction or restraining order, as such an injunction would adversely affect access to affordable medicine for a large number of cancer patients.[233]

After trial, the Tarveca patent was upheld, but Cipla's product was not found not to infringe the patent.[234] The injunction was therefore denied. The matter

[229] *Hoffman-La Roche Ltd. v. Cipla Ltd*, CS (OS) No.89/2008, Delhi High Court, available at http://lobis.nic.in/dhc/MAN/judgement/10-09-2012/MAN07092012S892008.pdf (last visited on June 1st, 2014).
[230] *See* Basheer, *supra* note 198.
[231] *See* C.H. Unnikrishnan, *Court to hear Roche petition on cancer drug Court to hear Roche petition on cancer drug*, The Mint, Jan 20 2008, available at http://www.livemint.com/Politics/IZICNGqN81LkVrJdSynkeJ/Court-to-hear-Roche-petition-on-cancer-drug.html (last visited on June 1st, 2014).
[232] *Id*.
[233] *See* Shamnad Basheer, *Breaking News: Supreme Court Dismisses Roche "Tarceva" Petition*, SpicyIP, August 28, 2009, available at http://spicyip.com/2009/08/breaking-news-supreme-court-dismisses.html (last visited on June 1st, 2014).
[234] *Hoffman-La Roche Ltd. v. Cipla Ltd*, CS (OS) No.89/2008, Delhi High Court, available at http://lobis.nic.in/dhc/MAN/judgement/10-09-2012/MAN07092012S892008.pdf

was then appealed before a Division Bench and was referred to mediation (where the case is pending currently).[235]

F. Transparency in Patents

Given that patents essentially represent a social bargain between the inventor (who promises to disclose her invention) and the state (which promises to grant an exclusive legal right in exchange for such disclosure), transparency of patent information lies at the heart of a robust patent system. Such transparency and ease of access of information (through free digital access), enables an ordinary member of the public to benefit from the teachings in patent documents. Further, she is also able to scrutinise patent documents and challenge those that are unworthy. While India boasts a comprehensive online patent database containing a variety of information (patent specification, exchanges between the patent office and the applicant, opposition decisions etc), [236] the information is not necessarily accurate, and suffers from a number of shortcomings.[237] The patent database is also not very user friendly.

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[235] *See* Soma Das, *Roche and Cipla enter talks to settle Erlotinib Patent row,* Economic Times, June 13, 2014, available at http://articles.economictimes.indiatimes.com/2014-06-13/news/50564611_1_erlotinib-patent-expert-shamnad-basheer-patent-battle (last visited on June 13, 2014).

[236] Information relating to patent applications, granted patents and the Controller's decisions on the grant of patents is now available on http://ipindia.nic.in/. Efforts have also been made to digitize information pertaining to traditional knowledge through the creation of the traditional knowledge digital library (http://www.tkdl.res.in/tkdl/langdefault/common/Abouttkdl.asp?GL=Eng). For more on this *see* Chapter VI titled 'Traditional Medicine, Biodiversity and Public Health'.

[237] Shamnad Basheer, *IPO v. IPAB: IT Prowess and Transparency*, SPICYIP (August 6, 2013), available at http://spicyip.com/2013/08/ipo-vs-ipab-it-prowess-and-transparency.html (last visited on May 25, 2014).

Further, important information relating to the "working" of patents is not readily available. Section 146(2) of the Patent Act read with Rule 131 of the Patent Rules 2003 compels patentees to submit annual statements detailing how their patent is being worked in the territory of India – the number of products sold, the value of sales, and whether the local demand has been adequately met – in the prescribed Form 27. Rule 131(3) states that the Controller 'may' publish such information. However, studies show that despite being a mandatory statutory requirement,[238] Form 27 reporting is very poor.[239] Even when reported, it is often with sizeable errors.[240] There is an urgent need to ensure stricter Form 27 compliance, as well as to make this information freely available to the public at large.[241]

Such information is very valuable in that it helps determine the nexus between patents and innovation i.e. to what extent do granted patents convert to useful innovative products for the public? This information is also vital for issues of compulsory licensing i.e. as discussed earlier, the lack of adequate "working" of a patented invention is a ground for the grant of a compulsory licence.

[238] Not filing a Form 27 or an incomplete Form 27 can lead to the Controller General imposing a fine of up to Rs. 10 lakhs under Section 122 of the Patent Act 1970.

[239] Shamnad Basheer, *Drug Firms and Patent "Working": Extent of Compliance with Form 27*, SPICYIP (April 9, 2011), available at http://spicyip.com/2011/04/drug-firms-and-patent-working-extent-of.html (last visited on May 25, 2014). SpicyIP Report, *RTI Applications and "Working" of Foreign Drugs in India?* available at http://spicyip.com/2011/04/drug-firms-and-patent-working-extent-of.html (last visited on May 25, 2014).

[240] *Ibid.*

[241] The team at SpicyIP prepared successfully petitioned for Form 27 information to be made available to the public. However, this was only done for the year 2012. Prashant Reddy, *Patent Office publishes all 'Statements of Working' – Finally!*, SPICYIP (June 25, 2013), available at http://spicyip.com/2013/06/patent-office-publishes-all-statements.html (last visited on May 25, 2014).

Table 15: No. of Form 27 fillings per year and no. of patents reported as working as against no. of patents in force

	2012-2013	2011-2012	2010-2011	2009-2010	2008-2009	2007-2008
Patents in force	43920	39989	39594	37334	30822	29688
Form 27 received	27946	27825	34112	24009	-	-
Reported as working	6201	7431	7431	4189	4752	3499

Source: Information collected from OFFICE OF THE CONTROLLER GEN. OF PATENT DESIGNS & TRADEMARKS, GOV'T OF INDIA, ANNUAL REPORTS FOR YEARS *2005-2013.*[242]

G. Regulatory Data Exclusivity

Regulatory exclusivity or data exclusivity is a species of intellectual property rights that provides a period of exclusivity for a drug originator to help it recover the significant sums of money invested in drug development (mainly clinical trials).

In most countries, no new drug can be introduced to the market without the approval of the drug regulator. Illustratively, in the US, firms are required to file a new drug application (hereinafter "NDA") before the Food and Drug Administration (FDA)[243] and submit extensive clinical trial information and other data to demonstrate the safety and efficacy of their drug.[244] However, the process for approving a generic is far less complex, with an applicant having to simply

[242] available at http://www.patentoffice.nic.in/ (last visited on May 25, 2014).
[243] *See* 21 U.S.C. § 355(a)
[244] *See* 21 U.S.C. § 355(b)

file an Abbreviated New Drug Application (hereinafter "ANDA") that demonstrates their generic version to be bio-equivalent to the existing originator drug.[245]

Proof of bio-equivalence, which largely hinges on a demonstration of equivalent bioavailability,[246] obviates the need to undertake fresh clinical trials by the generic applicant. The underlying rationale is that if the active ingredient is the same, the trial results for the originator drug (demonstrating that the drug is safe and effective) ought to hold good for the generic version as well. Consequently, a generic manufacturer can free-ride on the efforts of the originator and introduce a follow-on drug into the market by expending far less resources than the drug originator.

In order to prevent such free-riding, some legal regimes mandate that the data submitted by an originator cannot be relied upon to approve any generic version for a certain minimum number of years. The extent and length of protection varies between different countries and depends, in part, on the kind of drug/indication sought to be approved.[247] Illustratively, the US pegs data exclusivity in most cases at 5 years, whereas in the EU, it could go up to 8 years, a period during which no generic alternative can be approved, unless the generic manufacturer undertakes fresh expensive trials.

[245] *See* 21 U.S.C. § 355(j) (providing that in the United States, such an application by the generic company is referred to as an Abbreviated New Drug Application or ANDA.)
[246] *See* 21 CFR Section 320.1(a) ("Bioavailability means 'the rate and extent to which the active drug ingredient or active moiety is absorbed from a drug product and becomes available at the site of drug action.'")
[247] Manthan Janodia et. al, *Data Exclusivity Provisions in India: Impact on Public Health,* 13 JOURN. INTELLECTUAL PROPERTY RIGHTS 442 (2008).

Given that any data exclusivity norm effectively sets up another barrier for generic entry, a number of countries including India have resisted providing such additional exclusivity for drug originators in their domestic regime.

It bears noting that the TRIPS provision dealing with the protection of regulatory data is worded in ambiguous terms:

Table 16: Article 39.3 of TRIPS

"*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*."

The key term in the provision above is "unfair commercial use". The US, EU and multinational pharmaceutical companies argue that the phrase effectively means data exclusivity.[248] In other words, any use of the data, even by the government (to approve a follow on generic version of the same drug), amounts to "unfair commercial use". The other position, proffered mainly by developing countries, advocates that the Article does not prevent regulatory authorities from relying on data in its possession to assess "*a second and further applications, relating to the same drug*". It only precludes third parties from using the results of tests "if has been acquired though dishonest commercial practices."[249] This reading is also

[248] Shamnad Basheer, *Protection of Regulatory Data Under Article 39.3 of Trips: The Indian Context,* INTELLECTUAL PROPERTY INSTITUTE (IPI), available at SSRN: http://ssrn.com/abstract=934269 (last visited on May 25, 2014).

[249] African Group et. al, *Developing Countries Group Paper,* IP/C/W/296 (20 June 2001), available at http://www.wto.org/english/tratop_e/trips_e/paper_develop_w296_e.htm (last visited on

consistent with the common law position in *SmithKline & French Laboratories v. Licensing Authority*[250] where the House of Lords concluded that while the disclosure by regulatory authorities to third parties would be a breach of the duty of confidence, the use of any information for the discharge of its statutory functions, including in reviewing and approving applications by generics, is permissible. A third interpretation argues that a reading of the article in accordance with the rules of treaty interpretation effectively means that Article 39.3 envisages a 'compensatory liability' model where the data can be relied upon only when some 'fair' compensation is provided to the originator of the data.[251]

In a petition seeking the implementation of a data exclusivity norm for agrochemicals, the Delhi High Court categorically noted the absence of any statutory mandate for data exclusivity.[252] It did not adjudicate upon the petitioners claim that Article 39.3 of TRIPS mandated data exclusivity. Rather, the court imposed costs on the petitioner for attempting to lure it into making a policy declaration. [253]

May 25, 2014). *See also* CARLOS CORREA, PROTECTION OF DATA SUBMITTED FOR THE REGISTRATION OF PHARMACEUTICALS: IMPLEMENTING THE STANDARDS OF THE TRIPS AGREEMENT 15 (2002).

[250] [1989] 1 All. E. R. 578.

[251] *See* Shamnad Basheer *The Invention of an Investment Incentive for Pharmaceutical Innovation,* 15 (5-6) JOURNAL OF WORLD INTELLECTUAL PROPERTY 1 (2012); *See also* Xavier Fellmeth, *Secrecy, Monopoly, and Access to Pharmaceuticals in International Trade Law: Protection of Marketing Approval Under the TRIPS Agreement,* 45 HARV. INT'L L. J. 443, 464 (2004).

[252] *Syngenta India Ltd v. Union Of India*, W.P. (C) 8123/2008 available at http://indiankanoon.org/doc/165590985/ (Last visited on May 25, 2014) at ¶ 37. The court noted: "" There is no statutory guidance, either in the substantive portion of the enactment, or under the Rules, enabling even the rule making authority to prescribe a period of limitation for "data exclusivity".The decision was confirmed by a division bench of the High Court [judgment available at http://indiankanoon.org/doc/264613/ (last visited on May 25, 2014)].

[253] *Id.* The court noted "The court is of the opinion that this litigation was speculative, as the attempt was clearly to invite the court to make a policy declaration, which could not have been made under any circumstances." (at ¶ 45).

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The Satwant Reddy Committee, set up in 2007 to review India's compliance with Article 39.3, appeared to endorse the view that Article 39.3 is flexible and does not mandate data exclusivity.[254] It therefore suggested that countries adopt a position commensurate with their national interests and priorities. It noted that Indian legal provisions for the protection of pharmaceutical regulatory data (protection from fraudulent disclosure etc) was sufficient to comply with Article 39.3 and that the said position could continue for the present. However, it advocated that India move to a data exclusivity regime in future.[255] As far as agro chemicals and traditional medicines were concerned, it proposed an immediate implementation of data exclusivity norms.[256]

Subsequent to the publication of the Satwant Reddy report, the Department of Ayurveda, Yoga, Unani, Siddha and Homoeopathy (AYUSH) pressed for a review of the recommendation that a five year data exclusivity term be granted for traditional medicines. This was despite the fact that the very same AYUSH had initially proposed this five year period to the committee.

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[254] In pertinent part, it stated that Article 39.3 has been "interpreted differently by different countries owing to the flexibility in Article 39.3 enabling them to adopt an approach best suited to their needs and circumstances. Several countries have introduced trade secret form of protection in compliance of Article 39.3. On the other hand most developed countries have adopted data exclusivity as the mode of protection complying with Article 39.3 obligation." **Cite.**

[255] It contemplated the introduction of a five year data exclusivity term for pharmaceutical patents after the transition period.*Supra* note 254, at p. 50.

[256] It also rejected the system of compensatory liability on the ground that it was impractical to implement.Satwant Reddy report, available at http://chemicals.nic.in/DPBooklet.pdf at p. 36 (Last visited on May 25, 2014).

The reported reason for this turnaround was that the Department of AYUSH feared that the introduction of data exclusivity for traditional medicine would inevitably lead to a demand for the same in the case of allopathic medicines, an outcome, they believed would be detrimental to public health.[257]

[257] Joe Mathew, *Government May Not Provide Five Year Data Protection To Traditional Medicines*, BUSINESS STANDARD (February 9, 2008) available at http://www.business-standard.com/article/economy-policy/govt-may-not-provide-five-yr-data-protection-to-traditional-medicines-108020901007_1.html (Last visited on May 25, 2014).

As noted earlier in this report, the current patent framework fails to incentivize the production of drugs for "diseases of the poor". This, along with other systemic issues, such as the inherent inefficiency of a uniform period of patent protection for all inventions and the indeterminacy of the current patent filter,[258] has led scholars and policy makers to propose a number of alternative models for incentivizing drug innovation, particularly in relation to diseases of the poor. This part highlights some of these models.

A. Prize Regime

One of the earliest known incentives, a "prize" regime essentially entails the grant of a pre-announced reward for a specific type of innovation.

Table 17: Napolean's Food Preservation Prize, 1795

Napolean, keen to find a way to feed troops during food scarcity, announced a prize of 12,000 francs for an effective method of preserving food. Fifteen years later, Nicolas Francois Appert, claimed the prize for a method involving heating, boiling and sealing food in airtight glass jars – a process, the fundamentals of which survive to this day.

Source: James Love & Tim Hubbard, Prizes for Innovation in New Medicines and Vaccines 19 ANNALS HEALTH L. 155 (2009).[259]

Prizes are able to direct innovative efforts towards areas traditionally neglected by the patent system. Scholars have proposed prizes as effective incentives for

[258] *See* Basheer, *supra*note 251.

