THE "EXPERIMENTAL USE" EXCEPTION THROUGH A DEVELOPMENTAL LENS

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I. INTRODUCTION

Experimentation and research are necessary precursors to most scientific breakthroughs that we know of today. Little wonder then that many countries provide for what is commonly referred to as an "experimental use" exception use in their patent regimes, an exception that shields experimental activities from charges of patent infringement. The underlying rationale of such an exception appears to be that experimentation on a patented invention is necessary to test the invention and ensure that it works in the manner claimed—i.e., to validate the "disclosure" function of patents and provide credence to the "bargain" or the "social contract" theory. Some countries have gone further and permitted their exception to even cover the testing of patented inventions with a view to creating improvements or inventing around such patents. This Article argues that this latter rationale is particularly appealing in the context of developing countries that are often net importers of patented technology caught in the game of technological catch up. To that extent, this Article attempts to offer a "developmental" perspective on the experimental use exception.

This perspective is offered through the specific lens of India, a developing country that articulated a statutory exception in its patent regime as far back as 1970. A plain reading of the Indian section vests it with a latitude not found in most other regimes. The Indian provision may therefore serve as a model for other developing countries that wish to boost their innovative potential.

A wide experimental use provision is particularly appealing to "technologically proficient" developing countries such as India, China, and Brazil that are yet to witness significant levels of innovation. Since such countries are gaining proficiency as low cost hubs of outsourced research and development ("R&D") by multinational technology majors, we argue that a wide research exemption ought to be leveraged to attract even greater levels of outsourced research to such countries.

However, in order to effectively leverage the exception, developing countries must ensure that there is a complete and enabling disclosure of the patented invention. Most patent regimes, even those in the developed world, have been gamed by clever attorneys who hide more than they reveal in patent applications. Countries therefore ought to insist on higher disclsoure standards. This would not only ensure that patentees live up to their part of the bargain and merit the twenty-year monoploy that society grants them, but also help a number of countries to study patents effectively and experiment with underlying technology.

This Article also deals with a specific kind of experimental use exception that has evolved to cater to the testing of patented drugs by generic manufacturers, commonly referred to as the "*Bolar*" exception.

Lastly, this Article demonstrates that even an experimental use exception as wide as India's is likely to pass muster under the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS"), as it is "limited" in nature and does not unreasonably prejudice the normal exploitation of a patent. At a more prescriptive level, the reader is reminded of the fact that TRIPS was premised on the promise of transfer of technology. 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.

II. CONTEXTUALIZING THE "EXPERIMENTAL USE EXCEPTION" WITHIN THE PATENT LAW NARRATIVE

A soul searching of most patent regimes today throws up two rationales or theories underlying the grant of patents.[1] First, such grants incentivize innovation and spur advances in science and technology.[2] This theory, commonly termed as the "incentive" theory, is a heavily contested one, and scholars disagree on whether or not patents incentivize innovation and, if so, to what extent.[3]

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1 *See* A. Samuel Oddi, *Un-Unified Economic Theories of Patents—The Not-Quite-Holy Grail*, 71 NOTRE DAME L. REV. 267, 268 (1996) (drawing parallels to the unsuccessful quest for a single unifying scientific theory for the universe, the author theorizes that the quest for a single unifying economic theory of patents is destined to be similarly unsuccessful).

2 *See* Katherine J. Strandburg, *The Research Exemption to Patent Infringement: The Delicate Balance between Current and Future Technical Progress*, *in* 2 INTELLECTUAL PROPERTY AND INFORMATION WEALTH 1, 2 (Peter Yu ed., 2006) ("The patent system is often justified by the twin theories 'incentive to invent' and 'incentive to disclose.' The 'incentive to invent' theory is a free-rider theory based upon the assumption that investments in new ideas, unlike investments in capital equipment or materials, are appropriable by competitors at very little expense. Thus, patents are awarded lest would-be inventors be disinclined to make the investments necessary to develop new inventions. The 'incentive to disclose' theory, on the other hand, is based on the notion that a patent is a quid pro quo in which an inventor teaches her invention to the public in exchange for a limited period of exclusive rights.").

3 Pharmaceutical patents may be the one area where there is some broad consensus that a monopoly incentive in the form of a patent is needed to recoup the significant investments made in drug discovery and development. *See* James Bessen & Michael J. Muerers, PATENT FAILURE: HOW JUDGES, BUREAUCRATS AND LAWYERS PUT INNOVATORS AT RISK *passim* (2008) (pointing out that several case studies had shown that the patent system was 'critical' in encouraging R&D in the field of chemical and pharmaceutical research); *see also* James Bessen & Michael J. Muerers, *Of Patents and Property*, REGULATION, Winter 2008, at 18, 25

Scholars also point to the negative "blocking" effect of patents on researchers who wish to improve upon the patent and the high monopoly costs imposed on consumers and ask if these negative aspects are offset by the prospect of increased innovation promised by the "incentive" theory.[4]

The second theory, albeit one that is complementary to the incentive theory, postulates that the grant of a patent represents a "bargain" or a "social contract" between the state and the inventor—i.e., an inventor who discloses details of her new invention is granted a state sanctioned monopoly of twenty years in return for such disclosure.[5]

This theory rests on the assumption that were it not for patents, the putative patentee might have considered it more optimal to lock the invention away as a trade secret, thereby depriving society of important scientific knowledge.[6] There is considerable debate about whether or not the bargain theory works,

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(pointing out that in most sectors patents may actually reduce innovation, the one significant exception to the rule being the pharmaceutical industry where the patent system was critical to encouraging R&D).

4 The evidence on pricing/access issues and blocking is also inconclusive. *See* Michael A. Heller, Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anti-commons in Biomedical Research*, 280 SCIENCE 698, 698–701 (1998); *see also* John P. Walsh et al., *Working through the Patent Problem*, 299 SCIENCE 1021, 1021 (2003), *available at* http://www.prism.gatech.edu/~jwalsh6/WalshetalScience.pdf (carrying out empirical research to come to the conclusion that in reality patents were not impeding new R&D projects, therefore disproving Eisenberg's anti-commons thesis).

5 *See* Pfaff v. Wells Electronics, Inc., 525 U.S. 55, 63 (1998) ("[T]he patent system thus embodies a carefully crafted bargain for encouraging the creation and disclosure of new, useful, and nonobvious advances in technology and design in return for the exclusive right to practice the invention for a period of years"); Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 150–51 (1989). This "social contract" understanding of patent law received criticism from some academics who seek to view the operating fundamentals of patent law in terms of regulation rather contractual obligations. It is argued that to view the system through the lens of regulation widens the scope for debate and reform. *See* Shuba Ghosh, *Patents and the Regulatory State: Rethinking the Patent Bargain Metaphor After Eldred*, 19 BERKELEY TECH. L.J. 1315; *see also* Peter Drahos, *"Trust Me": Patent Offices in Developing Countries*, 34 AM. J.L. & MED. 151, 170 (2008) (commenting on how from the perspective of the patent social contract, the grant of frivolous patents constitutes a welfare loss to a society seeking to expand the social contract obligations of patentees from mere disclosure to increased social transaprency so as to create more certainity for both downstream innovators and society as a whole).

6 Trade secrecy in certain cases will be an inefficient form of protection for both the inventor and for society. This is because protecting the secrecy of the invention may be prohibitively high in cost, while at the same time society suffers since the details of the invention are not released to the public. Patent law thus is seen to be the more efficient form of protection. *See* Mark F. Grady & Jay I. Alexander, *Patent Law and Rent Dissipation*, 78 VA. L. REV. 305, 342 (1992).

with some skeptics contending that patent applications often hide more than what they reveal and that society does not really benefit from such disclosures to an extent sufficient enough to warrant the grant of a twenty-year monopoly.[7]

However, unlike the incentive theory, which is inconclusive owing to issues of evidence, the disclosure theory can perhaps be made to work through a rigorous application of doctrine of enablement. This doctrine, which encapsulates an essential prerequisite for the grant of a patent stipulates that a skilled person in the art ought to be able to arrive at the patented invention simply by means of the the specification without undue experimentation. This doctrine is known by various names, with the United Kingdom referring to it as the doctrine of sufficient disclosure, and the United States referring to it as the written description and the enablement requirement.[8]

Without a corresponding experimental use exception, the enablement or sufficient disclosure requirement is meaningless. For it would be paradoxical to enjoin someone who is merely testing a patented invention to determine whether it was sufficiently "enabled."

Secondly, and perhaps more importantly, an experimental use exception is likely to advance the broader goal of patent law—i.e., to induce more innovation. Specifically, it could offer critical insights to a researcher who might then improve upon the patented invention or to even work around it and create an alternative technology.

Most patent regimes vest patentees with a bundle of rights, including the right to manufacture, sell, and even "use" the patent in question.[9] A strict adherene to the exclusive right to "use" could potentially block research activities by third parties who attempt to "use" the patented invention in a bid to expand technological frontiers. It is therefore critical that such an exclusive right to use is derogated from in some cases, where the purpose is to experiment and unravel the technology underlying a patented invention.

Notwithstanding the importance of an experimental use exception as mentioned above, it must not be interpreted in so broad a manner as to detract

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7 In a finely nuanced, yet stinging criticism of the failure of the disclosure function of the patent system, one commentator has pointed out that the dissemination of information is severely deterred either due to inadequate disclosure in the patent application or due to the threat of patent infringement suits which arise because of strict conditions on the "use" of the disclosed information. *See* Benjamin Roin, Note, *The Disclosure Function of the Patent System (or Lack Thereof)*, 118 HARV. L. REV. 2007, 2008 (2005).

8 *See* Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1344 (Fed. Cir. 2010) (confirming that 35 U.S.C. § 112, ¶ 1 includes both a written description and enablement requirement).

9 Section 48 of the Indian Patent Act grants the patentee the sole rights to make, use, offer for sale, sell or import his patented invention. The Patents Act, No. 39 of 1970, § 48 (India).

significantly from the incentive to create in the first place. In other words, the breadth of any experimental use exception ought to be pegged at levels that appropriately balance out two competing concerns: the need to "use" a patented invention for experimental purposes in order to further society's understanding of the invention in question, and the need to provide sufficient incentives for a putative patentee to come up with the invention in the first place. After all, if the incentive to create were to be totally withered away, there would be no technology to experiment with in the first place.

To bring this balancing act into sharper focus, consider the problem of research tools patents. Such patents cover inventions, the sole purpose of which is use in research. If that very purpose is sought to be exempted as a whole under the experimental use exception, it would kill any incentive that putative patentees might have in arriving at such inventions in the first place.

There is also some debate about whether or not the bargain theory applies on all fours to self-disclosing inventions. Illustratively, consider the category of pharmaceutical drugs. Even assuming the patented invention at issue is self-disclosing and reveals itself once the product is sold in the market, there is some delay between the publishing of the patent application and the introduction of the product. Typically, in the case of pharmaceutical products, the time lag between the discovery of a lead and its final introduction into the market is, on average, about twelve years.[10] Therefore, even in the context of self-disclosing inventions, the theory of disclosure still plays a valid role.[11] Besides the distinction between self-disclosing and other inventions is not a static or clearly defined one. Rather what may be a "trade secret" at one point may reveal itself by clever reverse engineering at some later point in time.

