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PATENTING OF RESEARCH TOOLS – ISSUES AND SOME POINTERS

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This paper presents a comprehensive analysis of the patenting of research tools. It outlines the essentials of research tools and addresses the concerns that have cropped up in the post-Genomic era with a special emphasis on the issue of access. It further evaluates the issue from a legal perspective against the backdrop of the TRIPS Agreement and makes a comparative analysis between jurisdictions. It also gives an overview of the possible consequences of such patenting for India and concludes by recommending amendments to tackle the challenges raised.

Writing in Science, in the December of 1968, Garret Hardin introduced the metaphor 'Tragedy of the Commons', to analyse concerns of overpopulation, air pollution and species extinction.[1] Ever since, this metaphor has been used to describe situations where people overuse resources because they have no incentive to conserve them. Thirty years later, writing in Science, on patents, and referring to Hardin, Michael Heller and Rebecca Eisenberg suggested a different tragedy, an anti commons, in which people underuse scarce resources because too many owners block each other.[2] The research tool patents were at the core of their argument.

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1. G. Hardin, *The Tragedy of the Commons*, 162 SCIENCE 1243 (1968). Hardin postulated that the population problem fell into a class of problems which could be classified as "no technical solution problems". Talking about the population problem, he urged that the most important necessity of the times was to restrict the freedom to abandon breeding in order to restrict the population problem.

2. M.A. Heller & R.S. Eisenberg, *Can Patents Deter Innovation? The Anti Commons in Biomedical Research*, 280 SCIENCE 698 (1988).

TRIPS is now a fact of history. All developing and developed countries have the common minimum standards of Intellectual Property protection mandated in TRIPS, ensured through the mechanism of Dispute Settlement, and the TRIPS Council Reviews. In the post-TRIPS globalised era, countries at different stages of development can learn from the way the challenges created by intellectual property rights have been addressed by nations who had faced these challenges earlier.

A decade has passed since the anti commons tragedy was suggested, and it is time to look at how this issue has been addressed by various stakeholders. During this time, India has forged ahead as a fast growing economy. The Government of India is proposing to create a legal framework for government funded research, and grant universities and research institutions ownership and patent rights for their innovations, along the lines of the Bayh-Dole Act of the United States.[3] Hence, the United States experience will be increasingly relevant for India.

The purpose of this paper is to annotate the issues reported on the patenting of research tools and analyse the responses from a legal, policy and management perspective, and its consequences for India. **Part A** of this paper explains what research tools are and the concerns relating to access to them. **Part B** deals with the legal landscape and **Part C** gives an overview of some practical responses, as well as of the legal challenges involved. The article concludes by suggesting changes in the law, as well as the adoption of appropriate management strategies.

I. PART A

A. Research Tools

"Research tool" is a generic term, and refers to a range of resources that scientists use in the laboratory for conducting further experiments.[4] They may be broadly described as any tangible or informational input required in the process of discovering a drug, a medical therapy, a diagnostic method, or a new crop

3. K. Pathak, *Varsities May Soon Own Patent Rights*, BUSINESS STANDARD (Mar. 17, 2008).

4. The definition of "research tools" is necessarily broad, and it is acknowledged that the same material can have different uses, being a research tool in some contexts and a product in others. The National Institute of Health (NIH) in the United States has given some guidelines in determining how an NIH-funded resource that falls within the definition should be handled. Recipients should determine whether: 1) the primary usefulness of the resource is as a tool for discovery rather than an FDA-approved product or integral component of such a product;

variety.[5] Research tools commonly include cell lines, monoclonal antibodies, reagents, animal models, growth factors, nucleic acid and proteins, combinational chemistry libraries, proteomic libraries, drugs and drug targets, clones and cloning tools, expression and reporter systems, and databases, software, laboratory equipment and machines.[6]

The effect of patenting on access to research tools will vary.[7] Research tool patents are "upstream" technology, used in the research process itself. Patents are unlikely to interfere with access to research tools like chemical reagents that are readily available in the market at reasonable prices from patent holders (or licensees), through catalogues, under conditions that approach an anonymous market.[8] Some other research tools can be obtained only by approaching the patent holder directly and negotiating license conditions, or on onerous license conditions. In such cases, patents pose a threat to researchers.[9]

The following case studies cited by the United States National Institute of Health (NIH) demonstrate how license conditions impact access to research tools.[10] The three technologies discussed below have three different licensing paradigms.

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2) the resource is a broad, enabling invention that will be useful to many scientists (or multiple companies in developing multiple products), rather than a project or product-specific resource; and

3) the resource is readily useable or distributable as a tool, rather than the situation where private sector involvement is necessary or the most expedient means for developing or distributing the resource. Recipients of NIH funding should ensure that their intellectual property strategy for resources fitting one or more of the above criteria enhances, rather than restricts, the ultimate availability of the resource. If the recipient believes private sector involvement is desirable to achieve this goal, the recipient should strategically license the invention under terms commensurate with the goal. *See* http://ott.od.nih.gov/policy/rt_guide_final.html.