[259] *Available at http://lawecommons.luc.edu/cgi/viewcontent.cgi?article=1111&context=annals* (last accessed on June 1, 2014)

the creation of drugs for diseases of the poor.[260] Current prizes for medical innovations include 'InnoCentive', a platform which administers a series of commercially-sponsored prizes for solving problems, the X-Prize foundation, the Piramal Prize for Innovations that Democratize Healthcare, and the Gotham Prize.[261]

A key advantage of the prize model is that it delinks the costs of R&D from the costs of manufacturing, thereby permitting the sale of cheaper drugs.[262] However, as with any other incentive, prizes come with their fair share of problems.

First, the allocation of the prize may encourage inefficient 'rent seeking', in that it opens up the possibility of influence in the determination and allocation of the prize by the government or the prize administrator.[263]

Second, the requirement of certainty and risk mitigation may mean that the government or prize funder has to increase the magnitude of the proposed prize in order to make up for any hesitation felt by pharmaceutical companies to invest large sums of money into R&D.[264]

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[260] *See* Joseph Stiglitz, *Give Prizes not Patents*, NEW SCIENTIST 21 (Sept. 16, 2006) available at http://keionline.org/misc-docs/giveprizesnotpatents.pdf (last visited June 1, 2014).
[261] *See Selected Innovation Prizes and Reward Programs* 7-9 (KEI Research Note No. 1, 2008), http://www.keionline.org/misc-docs/research_notes/kei_rn_2008_1.pdf (last visited June 1, 2014) (enlisting comprehensive list of prizes).
[262] Tim Hubbard and James Love, *A New Trade Framework for Global Healthcare R&D*, 2(2) PLOS BIOLOGY, 0147 (2004).
[263] *See* William W. Fisher and Talha Syed, A Prize System as a Partial Solution to the Health Crisis in the Developing World, in INCENTIVES FOR GLOBAL PUBLIC HEALTH, ed. Thomas Pogge (2010)at 12-13.
[264] *Id.*, at 13-14.

Thirdly, prizes often skew the process towards solving specific problems, rather than more open-ended innovation.[265] However, the 'blue-sky' prize model can address this.[266] This model is problem agnostic, freeing contestants to choose the issues they wish to tackle.

The Health Impact Fund,[267] proposed by Aiden Hollis and Thomas Pogge, is a clever example of a pharmaceutical prize, where innovators are rewarded based on the therapeutic value of their products.

A.1. The Health Impact Fund

The Health Impact Fund (HIF) rewards innovators of new drugs in direct proportion to the health impact of their drug.[268] The HIF prize is to be disbursed from a global fund, with the authors of the model recommending an annual funding of at least US $2 – 10 billion, and a commitment to fund for a minimum of 12 years.[269] The prospect of a reduced global disease burden due to lowered drug pricing (induced by the model) is stated as one of the reasons why

[265] *Id.*, at 20-23.

[266] *See* STEPHEN MAURER, WHO COMMISSION ON INTELLECTUAL PROPERTY RIGHTS, INNOVATION AND PUBLIC HEALTH, THE RIGHT TOOL(S): DESIGNING COST-EFFECTIVE STRATEGIES FOR NEGLECTED DISEASE RESEARCH 79 (Mar. 29, 2005), *available at* http://www.who.int/intellectualproperty/studies/research_development/en/index.html (last visited June 1, 2014).

[267] *See* Aidan Hollis and Thomas Pogge, *The Health Impact Fund: Making New Medicines Accessible for All* (2008) available at http://healthimpactfund.org/wp-content/uploads/2012/11/hif_book.pdf (last visited June 1, 2014).

[268] The different measures that can be used to measure the health impact include Quality-Adjusted Life Years (QALYs) or Disability Adjusted Life Years (DALYs) amongst others. For the purposes of discussion of the model, HIF uses QALYs. *Id* at p.28

[269] *See* Aidan Hollis, *The Health Impact Fund: A Useful Supplement to the Patent System?*, 1(2) PUB. HEALTH ETHICS 124, 127 (2008).

governments,[270] and private philanthropic organizations such the Gates Foundation[271] ought to contribute to this fund.

When a new drug innovator registers with the HIF, they stake a claim for a portion of the fund. While they can continue holding their patents over the same drug, there is a cap on the price at which they can sell i.e., they are to sell at a price close to marginal cost of production and distribution. Although this permits the registrant to maintain market exclusivity, it does not allow the registrant to charge monopoly prices for the drug. The firm then receives a stream of payments from the fund (HIF) based on the relative incremental global health impact of the drug.[272] Thus, the model incentivizes the creation of high value drugs that are then sold at affordable costs.

WHO's Expert Working Group on R&D financing lauded the HIF as a promising regime that could appropriately incentivize R&D while also ensuring accessibility.[273]

However, the HIF has faced criticisms, some of which include:
i) Its dependence on external funding – presumably from taxpayers of developed countries who have little reason to pay up;[274]
ii) The potential for the fund to be gamed by manipulation of health impact estimates; and

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[270] *Id* at p.130
[271] *See* Bill and Melinda Gates Foundation, *Global Health Program*, *available at* http://www.gatesfoundation.org/what-we-do (last accessed 01/06/2014).
[272] *See* Hollis and Pogge, *supra* note 266.
[273] *See* Rudolf V. Van Puymbroeck, *The Health Impact Fund: Creation and Commitment* (IGH Discussion Paper No. 6, Feb., 2010), available at http://healthimpactfund.org/wp-content/uploads/2012/11/DP6_Van_Puymbroeck.pdf (last visited June 1, 2014).
[274] *See* Thomas Alured Faunce & Hitoshi Nasu, *Three Proposals for Rewarding Novel Health Technologies Benefitting People Living in Poverty: A Comparative Analysis of Prize Funds, Health Impact Funds and Cost-Effectiveness/Competitive Tender Treaty*, 1(2) PUB. HEALTH ETHICS 146 (2008).

iii) The initial uncertainty of eventual rewards vis-à-vis actual R&D expenditures.[275]

That being said, the HIF is still a 'work in progress', yet to be operationalized.

B. Advanced Market Commitment

An Advanced Market Commitment (AMC) is a financial commitment by donors to subsidize the final purchase of a drug that is yet to be created. Its working model is elaborated upon in the table below.

Table 18: AMC Model

Assume that the drug originator needs to make $10 per pill in order to ensure a decent rate of return on investment in the market. A sponsor makes an advance commitment by guaranteeing this price to the drug originator, once the drug is made. This permits a poor country to pay a low and affordable price for the drug (e.g., $1 per pill), while the sponsor effectively picks up the rest of the tab (e.g., $9 per pill) to provide returns comparable to market returns.

Source: Michael Kremer et al., Briefing Note on Advance Purchase Commitment's 19 (DFID Briefing Paper, May, 2005).[276]

In short, AMCs effectively substitute the expected lifetime revenues of a new drug, so as to provide an incentive for developing drugs for neglected

[275] *See* Matt Peterson et. al., *A Critique in Need of Critique*, 3(2) PUB. HEALTH ETHICS 178, 183 (2010).
[276] *Available at* http://www.who.int/intellectualproperty/submissions/MichealKremerKTW_CIPIH_submit_2.pdf (last visited on June 1, 2014).

diseases.[277] It also aims to speed up access to vaccines in poor countries, often beset with procurement delays due to high prices.[278]

Some of its criticisms include:

i) Its requirement for pre-specified results and outcomes;

ii) Its encouragement of duplicative, competitive research towards a single prize;[279]

iii) The finality once a commitment is made – preventing the possibility of purchasing future better drugs/vaccines; and

iv) The lack of incentives for improving upon drugs.[280]

C. Public Funding

As the name suggests, this model relies on extensive government funding for the innovative process. This can be done both nationally, as well as internationally. We first discuss the national model before moving onto the international model.

C.1 National Public Funding

Public sector funding can be critical for medical innovation, particularly in areas of market failure. [281] Illustratively the Brazilian "FIOCRUZ" model ensured a

[277] KREMER M AND GLENNESTER R. STRONG MEDICINE: CREATING INCENTIVES FOR PHARMACEUTICAL RESEARCH ON NEGLECTED DISEASES. (2004).
[278] *See* Ernst R. Berndt & John A. Hurvitz, *Vaccine Advance-Purchase Agreements for Low-Income Countries: Practical Issues*, 24(3) HEALTH AFF. 653, 654 (2005).
[279] Similar to the patent system today where only one competitor gets the final patent.
[280] E.R. Berndt and J.A. Hurvitz, *Vaccine Advance-Purchase Agreements for Low-Income Countries: Practical Issues*, 24(3) HEALTH AFFAIRS 653 (2005).
[281] *See* Ashley Stevens et al, *The Role of Public-Sector Research in the Discovery of Drugs and Vaccines*, THE NEW ENGLAND JOURNAL OF MEDICINE (2011).

steady stream of potential leads for a range of neglected diseases, that were otherwise ignored by pharmaceutical companies.[282]

For its part, India has had a history of significant public funding during the early days of the growth of the pharmaceutical industry, where government institutions such as the Central Drug Research Institute (CDRI) played a significant role in building technological capacity amongst fledgling private sector players.[283]

Unfortunately, with the rapid growth of the private pharmaceutical industry in India, the government began taking a back seat, and public sector institutions diminished in importance.[284] Given the recent spate of mergers and acquisitions in the Indian pharmaceutical industry and the fact that the Indian private sector is not investing in diseases of the poor,[285] the time may be right for the government to re-establish its presence in the innovation ecosystem and infuse more public funding into the pharmaceutical R&D process. It is already doing so in a modest manner, as highlighted below:

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[282]The Oswaldo Cruz Foundation or the FIOCRUZ is an institute under the Brazilian Ministry of Health and has a number of successful projects to its credit. E.g., in 2008, along with the nonprofit organization Drugs for Neglected Diseases initaitive (DNDi), they released the ASMQ, a fixed-dose combination of the drugs artesunate (AS) and mefloquine (MQ) to combat malaria. *See* Oswaldo Cruz Foundation, http://portal.fiocruz.br/en/content/home-ingl%C3%AAs (last visited June 1, 2014).

[283] CDRI, set up in 1951, is credited with creating 12 new drugs. *See more* http://www.cdriindia.org/orgnisation.htm (last visited June 1, 2014).

[284] Amit Shovon Ray, *Emerging through Technological Capability: An Overview of India's Technological Trajectory,* Indian Council for Research on International Economic Relations, Working Paper No. 227, (November 2008), available at http://www.environmentportal.in/files/WorkingPaper227.pdf (last visited June 1, 2014).

[285] *See* William Greene, *The Emergence of India's Pharmaceutical Industry and the Implications for the U.S. Generic Drug Market*, OFFICE OF ECONOMICS, U.S.I.T.C, WORKING PAPER NO. 2007-05-A (2007), available at http://usitc.gov/publications/332/working_papers/EC200705A.pdf (last visited June 1, 2014).

i) The CSIR's Open Source Drug Discovery (OSDD) project, (discussed in more detail below), has achieved a fair deal of success in identifying potential drug targets of *M.tuberculosis*.[286]

ii) India's first indigenously developed rotavirus vaccine (for the prevention of diarrhea) was developed through a Public-Private Partnership model, with the All India Institute of Medical Sciences (AIIMS) and the Department of Biotechnology (DBT) playing strong roles along with a private pharmaceutical company, Bharat Biotech.[287] It is due on the shelves by late 2014.

iii) Government initiated Public-Private Partnerships to build capacity include**:** [288]

a) Biotechnology Industry Partnership Program (BIPP): It was launched under the DBT in 2008, with the aim of promoting innovations of national importance. 31 of its first 58 projects have focused on health and 7 of those target neglected diseases.

b) Drugs and Pharmaceutical Research Program (DPRP): A program of the Department of Science and Technology launched to increase India's drug development capacity and support the development of products that meet India's health needs.

iv) Apart from the above, various government agencies have been supporting research on neglected diseases, as seen in table 19 below:

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[286] *Id.*

[287] *See* Manasi Vaidya, *Phase III trial of $1 vaccine RotaVac completed*, BIOSPECTRUM (March 6, 2013), available at http://www.biospectrumasia.com/biospectrum/news/175714/phase-iii-trial-usd1-vaccine-rotavac-completed (last visited June 1, 2014).

[288] *See* Paul Wilson and Aarthi Rao, *India's Role in Global R&D*, RESEARCH FOR DEVELOPMENT INSTITUTE 80 (2012) available at http://healthresearchpolicy.org/sites/healthresearchpolicy.org/files/assessments/files/R4D%20-%20Indias%20Role%20in%20Global%20Health%20RD%20Final.pdf (last visited June 1, 2014).

Table 19

Government Agency	2010 Neglected Disease Funding
Indian Council of Medical Research	$17,178,281
Department of Biotechnology	$9,742,057
Council of Scientific and Industrial Research	$3,957,939
GOI Support to WHO's Special Programme for Research and Training in Tropical Diseases	$23,769

Source: Paul Wilson and Aarthi Rao, India's Role in Global Health R&D, Center for Global Health R&D Policy Assessment.[289]

C2. International Public Funding

The best known example of an international public funding model is the proposed Medical Research and Development Treaty (MRDT). Aiming to separate the costs of R&D from that of drug production and distribution, the draft treaty rewards innovation from a prize fund created out of government contributions. All nations are required to pledge a fixed percentage of their GDP towards the fund for sponsoring global pharmaceutical R&D. Any spending by countries towards pre-determined priority research areas would generate proportional credits towards a country's overall obligation to the fund.[290] Credits could also be generated for open source public databases, preservation and dissemination of traditional knowledge, effectuating technology transfer, etc.

[289] *Id.*

[290] *See* Andrew Farlow, *A Global Medical Research and Development Treaty: An Answer to Global health needs?* 10 (IPN Working Paper on Intellectual Property, Health and Innovation, June, 2007), *available at* http://www.andrewfarlow.com/global_medical_research_treaty.pdf (last visited June 1, 2014).

In April, 2012, the WHO's Consultative Expert Working Group (CEWG) on Research and Development released a report calling for a binding treaty to regulate the financing of R&D for developing country diseases.[291] The 67th World Health Assembly (WHA) then adopted a decision[292] giving the WHO Secretariat the mandate to create the necessary pooled funding mechanism for R&D.[293] In line with the GSPA PHI, the adopted decision clarified that the pool could cover "Type III and Type II [diseases] and the specific development needs of developing countries, in relation to Type I diseases."[294] However, as the decision states that the fund will be administered by a Special Programme for Research and Training in Tropical Diseases, there are some apprehensions that the scope of engagement will be limited to tropical diseases, rather than a broader array of important diseases.[295]

D. Investment Protection Models

Owing to the sub-optimality of the current patent regime in protecting intensive pharmaceutical R&D investments, there have been proposals for a more direct investment protection model. This builds in many ways on the regulatory data exclusivity model, discussed earlier in this report.