The breadth, or otherwise, of an experimental use exception depends largely on how countries wish to balance the competing concerns outlined above. In other words, while some place more emphasis on the disclosure theory, others accord more deference to the incentive function of patents. We consider these theories in greater detail below.

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[10] Joseph A. DiMasi et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151, 181 (2003).

[11] *See* Katherine J. Strandburg, *What Does the Public Get?: Experimental Use and the Patent Bargain*, 2004 WIS. L. REV. 81, 119 (2004) (arguing that disclosure is irrelevant in the case of self-disclosing inventions).

III. THE CONTOURS OF THE "EXPERIMENTAL USE EXCEPTION"

The existence and extent of the "experimental use exception" has been the subject of several scholarly debates the world over. While one school of thought argues for a narrow interpretation of this exception, another argues for a broad interpretation of the same exception.[12] As can be expected, both schools claim that their mode of interpretation best fosters innovation and the progress of science and technology.

The debate in the United States often begins with *Whittemore v. Cutter*[13]—a case in which Justice Story appears to have carved out an "experimental use exception" for the first time in the United States by stating that "it could never have been the intention of the legislature to punish a man, who constructed such a machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects."[14]

Justice Story's exception appears to have been premised on two important rationales, touched upon earlier:

1. The need to ascertain whether the patentee has made a sufficient and enabling disclosure—i.e., the claimed invention works in the manner described in the patent application;

2. The need to encourage purely "philosophical experiments" on a patented invention so as to foster the growth of science and technology.

The first reason, verifying that the patent specification enables the technology being claimed to be implemented without undue experimentation by a person skilled in the art—a patentability criterion often referred to as the doctrine of enablement in the United States[15]—has not invited much controversy.

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12 This debate reflects some of the very same issues raised in the debate between the conflicting Tragedies of the Commons and the Anti-Commons. *See* Garrett Hardin, *The Tragedy of the Commons*, 162 SCIENCE 1243, 1244 (1968); *see also* Michael A. Heller, *The Tragedy of the Anticommons: Property in the Transition from Marx to Markets*, 111 HARV. L. REV. 621, 622 (1998).

13 29 F. Cas. 1120 (C.C.D. Mass. 1813) (No. 17,600).

14 *Id.* at 1121 (emphasis added).

15 The term "enabling disclosure" is drawn from the provisions 35 U.S.C. § 112; The equivalent Indian provision is section 10, of The Patents Act, 1970.

And with good reason, since it ensures that patentees fulfill their part of the bargain and thus merit the twenty-year monopoly granted to them by the State.[16]

Moreover, such an exception addresses an important constraint faced by most patent offices. Given the number of applications and the range of technologies that the patent office is confronted with on a regular basis, it is not possible to comprehensively determine whether or not each invention fulfills patentability criteria. Owing to this constraint, it makes sense from a policy perspective to encourage third-party competitors who are familiar with the claimed technology to expend their own time and resources to experiment and confirm that the invention actually works in the manner described by the patentee. If the said invention does not work as described, most patent regimes provide that the patent could be revoked, either through a stand-alone revocation petition or as a counter claim in an infringement suit filed by the patentee. Some regimes even provide for an administrative or quasi-judicial opposition mechanism at the patent office, where a patent could be challenged on this ground.[17]

The second reason for the experimental use exception, that is encouraging "philosophical experiments," is a hotly contested proposition. While one school of thought has vociferously argued for a narrow interpretation of "philosophical experiments," the opposing school has advocated a broadening of the scope of "philosophical experiments." We discuss these arguments in greater detail below.

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[16] *See generally* Rebecca S. Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 YALE L.J. 177, 221–22 (1987). Eisenberg draws her conclusions from Justice Story's judgment where he holds: "It was probably with a view to guard the public against the injury arising from defective specifications, that the statute requires the letters patent to be examined by the attorney general, and certified to be in conformity to the law, before the great seal is affixed to them." *Id.*

[17] It is important to note in this regard that the Indian Patent Act provides for a very comprehensive opposition mechanism, and includes both pre-grant and post-grant provisions. *See* Shamnad Basheer, *India's Tryst with TRIPS: The Patents (Amendment) Act, 2005*, 1 INDIAN J. L. & TECH. 15, 26 (2005). The key motivation behind such an extensive opposition mechanism appears to be that third-party competitors can be tremendously resourceful in terms of helping to separate the wheat from the chaff and ensure that only truly meritorious inventions pass through the filter. The system appears to be working quite well in India with several patents being challenged even before they are granted by the patent office. *See* Posting of Shamnad Basheer to Spicy IP, *Patent Oppositions in India: The "Efficacy" of Section 3(d)*, http://spicyipindia.blogspot.com/2009/09/patent-oppositions-in-india-efficacy-of.html (Sept. 16, 2009 7:03).

A. The Case for a Broad "Philosophical" Interpretation

A broad interpretation of the experimental use 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.[18]

Such an interpretation draws from the "bargain theory," albeit a stronger version of it—i.e., the reason for mandating disclosure of "invention" information prior to granting the twenty-year monopoly is to allow for innovators to use that information to further the progress of science and technology.[19] Proponents of the "broad" school of thought argue that such an interpretation does not detract from the incentive theory, since any follow-on innovation or improvement will likely use components of the original patented innovation and would therefore require a license from the patentee.[20] This school would also appear to suggest that access to "patented information" per se would be of little use, unless it could be used in meaningful ways to advance the technological arts.

The above argument is further buttressed by the fact that most patent law regimes expressly or impliedly provide for the patenting of improvements. Thus, it is argued that an "experimental use" exception helps speed up the progress of science and technology, without detracting significantly from the incentives of the patentee to invent in the first place.

However, in so far as experimenting on a patented invention in order to design around the patent is concerned, one may argue that the above arguments do not hold good. For one, the end product of a design around strategy will

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[18] *See generally* Andrew S. Baluch, Note, *Relating the Two Experimental Uses in Patent Law: Inventor's Negation & Infringer's Defense*, 87 B.U. L. REV. 213, 215, 243 (2007).

[19] Eisenberg, *supra* note 16, at 224. One of the most vocal and oft cited authorities of this school of thought is Judge Newman, who in her dissenting opinion in the *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860, 873 (Fed. Cir. 2003) (Newman, J., dissenting-in-part, concurring-in-part), held the following:

> The purpose of a patent system is not only to provide a financial incentive to create new knowledge and bring it to public benefit through new products; it also serves to add to the body of published scientific/technologic knowledge. The requirement of disclosure of the details of patented inventions facilitates further knowledge and understanding of what was done by the patentee, and may lead to further technologic advance. The right to conduct research to achieve such knowledge need not, and should not, await expiration of the patent. That is not the law, and it would be a practice impossible to administer.

[20] Baluch, *supra* note 18, at 244.

naturally avoid implicating the patentees' right. This being so, the ease or otherwise of a design around strategy is likely to impact the incentive of a putative patentee to invest in research and development of certain technologies. Proponents of the broader exception are, however, likely to counter such a concern by arguing that the need to encourage experimentation and research ought not to be solely dependent upon whether or not a patentee's incentives are likely to be implicated. After all, experimenting with a patent to help advance the technology in question is not quite the same thing as merely "using" the patent in question without any attendant benefits to society. Further, the law ought not to prevent the emergence of alternative technologies, only because such new technologies might render existing patented technology obsolete.

In fact, the fear of a third party working around the patent and rendering it obsolete will ensure that the patentee does not rest on her laurels but is continuously working to improve the patented technology.[21]

Notwithstanding all of the above, it is critical to bear in mind that inventing around is easier said than done and presents a realistic possibility only in some areas of patented technology, where the claims are narrow and the technology easy to invent around.

B. The Case for a Narrow "Philosophical" Interpretation

Proponents of the "narrow" approach advocate limiting the exception to only two cases: first, those experiments that are carried out to test whether the patentee has made an enabling disclosure, and second, only those experiments that are strictly "philosophical" in nature, i.e., those executed to satiate scientific curiosity and not with a view towards furthering commercial interests. Under such an interpretation, any use of the patented invention with a view to improve on it or to invent around it ought not be permitted as it significantly detracts from the "incentive" theory.[22]

Further, it might cause a putative patentee to opt for "trade secrecy." In other words, since a broad research exemption is likely to harm the pecuniary interests of a patentee, a putative patentee may shy away from disclosing details of her invention via the patent system.[23] Although this theory has some merit,

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21 *See* Mark A. Lemley, *The Economics of Improvement in Intellectual Property Law*, 75 TEX. L. REV. 989, 1084 (1997).

22 Jordan P. Karp, *Experimental Use as Patent Infringement: The Impropriety of a Broad Exception*, 100 YALE L.J. 2169, 2188 (1991).

23 Prof. Eisenberg, who is one of the principal proponents of having a broad use experimental exception, does concede this point when she says that "the rationale for such an [exception] is in tension with the incentives justification for patents" since allowing unlicensed use of pa-

the fear of a broad exception leading to a migration towards trade secrecy may be overstated, as trade secrecy fails to protect otherwise "self-disclosing" inventions, as discussed earlier. A good example is pharmaceutical drugs, which are routinely reverse engineered by generic manufacturers.

IV. THE EXPERIMENTAL USE EXCEPTION: A DEVELOPMENTAL PERSPECTIVE

Most of the current literature on the experimental use exception has focused on its scope in developed economies such as the United States, United Kingdom, Germany, and Japan.

This Article seeks to therefore offer a more "developmental" perspective by exploring the scope of the exception, as it exists in the patent regime of a prominent developing country, India.

In an earlier section, this Article considered the various patent theories that are implicated by the experimental use exception.[24] In so far as developing countries are concerned, an additional factor to be taken into consideration is the prospect or otherwise of "knowledge spillovers" through patents.

It could be argued that TRIPS is premised, to some extent, on the notion that higher intellectual property norms in developing countries that are net importers of technology will lead to a transfer of technology from the developed countries. Many scholars are highly skeptical of this theory and opine that, despite the passage of more than a decade since the signing of TRIPS, many developing countries are yet to see any promise of this transfer of technology.[25]

Indeed, developed countries are under no binding TRIPS obligation to transfer any technology to developing countries.[26] However, developing coun-

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tented invention for 'design around attempts' would reduce the value of the original patents by significantly cutting down the monopoly period. *See* Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1036 (1989).

24 *See supra* Part II.

25 *See generally* Dominique Foray, *Technology Transfer in the TRIPS Age: The Need for New Types of Partnerships Between Least Developed and Most Advanced Economies*, INT'L CENTRE FOR TRADE & SUSTAINABLE DEV. (ICTSD), May 2009, at 6–7, http://ictsd.org/downloads/2009/07/foray_may2009.pdf; Sunil Kanwar, *Intellectual Property Protection and Technology Transfer: Evidence From US Multinationals* 1 (Univ. of Cal. San Diego Dep't of Econ. Discussion Paper No. 2007-05, 2007), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1001128.

26 Article 66.2 of TRIPS mandates developed countries to provide incentives to their home enterprises for encouraging technology transfer to least developed countries ("LDCs"). However, from the various country reports to the TRIPS council, it would appear that this

tries have a number of flexibilities within TRIPS to tweak patent doctrine and acquire knowledge or technology by themselves.