5. C. Clift, *Patenting and Licensing Research Tools*, in INTELLECTUAL PROPERTY MANAGEMENT IN HEALTH AND AGRICULTURAL INNOVATION: A HANDBOOK OF BEST PRACTICES (A. Krattiger et al. eds., 2007).
6. Report of the NIH Working Group on Research Tools, *available at* www.nih.gov; *see also* R.K. Seide and M.M. LeCointe, *Research Tool Patents: Are there any Exceptions to Infringement?, available at* http://www7.nationalacademies.org/step/Seide_presentation_august_proteomics.PPT.
7. Eisenberg, *Patenting Research Tools and the Law, in* INTELLECTUAL PROPERTY RIGHTS AND RESEARCH TOOLS IN MOLECULAR BIOLOGY (1997).
8. *Id.*
9. Eisenberg, *supra* note 7.
10. *Supra* note 6.

Recombinant DNA technology, known as Cohen-Bayer technology, is the founding technology of the modern biotechnology industry.[11] Every molecular biologist uses this tool. The University of Stanford, which is the rights holder of the Cohen-Bayer patent, made this technology available for researchers with an inexpensive non-exclusive license with minimal riders. The decision of the University of Stanford to license this technology through a non-exclusive license, instead of an exclusive one, is regarded as critical to the development of the biotechnology industry.[12]

Polymerase Chain Reaction (PCR) allows the hitherto impossible - analysis of genes in biological samples, such as assays of gene expression in individual cells by specific and rapid amplification of targeted DNA or RNA sequences. PCR was invented in a corporate environment and originally patented by Cetus Corporation. Cetus subsequently sold the PCR patent to Hoffman LaRoche for US$300 million in 1991.[13] There is general agreement among the scientific community that Hoffman LaRoche has done well in making the patented technology available for research purposes.[14] While there was no controversy over whether such an important research tool should be patented, or over the principle of charging researchers license fees, there has been some debate over the amount of royalty fees.[15] For the PCR license, a company pays between US$100,000 and US$500,000, with a royalty rate of 15%. In contrast, a company pays US$10,000

11. This technology is used to insert foreign genes into bacteria to study the process of gene replication. It involved three patents: one process patent for making molecular chimeras and two product patents - one for proteins produced using recombinant prokaryote DNA, and another for proteins from recombinant eukaryote DNA.

12. The Cohen-Boyer patent is considered by many to be a classic model of technology transfer envisaged in the Bayh-Dole Act, which was intended to transfer university developed technology to the commercial sector. However, it has also been pointed out that this presents a different model of technology transfer than what is envisaged in the Bayh-Dole Act. Lita Nelson, Director of Technology at Massachusetts Institute of Technology, has noted that the premise of Bayh-Dole Act is the maximisation of revenue through exclusivity while the Cohen Boyer license is a non-exclusive. *See supra* note 6.

13. National Research Council (NRC) (1997), *Intellectual Property Rights and Research Tools in Molecular Biology, available at* www.nap.edu/readingroom/books/property.

14. *Id.*

15. *Supra* note 13. Roche established different categories of licenses related to PCR, depending on the application and the users. They included research applications, such as Human Genome project, the discovery of new genes, the studies of gene expression; diagnostic application, such as human in-vitro diagnostics, and the detection of disease linked mutations; the production of large quantities of DNA; and human diagnostic testing services. The licenses in the last category are the most expensive, but they are very broad. In 1999, the patent was held invalid for inequitable conduct. *See* J.P. Walsh et al., *Research Tool Patenting and Biomedical Innovation* in PATENTS IN KNOWLEDGE BASED ECONOMY (2003).

per year, and a royalty fee of 0.5%-10%, for the Cohen Bayer license. Some argue that this has resulted in the inhibition of the development of PCR related research tools.[16]

Protein sequencing has been a key step in deciphering gene function, as the effects of the genes depend on the proteins they encode. Until automated sequencing instruments became widely available, few laboratories had access to this technology. Automated and highly sensitive DNA and protein sequencers were developed by the California Institute of Technology (Cal Tech), which was funded by the private sector firm Applied Biosystems (ABI).[17] ABI insisted on and received an exclusive license from Cal Tech on this technology. Cal Tech licensed this technology to ABI with the stipulation that ABI would sublicense it on terms Cal Tech considered reasonable.

B. Issues in the Post-Genomic Era

Changes in the USPTO guidelines on utility requirements, and the adoption of stricter standards by courts, have curtailed the early rush of patents for Express Sequence Tags (ESTs) and Single Nucleotide Polymorphisms (SNPs).[18] However, concerns still persist. To illustrate, shortly after the SARS outbreak in 2003, patent applications covering the sequences of the SARS corona virus were filed by several research teams around the globe. Concerns were expressed that this may give rise to a complex and uncertain IP situation that could delay the development of the SARS vaccine.[19]

C. Issues of Access

Genetic testing tools have been widely patented. A study conducted by the Organization for Economic Cooperation and Development (OECD)[20] on the licensing practices of holders of patents on the diagnosis of genetic disorders,