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[291] *See* WORLD HEALTH ORGANIZATION, CONSULTATIVE EXPERT WORKING GROUP ON RESEARCH AND DEVELOPMENT: FINANCING AND COORDINATION, RESEARCH AND DEVELOPMENT TO MEET HEALTH NEEDS IN DEVELOPING COUNTRIES: STRENGTHENING GLOBAL FINANCING AND COORDINATION (APR. 2012), available at http://www.who.int/phi/CEWG_Report_5_April_2012.pdf (last visited June 1, 2014).

[292] The decision which was adopted in May 2014 was proposed by France. *See* WHO document A67/B/CONF./2 Rev.1 available at http://apps.who.int/gb/ebwha/pdf_files/WHA67/A67_BCONF2Rev1-en.pdf (last visited June 1, 2014).

[293] *See World Health Assembly Closes: News Release*, WHO, (24 May 2014) available at http://www.who.int/mediacentre/news/releases/2014/WHA-20140524/en/ (last accessed 01/06/2014) (last visited June 1, 2014).

[294] *Id.*

[295] *Id.*

Illustratively, Roin argues that the current patent regime is sub-optimal in that it does not always protect worthy inventions built on considerable investment.[296] Despite noting that it is difficult to calculate the precise optimal length of exclusivity for drugs, he goes on to advocate a data exclusivity period of 10 to 14 years for all pharmaceutical innovations, hoping that this would mimic the period of patent protection.[297]

Another commentator (the lead author of this report) proposes a comprehensive investment protection regime that covers all investments in the making of a drug (right from the inception of the lead molecule to the last stages of the regulatory process) and helps recoup it through a compensatory liability mechanism.[298] Unlike patents and data exclusivity, which offer uniform periods of protection, the model rewards investments in a proportionate manner, wherein drug originators are entitled to protection against free riders only until such time as they recoup their specific investments and earn a rate of return on investment dependent *inter alia* on the health value of the drug. To this extent, much like the HIF, it encourages drugs that have a significant health impact.

The model advocates a compensatory liability framework, based in turn on a novel cost sharing methodology, where follow-on entrants are free to manufacture the drug, but must pay a reasonable amount of compensation to the

[296] Benjamin N. Roin, *Unpatentable Drugs and the Standards of Patentability* 87 TEX. L. REV. 503 (2009). The model focuses on those pharmaceutical inventions that miss out on patent protection (for reasons of failing to meet patent laws stringent threshold requirements) and therefore the aim is to grant them patent like protection.

[297] *Id. See also* Brian B. Eller, *Promoting Innovation in the Pharmaceutical Industry by Expanding the FDA's Regulatory Powers to Grant Market Exclusivity* (UC Davis Legal Studies Research Paper, 2010), http://ssrn.com/abstract=1790566 (arguing on similar lines in favour of orphan drug exclusivity for those molecules that may have lost out in terms of patent protection, but require significant investments for its development).

[298] *See* Basheer, *supra* note 251.

originator.[299]

E. The Open / Commons Model

In sharp contrast to the proprietary patent model, the commons model eschews exclusionary legal rights/norms.[300] The poster child for the commons model is the "Free and Open Sourced Software" (FOSS) movement. The benefits of this model include significant cost reduction for users,[301] the prospect of continuous follow-on development, and the participation of a wider set of contributors.[302]

This open/commons model has been adopted in the biotechnology and pharmaceuticals sectors as well.[303] Examples include the SNP consortium[304], the HapMap Project[305] and BiOS.[306]

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[299] *See* Basheer, *supra* note 251 at p.38.

[300] *See* John Cahir, *The Withering Away of Property: The Rise of the Internet Information Commons*, 24 OX. J. LEGAL STUDIES 4, 619-641 (2004).

[301] *See* Carla Michler, *The Procurement Decision-"Open" or "Closed" Source Software?*, 10 DEAKIN L. REV. 261 (2005).

[302] For e.g., Wikipedia, open to editing by any interested member of the public, now boasts of innumerable contributors who have shared their knowledge on almost every area of human knowledge despite having no financial incentive or even academic credit for doing so. *See* Andrew George, *Avoiding Tragedy in the Wiki- Commons* 2 (Working Paper, 2008), http://papers.ssrn.com/sol3/papers.cfm?abstract_id=975096 (last visited June 1, 2014).

[303] *See* Stephen M. Maurer et al., *Finding Cures for Tropical Diseases: Is Open Source the Answer?* (Dec, 2004), 1(3) PLOS MED.

[304] The SNP Consortium involved Britain's Wellcome Trust Foundation and 13 private firms paying scientists to discover genome data and place it in the public domain. *See* Gudmundur Thorisson and Lincoln Stein, *The SNP Consortium Website: Past, Present and Future* 31 NUCLEIC ACIDS RESEARCH 124 (2003).

[305] *See* Arti Rai, *Open and Collaborative" Research: A New Model for Biomedicine,* in INTELLECTUAL PROPERTY RIGHTS IN FRONTIER INDUSTRIES, (R. Hahn, ed., 2005).

[306] Biological Innovation for the Open Society (BiOS) attempts to promote 'new platforms for cooperative invention, improvement and delivery of biological technologies with a dynamic 'protected commons'. *See* Cambia, *The Cambia BIOS Initiative* (2004), available at http://www.BiOS.net/daisy/BiOS/10/version/live/part/4/data (last visited June 1, 2014).

Drawing on the above framework, the Indian government kick-started the Open Source Drug Discovery (hereinafter "OSDD") project some years ago (see table below).

Table 20: The OSDD Model:

This initiative by CSIR deploys an online social networking platform to leverage the expertise of scientists, students, researchers, academics and other interested experts to arrive at a potential cure for tuberculosis (TB).[307] Small tasks/questions, each with a small set of associated reward points, are posted on the online platform. Contributors who fulfill the tasks/answer the questions earn points.

Source: Open Source Drug Discovery, How does OSDD Work.[308]

Given the "open" and "free" nature of the technological platform, the price of any resulting drug is likely to be low.[309] However, one of the main drawbacks is the uncertainty involved in financing the costs of development. While the project had received government funding in the past,[310] there is no guarantee that this will continue till the completion of the project.[311]

[307] *See* Open Source Drug Discovery, *About Us*, *available at* http://www.osdd.net/about-us (last visited June 1, 2014).
[308] *http://www.osdd.net/how-does-osdd-work* (last visited June 1, 2014).
[309] *See* Open Source Drug Discovery, *What Is OSDD*, *available at* http://www.osdd.net/what-is-osdd (last visited June 1, 2014).
[310] *See* Nikita Mehta, *CSIR tuberculosis drug project enters Phase II clinical trials*, LIVEMINT (March 25, 2014) available at http://www.livemint.com/Politics/Xi6ZczdYOYDspvjdvfGn1M/CSIR-tuberculosis-drug-project-enters-Phase-II-clinical-tria.html (last visited June 1, 2014).
[311] The government has not released the expected funds for this year. *See* Thomas Vallianeth, *Spicyip Tidbit: Bureaucracy may cost the OSDD a Year of Funding*, SPICYIP, (April 3, 2014) available at http://spicyip.com/?p=11257 (last visited June 1, 2014).

A. Introducing Copyright

A copyright is an exclusive set of legal rights granted to the owner of an original work of creative expression to prevent others from copying the said expression. Any written scientific or research paper which is "original" (not copied from elsewhere) is amenable to copyright protection for a period of the authors' life plus 60 years in most countries, including India.[312] A copyright owner has the exclusive right to do a variety of acts in relation to her work, such as the exclusive right to publish, copy, distribute etc. Therefore, in order for a third party to copy or distribute a copyrighted work, permission from the copyright owner in the form of a licence must be sought.[313]

However, as with most other IP regimes, the purpose of the Copyright Act is not only to grant a private right to an author/producer but also to balance this private right against the larger public interest in accessing creative expressions. In keeping with this need for balance, a number of copyright regimes (including the Indian Copyright Act, 1957) provide for various public policy exceptions from copyright infringement. These exceptions include the right of the user to copy and distribute the work for certain purposes such as teaching, research, critique etc., as detailed below.[314]

B. Copyright and Public Health

[312] Section 22 of the Indian Copyright Act, 1957.
[313] *Id.*, section 30 of the Indian Copyright Act, 1957.
[314] *Id.*, section 52 of the Indian Copyright Act, 1957; *See infra* Part IV.C: Indian Copyright and Public Health.

As noted in Table 21 below, the academic publishing industry appears a healthy one, with a sizeable amount of scholarly journals, a significant rate of new articles each year and a robust revenue base.

Table 21: Academic Journal Statistics (2012)

No. of scholarly peer reviewed journals in the world- 28,100.
No. of articles published in a year – 1.8 to 1.9 million.
Rate of increase of number of articles published each year – 3% per year.
Annual revenues generated from English-language STM journal publishing – $9.4 billion (2011)

Source: The STM Report, An overview of scientific and scholarly journal publishing, 2012.[315]

Unfortunately, despite the increasing proliferation of scholarly literature, most of the content is inaccessible, due to the rapid ratcheting up of subscription fees. Illustratively, certain academic journals could cost up to $40,000 every year and the top two publishers have increased the price of their content by 145% over the last six years.[316] Even Harvard, as the university with the highest endowment in the United States, cannot sustain such expensive subscriptions and is looking to promote alternate open access models that facilitate better access to information.[317]

[315] *Available at http://www.stm-assoc.org/2012_12_11_STM_Report_2012.pdf* (Last visited on June 17, 2014).
[316] *See* Keith Wagstaff, *If Harvard Can't Afford Academic Journal Subscriptions, Maybe It's Time for an Open Access Model*, TIME, April 26, 2012, available at http://techland.time.com/2012/04/26/if-harvard-cant-afford-academic-journal-subscriptions-maybe-its-time-for-an-open-access-model/ (Last visited on June 17, 2014).
[317] *Id.* (Harvard's Faculty Advisory Council revealed that the school spends close to $3.75 million on academic journal subscriptions annually).

Evidently, a large amount of scientific and medical research and knowledge is unaffordable to developing countries. A typical research article in a medical journal costs $30 to $50 (and a subscription to that journal costs hundreds of dollars).[318] As against these costs, developing countries have meager health care budgets. Illustratively, the health expenditure (including private health expenditures) in Uganda is just $44 per person per year;[319] while in India, health expenditure is only $61 per person per year.[320] Still, each doctor would have to spend $50 to read just one article in a medical journal.

Access to expensive articles for practitioners in the developing world is a growing public health concern – as evidenced in this telling narration by Arthur Amman, President of Global Strategies for HIV Prevention.[321] (See Table 22 below)

Table 22

"I recently met a physician from southern Africa, engaged in perinatal HIV prevention, whose primary access to information was abstracts posted on the Internet. Based on a single abstract, they had altered their perinatal HIV prevention program from an effective therapy to one with lesser efficacy. Had they read the full text article they would have undoubtedly realized that the study results were based on short- term follow-up, a small pivotal group, incomplete data, and were unlikely to be applicable to their country situation. Their decision to alter treatment

[318] Gavin Yamey, *Open Access to Medical Literature Can Boost Global Public Health*, Virtual Mentor, July 2009 (Volume 11, Number 7: 546-550) (Last visited on June 17, 2014)..
[319] *See Health Expenditure per Capita (Current US$),* THE WORLD BANK available at http://data.worldbank.org/indicator/SH.XPD.PCAP (last visited on June 1, 2014).
[320] *Id.*
[321] Virginia Barbour, Paul Chinnock, Barbara Cohen, and Gavin Yamey, *The impact of open access upon public health*, available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2627358/(Last visited on June 17, 2014).

based solely on the abstract's conclusions may have resulted in increased perinatal HIV transmission."

- *Arthur Amman, President of Global Strategies for HIV Prevention*

Another incident recounted by James Tumwine, a professor of pediatrics at Makere University, Kampala, Uganda throws light on the manner in which prohibitive costs of research articles adversely impact public health.[322] The WHO asked Professor James to investigate a mysterious and unusual illness - 'nodding disease', in southern Sudan.[323] Unfortunately, due to the prohibitively high download costs of research articles, the crucial research articles he needed were completely out of his reach.[324]

In addition to excessive costs, restrictive copyright licensing terms also act as obstacles in improving public health in developing countries.[325] Most authors are required to assign their rights to academic publishers, who then impose very restrictive licensing conditions on users, making it illegal for users to reproduce, distribute or even translate articles to local languages.[326] Vital research that may be useful for doctors and researchers gets locked up due to these restrictive licence terms.[327]

Table 23: Statement by Hooman Momen of the WHO on the importance of access to information for the betterment of public health

"Health is perhaps the area of most intense demand for greater access to

[322] Gavin Yamey, *Open Access to Medical Literature Can Boost Global Public Health*, Virtual Mentor, July 2009 (Volume 11, Number 7: 546-550).
[323] *Id.* (The unusual disease gets its name from the fact that some affected children experience absence seizures after they eat so it seems as if they are nodding).
[324] *Id.*
[325] *Id.*
[326] *Id.*
[327] *Id.*

> *scientific and technical information, partly because failure to obtain it can be literally fatal".*
>
> - Hooman Momen of the WHO.[328]

Copyright norms play a key role in technological capacity building, as they determine the level of access to scientific learning. A remarkable example of capacity building as a result of increased access to literature is 19th century Germany. During this period, Germany did not have any copyright law, which meant that all works that were created (specially scientific and technological literature) were freely available and accessible. [329] Studies have attributed Germany's rapid industrial expansion in the 19th century to this absence of copyright law which resulted in the extensive proliferation of books and knowledge that is said to have set the foundation for the country's technological development.[330] Drawing from this example, it is imperative for India to evolve flexible copyright norms that permit access to valuable scientific/technological literature. [331]

[328] Momen H, *Equitable access to scientific and technical information for health*, Bull. World Health Organ, (2003) 81(10):700.

[329] Frank Thadeusz, No *Copyright Law: The Real Reason for Germany's Industrial Expansion?*, SPIEGEL ONLINE INTERNATIONAL, August 18, 2010, available at http://www.spiegel.de/international/zeitgeist/no-copyright-law-the-real-reason-for-germany-s-industrial-expansion-a-710976.html#spRedirectedFrom=www&referrrer=http://m.facebook.com/l.php?u=http%3A%2F%2Fwww.spiegel.de%2Finternational%2Fzeitgeist%2Fno-copyright-law-the-real-reason-for-germany-s-industrial-expansion-a-710976.html&h=3AQFRL9I_&s=1&enc=AZMm9n4gsqvJBSWPmZ5PJsLKKiIzVhmqOA20VltPc63fVelrf1CrkWNMQS3BQJxTeq2F47GAo2PZWfioH-HZvpah (Last visited on June 29, 2014)

[330] *Id.*

[331] *See generally, Capacity Building In Science And Technology (Draft partnership proposal endorsed by participants in the Synthesis Workshop on Science and Technology for Sustainable Development)*, Mexico, 2002, http://www.hks.harvard.edu/sustsci/ists/synthesis02/output/capacity-bldg-st_proposal_draft.pdf (Last visited on June 17, 2014).