One such flexibility is the experimental use doctrine, a liberal reading of which would provide enough wiggle room for many developing countries to work on patented inventions and absorb underlying technology.[27] Such work is likely to enhance developing countries' technological capabilities, and could even help them invent around the patented invention or building follow-on improvements. However, in order for patents to effectively enable such knowledge "spillovers,"[28] the patent specification document has to be comprehensive and "enabling," an aspect dealt with *infra*.

Incremental pharmaceutical innovations in the context of India provide an excellent example in this regard. The Indian pharmaceutical industry, after thirty-five years of perfecting the process of manufacturing generic pharmaceuticals, has developed a strong set of skills in the field of incremental innovation, as opposed to pioneering or radical innovations that normally entail the discov-

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obligation has not been taken too seriously by developed countries. A commentator argues that the reports do not provide sufficiently detailed data to determine whether Article 66.2 led to any additional incentives beyond business-as-usual foreign aid. *See* SUERIE MOON, DOES TRIPS ART. 66.2 ENCOURAGE TECHNOLOGY TRANSFER TO THE LDC'S?: AN ANALYSIS OF COUNTRY SUBMISSIONS TO THE TRIPS COUNCIL (1999–2007), at 5–6 (2008), http://ictsd.org/downloads/2009/03/final-suerie-moon-version.pdf.

[27] In the context of a firm, absorptive capacity has been broadly defined as "A firm's capacity to assess the value of external knowledge and technology, and make the necessary investments and organizational changes to absorb and apply this in its productive activities." Itzhak Goldberg et al., *Globalization and Technology Absorption in Europe and Central Asia: The Role of Trade, FDI, and Cross-Border Knowledge Flows* xii (World Bank, Working Paper No. 150, 2008), *available at* http://siteresources.worldbank.org/EXTECAREGTOPKNOECO/Resources/globalization_tech_absorption_FullReport.pdf; *see also* Bin Xu & Eric P. Chiang, *Trade, Patents and International Technology Diffusion*, 14 J. INT'L TRADE & ECON. DEV. 115, 123 (2005) (discussing "the importance of human capital and technology catch-up in the process of technology diffusion").

[28] In the existing literature, "knowledge transfer" refers broadly to the "intentional" sharing of knowledge; "knowledge spillover," however, refers to the unintentional dissemination of knowledge. *See* Roger Smeets & Albert de Vaal, *An Integrated Framework of Knowledge Spillovers from FDI* 3 (Nijmegen Center for Economics (NiCE), Working Paper No. 06-103, 2006), *available at* http://www.ru.nl/economics/research/nice_working_papers (follow "An Integrated Framework of Knowledge Spillovers from FDI" hyperlink). Illustratively, a pharmaceutical drug that can be reverse engineered facilitates a "knowledge spillover," in that a third party could break up the drug and gain knowledge of its constituent parts. The same manufacturer could also effectuate a "knowledge transfer" by entering into a technology transfer agreement with a third party and communicating the nuances of the drug and the process of manufacture.

ery of new molecules or "New Chemical Entities."[29] Incremental innovations typically entail improvements over existing compounds and include the creation of new processes, salts, polymorphic forms, isomers, combinations, metabolites, pro-drugs, and new drug delivery systems.[30] Since incremental innovation is usually undertaken on pharmaceutical molecules that already exist and are mostly under patent, a liberal experimental use exception would enable Indian companies and other interested parties to experiment and improve upon such existing molecules.

A. Technologically Proficient Developing Countries and Outsourced R&D

A wide experimental use exception is particularly helpful for technologically proficient developing countries such as India, China, and Brazil. As the term indicates, such countries, though termed as "developing," when compared to their "developed" counterparts demonstrate significant technological capabilities.[31] However, such capabilities have yet to convert into significant levels of innovation.

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[29] This proposition is substantiated by the number of patents that Indian pharmaceutical companies have been applying for in the field of incremental innovation. One Government of India Report in fact listed at least 339 Patent Cooperation Treaty ("PCT") applications made by Indian pharmaceutical companies in the field of incremental innovation. *See* R.A. MASHELKAR ET AL., MINISTRY OF INDUS. & COMMERCE, GOV'T OF INDIA, REPORT OF THE TECHNICAL EXPERT GROUP ON PATENT LAW ISSUES annexure IV at 44–54 (rev. 2009), http://www.patentoffice.nic.in/RevisedReport_March2009.doc; *see also* Press Release, Coalition for Healthy India, Restricting Innovation is Hurting Indian Patients: United States Indian Business Council Coalition for Healthy India (Aug. 27, 2009) (India PRwire), *available at* http://www.indiaprwire.com/pressrelease/health-care/2009082632360.htm (commenting on a recent report titled "The Value of Incremental Pharmaceutical Innovation: Benefit for Indian Patients and Indian Business" released by the United States-India Business council, which reported that "[I]ncremental pharmaceutical innovations have accounted for as much as 65% of new drug approvals by regulatory agencies. Over 60% of the drugs on the World Health Organization' [sic] list of essential medicines reflect incremental improvements of older drugs.").

[30] *See* Secretariat, World Intellectual Property Organization, *Follow-On Innovation and Intellectual Property* 13–14 (World Intellectual Prop. Org., Working Paper, May 20, 2005), *available at* http://www.wipo.int/export/sites/www/patentscope/en/lifesciences/pdf/who_wipo.pdf.

[31] Shamnad Basheer & Annalisa Primi, *The WIPO Development Agenda: Factoring in the "Technologically Proficient" Developing Countries*, *in* IMPLEMENTING WIPO'S DEVELOPMENT AGENDA 100, 101–02 (Jeremy de Beer ed., 2009), *available at* http://ssrn.com/abstract=128928.

Globalization has meant not just the breaking down of national barriers for the cross-border passage of goods and services, but also of R&D. Indeed, multinational companies are increasingly outsourcing their R&D to low cost developing countries, such as India, Brazil, and China, that boast technological proficiency and highly skilled personnel.[32]

Consider the case of India. A 2007 report states that more than 150 foreign companies carried out R&D in India.[33] Between 1998 and 2003, these companies invested over $1.1 billion in R&D.[34] In 2005–2006, these companies pledged investments of $8.6 billion.[35] These companies included Microsoft, Intel, Cisco Systems, IBM, Alcatel, Ericsson, EMC Elcoteq, Flextronics, Nokia, Samsung, Siemens, General Electric, Texas Instruments, etc.[36] These R&D operations are carried out in the any of the three following modes: (1) in-house R&D, (2) collaborations with other companies, and (3) contracts research with private entities, public sector laboratories, and universities.[37]

The variety of outsourced work ranges from software development and computer chip design, to clinical trials, and in some cases, even drug discovery.[38] According to a consultancy report, as of 2008, there were at least 737 ongoing clinical trials in India.[39] The reasons were obvious: trials in India cost significantly less than what they could cost in the developed world.[40] Further,

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32 *See* Paul Maidment, *Outsourcing Innovation?*, FORBES, May 29, 2007, http://www.forbes.com/2007/05/21/outsourcing-china-innovation-oped-cx_pm_0529china.html (discussing the growth of China's R&D); *see also* Martin Grueber & Tim Studt, *Global Perspective: Emerging Nations Gain R&D Ground*, R&D MAG., Dec. 2009, at 20, 20, *available at* http://www.rdmag.com/uploadedFiles/RD/Featured_Articles/2009/12/GFF2010_ads_small.pdf.

33 Raja M. Mitra, *India's Emergence as a Global R&D Center—An Overview of the Indian R&D System and Potential* 53 (ITPS, Swedish Inst. for Growth Policy Studies, Working Paper No. R2007:012, 2007), *available at* http://www.itps.se/Archive/Documents/Swedish/Publikationer/Rapporter/Arbetsrapporter%20(R)/R2007/R2007_012_webb.pdf.

34 *Id.*

35 *Id.*

36 *Id.* at 53–54; *see also* N. Mrinalini & Sandhya Wakdikar, *Foreign R&D Centres in India: Is There Any Positive Impact?*, 94 CURRENT SCI. 452, 455 (2008) (discussing the large number of foreign organizations having R&D centers in India).

37 Mitra, *supra* note 33, at 56.

38 PRICE WATERHOUSE COOPERS, THE CHANGING DYNAMICS OF PHARMA OUTSOURCING IN ASIA: ARE YOU READJUSTING YOUR SIGHTS? 7 (2008), http://www.pwc.com/en_GX/gx/pharma-life-sciences/pdf/change_asia_10_08_08.pdf.

39 *Id.* at 14.

40 *Id.* at 27–28.

India offers a large population pool with a diverse disease pool, thereby making it easier to identify and enroll patients into clinical research programs.[41]

Given that the world's R&D leader, the United States, has a fairly parsimonious research exception, India must actively leverage the existence of its rather wide research exception to attract more research from the United States. In a study by the American Association for the Advancement of Sciences ("AAAS"), forty percent of the respondents reported problems in securing patent licences to carry out research projects; fifty-eight percent reported that their research was delayed as a result; while another twenty-eight percent reported that their research had been abandoned due to difficulties in securing licenses.[42] Illustratively, take the case of Arupa Ganguly, a researcher at the University of Pennsylvania who had to desist from testing a patented gene (for both clinical and research purposes) owing to the forceful assertions of Myriad Genetics, the patentee.[43] Given the wide experimental use exception and the technically sophisticated labs and personnel in India, Ms. Ganguly could have easily shipped her research to India and continued it there.

She could have improved upon the patented testing kit of Myriad without risking infringement actions. The potential for the progress of science and innovation, if only a liberal research exception existed, is evident from the fact that Institut Curie, a French institute, had used one of its technologies called "combed DNA colour bar coding" to identify a mutation in BRCA1 in a patient who had received a negative result (meaning no mutations detected) when tested by Myriad.[44] This indicated that Myriad's tests were far from perfect and that Myriad's approach to testing, which involved full DNA sequencing of the two BRCA genes, could detect only small-scale deletions and rearrangements.[45] Myriad's patents, however, ensured that the company could stunt the emergence of any other tests, at least in the European Union and United States.[46]

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41 *Id.* at 28.

42 STEPHEN HANSEN ET AL., INTELLECTUAL PROPERTY IN THE AAAS SCIENTIFIC COMMUNITY: A DESCRIPTIVE ANALYSIS OF THE RESULTS OF A PILOT SURVEY ON THE EFFECTS OF PATENTING ON SCIENCE 4 (2005), http://www.juergen-ernst.de/download_swpat/studie_sippi.pdf.

43 *See* Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 669 F. Supp. 2d 365, 372 (S.D.N.Y. 2009).

44 *See* Bryn Williams-Jones, *History of a Gene Patent: Tracing the Development and Application of Commercial BRCA Testing*, 10 HEALTH L.J. 123, 139 (2002).

45 *Id.*

46 *See* Shamnad Basheer, *Block Me Not: How "Essential" Are Patented Genes?*, 1 J.L. TECH. & POL'Y 55, 61 (2005).