In addition to rigid copyright norms, a growing concern for public health has been the recent attempt to appropriate traditional healing techniques, such as yoga and pranic healing, through copyright law.

make a table here for this

The Hot Yoga Case

Bikram Choudhury, a US yoga instructor, claimed copyright over a compilation of twenty six yoga asanas performed in a hot environment (owing to which this was popularly called "hot yoga")[332] The court, however, denied his claim and held that yoga sequences are not copyrightable.[333] The court reasoned as below:

i) the yoga sequence in question was nothing but a collection of existing asanas and was similar to a mere collection of facts/ideas, which are not copyrightable.[334]

ii) Since the sequence was a mere compilation of simple physical movements it failed to reach the level of a 'choreographic work'.[335]

iii) Thirdly, since the yoga sequence had a 'functional aspect' i.e. ability to cure and alleviate diseases, it was a 'system or a process' and not a copyrightable subject matter.[336]

The Pranic Healing Case (make a table here as well)

More recently, the Delhi High Court dismissed a copyright claim over 'pranic healing' techniques in the *Institute for Inner Studies & Ors vs Charlotte Anderson &*

[332] Bikram Choudhury and Ors. v. Evolation Yoga, 2012 WL 6548505 (C.D.Cal.). See also Shamnad Basheer, *Stretching The Wrong Way!! Metaphysical Musings On The Yoga–Patent Controversy*, SpicyIP, May 31, 2007, available at http://spicyip.com/2007/05/stretching-wrong-way-metaphysical.html (Last visited June 29, 2014).copyrightability of 'hot yoga'.

[333] *Id.*

[334] *Id.*

[335] *Id.*

[336] *Id.*

Ors.[337] The court categorically held that copyright cannot subsist over techniques of pranic healing as they have been in the public domain for centuries.[338]

C. Indian copyright law and public health

As noted earlier, the Indian Copyright Act does not grant an absolute monopoly to copyright owners, but limits their exclusive rights in order to further public interest. These limitations (in the form of copyright exceptions) allow users to use and reproduce copyrighted works without obtaining a licence/permission from the owner of the copyright. Some of the key exceptions that foster access to scientific literature are highlighted below:

C. 1. Section 52(1) (a):

Under this exception, any member of the public may use a copyrighted work (such as an academic article) in a fair manner, for private use, including research as well as for criticism or review.

C.2. Section 52 (1) (i):

This exception allows the reproduction of any copyrighted material by a teacher or pupil in the course of instruction. It is now at the centre of a legal controversy after publishers slapped a lawsuit against Delhi University and its photocopy

[337] CS(OS) 2252/2011, Delhi High Court, available at http://lobis.nic.in/dhc/MAN/judgement/13-01-2014/MAN10012014S22522011.pdf (Last visited on June 29, 2014).

[338] The court noted that such protection cannot be granted since doing so "*would be giving the monopoly right to the art or technique itself which is available in public domain from time immemorial..*" *Id*, para 98.

shop[339] for allegedly infringing their copyrights by including extracts of their books in course-packs used by students.[340] The University claims (as does a group of academics and students who've impleaded themselves in this litigation) that the photocopying of extracts of books to create course-packs, in accordance with a carefully crafted course outline, is covered under the section 52(1)(i) exception.[341]A decision from the Delhi high court is awaited.

This case is symbolic of the serious access concerns plaguing India. Photocopies are indispensable to Indian students who find it impossible to access prohibitively priced textbooks.[342] For instance, as of June 12th, 2014, the famous '*Harrison's Principles of Internal Medicine*' was priced at Rs. 7,062 and '*Baley and Love's Short Practice of Surgery*' sold for Rs. 9,751 on Amazon.in (a popular online book store).[343] In such cases, photocopies are the only affordable substitutes for students to learn and write research papers.

Both clauses (a)[344] and (i)[345] of Section 52 of the Indian Copyright Act, 1957 form the bedrock of access to knowledge in India. These provisions enable medical practitioners to not only learn about existing research but also to contribute to the existing body of knowledge through critique and reviews, thereby advancing

[339] *See* Shamnad Basheer, *Why Students Need the Right to Copy*, The Hindu, April 26, 2013, available at http://www.thehindu.com/opinion/op-ed/why-students-need-the-right-to-copy/article4654452.ece (Last visited on June 17, 2014).
[340] *Id*.
[341] *Id*;
[342] National Council for Applied Economic Research, *The Impact of Parallel Imports of Books, Films / Music and Software on the Indian Economy with Special Reference to Students*, January 2014, available at http://copyright.gov.in/Documents/Parallel_Imports_Report.pdf (Last visited on June 17, 2014); Shamnad Basheer, Debanshu Khettry, Shambo Nandi, Shree Mitra, *Exhausting Copyrights and Promoting Access to Education: An Empirical Take*, 17(4) JIPR 2012.
[343] *See* webpages - http://www.amazon.in/Bailey-Loves-Short-Practice-Surgery/dp/1444121278; http://www.amazon.in/Harrisons-Principles-Internal-Medicine-2/dp/0071748873?tag=googinhydr17831-21 (Last visited on June 17, 2014).
[344] Section 52(1)(a), Copyright Act, 1957 (this clause allows the private use, in a fair manner, of a copyrighted work for purposes such as research, review, criticism).
[345] Section 52(1)(i), Copyright Act, 1957 (this clause allows reproduction of copyrighted material by a teacher or pupil in the course of instruction).

medical research and public health in India. Indian courts have, in the past, interpreted these copyright exceptions fairly liberally, especially with regard to the educational exceptions e.g. creating guidebooks.[346]

C.3. Section 52(1)(zb):

The exception is one of the widest in the world, and permits the conversion of any copyrighted work to an accessible format, so long as the converter operates on a non-profit basis and ensures that such formats are accessed only by persons with disabilities.[347] This exception aims at redressing the "book famine" wherein the vast majority of books are unavailable in accessible formats to persons with disabilities (particularly the visually impaired). India also recently signed an international instrument in this regard making it easier to import and export works in accessible formats for the disabled.[348]

C.4. Section 52(1)(j):

This sub-clause deals with the performance of literary, dramatic, musical works and sound recordings and cinematograph films to an audience limited to staff, students, parents, guardians and persons directly connected with the activities of the educational institution.

C.5. Section 52(1)(h):

[346] *Chancellor Masters of Oxford v. Narendra Publishing House,* 2008 (38). PTC 385 (Del).
[347] If the converter charges for access to such converted works, then it must pay a reasonable royalty to the copyright owner. *See* Rahul Cherian Jacob, Sam Taraporevala & Shamnad Basheer, *The disability exception and the Triumph of new rights advocacy*, 5(4) NUJS L. Rev. 2013.
[348] Marrakesh Treaty to Facilitate Access to Published Works by Visually Impaired Persons and Persons with Print Disabilities (signed in Marrakesh, Morocco, on 28 June 2013).

This exception permits publication of copyrighted works in a collection of essentially non-copyrighted matter for use in educational institutions. [349]

C.6. Section 52(1)(o):

Commonly labeled as the 'library exception', this exception allows non-commercial public libraries to make not more than three copies of a book for the use of the library. However, this exception is triggered only when the book is not available for sale in India.

C.7. Section 52(1)(m):

This exception allows the reproduction (unless the author has expressly reserved this right to himself) of copyrighted works in a newspaper or magazine, if the research is related to current social, economic, political or religious topics. One might argue that certain aspects of public health/medical advances could potentially fall within the ambit of an important 'social' development.

C.8. Compulsory Licences:

Much like patent law, copyright law also provides for compulsory licensing in instances where the IP owner is at odds with the interests of the general public. Illustratively, section 31 of the Act allows a third party to file a complaint with the Copyright Board if a work has been withheld from public. The Copyright Board can then force the copyright owner to license the work to a third party who then publishes it and makes it available to the public. Additionally, section 31A of the Act enables a third party to apply for a licence in respect of an 'orphan

[349] *See* Lawrence Liang, *Exceptions and Limitations in Indian Copyright Law for Education: An Assessment*, 3(2) The Law and Development Review (2010).

work'.[350] Orphan works are copyrighted works whose owners cannot be traced thereby making them eligible for reproduction and dissemination by third parts on payment of fees to the government.[351] Very often publishers may cave in to pressure from various interest groups, and refuse to republish books, resulting in a lack of access for the general public.[352] In all such cases, the compulsory license provision can be invoked. Unfortunately, a Copyright Board has not yet been constituted in India and a writ petition seeking its creation is pending before the Delhi High Court.[353]

C. 9. Parallel Imports

Much like patents, the issue of parallel imports has been a controversial one even in copyright law, particularly in relation to educational books.[354] Parallel imports are premised on the notion of price arbitrage, where traders take advantage of the price difference of books in two countries.

Publishers/copyright owners oppose parallel imports of books, since it threatens their unilateral ability to regulate prices in individual markets.[355] Users on the other hand, benefit from such a provision as it enables a free flow of books across borders, thereby ensuring lower prices as well as access to the latest editions.[356]

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[350] Shamnad Basheer, *From Ambedkar to Doniger: Can copyright law rescue books at risk*, Firstpost, March 28, 2014, available at http://www.firstpost.com/living/from-ambedkar-to-doniger-can-copyright-law-rescue-books-at-risk-1454655.html (Last visited on June 17, 2014).

[351] *Id*.

[352] *Id*; Alison Flood, *Penguin's withdrawal of The Hindus causes international outcry*, The Guardian, February 13, 2014, available at http://www.theguardian.com/books/2014/feb/13/penguin-withdrawal-hindus-arundhati-roy-neil-gaiman (Last visited on June 17, 2014).

[353] *Id*.

[354] Shamnad Basheer, *Govt for legalising parallel import of copyright works; publishers oppose*, THE ECONOMIC TIMES, March 17, 2011, available at http://economictimes.indiatimes.com/opinion/policy/govt-for-legalising-parallel-import-of-copyright-works-publishers-oppose/articleshow/7723572.cms (Last visited June 29, 2014).

[355] CE Barfield and MA Groombridge,*The Economic Case for Copyright Owner Control over Parallel Imports* (1998) 1(6) JWIP 903

[356] Pranesh Prakash, *Exhaustion: Imports, Exports, and the Doctrine of First Sale in Indian Copyright Law* (2012) 4 NUJS L Rev 635, available at

Scholars and commentators continue to debate on whether or not parallel imports of copyrighted works are legal under Indian law. Some years ago, the government attempted to introduce a specific amendment to the Copyright Act to make clear that parallel imports were legal .[357] Despite such a provision receiving wholehearted support from a Parliamentary Standing Committee tasked with reviewing the copyright amendments, the government did a volte face and withdrew the proposed amendment.

Owing to the controversy that erupted from the sudden turn around, the government appointed a committee to suggest whether or not a specific provision for legalising parallel imports ought to be introduced.[358] The committee's report adequately considered views of all important stakeholders [359] However the committee did not make any strong recommendation either way. Rather it proferred what appears to be a compromise solution noting:

"A cautious opening may be a good way to start. Acrimonious debate must give way to harmonious meetings between producers, consumers and other stakeholders. It is only through mutual understanding and healthy exchange of views that we can come to

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http://www.nujslawreview.org/pdf/articles/2012_3/06_pranesh.pdf (Last visited on June 29, 2014).

[357] *See* Shamnad Basheer, *Parallel Imports: The Unexpected Dumping of Section 2(m)*, SpicyIP, September 4, 2011, available at http://spicyip.com/2011/09/parallel-imports-unexpected-dumping-of.html (Last visited July 17, 2014); Section 2(m), The Copyright (Amendment) Bill 2010. (The amendment proposed to add a proviso to section 2(m) which read: 'Provided that a copy of a work published in any country outside India with the permission of the author of the work and imported from that country shall not be deemed to be an infringing copy.' However, this proposal was withdrawn.)

[358] *See Did Sibal just get arm-twisted by book publishers?*, FIRSTPOST, May 25, 2012, available at http://www.firstpost.com/india/did-sibal-just-get-arm-twisted-by-book-publishers-321144.html (Last visited on June 28, 2014)

[359] National Council for Applied Economic Research, *The Impact of Parallel Imports of Books, Films / Music and Software on the Indian Economy with Special Reference to Students*, January 2014, available at http://copyright.gov.in/Documents/Parallel_Imports_Report.pdf; See Aparajita Lath, *NCAER Report on Parallel Imports OUT!*, SPICYIP, March 6, 2014, available at http://spicyip.com/2014/03/ncaer-report-on-parallel-imports-out.html (Last visited on June 29, 2014).

an optimal solution. If such a meaningful exchange is not feasible, we suggest going ahead to add the new proviso to Clause 2(m) with the requisite safety valves. India must learn to manage its affairs with its own logic and on its own terms."[360]

This history arguably suggests that barring an express exception (which did not come to pass), parallel imports are not legal in India. However, some commentators argue that a careful reading of the provisions of the Copyright Act suggests that parallel imports are legal, even despite the unfortunate Parliamentary history recounted above.[361]

It is interesting to note that in a recent decision, the US Supreme Court endorsed the concept of international exhaustion and supported parallel imports of copyright works.[362]

Since high prices and old editions are major obstacles to scientific and medical learning in India, legalizing parallel imports will go a long way in increasing access to knowledge and public health.

D. Interpreting exceptions:

The Canadian Supreme Court, characterized copyright exceptions (most notably 'fair dealing' provisions) as a 'user's rights' and not merely as 'limitations or exceptions' to copyright.[363] In pertinent part, they noted:

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[360] *Id.*

[361] Pranesh Prakash, *Exhaustion: Imports, Exports, and the Doctrine of First Sale in Indian Copyright Law* (2012) 4 NUJS L Rev 635, available at http://www.nujslawreview.org/pdf/articles/2012_3/06_pranesh.pdf (Last visited on June 29, 2014).

[362] *Kirtsaeng v. John Wiley and Sons*, March 2013, US Supreme Court.

[363] *CCH Canadian Ltd. v. Law Society of Upper Canada*, [2004] 1 SCR 339.

> *"The fair dealing exception, like other exceptions in the Copyright Act, is a user's right. In order to maintain the proper balance between the rights of a copyright owner and users' interests, it must not be interpreted restrictively."* (para 48)

This paradigm shift ensures that what were hitherto understood as narrow copyright exceptions are now construed as entitlements and interpreted broadly. Another milestone for the Access to Knowledge movement is the recent victory of the Google Books Library Project,[364] wherein a US court held the activities of scanning books, and providing a searchable summary online falls within "fair use".[365] Similarly, HathiTrust Digital Library, which scans and creates a searchable index that displays whether or not a search term is present in a (copyrighted) book, was found not to have violated authors' copyright protections as it is protected by "fair use".[366]

One hopes that the Indian courts will pick up on these comparative developments and usher in a meaningful set of user rights for India.

E. Open / Commons Model:

Given the various restrictions around access to knowledge posed by current copyright laws, two alternative models have been emerging. One is the creative commons model and the other is the open access model.

The creative commons model is not exactly an alternative model, since it works within the confines of the current copyright framework. However, it has

[364] *Authors Guild v. Google (Google Books),* United States District Court, Southern District of New York, 2013.
[365] *Id*.
[366] *Authors Guild v. HathiTrust,* 2d Cir. (June 10, 2014).

tremendous potential for unlocking a number of copyrighted works for easy access and is therefore discussed here.

E.1. Creative Commons Model

As per the current copyright regime, in most countries including India, for every use of a work (which is not exempt under one or more of the copyright exceptions) permission must be obtained from the copyright owner. Since 'all rights are reserved' with the creator, use and access to works is limited. More problematically, it is often difficult and time consuming to locate the owner of a copyrighted work and secure permission.

The Creative Commons model effectuates a paradigm shift by changing the default norms from an 'all rights reserved' model to 'some rights reserved' model.[367] In doing so, this model enables authors to choose the rights they reserve and the ones they waive.[368] This way, though copyright is retained, authors can choose which restrictions they wish to reserve potentially freeing up users to re-use, re-mix and re-distribute copyrighted works with appropriate attribution.[369]

[367] *See* Creative Commons - http://creativecommons.org/.
[368] *Id*.
[369] *Id*.

Table 24: Examples of Organizations that use Creative Commons Licences

- The Public Library of Science (PLoS) and BioMed Central. PLoS publishes seven scientific journals all of which are under CC licences, which includes *PLoS Medicine* and *PLoS Biology*.
- In India, a significant example is Pratham Books, a non-profit children's book publishing house.

E.2. Open Access Model

The open access model ensures that copyrighted works are largely available free of charge and free from restrictions for users. It, therefore, removes 'price barriers' (subscription fees, licensing fees etc.) as well as 'permission barriers' (copyright restrictions).[370] As such, it has tremendous potential for the proliferation of valuable cultural, social and technical knowledge.[371]

The Berlin Declaration on Open Access to Knowledge in the Sciences and Humanities, which emerged in 2003, is a significant international statement on open access. (See table 25 below)

Table 25

"*For a work to be open access, the copyright holder must consent in advance*

[370] *See Open Access Overview*, available at http://legacy.earlham.edu/~peters/fos/overview.htm (Last visited on June 17, 2014).

[371]Historically, the absence of copyright protection in some countries (and the presence of a de facto open access model) arguably resulted in rapid knowledge proliferation and industrial growth. *See* Frank Thadeusz, *No Copyright Law: The Real Reason for Germany's Industrial Expansion?* available at http://www.spiegel.de/international/zeitgeist/no-copyright-law-the-real-reason-for-germany-s-industrial-expansion-a-710976.html.

> *to let users copy, use, distribute, transmit and display the work publicly and to make and distribute derivative works, in any digital medium for any responsible purpose, subject to proper attribution of authorship....*"

Source: The Berlin Declaration on Open Access to Knowledge in the Sciences and Humanities 2003.

In the spirit of 'open access', several universities worldwide, such as Harvard University Faculty of Arts and Sciences and the University of Zurich, Switzerland, have also begun to mandate that their faculty put a copy of all articles they publish into a freely available repository.[372]

The Indian government is also pushing open access models for educational material. To this end, the Ministry of Human Resources and Development launched the National Repository of Open Educational Resources (NROER), in 2013.[373] The NROER is a free online repository of the National Council of Educational Research and Training (NCERT) courseware. It houses open-licensed school textbooks and other educational content developed and published by the government-funded NCERT.[374] Though aimed at students from class 1 to 12, this is a step in the right direction. Such a model could be used to build a stronger and wider web of information for medical students, faculty and doctors.

From a legal/policy perspective, it is important to note that the US law now mandates that publicly funded research be made available for free. The passage of the Omnibus Appropriations Bill, 2014 is a watershed event for the Open

[372]Gavin Yamey, *Open Access to Medical Literature Can Boost Global Public Health*, Virtual Mentor, July 2009 (Volume 11, Number 7: 546-550).

[373] Available at http://nroer.in/home/.

[374] *See* Rohini Lakshane, *Widening Access to Educational Resources*, Economic and Political Weekly, September 14, 2013 (Vol - XLVIII No. 37).

Access movement.[375] The law now requires federal agencies with research budgets of $100 million or more to provide the public with free online access to articles that flow out of federally funded research,[376] no later than 12 months after publication of the same in a peer-reviewed journal.[377] This law builds and expands on the National Institute of Health's Public Access Policy, 2008, which had similar provisions.[378]

Table 27: Examples from other Countries

In 2013, Argentina passed a law (No. 26.899, Creating Institutional Open Access Digital Repositories, Owned or Shared) that made publically funded science and technology research open access.[379] The European Organization for Nuclear Research (CERN) announced that it would commence its open access initiative (Sponsoring Consortium for Open Access Publishing in Particle Physics) from January 1, 2014. This is claimed to be the largest scientific open access initiative.[380]

India would do well to follow such an initiative. Unfortunately, a bill that sought to deal with publicly funded research was flush with erroneous assumptions and

[375] Timothy Vollmer, *Congress passes spending bill requiring free access to publicly funded research*, Creative Commons, January 16, 2014, available at http://creativecommons.org/weblog/entry/41802; *PLOS Applauds Congress for Action on Open Access*, PLOS, January 17, 2014, available at http://www.plos.org/plos-applauds-congress-for-action-on-open-access/ (Last visited on June 17, 2014).
[376] *Id*.
[377] *Id*.
[378] *Id*.

[379] *IP Watch - http://www.ip-watch.org/2013/12/16/argentina-passes-open-access-act-making-publicly-funded-research-available/* (Last visited on June 17, 2014).
[380] *CERN press release- http://home.web.cern.ch/about/updates/2013/12/open-access-publishing-initiative-start-2014* (Last visited on June 17, 2014).

never saw the light of day.[381] After a rigorous parliamentary committee hearing, the committee sent the bill back to the government to re-examine and re-draft. Thus far, the government has not come back with a revised version.[382]

[381] Shamnad Basheer, *The Indian Bayh Dole Bill: A Critique and Some Suggestions*, SpicyIP, January 27, 2010, available at http://spicyip.com/2010/01/indian-bayh-dole-bill-critique-and-some.html (Last visited on June 17, 2014).

[382] C.H. Unnikrishnan, *Parliament panel wants govt review on Innovation Bill*, Mint, February 09 2010, available at http://www.livemint.com/Politics/y24CUvJ1ppJEDfSeHHuHEN/Parliament-panel-wants-govt-review-on-Innovation-Bill.html (Last visited on June 17, 2014).

A. Introduction and Legal Framework

In the debates around intellectual property and public health, the trademark - public health interface has not merited much attention. By way of introduction, trademarks are words, symbols, phrases, colours, and more recently, shapes and smells of products that help consumers identify the origin of a particular product or service. Popular trademarks include Nike, Coca Cola or Toyota, each signifying their respective corporate houses and embodying the massive reputation that they have built over time.

In order to be registered as a trademark, national trademark laws spell out certain pre-requisites such as the requirement that a mark be distinctive.[383] Once registered, a trademark owner has the right to prevent a competitor from using the said mark (or a confusingly similar variant) on similar goods/services. In most cases, trademark rights are territorial in nature i.e. rights are often localised to the country or jurisdiction where they have either been registered or are in use.

In India, trademarks are registered with the office of the Registrar for Trademarks.[384] A registration operates as *prima facie* validity of a trademark.[385] Unlike most other species of intellectual property rights, trademarks effectively confer perpetual protection, so long as they are renewed and continue to function as distinctive source identifiers.[386] The Madrid Protocol attempts to

[383] *See Trademark Basics – A Guide for Businesses,* International Trademark Association, p. 7 accessible at http://www.inta.org/Media/Documents/2012_TMBasicsBusiness.pdf.
[384] Sections 3, 5 and 6 of The Trade Marks Act, 1999 [Hereinafter "TM Act"].
[385] Section 31 of the TM Act.
[386] A registered trademark also needs to be renewed every ten years as per section 25(1) of the TM Act.

internationalise the trademark regime to some extent by allowing the filing of a single "international application" in various countries, subject however to each jurisdiction approving the mark.

Apart from a registered system of trademarks outlined above, some countries such as India and the US[387] also protect unregistered trademarks through the common law remedy of passing off. In this kind of proceeding, the trademark owner must establish that the mark has a reputation and has acquired distinctiveness through use.

The trademark - public health interface plays out very significantly in the area of pharmaceutical drugs, as detailed below:[388]

B. Trademarking Drugs

Pharmaceutical names can be broken down into three categories:

i) A generic name or an International Non-Proprietary Name ("INN")[389]
ii) An IUPAC name or a chemical name.[390]
iii) A brand name or a proprietary name

Illustratively, consider the various names of the commonly used drug "Paracetamol" in table 28 below:

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[387] *Trademark Registration,* International Trademark Association, available at http://www.inta.org/TrademarkBasics/FactSheets/Pages/TrademarkRegistrationFactSheet.aspx (Last visited on June 17, 2014).

[388] While the interface also plays out in other areas of public health such as tobacco consumption, we restrict our report and this analysis to drugs.

[389] *See Guidance on INN*, WORLD HEALTH ORGANIZATION, available at http://www.who.int/medicines/services/inn/innquidance/en/index.html. (last visited May 26, 2014)

[390] Carlos Rados, *Drug Name Confusion: Preventing Medication Errors*, FDA CONSUMER MAG., July-Aug. 2005.

Table 28: The Many Faces of Paracetamol

- The generic name or INN of the molecule: Paracetamol
- The IUPAC name: N-(4-hydroxyphenyl) acetamide
- The brand names (sold by different drug majors): Tylenol®, Crocin etc

In jurisdictions such as the US, registering drug names as trademarks is subject to regulatory supervision.[391] Apart from the regular trademark registration process (overseen by the Patent and Trademark Office),[392] the Food and Drug Administration (FDA) checks to see if the name could potentially lead to a prescription or dispensation error.[393] Unfortunately, despite these safeguards,[394] it is estimated that one in every ten medication related errors is caused due to

[391] For example, in the United States, the DMEPA, a division of the FDA reviews drug trademarks before and after they have been selected. The review criteria includes considerations as to whether a drug name will be confusing for consumers, physicians, pharmacists, and nurses; whether they suggest potentially exaggerated efficacy claims, and the avoidance of terms that imply a unique effectiveness among others. *See* Dana M. Herberholz, *Curing Confusion: An Overview of the Regulatory Complexities of Obtaining Pharmaceutical Trademarks and a Prescription for Reform*, 8(1) MINN. J.L. SCI. & TECH. 97 (2006).

[392] Prior to granting registration, the PTO checks to see if the proposed mark is confusingly similar to an earlier mark, an analysis that takes into account factors such as the similarity in names (phonetic or otherwise), the market in which the product is to be sold, the appearance and sound of other marks, the relevant consumer base and the like.

[393] Herberholz D. *Curing Confusion: An Overview of the Regulatory Complexities of Obtaining Pharmaceutical Trademarks and a Prescription for Reform,* MINN. J.L. SCI. & TECH. 2006;8(1):97-126, at 111. Europe has a similar mechanism. *See generally, Guideline on the Acceptability of Names for Human Medicinal Products Processed Through The Centralised Procedure*, EUROPEAN MEDICINES AGENCY, CPMP/328/98, Revision 5 (Dec. 11, 2007), http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004142.pdf (Last visited on June 17, 2014).

[394] In the EU, the corresponding agency is the European Medicines Agency or the EMA which operates on the same principles as its counterpart in the US. For a general discussion on regulatory approaches in various countries regarding trademarks and drug names, *see Increased Regulation of Pharmaceutical Trademarks*, NORTON ROSE FULBRIGHT (June 2013), http://www.nortonrosefulbright.com/files/increased-regulation-of-pharmaceutical-trademarks-pdf-102024.pdf; Only about 66% of the proposed names are approved by the DMEPA and about 53% by the NRG working under the EMA.

incorrect prescription/dispensation of similar sounding drugs.[395] Consider the example of a woman who was hospitalised and consumed the prostate drug FLOMAX®, believing it to be VOLMAX®, a drug to treat bronchospasms.[396]

In developing countries such as India, rife with issues of illiteracy, poverty and poor healthcare facilities, the rate and scope for confusion in medicines is even higher. The courts have therefore taken a stricter view of pharmaceutical trademarks when compared with other trademarks. In *Cadila Health Care Ltd. v. Cadila Pharmaceuticals Ltd,*[397] the Supreme Court of India stated that drug names must be such as to not confuse a person of average intelligence and imperfect recollection. The court cautioned that a stricter standard must prevail in cases where the drug was sold in rural markets to patient populations who were often illiterate and unable to discern between medicines with similar sounding names.

B.1 The INN system

While branded names can be registered as trademarks, entitling them to exclusive rights, pharmaceutical substances are also assigned an INN or International Non-Proprietary Name, which allows easy identification of the particular drug across the world by doctors and patients alike.

Unlike proprietary trademarks, an INN is public property and can be used by anyone to identify the particular active ingredient.[398] The WHO maintains a

[395] Carlos Rados, *Drug Name Confusion: Preventing Medication Errors*, FDA CONSUMER MAG., July-Aug. 2005, at 35.
[396] *Id.*
[397] 2001 (21) PTC 300 (SC) (Supreme Court of India).
[398] Debra A. Shelinsky Greene et. al., *The Importance of Pharmaceutical Trademarks in Protecting Public Health*, INTERNATIONAL TRADEMARK ASSOCIATION (April, 2007), http://www.inta.org/Advocacy/Documents/INTAPharmaceuticalTrademarksPublicHealth2007.pdf; *Guidance on INN*, WORLD HEALTH ORGANIZATION,

system of INN in keeping with its mandate to "develop, establish and promote international standards with respect to biological, pharmaceutical and similar products".[399] The process of creating an INN is shown in table 29 below.

Table 29: Creating an INN[400]

- A proposal is made by the manufacturer to the WHO that a certain name be considered an INN
- If convinced that the proposed name does not conflict with existing trademarks and INNs, the WHO refers this to a group of experts called the INN Expert Group who then decide on what the appropriate INN should be.
- The INN is then published and a four-month period is granted for objections. If there are none, the INN is published by the WHO in a periodical titled "WHO Drug Information".

Source: WHO, Guidelines on the Use of International Nonproprietary Names (INNs) for Pharmaceutical Substances, 2 World Health Organization (1997).

An important feature of the INN system is that the names of pharmacologically related substances are connected through a common "stem". By the use of such stems, all parties dealing with pharmaceutical products (pharmacist, physician etc) are able to recognize that the substance belongs to a group of substances having similar pharmacological activity.[401]

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http://www.who.int/medicines/services/inn/innquidance/en/index.html (Last visited on June 17, 2014).

[399] WIPO-WHO-WTO Trilateral Study, *Promoting Access to Medical Technologies and Innovation: Intersections between public health, intellectual property and trade* (2012) at 69, available at http://www.who.int/phi/implementation/trilateral_cooperation/en/ (Last visited on June 17, 2014).

[400] The flowchart is available at http://www.who.int/medicines/services/inn/inn_b_proc_simplified_Nov2005.jpg?ua=1 (Last visited on June 17, 2014).