B. Investor Perception

One may argue that an extremely broad experimental use exception may discourage potential investors from off-shoring R&D activities to India, because such investors may fear that lax patent laws may impact the protection that their own inventions are likely to receive in India. However, the empirical evidence has not borne out this fear and, if anything, the quantum of outsourced R&D activities in India has only been increasing each year.[47]

This is not all that surprising. For one, the dramatic cost savings from R&D outsourcing more than compensates for what some may perceive as weak patent protection. Secondly, and perhaps more importantly, weak patent protection and its perceived impact on India's potential as a desirable R&D base may be nothing more than a false signal. Consider the fact that most global R&D centers in India aim to build products or services for the global markets.[48] These products are likely to be patented in developed country markets such as the United States, the European Union, and Japan. Therefore, the lack of strong patent protection in India, which is a relatively insignificant market, may not pose a strong enough disincentive when a global company considers outsourcing its R&D to India.[49]

In other words, the decision to outsource R&D to India is primarily dependant on India's attractiveness as a low cost and high skilled destination, and has but a weak nexus to the strength of patent protection in India.

What might turn out to be more significant for multinational corporations that wish to outsource R&D to India is the strength of "trade secrecy" protection in India.[50] This link is an easy one to appreciate, as often times em-

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47 "A positive picture of India's IP regime was supported by most of the companies we interviewed during our field research in India: Nearly all respondents recognized the relative safety of IPRs in India and the impartial judicial process by the authorities concerned . . . ." Cornelius Herstatt et al., *India's National Innovation System: Key Elements and Corporate Perspectives* 31 (Hamburg Univ. of Tech., Working Paper No. 51 2008), *available at* http://www.tu-harburg.de/tim/downloads/arbeitspapiere/Working_Paper_51.pdf. In fact, when asked the question "Safety of intellectual property rights in India—a positive factor?," 88% of respondents replied in the positive. *Id.* at 32.

48 *Id.* For example the website of the GE's largest R&D center in India, the John F. Welsh Technology Centre (JFWTC), clearly states that the facility has been set up to to "to conduct research, development and engineering activities for all of GE's diverse businesses worldwide." GE in India, http://www.ge.com/in/company/factsheet_in.html (last visited Mar. 20, 2010).

49 Indian patent laws may matter only when the invention caters primarily to the local market.

50 *See* Edwin L.-C. Lai et al., *Outsourcing of Innovation*, 38 ECON. THEORY 485, 506–07 (2009) (explaining how trade secrecy can can increase the benefits of outsourcing).

ployees working on cutting edge research in a particular R&D unit cross over to a competitor and disclose earlier R&D ideas, giving them an undue advantage.[51] Since India recognizes a common law right of trade secrecy or confidentiality that bars such disclsoure to a competitor, it offers some level of protection to corporations that wish to open R&D units in India.[52]

Be that as it may, India and other technologically proficient developing countries ought to leverage its liberal experimental use exception in order to attract more outsourced research from the developed countries such as the United States, where the exception may be of narrower scope.[53]

We demonstrate below that the experimental use exception in India is wide enough to accommodate the above interests.

V. ENABLING EFFECTIVE DISCLOSURE FUNCTION UNDER PATENT LAW

As noted earlier, in order to effectively leverage the exception, developing countries must ensure that there is a complete and enabling disclosure of the patented invention. Most patent regimes require that a skilled person in the art ought to be able to arrive at the patented invention from the specification without undue experimentation. This doctrine is known by various names, with the United Kingdom referring to it was the doctrine of sufficient disclosure, and the United States referring to it as the written description and the enablement requirements.[54]

Without a corresponding experimental use exception, the enablement or sufficient disclosure requirement is meaningless. For it would be paradoxical to enjoin someone who is merely testing a patented invention with a view to determining if it was sufficiently "enabled."

Secondly, and perhaps more importantly, an experimental use exemption is likely to advance the broader goal of patent law, i.e., to induce more innovation. Specifically, it could offer critical insights to a researcher who might

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51 Bibhu Ranjan Mishra, *Data theft more common in India, China*, BUS. STANDARD, Oct. 2, 2008, at 13, 13, *available at* http://www.business-standard.com/india/storypage.php?autono=336073.

52 *See* Satwant Reddy & Gurdial Singh Sandhu, REPORT ON STEPS TO BE TAKEN BY GOVERNMENT OF INDIA IN THE CONTEXT OF DATA PROTECTION PROVISIONS OF ARTICLE 39.3 OF TRIPS AGREEMENT 13 (2007), *available at* http://chemicals.nic.in/DPBooklet.pdf.

53 As discussed below, the scope of the common law experimental use exception prevalent in the United States was whittled down considerably in *Madey v. Duke University*, 307 F.3d 1351 (Fed. Cir. 2002). *See infra* text accompanying notes 94–102.

54 Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1344 (Fed. Cir. 2010).

then improve upon the patented invention or to even work around it and create an alternative technology.

However, the above disclsoure requirement has been gamed by clever attorneys who hide more than they reveal in patent applications.[55] The information technology industry, in particular, is infamous for producing patents that grant little, if any, information about the underlying nature of the patented discovery.[56] A Microsoft employee admitted that patent claims are drafted in such a way that they never actually disclose anything useful.[57]

The upshot of all this is that many published patents are of little use to others as a result of "intentional obscurity."[58] As a commentator rightly notes, "When specifications fail to teach how protected technologies operate, the disclosure function of the patent laws is subverted."[59] Countries therefore ought to insist on higher disclsoure standards. This would not only ensure that patentees live up to their part of the bargain and merit the twenty-year monoploy that society grants them, but also help a number of countries to study patents effectively and experiment with underlying technology.

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55 Sean B. Seymore, *The Teaching Function of Patents*, 85 NOTRE DAME L. REV. 621, 625–27 (2010).

56 Dan L. Burk & Mark A. Lemley, *Is Patent Law Technology-Specific?*, 17 BERKELEY TECH. L.J. 1155, 1164 (2002); Alan Devlin, *The Misunderstood Function of Disclosure in Patent Law* 15, 23 HARVARD J.L. & TECH. (forthcoming 2010), *available at* http://ssrn.com/abstract=1490722; Ben Klemens, *The Rise of the Information Processing Patent*, 14 B.U. J. SCI. & TECH. L. 1, 35 (2008) (concluding that "patents on software and other information-processing technologies are virtually useless for disclosure purposes"); Henry E. Smith, *Institutions and Indirectness in Intellectual Property*, 157 U. PA. L. REV. 2083, 2127–28 (2009); Bruce Perens, *The Problem of Software Patents in Standards*, http://perens.com/Articles/PatentFarming.html (Aug. 22, 2005).

57 I. M. Wright's "Hard Code", NIHilism and Other Innovation Poison, http://blogs.msdn.com/eric_brechner/archive/2008/11/01/nihilism-and-other-innovation-poison.aspx (Nov. 1, 2008, 18:13).

58 *See* Patently-O, Philips v. AWH Takes a Casualty: "Interface" Construed as "Parallel Bus Interface," www.patentlyo.com/patent/2006/05/philips_v_awh_t.html (May 11, 2006, 22:32) (explaining that there is a "trend of intentional obscurity in patent drafting").

59 Devlin, *supra* note 56, at 16.

VI. THE EXPERIMENTAL USE EXCEPTION IN INDIA: A HISTORICAL JAUNT

Although Indian patent law has had a fairly long history,[60] a statutory "experimental use" exception was added only in 1970.[61] At the time of its enactment, the Indian experimental use exception had no parallel in any of the major patent legislations around the world.[62] The credit for its articulation goes to Justice N. Rajagopala Ayyangar, whose visionary report formed the backbone of India's first "indigenous" patent regime in 1970.[63]

This report found *inter alia* that the predecessor regime, Patents Act 1911, was skewed in favor of foreign patentees, who merely obtained patent rights in India to secure monopolies and import their patented articles into India.[64] Most such patentees did not use the patent in India nor help indigenous industry in any way; rather, the cost of imported products, particularly drugs, was often excessive and unaffordable by the Indian consumer.[65] In order to reverse this trend and to encourage indigenous innovation, the Ayyangar Committee made numerous recommendations to amend Indian patent law.[66]

One such suggestion was the creation of the "experimental use" exception, so that the rights conferred upon the patentees do not impede "the rights of research workers to use the invention—whether it be an article or a process—for

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60 The first patent legislation came into force in 1856. Controller General of Patents Designs and Trademarks, History of Indian Patent System, http://www.patentoffice.nic.in/ipr/patent/patents.htm (last visited Mar. 22, 2010).

61 Section 47(3) was introduced for the first time in the Indian Patents Act 1970. The Patents Act, No. 39 of 1970, § 47(3) (India).

62 At the time that the Indian Patents Act 1970 was enacted, none of the major jurisdictions, including the United States, the United Kingdom, Canada, and Australia, had a statutory experimental use exception.

63 The Patents Act 1970, enacted by the Indian legislature to replace the Patents and Designs Act 1911, was based substantially on the findings of the Ayyangar Committee Report. *See* Shamnad Basheer, *"Policy Style" Reasoning at the Indian Patent Office*, 3 INTELL. PROP. Q. 309, 318 n.56 (2005).

64 N. RAJAGOPALA AYYANGAR, REPORT ON THE REVISION OF THE PATENT LAW ¶ 478 (1959).

65 The U.S. Senate Subcommittee on Antitrust and Monopoly, under the leadership of Senator Keufeur, conducted an in-depth investigation into the pricing of the pharmaceutical drugs in 1961, and one of its many findings was that the price of some pharmaceutical drugs, such as Meprobamate in India was a 50% more in India than in the United States. This report is popularly referred to as the Keufeur Committee Report (1961). SUBCOMM. ON ANTITRUST & MONOPOLY, ADMINISTERED PRICES DRUGS, S. REP. NO. 87-448, at 35 (1961).

66 One of the main recommendations was to do away with product patents for inventions pertaining to foods and drugs. AYYANGAR, *supra* note 64, ¶ 478.

the purposes of carrying out experiments—in the course of research as distinguished from use for a commercial purpose."[67] However, the Committee drew an important distinction between the use of a patented invention for the purpose of carrying out experiments, and its use for a commercial purpose. While the former was desirable, the latter was to be enjoined, as below:

> Notwithstanding anything in this Act, the making or using of a patented machine or apparatus or other article, or the use of a patented process or the use of an article made by the use of the patented process, machine or apparatus for the purpose merely of experiment or research including the imparting of instruction to pupils and not by way of commercial use, shall not be deemed to constitute an infringement of the rights conferred on a patentee by this Act.[68]

While enacting section 47 of the Indian Patents Act, the Indian legislature chose to ignore this important limitation in relation to a prohibition on "commercial use," thereby suggesting that the exception was to be of even wider amplitude than that envisaged by the Ayyangar Committee.

VII. INTERPRETING SECTION 47(3) OF THE INDIAN PATENTS ACT 1970

Unfortunately section 47(3), which encapsulates the experimental use exception, has yet to be invoked before a court of law. Therefore, one has to interpret this in accordance with the text of the statutory provision, and legislative history, wherever possible.

It reads as follows:

> 47. Grant of patents to be subject to certain conditions
>
> The grant of a patent under this Act shall be subject to the condition that—
>
> . . . .
>
> (3) any machine, apparatus or other article in respect of which the patent is granted or any article made by the use of the process in respect of which the patent is granted, may be made or used, and any process in respect of which the patent is granted may be used, by any person, for the purpose merely of experiment or research including the imparting of instructions to pupils . . . .[69]

In short, section 47(3) provides that any person may make or use the patented invention, whether it be a product or a process or even an article or prod-

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67 *Id.* ¶ 488.