[401] *Supra* note 352, at 69.

The Indian Trademarks Act of 1999 prohibits the registration of any name, declared as an INN by the WHO or one that is deceptively similar to such a name.[402] Pursuant to this, the Controller General of Patents and Trademarks published a list of WHO approved INN's.[403]

INNs are extremely beneficial, in that they help consumers and doctors identify the most cost effective medicine for a certain ailment. However, drug companies prefer brand names and advertise them aggressively. Mainstream media also often refers to these drugs by their proprietary rather than generic names.[404] Given this state of affairs, ordinary consumers are often not able to identify cheaper generic alternatives to brand name versions. There is therefore a pressing need to publicize INNs and to develop a system where generic names are displayed prominently on pharmaceutical packaging.

Some years ago, the government sought to create public pharmacies to sell only unbranded generic drugs.[405] This was implemented in 2008, in the form of the Jan Aushadi scheme launched by the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers. Under this scheme, generic stores run by NGOs, Institutions, Co-operative societies etc., were opened to sell generic drugs at a

[402] Section 13(b) of the TM Act.
[403] Prashant Reddy, *India Finally Publishes a List of International Non-proprietary Names (INNs) for Pharma-trademarks!,* SPICYIP (February 8, 2012), available at http://spicyip.com/2012/02/india-finally-publishes-list-of.html (last visited June 11, 2014)
[404] For a brief discussion on this, *see* Prashant Reddy, *Whats in a proprietary drug name? Apparently quite a lot!,* SPICY IP (October. 9, 2008), available at http://spicyip.com/2008/10/whats-in-proprietary-drug-name.html (last visited May 26, 2014).
[405] *Id*.

fraction of their market cost.[406] Unfortunately, this scheme has not met with much success.[407]

There is an additional advantage of using INNs. A disclosure of the INN at the time of filing a patent for the active pharmaceutical ingredient could trigger the attention of the patent office to then examine whether or not the claimed substances is effectively an "evergreened variety" of an already existing substance. In fact, the Indian government did consider a proposal to make it mandatory for drug companies to disclose the INN of the active ingredient that they were filing a patent for.[408] However, this was met with stiff resistance from the pharmaceutical industry.

C. Trademarks and Illicit Drugs

A number of national governments and international agencies including the WHO have taken various measures to combat trafficking in "drugs" that are referred to variously as "counterfeits", "spurious", "sub-standard" and "falsified".[409] Needless to state, the nomenclature itself has fuelled a large part of the controversy.

It bears noting that the TRIPS Agreement defines the term "counterfeit" thus:

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[406] A representative comparison of the price differences can be found at http://pib.nic.in/newsite/erelease.aspx?relid=61113.(Last visited on June 17, 2014). They indicate a scenario where medicines sold in the regular market cost 6 times (on an average) the price of the generic drugs sold at these stores.

[407] 2 of 3 Jan Aushadhi stores in city apply for closure, THE INDIAN EXPRESS, June 5, 2013, http://archive.indianexpress.com/news/2-of-3-jan-aushadhi-stores-in-city-apply-for-closure/1125187/(Last visited on June 17, 2014).

[408] For the advantages and disadvantages of such a proposal, *see* L. Gopika Murthy, *The INN Proposal: Boon Or Bane?*, SPICY IP (December. 3, 2013) available at http://spicyip.com/2013/12/the-inn-proposal-boon-or-bane.html (last visited May 26, 2014).

[409] WHO member states appear to now use the term "substandard/spurious/falsely-labeled/falsified/counterfeit medical products" (SSFFC).

> "Counterfeit trademark goods" shall mean any goods, including packaging, bearing without authorization a trademark which is identical to the trademark validly registered in respect of such goods, or which cannot be distinguished in its essential aspects from such a trademark, and which thereby infringes the rights of the owner of the trademark in question.[410]

Under this definition, a high quality generic drug that infringes the trademark of an innovator drug will count as a "counterfeit". Needless to state, this is problematic from a public health perspective.[411] Therefore, it is important to restrict the term "counterfeit" to its IP-related definition (a drug that infringes upon a registered trademark),[412] and use another term to refer to drugs that fail to comply with regulatory standards of the country of manufacture/trade i.e. falsely labelled, falsified, sub-standard,[413] adulterated, lacking an active ingredient etc.[414] We propose the use of the term "illicit medicines" to refer to this category of problematic drugs.

In short, from a public health perspective, it may help to keep the IP dimension out and refrain from using the term counterfeit.[415] Rather the term "illicit

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[410] Agreement on Trade-Related Aspects of Intellectual Property Rights, 1869 U.N.T.S. 299, art. 51.
[411] Leena Menghaney, Counterfeit' confusion diverts action from drug quality. SciDevNet, available at http://www.scidev.net/global/health/opinion/-counterfeit-confusion-diverts-action-from-drug-quality-1.html
[412] Amir Attaran et. al., *How to Achieve International Action on Falsified and Substandard Medicines,* BMJ 2012;345:e731.
[413] Substandard drugs are defined by the WHO to be "genuine medicines produced by manufacturers authorized by the NMRA [National Medical Regulatory Authority] which do not meet quality specifications set for them by national standards" *see* http://www.who.int/medicines/services/counterfeit/faqs/06/en *as cited in* Charles Clift, *Combating Counterfeit, Falsified and Substandard Medicines: Defining the Way Forward*, Centre on Global Health Security, November2010, GHBP2010/01.
[414] *Id.*
[415] Amir Attaran et. al., *How to Achieve International Action on Falsified and Substandard Medicines,* BMJ 2012;345:e731; Shamnad Basheer, *Saying No to the Wrong Drugs,* THE INDIAN EXPRESS,

medicines" could capture the regulatory/public health dimensions that are sought to be addressed by public health agencies as they seek to ensure patient safety.[416]

September. 24, 2009, available at http://archive.indianexpress.com/story-print/520860 (last visited May 27, 2014).

[416] *Id.*

A. Introduction:

A number of developing countries rely on traditional medicines for their primary health care. Illustratively, 60-70% of the Indian population[417] and upto 80% of the population of Africa use traditional medicines.[418] Even in the developed world, estimates suggest that 90% of Germans, 70% of Canadians and 50% of the European and North American population have used traditional medicines in one form or the other.[419]

Moreover, traditional medicine has also contributed herbal leads for active ingredients used in a number of allopathic prescription drugs.[420] Given the sheer importance of traditional medicine, it is surprising that scant attention is paid to it in the debates around public health and intellectual property.

Traditional medicine often goes beyond the purely 'physical' and aims at a holistic integration of the physical, mental, social and ecological aspects of well-being.[421] A number of commentators assail traditional medicines as

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[417] Report by the Secretariat, *Traditional medicine*, A56/18, 2003, WHO, available at http://apps.who.int/gb/archive/pdf_files/WHA56/ea5618.pdf; Ashok D.B. Vaidya and Thomas P.A. Devasagayam, *Current Status of Herbal Drugs in India: An Overview*, 41(1) J Clin Biochem Nutr. 1–11 (Jul 2007), available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2274994/(Last visited on June 17, 2014).

[418] It is estimated that in China, traditional medicines constitute upto 50% of total medicine consumption Traditional Medicine, Fact Sheet No. 134, WHO, 2008, available at http://www.who.int/mediacentre/factsheets/2003/fs134/en/ (Last visited on June 17, 2014).

[419] *Id*.

[420] *See* A. Gray, *Between the Spice of Life and the Melting Pot: Biodiversity Conservation and its Impact on Indigenous Peoples,* International Working Group for Indigenous Affairs (IWGIA) (1991), Doc. 70.

[421] *Id*.

"unscientific".[422] While a number of traditional medicines are now being subjected to scientific experimentation, clinical trials and the like,[423] it is important to appreciate that traditional medicinal practices may not comport well with a Western scientific framework that does not admit of alternative systems of knowledge/epistemology. In any case, it is important to appreciate that the efficacy of many a traditional medicine has withstood the test of time, making it culturally acceptable and trusted.[424] Moreover, given the health care needs of developing countries, traditional medicine is often more accessible, available and affordable than allopathic medicine and related health care.[425]

B. WHO and TM

In its Traditional Medicine Strategy, the WHO documented the key challenges faced by governments in dealing with traditional and complementary medicine (T&CM).[426] These include problems such as the integration of traditional medicine in national and primary health care polices and the regulation of safety and quality of traditional medicines. In this regard, the WHO recommendations (suggestions to member states) are outlined in the table below:

[422] *See* V Sujatha, Leena Abraham, *Medicine, State and Society*, Economic and Political Weekly, April 18, 2009 (Vol. xliv No. 16).
[423] *See* Y.K.Gupta (Professor & Head, Department of Pharmacology, All India Institute of Medical Sciences), *Clinical Trials of Traditional Herbal Medicines In India*, available at http://www.niscair.res.in/conclave/downloadables/Plenary%20Session%202/pdf/Y%20K%20Gupta.pdf (Last visited on June 17, 2014).
[424] WHO, *Traditional Medicinal Strategy: 2014-2023*, available at http://apps.who.int/iris/bitstream/10665/92455/1/9789241506090_eng.pdf?ua=1 (Last visited on June 17, 2014).
[425] *Id*.
[426] *Id*.

Table30: WHO Recommendations

- *Build knowledge base so that T&CM can be managed actively through appropriate national policies that understand and recognize the role and potential of T&CM.*
- *Strengthen the quality assurance, safety, proper use and effectiveness of T&CM by regulating products, practices and practitioners through T&CM education and training, skills development, services and therapies.*
- *Promote universal health coverage by integrating T&CM services into health service delivery and self-health care by capitalizing on their potential contribution to improve health services and health outcomes, and by ensuring users are able to make informed choices about self-health care.*

In 1978, following the Alma Ata conference, the WHO became part of an ambitious program: "Health for All by the Year 2000".[427] This program sought to integrate traditional healers into the official healthcare system by adding them to the base of the healthcare pyramid.[428] Later in 1993, the WHO along with the International Union for Conservation of Nature (IUCN) and World Wide Fund for Nature (WWF) published guidelines for the conservation of medicinal plants.[429] In 2005, the WHO published its global strategy on traditional medicine.[430] This was later updated through the "WHO Traditional Medicine

[427] WHO, *Primary Health Care, Report of the Inter- national Conference on Primary Health Care*, Alma Ata, USSR, 6-12 September 1978.
[428] *Id*.
[429] This was later revised in 2003. UNU-IAS Policy Report, *Biodiversity, Traditional Knowledge and Community Health: Strengthening Linkages* , 2012, available at http://archive.ias.unu.edu/resource_centre/Biodiversity%20Traditional%20Knowledge%20and%20Community%20Health_final.pdf (last visited on June 17, 2014).
[430] "WHO Traditional Medicine Strategy 2002-2005WHO, *WHO Traditional Medicine Strategy 2002-2005*, available at http://www.wpro.who.int/health_technology/book_who_traditional_medicine_strategy_2002_2005.pdf (last visited on June 17, 2014).

Strategy 2014-2023".[431]

B.1 Defining Traditional Medicine

Traditional medicine ('TM') is defined by the WHO as the knowledge, skills and practices based on the theories, beliefs and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health, as well as to prevent, diagnose, improve or treat physical and mental illnesses.[432]

Relatedly, a working definition of traditional knowledge ('TK') (which comprises all forms of traditional knowledge, including traditional medicine) was proffered by WIPO as below-

> "*tradition-based literary, artistic or scientific works; performances; inventions; scientific discoveries; designs; marks, names and symbols; undisclosed information; and all other tradition-based innovations and creations resulting from intellectual activity in the industrial, scientific, literary or artistic fields*."[433]

The Indian traditional medicine system can be broadly divided into two systems: (i) documented and organized systems and (ii) undocumented and largely unorganized systems.[434] The first category (documented knowledge), also referred to as the Indian Systems of Medicine (ISMs) comprises largely of

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[431] WHO, *Traditional Medicinal Strategy: 2014-2023*, available at http://apps.who.int/iris/bitstream/10665/92455/1/9789241506090_eng.pdf?ua=1 (last visited on June 1, 2014).
[432] *Supra* note 352.
[433] World Intellectual Prop. Org. (WIPO), *Intellectual Property Needs and Expectations of Traditional Knowledge Holders: WIPO Report on Fact-finding Missions on Intellectual Property and Traditional Knowledge*, April 2001, available at http://www.wipo.int/tk/en/tk/ffm/report/index.html (last visited on June 17, 2014).
[434] T C James, *Traditional Medicine and Intellectual Property Policies* in LIVING TREE: TRADITIONAL MEDICINE AND PUBLIC HEALTH IN CHINA AND INDIA 243 (Sachin Chaturvedi, et. al, eds. 2014).

Ayurveda, Siddha and Unani.[435] The second category comprises folk and tribal medicinal practices that are largely undocumented.[436] As of 2009, there were approximately 430,000 Ayurvedic medical practitioners registered by the government in the country.[437]

C. TM and Biodiversity

Traditional medicine is inextricably linked to biological resources and biodiversity. Prospectable biological resources comprise both organic resources and informational resources.[438] Estimates suggest that around 50,000-70,000 species of medicinal plants are used in traditional and modern medicinal systems.[439] It is pertinent to note that most indigenous populations live in developing countries, and such countries possess the largest proportion of the world's biodiversity.[440]

Informational resources relating to biodiversity and medicinal plants are commercially sought after as they reduce the time and cost of research and

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[435] *Id*.

[436] *Id*.

[437] Randeep Ramesh, *India moves to protect traditional medicines from foreign patents India fights to protect ancient treatments from western pharmaceutical companies*, The Guardian, February 22, 2009, available at http://www.theguardian.com/world/2009/feb/22/india-protect-traditional-medicines (last visited on June 17, 2014).

[438] *Id.*

[439] Over-harvesting and habitat loss had led to around 15,000 global medicinal plant species being labelled as endangered. *See* International Standard for Sustainable Wild Collection of Medicinal and Aromatic Plants ISSC MAP, available at http://envis.frlht.org/articles_p/saving-plants-that-save-lives.pdf; Brett Tolman, Mai Nguyen, Anastasiya Timoshyna, *TRAFFIC pilots sustainable medicinal and aromatic plant harvesting project in Viet Nam*, International Union for Conservation of Nature, available at http://www.iucn.org/about/union/commissions/sustainable_use_and_livelihoods_specialist_group/sulinews/issue_2/sn2_vietnam/ (last visited on June 17, 2014).; WWF Global, *New standard offers more protection for wild medicines and collectors*, 2010, available at http://wwf.panda.org/?194868/New-standard-offers-more-protection-for-wild-medicines-and-collectors (last visited on June 17, 2014).

[440] *See generally* Ajeet Mathur, *Who Owns Traditional Knowledge?*, Economic and Political Weekly, October 18, 2003.

development.[441] Indeed, indigenous communities are honeycombs of ethno-biological information. All of this leads one to the issue of legal rights and protection of such resources and associated knowledge, discussed below.