68 *Id.* ¶ 492.

69 The Patents Act, 1970, No. 39 of 1970, § 47(3) (India).

uct made by a process, for the "purpose merely of experimentation, research, or for imparting instruction to pupils."[70]

This provision appears more liberal than corresponding provisions in most other countries, as demonstrated below.[71]

A. Investigating the Scope of "Experiment"

A plain reading of the Indian exception is in line with the "broad" school of thought outlined earlier, which suggests that the exception be wide enough to even support activities such as "inventing around" the patented invention or the making of improvements thereto.

This is buttressed by the fact that the Indian legislature consciously avoided limiting the scope of the exception to "non commercial" purposes. However, the key limitation is that the alleged use has to qualify as an "experiment" and cannot be a mere consumer type "use" where the patented product is merely enjoyed as it is without any investigation of underlying technology. Some scholars cater to this concern by advocating a distinction between "experimenting on" and "experimenting with" the patented invention in question.[72]

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70 *Id.*

71 In a report on the "experimental use" exception, the Australian Law Reform Commission pointed out that there may exist an implied experimental use defense in Australian common law and that the same had never been tested in a court of law. AUSTL. LAW REFORM COMM'N, GENES AND INGENUITY: GENE PATENTING AND HUMAN HEALTH ¶ 13.5 (2004), *available at* http://www.austlii.edu.au/au/other/alrc/publications/reports/99/. It further clarified that Australia has only a *Bolar* exception. In the same report the Australian Law Reforms Commission has recommended the insertion of an "experimental use exemption." *Id.* ¶ 13.3. In 2005, the Advisory Council for Intellectual Property submitted to the Australian Government an exhaustive report recommending that the Australian law be amended to provide for an experimental use exception. *See* ADVISORY COUNCIL ON INTELLECTUAL PROP., AUSTL. GOV'T, PATENTS AND EXPERIMENTAL USE 5 (2005), *available at* http://www.acip.gov.au/ (search "Patents and Experimental Use"; then follow "Patents and Experimental Use" hyperlink). Canadian Law provides for an experimental use exception but it is limited only to' non-commercial' uses. Patent Act, R.S.C., ch. P 4, § 55.2(6) (1985) (Can.).

> For greater certainty, subsection (1) does not affect any exception to the exclusive property or privilege granted by a patent that exists at law in respect of acts done privately and on a non-commercial scale or for a non-commercial purpose or in respect of any use, manufacture, construction or sale of the patented invention solely for the purpose of experiments that relate to the subject-matter of the patent.

Id.

72 Janice M. Mueller, *No "Dilettante Affair": Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools*, 76 WASH. L. REV. 1, 39 (2001).

The former, "experimenting on," involves the use of a patented invention with a view towards studying the underlying technology and confirming that it indeed works in the manner spelled out by the patentee. Such study could also be geared towards improving the patented technology or even inventing around it. On the other hand, the latter, "experimenting with," often entails the use of a patented invention—as it is—and not necessarily to study or appreciate the invention or underlying technology or to improve it.

This distinction is best explained in the context of research tools, which for the sake of convenience can be defined as those inventions whose predominant utility is research itself.[73] Illustratively, consider a patented substance X whose only purpose is to act as a catalyst in a particular chemical reaction. Assume that such catalyst could be manufactured with relative ease in a lab with some basic chemical ingredients. If the manufacture and use of X was permitted under an experimental use exception, then no one would ever license it from the patentee. Rather, they would make this research tool themselves in the lab and use it as a catalyst. In such a context, the grant of a patent to such a "research tool" becomes virtually meaningless.[74] The logical fallout of this is that, if the incentive theory holds good for patented research tools, then the number of such inventions are likely to decrease over the years.

The distinction between "experimenting on" and "experimenting with" appears logical and consistent with the broad rationales underlying patent grants. While experimenting *with* an invention, particularly research tools, would significantly impact a patentees' exclusive rights and thereby impact the "incentive" to create such an invention, experimenting *on* an invention may not disturb the putative patentees' incentive for innovation to the same degree.[75]

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[73] According to the National Institute of Health (NIH), research tools or "unique research resources" are defined to be "tools that scientists use in the laboratory, including cell lines, monoclonal antibodies, reagents, animal models, growth factors, combinatorial chemistry and DNA libraries, clones and cloning tools (such as PCR), methods, laboratory equipment and machines." Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources: Final Notice, 64 Fed. Reg. 72,090, 72,092 (Dec. 23, 1999). In *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860 (Fed. Cir. 2003), *vacated*, 545 U.S. 193 (2005), one fundamental point of disagreement between the majority and minority opinion was whether or not the invention in question was in fact a research tool or a regular invention. *See id*. at 877–88 (Newman, J., concurring-in-part, dissenting-in-part).

[74] Mueller, *supra* note 72, at 39–40.

[75] The NIH Working Group supports this distinction between "on" and "with." *See* WORKING GROUP ON RESEARCH TOOLS, NAT'L INST. OF HEALTH, REPORT OF THE NATIONAL INSTITUTES OF HEALTH (NIH) WORKING GROUP ON RESEARCH TOOLS app. D (1998), http://www.nih.gov/news/researchtools/appendd.htm.

The "experimental use" exception under section 47(3) of the Patents Act 1970 does not expressly strike a distinction between "experimenting with" and "experimenting on."[76] However, one might interpret the word "merely" that appears before the words "experiment or research" to reach such a result.[77]

Firstly, the term "merely" follows the word "purpose"; it is therefore logical to assume that it limits the *purpose* for which the use of the patented invention can be used, i.e., the purpose must be primarily intended for "experimental," "research," or "educational' purposes." Assuming that the key purpose of the use of a patented invention is to "experiment with" it, such use will not presumably qualify as a use "merely for the purpose of experiment or research."[78]

Apart from the above, a failure to strike such a distinction would virtually obliterate the rights of a research tool patentee and hit at the very essence of section 48 of the Indian Patents Act, which lays down that every patentee shall have the exclusive right to make, use, sell, etc. her patented invention.[79] It will also arguably fall foul of TRIPS, under which a patent exception cannot affect the legitimate rights of a patentee, a point that will be discussed in detail in the section below. Given these concerns, an Indian judge is likely to read in such a distinction into the section, at least in so far as research tool patents are concerned.

It must be borne in mind that the Japanese provision is similarly worded and has read in such a limitation. Article 69(1) of the Japanese Patent Act provides that "the effects of the patent right shall not extend to the working of the patent right for the purposes of experiment or research."[80]

In this context, it is interesting to note that, much like the Indian provision, the Japanese provision also uses the term "research" along with the term "experiment."[81] Absent a court ruling in this regard, it is not clear whether or not the word "research" necessarily broadens the scope of this provision. Assuming, however, that the word experiment is limited to "experimenting on," the word "research" also is likely to be limited to "researching on."

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76 *See* The Patents Act, No. 39 of 1970, § 47(3) (India).

77 *Id.*

78 *Id.*

79 Consider for example, Judge Rader's observation in *Integra Lifesciences I, Ltd. v. Merck KGaA* that a very broad "experimental use" exemption would render a "research tool" patent "a charitable (but nondeductible) gift to the pharmaceutical industry." 496 F.3d 1334, 1352–53 (Fed. Cir. 2007) (Rader, J., dissenting-in-part, concurring-in-part).

80 Tokkyohō [Patent Act], Law No. 121 of 1959, art. 69(1) (Japan).

81 *Id.*

T.A. Blanco White, the British commentator on whose analysis Justice Ayyangar appears to have relied, drew this subtle, far-sighted distinction between "experimenting on" and "experimenting with" in his treatise on patent law, where he noted:

> Mere experiment with a patented invention would appear not to amount to infringement; but it is the invention itself that must for this purpose be the subject of experiment and not (for instance) the product of a patented process or the commercial potentialities of the invention. And it would seem that a claim of right to exercise the invention may convert an experimental exercise into an actionable threat to infringe.[82]

The current English section, section 60(5) of the Copyright, Designs and Patents Act 1988, which states that the experimental use has to "relat[e] to the subject matter of the invention,"[83] might support such a distinction as well.[84]

B. "Educational" Purposes

The Ayyangar Committee report recommended that the experimental use exception also cover use for educational purposes.[85]

The main motivation for articulating this express exemption appears to have been a U.K. ruling, which suggested that the use of a patent for an educational purpose would still qualify as infringement.[86] The Committee opined that

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82 *See* T.A. BLANCO WHITE, PATENTS FOR INVENTIONS AND THE PROTECTION OF INDUSTRIAL DESIGNS ¶ 3-216 (4th ed. 1974) (internal citations omitted). For example, to see whether it can be improved upon. This example was given by Blanco White himself in his treatise. *Id.* He went on to state in his treatise that the commercial potentialities of the invention must also not be the subject of experiment. *Id.*

83 Patents Act, 1977, c. 37, § 60(5)(b) (Eng.). The Act states:

> An act which, apart from this subsection, would constitute an infringement of a patent for an invention shall not do so if—
>
> (a) it is done privately and for purposes which are not commercial;
>
> (b) it is done for experimental purposes relating to the subject-matter of the invention.

Id. § 60(5)(a)–(b).

84 The court, in *Auchincloss v. Agricultural & Veterinary Supplies*, stated that "[t]he subject-matter of the invention, for the purposes of section 60(5)(b), must be ascertained from the patent as a whole." [1999] R.P.C. 397, 399 (Eng.).

85 AYYANGAR, *supra* note 64, ¶ 489.

86 *See id.* ¶ 489 (discussing the British case of *United Telephone Co. v Sharples*, [1885] 29 Ch.D. 164). However, Justice Ayyangar appears to have overlooked the fact that in *United Telephone Co.* the articles being used for the alleged "experimental purpose" were actually "infringing" goods. *See* 29 Ch.D. at 166.

any enjoinment of legitimate educational use would "unduly hamper[] technical education."[87]

The value of such an express exemption cannot be overstated. Given the ruling in *Madey v. Duke University*,[88] one cannot readily assume that educational purposes would automatically fall within an "experimental use" exception.

C. The "Commercial" Requirement

As noted earlier, the Ayyangar Committee expressed one important reservation as to the permissible "purpose" of experimental use—i.e., the *purpose* ought not to be "commercial"—if it was to secure immunity from patent infringement.[89]

The fact that the Parliament chose to ignore this, while adopting most of the other recommendations of Justice Ayyangar, indicates a clear parliamentary intent to avoid limiting the scope of the experimental use exception to only non commercial uses.

While this position resonates broadly with English law, it stands diametrically opposed to U.S. law on this count, which would appear to test every alleged experimental use on the anvil of "commerciality."[90] Both of these legal regimes are considered in turn below.

1. U.K. Law

Section 60(5) of the 1977 Patent Act reads as follows:

> An act which, apart from this subsection, would constitute an infringement of a patent for an invention shall not do so if—
>
> (a) it is done privately and for purposes which are non-commercial;
>
> (b) it is done for experimental purposes relating to the subject matter of the invention.[91]

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87 AYYANGAR, *supra* note 64, ¶ 489.