As evidenced by its character and content, traditional knowledge does not lend itself easily to the mainstream IP framework. For one, it often involves a community-based knowledge base, as opposed to individual centric knowledge, which is the mainstay of the current IP regime.

There is also the danger of treating TK as *res communes* or as the 'common heritage of mankind'. This does great disservice to indigenous communities that possess such knowledge and may not wish for it to be freely appropriable. Such ambiguity has resulted in the unauthorized commercial exploitation of TK, commonly referred to as "biopiracy", amply illustrated by two high profile cases involving Neem and Turmeric.[442]

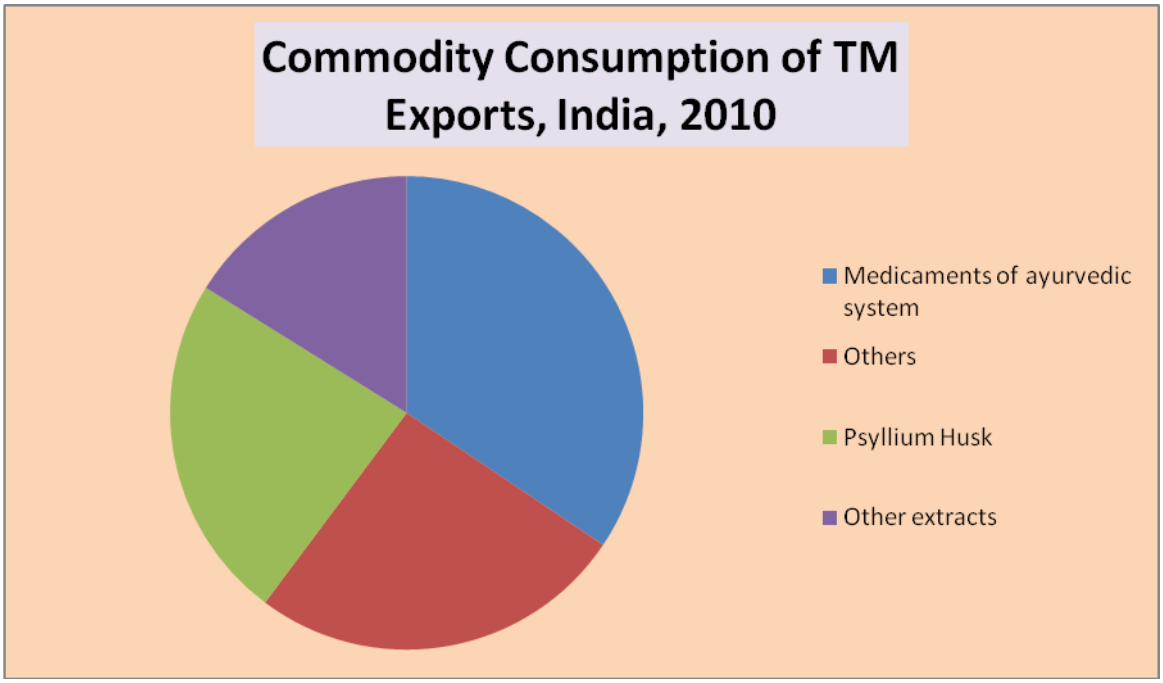
Table 31: Case Studies - Turmeric and Neem

Turmeric: In 1995, two Indian nationals at the University of Mississippi Medical Centre were granted US patent no. 5,401,504 on the "use of turmeric in wound healing" which was then successfully challenged by the Indian Council of Scientific and Industrial Research (CSIR) on the ground that it was not novel and was well known traditional knowledge in India. **Neem:** In 1994 the EPO granted European Patent No. 0436257 to the US Corporation, W.R. Grace and the USDA for a "method for controlling fungi on plants by the aid of a hydrophobic extracted neem oil" which was then challenged by a group of international NGOs and Indian farmers groups on the

[441] *Id*.
[442] *See* TKDL, *supra* note 64.

ground that the use of neem as fungicide was well known traditional knowledge of local farmers.

Table 32: Commodity Consumption of TM Exports (2010)



Source: Living Tree: Traditional Medicine And Public Health In China And India.[443]

Against this background, two pertinent questions arise: First, how does one prevent the misappropriation of valuable medicinal knowledge without due credit to the community in question i.e. 'defensive protection'? Secondly, what kind of 'positive protection' can be afforded to holders of TK in order to recognize and protect their rights, and help them appropriate their intangible assets?

The Indian legal framework attempts to address both these questions. However, let us first survey the international framework in this regard.

[443] Available at http://healthimpactfund.com/wp-content/uploads/2013/09/combined-file.pdf (last visited on June 17, 2014).

C.1. International Legal Framework

The Convention on Biological Diversity ('CBD'), 1992, recognizes that States have sovereign rights over their biological resources and that these resources cannot be treated as the 'common heritage of mankind'.[444] The CBD seeks to protect biodiversity and promote sustainable development by balancing the needs of resource-rich developing countries with that of the technologically advanced developed countries.[445] Article 15 and 16 require resource-rich countries to facilitate access to genetic resources on the one hand, and developed counties to transfer technology for the sustainable use of such resources, on the other.[446] Access to such resources is to be on "mutually agreed terms" with "prior informed consent" for fair and equitable sharing of benefits from the commercial or other utilization of genetic resources. [447]

The Convention also recognizes the traditional inter-dependence of local communities and biological resources.[448] It envisages equitable sharing of benefits for the use of traditional knowledge, innovations and practices.

Table 33

Article 8(j) of the CBD requires each party to

[444] Article 3 and Article 15 of the Convention on Biological Diversity, 1992,; *See generally* Christoph Antons, *Sui Generis Protection For Plant Varieties And Traditional Knowledge In Biodiversity And Agriculture: The International Framework And National Approaches In The Philippines And India*, IJLT (2010).
[445] *Id.*, Preamble.
[446] *Id.*, Article 15(2) & (6) and Article 16.
[447] *Id.*, Article 15(4) & (5).
[448] *Id.*, Preamble.

> *"respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices."*[449]

C.2. Indian Legal Framework

C2.1. Biodiversity Act

Pursuant to its international obligations under the CBD, India passed the Biological Diversity Act (BDA) in 2002. India also ratified the Nagoya Protocol on Access and Benefit Sharing.[450] Through the BDA, India reaffirmed its sovereign rights over its biological resources and committed to an equitable sharing of benefits from the utilization of these resources.[451] The key provisions of the Act are highlighted below:

i) Regulating access to biological resources and associated knowledge; transfer of technology/knowledge and acquisition of intellectual property rights based on such biological resources.

ii) Constituting several bodies responsible for supervision and implementation- the National Biodiversity Authority, various State Biodiversity Boards and local

[449] *Id.*, Article 8(j).
[450] *See* Swaraj Paul Barooah, *India signs Nagoya protocol ahead of Hyderabad CBD meet*, October 6, 2012, available at http://spicyip.com/2012/10/india-signs-nagoya-protocol-ahead-of.html (last visited on June 17, 2014).
[451] *See generally* Christoph Antons, *Sui Generis Protection For Plant Varieties And Traditional Knowledge In Biodiversity And Agriculture: The International Framework And National Approaches In The Philippines And India*, IJLT (2010).

level Biodiversity Management Committees constituted by panchayats and municipalities.

iii) Access and benefit sharing on mutually agreed terms between bio-prospecting applicants, local bodies and local beneficiaries (such as indigenous populations holding the knowledge).[452] To this extent, the Act clearly envisages a positive protection for indigenous and other holders of TK in that they benefit from an appropriation of their intangible medicinal knowledge.[453]

Table 34: Case Study - Jeevani

The development of Jeevani, an anti-stress and anti-fatigue formulation is a good example of equitable benefit sharing-

> *"Indian scientists at the Tropical Botanic Garden and Research Institute (TBGRI) learnt of the anti fatigue properties of Arogyapacha, a medicinal herb from the Kanis, an indigenous tribe inhabiting the Augustyamuni forest in South India. They then isolated 12 active compounds from arogyapaacha, developed the formulation Jeevani, and filed two patent applications on the drug. The technology was then licensed to the Arya Vaidya Pharmacy, Ltd., an Indian pharmaceutical manufacturer, which*

[452] If paid in money, the National Biodiversity Authority may direct these funds to individuals, groups or organizations that can be identified as the source of the resource or knowledge. If that is not possible, the benefits are deposited in the National Biodiversity Fund. Section 21 (3) of the Biological Diversity Act, 2002, and Rule 20 of the Biological Diversity Rules, 2004.

[453] Section 21 of the Biological Diversity Act, 2002, and Rule 20(8) of the Biological Diversity Rules, 2004.

manufactured Jeevani. A trust fund was established to share the benefits arising from the commercialization of Jeevani."[454]

C.2.2 Patents Act

The Patents Act, 1970 contains provisions to prevent misappropriation of traditional knowledge. Section 3(p) prohibits "*an invention which, in effect, is traditional knowledge or which is an aggregate or duplication of known properties of traditionally known component or components*" from patent protection. Unfortunately this provision throws up an ambiguity in terms of positive protection of traditional knowledge. Given that the provision effectively precludes all patenting of traditional knowledge, would it also prevent TK holders from patenting their own knowledge (provided of course the knowledge has been kept secret from public and is "new" in that sense)? [455]

Further, under section 25(j) and section 64(p), a patent can be opposed or revoked on the ground "*that the complete specification does not disclose or wrongly mentions the source or geographical origin of biological material used for the invention*." Also, under sections 25(k) and 64 (q) a patent can be opposed or revoked if "*that the invention so far as claimed in any claim of the complete specification was anticipated having regard to the knowledge, oral or otherwise, available within any local or indigenous community in India or elsewhere*."

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[454] WIPO, *Traditional Knowledge*, http://www.wipo.int/export/sites/www/freepublications/en/tk/920/wipo_pub_920.pdf (last visited on June 17, 2014).

[455] Shamnad Basheer, *Patent Discrimination Against Indigenous Communities?*, SpicyIP, July 20, 2011, available at http://spicyip.com/2011/07/patent-discrimination-against.html (last visited on June 17, 2014).

Apart from the above, it is important to appreciate that the traditional patentability criteria of novelty, inventive step and utility can be used to prevent patents on traditional knowledge/medicine,[456] as illustrated by cases in table 35 below.

Table 35: Traditional Medicine and Patentability

Traditional Medicine and Patentability: Some Cases
In Natural Remedies Private Limited v. India Herbs Research and Supply Co,[457] the Karnataka High Court revoked a patent for 'Zigbir', a herbal composition of four medicinal plants used to cure liver ailments on the ground that it was obvious. Similarly, Patent Application No. 1576/DEL/2006/ by the Central Council for Research in Unani Medicine was refused by the Controller of Patents in December 2012 on the ground that the said invention, consisting of a combination of herbal extracts, was traditional knowledge and obvious to those working in the field.

C.3. Other Efforts

C.3.1. Traditional Knowledge Digital Library (TKDL)

The Traditional Knowledge Digital Library (TKDL) is an excellent example of defensive protection. Much of Indian TK has been passed down over generations by word of mouth; of the TK that has been documented, most are found in

[456] *See* Guidelines for Processing Patent Applications Relating to Traditional Knowledge and Biological Material, Indian Patent Office, available at http://www.ipindia.nic.in/iponew/TK_Guidelines_18December2012.pdf (last visited on June 17, 2014).

[457] Natural Remedies Private Limited v. India Herbs Research and Supply Co, MANU/KA/2739/2011.

ancient classical texts and other literature, which are often inaccessible and not easily understood. The TKDL project essentially translated all of this documented traditional medical knowledge (Ayurveda, Unani, Siddha and Yoga) into five international languages (English, Japanese, French, German and Spanish) and organized the resulting information in a user friendly database. [458]

The TKDL database is available to eight International Patent Offices (including the Indian Patent Office) under Access Agreements. These include the US Patent Office, European Patent Office, Canadian Patent Office, United Kingdom Patent Office, German Patent Office, Australian Intellectual Property Rights Office and the Japanese Patent Office. This access was provided in order to prevent the patenting of TK, both in India[459] and abroad.[460]

Table 36: Examples of decisions to set aside granted patents on TM based on evidence from the TKDL (submitted by CSIR)

No	Pub. No.	Title	Applicant	TKDL Evidence	Cancellation of patent
1	EP1747786	Natural product in cream with anti-vitiligo therapeutic properties	Perdix Eurogroup S.L., Spain	8-Jul-09	27-Jul-09
2	EP1520585	Cancer treatment using natural plant products or	Data Medica Padova S.P.A.,	9-Jul-09	14-Jul-09

[458] The project is a collaborative project between the Council of Scientific and Industrial Research (CSIR), Ministry of Science and Technology and Department of AYUSH, Ministry of Health and Family Welfare, and is being implemented at CSIR. Traditional Knowledge Digital Library, available at http://www.tkdl.res.in/tkdl/langdefault/common/Home.asp?GL=Eng.

[459] *See* Prashant Reddy, *Govt. of India follows up on SpicyIP reporting – revokes Avesthagen patent – first Indian victory for TKDL*, SpicyIP, October 27, 2012, available at http://spicyip.com/2012/10/govt-of-india-follows-up-on-spicyip.html (last visited on June 17, 2014).

[460] *See* V.K. Gupta, *An Approach for Establishing a Traditional Knowledge Digital Library*, 5 JIPR 307–319 (2000).

		essential oils or components from some pistacia species	Italy		

Source: Living Tree: Traditional Medicine And Public Health In China And India.[461]

C.4. Positive Protection?

While India appears to have unleashed a robust defensive protection policy, a lot more needs to be done on the positive protection front. Although the government continues to contemplate legislation in this regard, no concrete policy has emerged as yet. The international efforts on this count appear to be progressing well, though there is no draft treaty as yet.

Article 31 of the UN Declaration on the Rights of Indigenous Peoples states that indigenous people have the right to maintain, control, protect and develop their Intellectual Property over their cultural heritage, traditional knowledge and traditional cultural expressions.[462]

In 2000, an Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (the IGC) was created under the aegis of WIPO, to discuss possible protection for economically valuable TK, genetic resources and traditional folklore.[463] The IGC has engendered active

[461] *Supra* note 396.
[462] *UN General Assembly, United Nations Declaration on the Rights of Indigenous Peoples, Resolution, Adopted by the General Assembly, October 2, 2007, A/RES/61/295, available at http://www.un.org/esa/socdev/unpfii/documents/DRIPS_en.pdf* (last visited on June 17, 2014).
[463] *See* David Vivas-Eugui, Anamika, *Bridging the Gap on Intellectual Property and Genetic Resources in WIPO's Intergovernmental Committee (IGC)*, ICTSD Programme on Innovation, Technology and Intellectual Property, January 2012, available at http://www.ictsd.org/downloads/2012/02/bridging-the-gap-on-intellectual-property-and-genetic-resources-in-wipos-intergovernmental-committee-igc.pdf (last visited on June 17, 2014).

participation from various stakeholders including indigenous people.[464] In 2009, the WIPO General Assembly gave the IGC a renewed mandate towards the creation of an international instrument (or instruments) for the "effective protection of GR (genetic resources), TK (traditional knowledge) and TCEs (traditional cultural expression)" through text-based negotiation.[465]

The mandate does not specify the legal character of the international instrument, but simply states that it should afford *effective* protection. Draft articles on the protection of TK, genetic resources and traditional folklore have been prepared by the IGC. Various meetings have been held to finalize the treaty text and discuss issues such as defining traditional knowledge, identification of beneficiaries, scope of protection, remedies and sanctions, administration of rights, disclosure requirements, exceptions and limitations as well as term of protection.[466]

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[464] *Id*.