88 307 F.3d 1351, 1362 (Fed Cir. 2002) (disregarding the educational use of the patented invention and finding that "so long as the act is in furtherance of the alleged infringer's legitimate business and is not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry, the act does not qualify for the very narrow and strictly limited experimental use defense"); *see also infra* text accompanying notes 96–104.

89 AYYANGAR, *supra* note 64, ¶ 488.

90 *See supra* text accompanying note 88.

91 Patents Act, 1977, c. 37, § 60(5)(b) (Eng.).

The express mention of the term "non-commercial" in clause (a) would suggest that clause (b) covers "commercial" purposes as well. In other words, clause (b) is not limited by the "commerciality" of the purpose for which an experiment is undertaken.[92] This line of argument finds support in the U.K. court's ruling in *Monsanto Co. v. Stauffer Chemical Co.*[93]

2. U.S. Position

In the United States, where the "experimental use" exception is a common law defense not yet articulated in statutory language, the "commerciality" or otherwise of one's intent would appear to be critical to a determination of the applicability of the defense. However, there is no "precedential" consistency in terms of the various case law in this regard.

In the first case to have expounded on the experimental use doctrine, *Whittemore* v. *Cutter*,[94] Justice Story limited the exception to only those cases which were of a purely philosophical nature, that is where the user merely played around with the patent to understand the underlying technology and satisfy her curiosity.[95] In *Sawin* v. *Guild*,[96] Justice Story once again had to determine the scope of the "experimental use" exception.[97] Drawing on his previous dicta in *Cutter*, Justice Story held:

> [T]he making [of the invention] with an intent to use for profit, and not for the mere purpose of philosophical experiment, or to ascertain the verity and exactness of the specification. In other words, that the making must be with an intent to infringe the patent-right, and deprive the owner of the lawful rewards of his discovery.[98]

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92 A commentator opines that the existence of clause (a) makes it clear that "the separate defence for experimental purposes relating to the subject matter of the invention must apply also to commercial activities (as otherwise that for private and non-commercial use would be otiose)." TREVOR COOK, A EUROPEAN PERSPECTIVE AS TO THE EXTENT TO WHICH EXPERIMENTAL USE AND CERTAIN OTHER DEFENCES TO PATENT INFRINGEMENT APPLY TO DIFFERING TYPES OF RESEARCH 27 (2006).

93 [1985] R.P.C. 515, 538 (Eng.) ("The distinction between the wording of sub-head (a) and the wording of sub-head (b) in section 60(5) indicates that experimental purposes in sub-head (b) may yet have a commercial end in view, as do all the activities of companies such as the parties to this dispute.").

94 29 F. Cas. 1120 (C.C.D. Mass. 1813) (No. 17,600).

95 *Id.* at 1121.

96 21 F. Cas. 554 (C.C.D. Mass. 1813) (No. 12,391).

97 *Id.* at 555.

98 *Id.* (citation omitted).

The above statement categorically introduced the "commercial intent" requirement into U.S. law. In other words, if the potential infringer did have an intent to use the invention for profit and in the process deprive the patentee of the lawful rewards of her invention, the use cannot be shielded under the exemption.[99]

The commercial intent theory gradually metamorphosed into the "legitimate business" theory in the *Pitcairn* v. *United States*[100] case, whereby if the infringer was "using" the invention in pursuit of her legitimate business, she could not claim an "experimental use" exception.[101] The "legitimate business" limb of the *Pitcairn* ruling was, however, misunderstood by the court in *Madey*, which proceeded to rely on this proposition in the abstract, when the fact situation was very different from what prevailed in *Pitcairn*.[102] In *Madey*, Duke University was sued for using a patented invention belonging to one of its erstwhile employees.[103] In its judgment, which has been roundly criticized by most academics, the court held that although there was no commercial motive to Duke's use of Madey's invention, the fact remained that Duke's use of such a research tool, a laser-related invention, in the course of experimentation increased its status in academia and thus attracted the best students, teachers, and grants, thereby furthering its legitimate business.[104] In the course of coming to this conclusion the *Madey* court held that it was irrelevant as to whether or not there was a commercial motive or whether the entity was a profit or non-profit institution.[105] The only relevant point was whether the patented invention was used in the course of furthering the legitimate business.[106]

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99 *See generally* Janice M. Mueller, *The Evanescent Experimental Use Exemption from United States Patent Infringement Liability: Implications for University and Nonprofit Research and Development*, 56 BAYLOR L. REV. 917, 928 (2004).

100 212 Ct. Cl. 168, 199 (1976).

101 *See* Mueller, *supra* note 99, at 931.

102 *See* Madey v. Duke Univ., 307 F.3d 1351, 1362 (Fed. Cir. 2002) ("In short, regardless of whether a particular institution or entity is engaged in an endeavor for commercial gain, so long as the act is in furtherance of the alleged infringer's legitimate business and is not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry, the act does not qualify for the very narrow and strictly limited experimental use defense.").

103 *Id.* at 1352–53.

104 *Id.* at 1362.

105 *Id.*

106 *Id.*

The *Madey* decision has been severely criticized for unduly narrowing the "experimental use exception" by convoluting precedents on the point.[107] As a commentator rightly points out, Duke could have been easily denied the exception on the ground that it merely experimented with Madey's invention—use of the free electron laser to get somewhere else—and not "on" the patented invention—i.e., to improve the laser.[108]

The restriction of any experimental use exception to non-commercial purposes is bad enough, as almost every research activity today can be said to have a commercial implication of some sort. With the sad metamorphosis of "commercial intent" to "legitimate business," one wonders what is left of the U.S. exception. Almost every user of the exception would presumably be doing so under the rubric of one or more "legitimate businesses."

The dangers of a judicially crafted exception are best exemplified by the United States, where the very same judiciary that created the exception in the first place literally killed it through a later judgment. Given this uncertainty with judicial interpretation, the express articulation of a rather wide exception in India and a refusal to induct the "commercial" requirement ought to be appreciated.

More importantly, given the obliteration of the exception in the United States and the risk of conducting research within U.S. soil, India ought to actively leverage its wide exception to attract more outsourced research from the United States. This will be discussed in further detail below.

D. Products of Patented Processes

Quoting Blanco White, Justice Ayyangar stated:

> Mere experiment with a patented invention would appear not to amount to infringement; but it is the patent itself that must be the subject of experiment and not (for instance) the product of a patented process. And it would seem that a claim of right to exercise the invention may convert an experimental exercise into an actionable threat to infringe.[109]

In the light of the above statement from Blanco White's treatise, Justice Ayyangar realized that there could arise an uncertainty as to the *extent* to which a pa-

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107 *See* Jennifer Miller, *Sealing the Coffin on the Experimental Use Exception*, 2003 DUKE L. & TECH. REV. 0012, ¶ 25 (2003); *see also* Tom Saunders, Comment, *Renting Space on the Shoulders of Giants:* Madey *and the Future of the Experimental Use Doctrine*, 113 YALE L.J. 261, 268 (2003).

108 Mueller, *supra* note 99, at 940.

109 AYYANGAR, *supra* note 64, ¶ 488 (quoting BLANCO WHITE, *supra* note 82, ¶ 3-216).

tented process could be used for experimental purposes.[110] He therefore recommended that the Indian Patents Act must not only exempt the experimental use of a "patented process," but also specifically exempt the experimental use of the product obtained from such a process.[111]

However, even in such a context, the use must comply with the other prerequisites of this section—i.e., it must be for the mere purpose of experiment or research, or for educational purposes. To this extent, there may not be an actual divergence between the views of Blanco White and Justice Ayyangar. Blanco White's concern might have been that an experiment with the "product" of a patented process may have nothing whatsoever to do with the subject matter of the patented process. In other words, one would merely "experiment with" the process or product and not "on" the patented process. However, if while in the course of "experimenting on" the process, the researcher also incidentally uses the patented product, Blanco White may have been likely to support the exemption of the activity from infringement.

VIII. TRIPS ANALYSIS

The TRIPS agreement allows for two broad kinds of exceptions to patent rights. The first set of exceptions are general exceptions under the broad rubric of Article 30, which stipulates 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."[112]

The second exception encapsulated in Article 31 specifically caters to compulsory licensing.[113]

The TRIPS compatibility or otherwise of an experimental use exception has to be analyzed within the broad rubric of Article 30.[114]

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110 *Id.*

111 *Id.*

112 Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments—Results of the Uruguay Round, art. 30, 33 I.L.M. 1125, 1197, 1209 (1994) [hereinafter TRIPS].

113 *See Id*. art. 31(b), 33 I.L.M. at 1209. Articles 30 and 31 should be read separately since a footnote to Article 31 clearly mentions that "other uses" are those uses which are allowed for under Article 30. *See Id.* art. 31(b) n.7, 33 I.L.M. at 1209–10 & n.29.

114 Therefore, when there is no specific "experimental use" exception under Article 31, it is presumed that the general exception under "Article 30 would thus typically apply to cases

A. The Canadian Pharmaceuticals Case

The scope of Article 30 was discussed by the World Trade Organization ("WTO") Dispute Settlement Panel in *Canada: Patent Protection of Pharmaceutical Products*,[115] a case in which the European Communities and their member states, the European Union, challenged the TRIPS compatibility of certain provisions under the Canadian Patents Act.[116] Section 55.2 of the Canadian Patents Act provided that,

> (1) It is not an infringement of a patent for any person to make, construct, use or sell the patented invention solely for uses reasonably related to the development and submission of information required under any law . . . that regulates the manufacture, construction, use or sale of any product [also referred to as the "early working exception"].
>
> (2) It is not an infringement of a patent for any person who makes, constructs, uses or sells a patented invention in accordance with subsection (1) to make, construct or use the invention, during the applicable period provided for by the [Manufacturing and Storage of Patented Medicines Regulations], for the manufacture and storage of articles intended for sale after the date on which the term of the patent expires [also referred to as the "stockpiling exception"].[117]

The European Union argued that the above provisions contravened Articles 27.1, 28, and 33 of TRIPS.[118] In particular, they argued that the provisions were not "limited exceptions to the exclusive rights conferred by a patent," within the meaning of Article 30 of TRIPS.[119]

The WTO Panel found in favor of Canada on one count and against Canada on the other.[120]

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such as non-commercial research." DANIEL GERVAIS, THE TRIPS AGREEMENT: DRAFTING HISTORY & ANALYSIS 242 (2d ed. 2003).

115 Panel Report, *Canada—Patent Protection of Pharmaceutical Products*, ¶ 4.13, WT/DS114/R (Mar. 17, 2000), *available at* http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds114_e.htm.

116 *Id.* ¶ 1.1.

117 Patent Act, R.S.C., ch. P 4, § 55.2(1)–(2) (repealed 2001) (Can.). By virtue of the Manufacturing and Storage of Patented Medicines Regulations, "the applicable period referred to in sub-section 55.2(2) of the Patent Act is the *six month period* immediately preceding the date on which the term of the patent expires." Manufacturing and Storage of Patented Medicines Regulations SOR/93-134, § 2 (repealed 2000) (Can.).

118 Panel Report, *supra* note 115, ¶¶ 4.2–4.5.

119 *Id.* ¶ 4.8.

120 *Id.* ¶ 8.1.

1. The Regulatory Review Exception

The panel held that this exception was TRIPS compliant and passed muster under Article 30 of TRIPS[121] because:

1. The regulatory review exception embodied in section 55.2(1) was "limited."[122]

2. It did "not conflict with the normal exploitation of a patent" because the additional period of de facto market exclusivity created by using patent rights to delay the grant of marketing approval was not to be considered "normal" in the context of patent rights as understood by the TRIPS Agreement.[123] The fact that the process of obtaining marketing approval usually extends marketing exclusivity of the patentee is an unintended consequence rather than a calculated policy objective and hence the same cannot be considered "normal."[124]

3. The exclusion served an important public policy end because it helped expedite approval of drugs requiring regulatory review and thereby reduced healthcare costs.[125] In addition, the panel found that the patent owner does not have a "legitimate interest" in a de facto patent term extension that results from the arduous

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121 *Id.* ¶ 7.83.

122 *Id.* ¶ 7.50. While interpreting the term "limited" used in Article 30, the panel relied on its close proximity with the word "exception" and noted that:

> Although the word itself can have both broad and narrow definitions, the narrower being indicated by examples such as "a mail train taking only a limited number of passengers", the narrower definition is the more appropriate when the word "limited" is used as part of the phrase "limited exception". The word "exception" by itself connotes a limited derogation, one that does not undercut the body of rules from which it is made. When a treaty uses the term "limited exception", the word "limited" must be given a meaning separate from the limitation implicit in the word "exception" itself. The term "limited exception" must therefore be read to connote a narrow exception—one which makes only a small diminution of the rights in question.

Id. ¶ 7.30 (internal citation omitted).

123 *Id.* ¶¶ 7.57, 7.59.

124 *See* Panel Report, *supra* note 115, ¶¶ 7.57, 7.59.

125 *Id.* ¶ 7.61.

> marketing approval process adopted by most national drug regulatory authorities.[126] Thus, the provision catered to the legitimate interests of third parties without prejudicing the interests of patent owners.[127]

Therefore, the panel held that the regulatory review exception passed muster under Article 30.

2. The Stockpiling Exception

The panel concluded that the stockpiling exception was inconsistent with the rights of a patentee guaranteed under Article 28.1 of the TRIPS Agreement.[128] The panel held that the "manufacturing [of a patented product] for commercial sale is a quintessential competitive commercial activity, whose character is not altered by a mere delay of the commercial reward."[129] In practical terms, it ought to be recognized that the enforcement of the right to exclude "making" and "using" during the patent term was likely to offer most patent owners a short period of extended exclusivity after the patent expired.

Based on the above, the panel held that the stockpiling provision in the Canadian patent law contravened TRIPS.[130] Canada accepted the result and requested a reasonable period of time to change the provision, to be determined by arbitration.[131]

3. India's Stand

In the European Union-Canada dispute outlined above, India argued that it had a substantial systemic interest in the case, pertaining to the fundamental issue of the appropriate balance under the TRIPS Agreement between the rights and obligations of the producers of technical knowledge on the one hand and the users of that knowledge on the other.[132] In particular, India advocated the need to balance pharmaceutical patents against public health imperatives and

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126 *Id.* ¶ 7.82.

127 *Id.* ¶ 7.83.

128 *Id.* ¶ 7.38.

129 *Id.* ¶ 7.35.

130 Panel Report, *supra* note 115, ¶ 7.38.

131 *Id.* ¶ 8.1.

132 *Id.* ¶ 5.20.

highlighted the benefits of a robust generic drugs industry in making affordable drugs available in poor developing economies.[133]

By virtue of being an interested party, India is bound by the above-mentioned WTO panel ruling.[134] Any argument by India to support the TRIPS compatibility of its experimental use exception must therefore broadly conform to the WTO ruling detailed above.

By permitting a third party to make and/or use a patented invention, the experimental use exception in India impacts the exclusive rights of a patentee guaranteed under Article 28 of TRIPS. The key question then is: can this intrusion into Article 28 be justified under the broad rubric of Article 30?

To pass muster under Article 30, it is necessary to prove the following:

1. that the exception to the exclusive rights guaranteed under Article 28 is a "limited" one;
2. that the exception "do[es] not unreasonably conflict with a normal exploitation of the patent"; and
3. that it "do[es] not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties."[135]

An exception that permits the use of a patented invention only for the purpose of experiment or research or education is likely to be seen as a "limited" exception. Further, even assuming that it impacts the "normal" exploitation of a patent to some extent, it does not do so "unreasonably." For a study of the underlying technology with a view towards improving the patented technology, or to invent around it cannot be said to be an unreasonable interference with the "normal" exploitation of a patent. For if that were the case, patents would end up blocking the advance of science and technology, the very purpose for which they were instituted in the first place. Such a reading would also be at odds with the disclosure function of patents, outlined right at the start.

For the same reasons as above, a WTO panel is likely to find that the experimental use exception does not unreasonably prejudice the "legitimate" interests of a patent owner. For any exception that is geared towards assessing

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133 *Id.* ¶ 5.21.

134 *Id.* ¶ 5.22.

135 TRIPS, *supra* note 112, art. 30, 33 I.L.M. at 1209. "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." *Id.*

whether the patentee has complied with her part of the twenty-year monopoly bargain by disclosing a valuable technological advance cannot be said to prejudice the legitimate interests of a patent owner. Similarly, the experimenting on a patented invention to help improve it or to invent around it cannot be said to "unreasonably" prejudice the legitimate interests of the patentee. After all, the interests of third parties and society at large demand that such patented inventions be subjected to such uses so that society gains from the consequent advancements in technology.

A panel is therefore likely to hold that an experimental use of a patented invention, as outlined above, is in conformity with TRIPS.

More particularly, as noted earlier, the case for an experimental use exception is even stronger in the context of developing countries, such as India. TRIPS was premised on the promise of transfer of technology.[136] 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, as is the case with the Indian pharmaceutical sector.

In this context, it is important to note that Article 7 of TRIPS lends support to the above interpretation in favor of developing countries. This Article reads as follows:

> 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.[137]

As can be seen, this article declares that one of the key goals of the TRIPS Agreement is to foster the tansfer and dissemination of technoology in a manner conducive to social and economic welfare.[138]

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136 TRIPS, *supra* note 112, art. 7, 33 I.L.M. at 1200.

137 *Id.*

138 *See* Andrew Michaels, *International technology transfer and TRIPS article 66.2: can global administrative law help least-developed countries get what they bargained for?*, FREE LIBRARY, Sept. 22, 2009, http://www.thefreelibrary.com/International technology transfer and TRIPS article 66.2: can global...-a0216848574.

IX. THE "REGULATORY REVIEW" DEFENSE

Apart from a general experimental use exception, some countries provide for a specific exception in favor of experimental trials conducted on patented drugs, popularly referred to as the "*Bolar*" exception. The name derives from a U.S. case, which interpreted the common law experimental use exception prevalent in the United States to exclude any "clinical trial" uses.[139] In order to reverse this court ruling, the U.S. legislature introduced a statutory exemption for all those cases of experimental use of a drug solely for the purposes of generating data for regulatory authorities.[140] Similarly, the Indian legislature also thought it fit to enact a separate provision (section 107A) for this purpose.[141]

It is important to note at this juncture that not all countries provide for a specific *Bolar* type exception in their patent regimes. For instance, countries such as Germany and Japan merely interpret their existing statutory "experimental use" defenses to exempt clinical trials.[142]

The section below covers three important aspects—a discussion of *Roche Products, Inc. v. Bolar Pharmaceutical Co.*[143] and the consequent enactment of the *Bolar* exception in U.S. law, the scope of such an exception in the light of the U.S. Supreme Court decision in *Merck KGaA v. Integra Lifesciences I, Ltd.*,[144] and lastly, a discussion of the corresponding Indian statutory provision on this count.

A. *The* Roche Products, Inc. v. Bolar Pharmaceutical Co. *Case*

Bolar related to the legality of clinical trials and other tests conducted on patented drugs with a view of establishing the bio-equivalency of the generic

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139 Roche Prods., Inc. v. Bolar Pharm. Co., 733 F.2d 858, 863 (Fed. Cir. 1984).

140 *See* Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

141 The Patents (Amendment) Act, 2002, No. 38, § 44, Acts of Parliament, 2002 (India).

142 See Bundesgerichtshof [BGH] [Federal Court of Justice] Apr. 17, 1998 (F.R.G.), *translated in* Clinical Trial II [1998] R.P.C. 423; Bundesgerichtshof [BGH] [Federal Court of Justice] July 11, 1995 (F.R.G.), *translated in* Clinical Trial I [1997] R.P.C. 623 (BGH CASE XZR 68/94), for the German position, and *Ono Pharmaceutical Co.Ltd. v. Kyoto Pharmaceutical Ltd.*, Case No. 1998 (Ju) No. 153 (2d Petty Bench of the Sup. Ct., Apr. 16, 1999) (Japan), *translated at* http://www.courts.go.jp/english/judgments/text/1999.04.16-1998-Ju-No.153.html, for the Japanese position. However, the U.K. courts have held against the inclusion of "clinical trial" use within the general scope of the common law experimental use exception. *See* Monsanto Co. v. Stauffer Chem. Co., [1985] R.P.C. 515, 542 (Eng.).

143 733 F.2d 858 (Fed. Cir. 1984).

144 545 U.S. 193 (2005).

drug in question and the consequent submission of information in this regard to the drug regulator to procure approval.[145] Such testing served an important public health goal, as it permitted the introduction and sale of more affordable generic versions of a drug, soon after the expiry of a patent.

The Court of Appeals for the Federal Circuit held that "testing" the patented product in order to generate clinical trial data was likely to implicate the commercial interests of a patentee and went far beyond the *de minimis* use permitted under the common law "experimental use" exemption.[146] In other words, such testing would permit the entry of generics soon after patent expiration and would adversely impact a patentee's prospect of an extended monopoly beyond the statutorily authorized time period.

In order to reverse the *Bolar* decision above, the U.S. legislature immediately enacted Section 202 of the Drug Price Competition and Patent Term Restoration Act of 1984.[147] Section 202 amended 35 U.S.C. § 271(e), which provides:

> It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.[148]

This provision soon came to be known as the *Bolar* provision or the "regulatory review" exception.[149]

An interesting issue that arises is whether such a provision permits a patented drug to be experimented upon with a view to arriving at a new use for such known drug. Could the researcher in question claim that the discovery of the new use would also entail a submission of regulatory information pertaining

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145 *Bolar*, 733 F.2d at 860.

146 *Id.* at 863.

147 *See* Alfred B. Engelberg, *Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness? A Political, Legislative and Legal History of U.S. Law and Observations for the Future*, 39 IDEA 389, 398–407 (1999).

148 35 U.S.C. § 271(e)(1) (2006).

149 Engelberg, *supra* note 147; *see* Natalie M. Derzko, *A Local and Comparative Analysis of the Experimental Use Exception—Is Harmonization Appropriate?*, 44 IDEA 1, 7, 44 (2003).

to such new use?[150] And that therefore an investigation into the new use was also with a view towards generating information necessary for drug regulatory approval?