[465] WIPO General Assembly, *Agenda Item 28: Matters Concerning the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore*, 38th Session, September 22 to October 1, 2009, available at http://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_15/wipo_grtkf_ic_15_ref_decision_28.pdf (last visited on June 17, 2014).

[466] *See generally* Maëli Astruc and Julia Fraser, *Indigenous Peoples Present Their Perspectives On Traditional Knowledge At WIPO*, IP Watch, March 25, 2014, available at http://www.ip-watch.org/2014/03/25/indigenous-peoples-present-their-perspectives-on-traditional-knowledge-at-wipo/(last visited on June 17, 2014).

APPENDIX A: TRIPS PROVISIONS/COMPATIBILITY

The formulation of the TRIPS Agreement involved highly contentious negotiations between developed and developing countries over fundamentally different approaches to intellectual property and innovation.[467] While developing countries stressed issues of access and development, the developed world propagated a strong IP regime that protected their industrial interests.[468] This division was especially stark in the case of pharmaceutical patents, with India leading the opposition against a near universal regime in this regard.[469] These divergent concerns were addressed through the insertion of a number of 'flexibilities' in the TRIPS Agreement, giving considerable room to developing countries to implement TRIPS obligations in a manner commensurate with their national interest.[470]

The overarching framework of TRIPS permits member states to adequately protect public interest and public health whilst fostering technological development. In particular, Article 7 stresses that the protection and enforcement of IP must be "in a manner conducive to social and economic welfare."[471]

Similarly, Article 8 states the countries, in formulating their laws, can "adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and

[467] SUSAN SELL, PRIVATE POWER, PUBLIC LAW 108 (2003)
[468] *Ibid.* at 110..
[469] *See* Kapczynski, *supra* note 179.
[470] *Ibid* at p. 1581.
[471] Article 7: The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

technological development."[472] The Doha Declaration further strengthens this position in reaffirming "the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose."[473]

We highlight some of the key "public health" provisions in the Indian patents regime and demonstrate how they are likely to be TRIPS compliant. Central to the issue of TRIPS compatibility is Article 27, as reproduced below:

Table 36: Article 27 of TRIPS (Patentable Subject Matter)

1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced. 2. Members may exclude from patentability 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, provided that such

[472] Article 8 of TRIPS: "1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.
2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology."

[473] Doha Declaration at paragraph 4.

exclusion is not made merely because the exploitation is prohibited by their law.

3. Members may also exclude from patentability:

(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;

(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

1. Section 3(i): Methods of treatment

Section 3(i) of the Indian Patents Act excludes from patentability "any process for the medicinal, surgical, curative, prophylactic [diagnostic, therapeutic] or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products.

This exception draws strength from Article 27.3(a) of the TRIPS agreement (see table above), which excludes "diagnostic, therapeutic and surgical methods for the treatment of humans or animals." It is interesting to note that the Indian exception goes beyond the TRIPS provision as it also seeks to exclude "other treatment" as well (presumably non medical treatment) aimed at "increasing the economic value" of the animals in question or their products. One might therefore argue that, to this extent, the provision is incompatible with TRIPS.

2. Section 3(j): Micro-organisms

Article 27.3 (b) of the TRIPS Agreement provides that members may also exclude from patentability, "plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes." The Indian exclusion hews close to this provision. [474]

This indicates that micro-organisms per se cannot be excluded from patentable subject matter. However the word 'micro-organism' has not been defined, and remains open to interpretation by member states.

Even if micro-organisms are to be granted patents under Article 27.3 (b), member states may exclude them for falling within the scope of other exclusions (such as section 3(c) which denies patents to mere discoveries) and patentability criteria such as novelty, non-obviousness and utility. Hence, the IPO guidelines referenced earlier which provide that although microorganisms are patentable under section 3(j), a conjoint reading with section 3(c) of the Act (excluding mere discoveries) implies that only modified microorganisms (distinct from microorganisms found in nature) are patentable is perfectly compatible with TRIPS.[475]

3. Section 3(d)

[474] Section 3(j) excludes from patentability "plants and animals in whole or any part thereof other than micro-organisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals."

[475] See *IPO Guidelines for Examination of Biotechnology Applications for Patent* __ **cite this and the earlier portion (section on patents) where this is discussed.**

A number of commentators argue that Section 3(d) is TRIPS compliant.[476] There are three main reasons for this:

1) *Defining Invention*

While Article 27 mandates that "patents shall be available for any inventions, whether products or processes, in all fields of technology", it does not specify as to what an 'invention' is. Consequently, member states are free to define the term in a manner commensurate with legitimate public health objectives.

ii) Defining Inventive Step

Even assuming that there were no flexibility in the term "invention", India could still filter out alleged pharmaceutical inventions under section 3(d) on the ground arguing that such inventions were not really "inventive" or non obvious. To this extent, section 3(d) would be considered a refined "inventive step" or non-obviousness standard.

Here again, TRIPS does not define what "inventive step" or non-obviousness is. Member states have interpreted this term in a varied manner and while the same pharmaceutical invention has been held patentable in one jurisdiction, it has been denied patents in another.

A wide array of cases in the US and other key jurisdictions bear this point out well. Illustratively, consider the *Escitalopram* case involving a patented

[476] *See e.g.,* Shamnad Basheer and Prashant Reddy, '*Ducking*' *TRIPS in India: A Saga Involving Novartis and the Legality of Section 3(d)* 20(2) NATIONAL LAW SCHOOL OF INDIA REVIEW 131-155 (2008); Kapczynski, supra note 179; Carlos Correa, *Is Section 3(d) Consistent with TRIPS?* XLVIII (32) ECONOMIC AND POLITICAL WEEKLY (August 10, 2013).

pharmaceutical enantiomer.[477] While the U.K.,[478] German,[479] Canadian[480] and Australian courts[481] adjudicated the patent to be a valid one, the Dutch court held that the patent was invalid for obviousness.[482]

Another instance of divergent interpretation of the obviousness criterion is illustrated by the *Viagra* case. The U.K. courts[483] invalidated the patent on the ground that it was obvious in the light of prior art, which suggested the utility of the claimed PDE VA inhibitor in potentially curing erectile dysfunction. However, the Federal Court of Appeal in Canada rejected the above line of reasoning and held that a mere "worth a try" possibility did not preclude inventiveness. Rather, the claimed invention would be obvious, only when the "try" was a matter of routine and required no significant thinking or effort.[484]

The divergent conclusions on obviousness discussed above stem not only from a differential subjective assessment of the same facts,[485] but can also be attributed to a difference in legal standards. As can be seen from the above discussion, Canada preferred a lower non-obviousness or inventive step threshold that

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[477] *See* Jonathan J. Darrow *The Patentability of Enantiomers: Implications for the Pharmaceutical Industry*, 2007 STAN. TECH. L. REV. 2, (discussing different aspects of enantiomers).
[478] *See* Generics (UK) Limited and others v. H Lundbeck A/S, [2009] UKHL 12.
[479] *See* Lundbeck A/S v. Neolab Ltd. et al. (Escitalopram), invalidity proceedings, Federal Supreme Court, Germany, 10 September 2009, Docket number Xa ZR 130/07.
[480] *See* Apotex v. Lundbeck Canada Inc., 2010 FCA 32.
[481] *See* H. Lundbeck A/S v. Alphapharm Pty. Ltd., [2009] FCAFC 70.
[482] *See* Alfred E. Tiefenbacher GmbH s. H. Lundbeck A/S, 312468 / HA ZA 08-1827 (District Court); *see also* Jeremy Phillips, *That (Es)citalopram Patent Again*, THE IPKAT BLOG (Apr. 13, 2009) http://ipkitten.blogspot.com/2009/04/that-escitalopram-patent-again.html (discussing how the Dutch court may have been influenced by the presentation of additional evidence and the presence of Jack Baldwin, a Chemistry expert who did not appear in any of the other trials)
[483] *See* Lilly Icos Llc v Pfizer Ltd., [2002] EWCA Civ 1, *available at* http://www.bailii.org/ew/cases/EWCA/Civ/2002/1.html (last visited June 1, 2014).
[484] *See* Pfizer Canada Inc. v. Apotex Inc. (F.C.A.), 2009 FCA 8, [2009] 4 F.C.R. 223, ¶ 28-31 *available at* http://reports.fja.gc.ca/eng/2009/2009fca8/2009fca8.html (last visited June 1, 2014).
[485] The US and other leading patent jurisdictions hold non-obviousness or inventive step to be a question of law, albeit one is that predicated heavily on underlying facts; for e.g., *In re* Kubin, 561 F.3d 1351, 1355 (Fed. Cir. 2009) ("Obviousness is a question of law based on underlying findings of fact.").

would have found in favour of the patentability of a larger number of inventions than the U.K. regime.

2) *Non Discrimination*

Could one argue that section 3(d) discriminates against pharmaceutical inventions, as it effectively sets a higher bar for patentability? The WTO Panel in the *Canada- Patent Protection of Pharmaceutical Products case*[486] interpreted discrimination under Article 27.1 as "the *unjustified* imposition of differentially disadvantageous treatment."[487] In other words, not every differentiation, but only an "unjustified" one would be hit by Article 27. It could well be argued that the justification for Section 3(d) lies in public health imperatives and the need to prevent the possibility of evergreening through a rigorous patent threshold.[488]

4. Local Working

Section 84(1)(c) provides that an application for a compulsory licence can be made when the patented invention is not worked in the territory of India. In *Bayer v. Natco*, the IPO and IPAB considered whether the term 'worked' included imports. While the Patent Office held that mere imports could not amount to working[489], the IPAB differed and held that in some cases, imports could amount to working: "…*we find that the word 'worked' must be decided on a case to case basis*

[486] Panel Report, *supra* note 171.
[487] Panel Report, *supra note 171* at 7.94
[488] Swaraj Paul Barooah, *India's Pharmaceutical Innovation Policy: Developing Strategies for Developing Country Need,* 5(1) TRADE L. & DEV. 150 (2013).
[489] *Natco v. Bayer* C.L. N. 1 of 2011, available at http://www.ipindia.nic.in/iponew/compulsory_license_12032012.pdf (last visited on May 25, 2012) at p. 44: "From all the aforementioned indications, it is clear to me that the Paris Convention and TRIPS Agreement and Patents Act, 1970 read together do not in any manner imply that working means importation. I am therefore convinced that 'worked in the territory of India' means 'manufactured to a reasonable extent in India.'

and it may be proved in a given case, that 'working' can be done only by way of import".[490]

The Patent Office view appears a better one since section 83(b) of the Indian Patents Act states that 'Patents are not granted merely to enable patentees to enjoy monopolies for the importation of the patented article'. Secondly, the Indian Patents Act uses the terms "working" and "importation" quite distinctly throughout the Act, making it evident that "working" as used in the Act cannot include "importation".

Some argue that a "local working" provision contravenes the mandate under Article 27 of TRIPS to not "discriminate" between locally produced and imported patented products.[491] Given the fact that in *Canada - Patent Protection of Pharmaceutical Products,*[492], the WTO panel stated that discrimination meant "unjustified differentiation", one could argue that "local working" is a "justified" differentiation. For one, the Paris Convention (which is now incorporated into TRIPS for the large part) clearly draws a distinction between "working" and "importation", and suggests that if a patent wasn't worked, this could be treated as an "abuse".[493]

Secondly, TRIPS is premised on the promise of technology transfer to developing countries.[494] And a local working provision is geared towards encouraging such

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[490] *Bayer v. Natco* at ¶ 52.
[491] Roy Waldron, TESTIMONY BEFORE THE HOUSE COMMITTEE ON WAYS AND MEANS, SUBCOMMITTEE ON TRADE, March 13, 2013, *available at:* http://waysandmeans.house.gov/uploadedfiles/pfizer_testimony31313.pdf (last visited on May 25, 2014).
[492] *Supra* note 171.
[493] *See* Article 5A(1), Art 5A(2), Art 5A(4) and Art 5B) of the Paris Convention. *See supra* note 139;. See also Shamnad Basheer, *India's First Compulsory Licence: Patents vs Public Health?* available at http://www.iposgoode.ca/2012/04/india%E2%80%99s-first-compulsory-license-patents-vs-public-health/#sthash.RK3B6ya0.dpuf (last visited on May 25, 2014).
[494] The objectives listed in Article 7 of TRIPS open with: "the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to

technology transfer. By forcing patentees to "work" their patents in India, the regime encourages local use/transfer of the said technology.[495] In other words, the 'local' working requirement does not require the setting up of manufacturing units by foreign companies, but can be satisfied by licensing manufacture of drugs to domestic generic companies. This could thus be an important requirement that would bring down the price of drugs as well as ensure larger availability of drug, by enabling stronger generic competition.

A similar provision on "local working" in Brazil's regime was challenged by the US—however, the case was later withdrawn and there was no ruling.[496]

5. Experimental Use Exception

As noted earlier, the Indian regime houses a fairly liberal experimental use exception that permits third parties to work with and on the experimented invention. This is compatible with Article 30 of TRIPS which provides that "Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties."[497]

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the transfer and dissemination of technology." See also Shamnad Basheer, *India's First Compulsory License Granted* available at http://spicyip.com/2012/03/breaking-news-indias-first-compulsory.html (5th February, 2014).

[495] Section 83 of the Patents Act, 1970, which lists the guiding principle of interpretation for patents under the Act, clearly reflects this principle in clause (b) that patents "are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article;" and in clause (c) "that the protection and enforcement of patent rights contribute to the promotion of technological innovation and to the transfer and dissemination of technology."

[496] *See* WTO Doc. WT/DS199/1,G/L/385,IP/D/23, 8 June 2000; WT/DS199/39, January 2001; Helene Cooper, *White House Drops WTO Claim Against Brazilian Patent Law,* Wall Street Journal (June 26, 2001) available at http://online.wsj.com/news/articles/SB993505161637017687 (last visited on May 25, 2014).

[497] Article 30 of the TRIPS Agreement.

As is evident from the above, the only qualification under Article 30 is that the exception cannot be so broad that it unreasonably prejudices legitimate interests of a patentee and the normal exploitation of a patent. Further, TRIPS was premised on the concept of technology transfer. Given that there is no meaningful way of obligating developed countries to transfer technology, TRIPS should at the very least enable countries to ramp up technological capabilities by themselves. One way of doing so is by having a robust experimental use exception, enabling such countries to work with registered patents, understand and absorb underlying technology, and perhaps even to come up with improvements.