This issue arose in *Integra*, a case that made its way to the U.S. Supreme Court.[151] At the stage of its first appeal to the Federal Circuit, the majority stated that "the focus of the entire exemption is the provision of information to the FDA. Activities that do not directly produce information for the FDA are already straining the relationship to the central purpose of the safe harbor."[152]

The majority further held that § 271(e)(1) does not "encompass drug development activities far beyond those necessary to acquire information for FDA approval of a patented pioneer drug already on the market."[153] Further, the phrase "reasonably related" cannot be expanded "to embrace all stages of the development of new drugs merely because those new products will also need FDA approval."[154]

While interpreting this section, the majority appeared to emphasize more the word "solely" rather than the words "reasonably related."[155] The reason given by the Federal Circuit for this narrow interpretation of this section was the legislative history of this section, i.e., this provision was enacted for the sole purpose of facilitating the faster entry of generic drugs into the market and therefore this provision of law could be used only to allow the testing of a generic version of an already patented drug.[156]

The U.S. Supreme Court, however, disagreed with this narrow interpretation and overruled the Federal Circuit on this count. It held as below:

> Properly construed, § 271(e)(1) leaves adequate space for experimentation and failure on the road to regulatory approval: At least where a drugmaker has a reasonable basis for believing that a patented compound may work, through a particular biological process, to produce a particular physiological effect, and uses the compound in research that, if successful, would be appropriate to in-

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150 For a detailed discussion on this issue, see George Fox, Integra v. Merck*: Limiting the Scope of the § 271(e)(1) Exception to Patent Infringement*, 19 BERKELEY TECH. L.J. 193 (2004).

151 Integra Lifesciences I, Ltd. v. Merck KGaA, 331 F.3d 860 (Fed. Cir. 2003), *vacated*, 545 U.S. 193 (2005).

152 *Id.* at 866.

153 *Id.* at 867.

154 *Id.*

155 *Id.*

156 *Id.* at 865; *see also* Daniel A. Lev, Comment, *A Realist Approach to* Merck KGaA v. Integra, 5 NW. J. TECH. & INTELL. PROP. 135, 138 (2006).

> clude in a submission to the FDA, that use is "reasonably related" to the "development and submission of information under . . . Federal law.[157]

The Supreme Court's line between those cases where a drug maker has a reasonable basis for believing that a patented invention may work and those where she may not appears a rather indeterminate and uncertain one. For almost every experiment with a drug could be said to be "reasonably" related to the submission of regulatory information. It would appear that the Supreme Court resorted to such an overly liberal and indeterminate interpretation in order to fill the void left by an unduly narrow interpretation of the experimental use defense by the courts in *Madey*.

Fortunately, the Indian provision on experimental use, section 47, is of sufficiently wide amplitude to permit any kind of experimentation on a drug, whether or not such experiments are reasonably related to the generation of regulatory information.[158] And therefore, one does not need to take refuge under section 107A, the Indian version of the U.S. "*Bolar*" provision.

B. The Indian Bolar *Provision*

In a bid to kick-start indigenous drug production and to keep drug prices at affordable levels, the Indian Patents Act 1970 did away with pharmaceutical product patents.[159] However, India was forced to reintroduce such patents in 2005, owing to a TRIPS mandate.[160]

The absence of a product patent regime for more than thirty years (from 1970 until 2005) enabled Indian pharmaceutical companies to develop generic versions of patented drugs without fear of patent infringement. Naturally, they

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157 Merck KGaA v. Integra Lifesciences I, Ltd., 545 U.S. 193, 207 (2005). However, on August 5, 2008, in the case of *Proveris Scientific Corp. v. Innovasystems, Inc.*, the Federal Circuit distinguished the facts at hand from the *Integra* case, while declining to accept the defendant's claim that the alleged patent infringement fell within the scope of the "safe harbor" principle as laid down in the *Integra* case. 536 F.3d 1256, 1265–66 (Fed. Cir. 2008). The invention in question was a device which could be used by other inventors to generate test results for their FDA applications. *Id.* at 1259. This case is expected to be appealed to the U.S. Supreme Court.

158 *See* The Patents Act, No. 39 of 1970, § 47(3) (India) (allowing the use of a patented invention, "by any person, for the purpose merely of experiment or research including the imparting of instructions to pupils").

159 The 1970 Patents Act did not recognize product patents in pharmaceuticals and substances made from chemical/biochemical/biotechnological processes. Rather only pharmaceutical processes were permitted to be patented. The Patents Act, 1970, No. 39 of 1970, § 5 (India).

160 Basheer, *India's Tryst with TRIPS*, *supra* note 17, at 16.

were also free to conduct clinical trials and pursue other activities necessary to procure drug regulatory approval.[161]

However, given the prospect of an impending product patent regime in 2005, the Indian Parliament introduced a "*Bolar*"-like provision.[162] The Joint Parliamentary Committee set up to evaluate and recommend changes in India's patent regime[163] submitted its report to the Lok Sabha and the Rajya Sabha on December 19, 2001.[164] The Joint Committee recommended the insertion of section 107A.[165] According to the joint committee report, "This provision has been made to ensure prompt availability of products, particularly generic drugs, immediately after the expiry of the term of the patent."[166] The Committee drew its inspiration from the *Bolar* provision in the United States and corresponding provisions in other patent regimes.[167]

Section 107A reads as follows:

> Certain acts not to be considered as infringement.— For the purposes of this Act,—
>
> (a) any act of making, constructing, using or selling a patented invention solely for uses reasonably relating 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 or sale of any product;

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161 Prior to the 2002 amendments, the burden of proof even in the case of process patent infringement was on the patentee. Section 104A of the Patents Act, inserted by the Patents Amendment Act 2002 now provides that the burden of proof in the case of process patents shall be on the infringer. The Patents (Amendment) Act, 2002, No. 38, § 43, Acts of Parliament, 2002 (India).

162 A perusal of the parliamentary debates in both the Lok Sabha and the Rajya Sabha reveal that there was no debate accompanying the introduction of this provision. This could either mean that it was overlooked or that there was a consensus from all that this provision ought to have been introduced. Interestingly, the only reference to the word "Bolar" is in the context of "ever-greening," which is not relevant for the purpose of the current Article.

163 The Patents (Second Amendment) Bill 1999 became the Patent Amendment Act of 2002. *See* The Patents (Amendment) Act, 2002, No. 38, Acts of Parliament, 2002 (India).

164 JOINT COMM. OF THE RAJYA SABHA & THE LOK SABHA, COMM. 91, REPORT ON THE PATENTS (SECOND AMENDMENT) BILL, 1999 (Comm. Print 2001) (India).

165 *Id.* at cl. 51.

166 *Id.*

167 *Id.*; *see* 35 U.S.C. § 271(e)(1) (2006); *see also* Patent Act, R.S.C., ch. P 4, § 55.2(1) (1985) (Can.).

> (b) importation of patented products by any person from a person who is duly authorised by the patentee to sell or distribute the product, shall not be considered as an infringement of patent rights.[168]

Section 107A allows the making, constructing, using or selling of a "patented invention"[169] for certain specific purposes. Section 107A is wider than the corresponding U.S. provision because it permits the making, constructing, using or selling of a "patented invention" for the purpose of generating regulatory data to comply with both domestic (Indian) drug regulatory law, and any corresponding foreign law. U.S. law on the other hand permits a defense only in so far as the activities are connected with a regulatory submission within the United States.[170] One wonders as to why the additional acts of "selling" and "importation" are necessary if the sole purpose is to generate clinical trial information. The inclusion of these additional acts may even be construed as violating the narrow latitude vested in respect of such provisions by the WTO panel in the Canada case**.**

In an acknowledgement of the increasing export focus of India's generic sector, the exception also extends to acts done with a view to gaining regulatory approval in countries outside India.[171] The breadth of this exception may have been guided by the fact that India's pharmaceuticals exports grew from almost nothing in the 1990s to Rs. 29,139.57 crores ($7.25 billion) by the year 2007–2008.[172] A report by the Ministry of Commerce for the government of India has estimated that the Indian pharmaceutical industry's export opportunity is worth almost $19.5 billion dollars.[173]

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168 The Patents (Amendment) Act, 2002, No. 38, § 44, Acts of Parliament, 2002 (India).

169 The Indian Patents Act does not define the term "patented invention" but defines "patented article" and "patented process." The Patents Act, 1970, No. 39 of 1970, § (2)(1)(l) (India).

170 *Compare* The Patents (Amendment) Act, 2002, No. 38, § 44, Acts of Parliament, 2002 (India) (excluding from infringement "any act of making, constructing, using or selling a patented invention for uses reasonably relating" to seeking regulatory approval "in India, or in a country other than India"), *with* 35 U.S.C. § 271(e) (limiting the exception to seeking approval in the United States).

171 *See* The Patents (Amendment) Act, 2002, No. 38, § 44, Acts of Parliament, 2002 (India) (excluding from infringement "uses reasonably relating 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").

172 MINISTRY OF COMMERCE AND INDUS., DEP'T OF COMMERCE, GOV'T OF INDIA, STRATEGY FOR INCREASING EXPORTS OF PHARMACEUTICAL PRODUCTS 30 (2008).

173 *Id.*

X. CONCLUSION

The experimental use exception is one of the most contested doctrines in patent law, not so much in terms of its existence, but more in terms of its permissible extent. Most of the current literature examines this exception from the perspective of the developed world. Our attempt is to frame the debate through a "developmental" lens, i.e., in the context of countries that are net importers of patented technology. Framed this way, we argue that the provision ought to be wide enough to permit developing country entities to experiment on patented inventions with a view towards arriving at improvements or even inventing around such patents. Apart from this, technologically proficient developing countries such as India, China, and Brazil ought to leverage this exception to attract more outsourced R&D and build up indigenous technological and innovation capabilities.

However, in order to effectively leverage the exception, developing countries must ensure that there is a complete and enabling disclosure of the patented invention. Most patent regimes, even those in the developed world, have been gamed by clever attorneys who hide more than they reveal in patent applications. Countries therefore ought to insist on higher disclsoure standards. This would not only ensure that patentees live up to their part of the bargain and merit the twenty-year monoploy that society grants them, but would also help a number of countries study patents effectively and experiment with underlying technology.

This Article demonstrates that the Indian section is wide enough to permit all of the above and therefore might serve as an important model for other developing countries, particularly technologically proficient ones. Given that there has been no case that has yet adjudicated the contours of this provision, we have interpreted the section in accordance with the standard tools of statutory interpretation. We have, however, backed our analysis from time to time with a historical jaunt and an attempt to glean what parliamentary intention is in this regard. Also, wherever possible, we have undertaken a comparative analysis by examining the position in other countries.

We also argue that, given the specific context of research tool patents and the likelihood of such patents being virtually obliterated by a wide research exemption, it is likely that Indian courts would strike a distinction between "experimenting on" and "experimenting with" a patented research tool, permitting only the former.

Lastly, we argue that even an experimental use exception as wide as India's is likely to pass muster under TRIPS, as it is "limited' in nature and does not unreasonably prejudice the normal exploitation of a patent. At a more prescriptive level, the reader is reminded of the fact that TRIPS was premised on

the promise of transfer of technology to developing countries. Given that there is no meaningful way of obligating developed countries to transfer technology, TRIPS should, at the very least, enable developing countries to ramp up technological capabilities by themselves.