16. *Id.* There is also the consequent reduction in the total royalty stream for the company itself.
17. J.P. Walsh et al., *Research Tool Patenting and Biomedical Innovation* in PATENTS IN KNOWLEDGE BASED ECONOMY (2003).
18. SNPs are points in the genetic sequence where one person's DNA differs from another's. These sequences can be used to identify particular genetic conditions.
19. A. Krattinger & S.P. Kowalski, *Facilitating Assembly of and Access to Intellectual Property: Focus on Patent Pools and a Review of Other Mechanisms in* INTELLECTUAL PROPERTY MANAGEMENT IN HEALTH AND AGRICULTURAL INNOVATION: A HANDBOOK OF BEST PRACTICES (A. Krattiger et al. eds., 2007).
20. OECD, *Genetic Inventions, Intellectual Property Rights Licences and Practices: Evidence and Policies, available at* http://www.oecd.org/dataoecd/ 42/21/ 2491084. pdf.

showed that almost all the patents were being licensed exclusively, thus raising issues of access to such tools. The following two examples are illustrative.

Canavan's disease: Canavan's disease is a rare and fatal genetic disorder, in which the myelin sheathing of nerves in the central nervous system degenerates in infants.[21] In order to study the disease, and develop a screening test for the gene that gives rise to it, a group of families co-operated with researchers by donating tissue samples from their children. In 1997, scientists at Miami Children's Hospital (MCH) received a patent on the method of diagnosis, which also covered therapies potentially arising from the test. MCH subsequently sought to license the test exclusively, prompting some clinical laboratories to stop offering the test, and potentially impeding research on the disease. The parents of the affected families argued that the test should have been offered non-exclusively and free of charge. In response to the criticism, MCH halved its per-test fee.[22]

Myriad Genetics: A researcher at the University of Utah found that the mutation of two genes, BRCA1 and BRCA2, is involved in 5-10% of breast cancer cases. Women with these gene mutations are seven times more likely to develop breast cancer than the general female population. Myriad Genetics, a private sector corporation, holds the patents to the diagnostic tests for BRCA1 and BRCA2. Myriad's licensing strategy has met with strong opposition.[23] The company insists that all testing worldwide be performed by Myriad's own laboratories. However, its charge per test, in many cases, is over US$ 2,500. Many healthcare authorities and providers believe that the terms of access to this technology are too stringent, that the costs are too high, and that they may constitute an abuse of monopoly power.

D. Patent Thickets

The notion of cumulative innovation - each discovery building on many previous findings - is central to the scientific method.[24] In biotechnology, this is

21. *Id.*

22. OECD, *supra* note 20.

23. The reaction worldwide was swift. In France, the Institut Curie, the Assistance Publique and the Gustave Roussy Institute filed oppositions to the European patents. The Belgian Society for Human Genetics and the Danish Society for Medical Genetics filed separate oppositions. In the United Kingdom, negotiations are ongoing between the Department of Health and Myriad regarding the terms of the provision of testing for BRCA1. All Canadian provinces but one, are ignoring Myriad's injunctions to stop offering breast cancer genetic testing, despite Myriad's Canadian patents.

24. C. Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard Setting, available at* http:// faculty.haas.berkeley.edu/shapito/thicket. pdf.

even more so. Encumbrances of patents on research tools used in an invention can necessitate negotiating multiple licenses when developing a single product or process. The term 'patent thicket' refers to the dense web of overlapping intellectual property rights that a company must make its way through, in order to commercialise a new technology.[25] Such 'patent thickets' have the potential to raise the transaction costs of conducting research, and possibly the ultimate cost of products, owing to stacking of royalties. For example, the development of a medicine may require licenses to access genomics technologies, such as receptors, assays and high-throughput technologies. Companies report that royalty exposure to net sales price of a given product can exceed 20% in some cases.[26] As more and more biotechnology companies commercialise "research tools" – genomics sequencing and expression technologies, targets, screening assays, etc. – the pharmaceutical companies that develop end products must enter into multiple licensing agreements and agree to the payment of royalties to many parties, leading to the problem of royalty stacking.[27]

The number of patents required to be licensed for a malaria vaccine, relying on the MSP-1 protein of the malaria parasite, is illustrative of the thickets problem. A study mapped close to 40 relevant patents, which included five core U.S. patents relating to MSP-1, a dozen patents useful in constructing vaccines, and five specialised patents for the production of MSP-1 vaccines.[28]

The celebrated illustration of the thicket problem in agricultural biotechnology is the case of Golden Rice, or beta carotene enhanced rice.[29] Three genes were inserted into the rice plant to complete the beta-carotene biosynthetic pathway. In addition to the proprietary genes, the methodology involved the use of a number of plant transformation vectors, promoters and antibiotic resistance markers, all of which are the subject of patents held by various owners, or covered by MTAs. Cumulatively, over 70 patents, held by a dozen or so patentees, were identified as posing potential licensing issues.[30]

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25. *Id.*
26. OECD, *supra* note 20, at 15, quoting *Signals Magazine*. Royalty exposure to net sales means the percentage of net sales on a product that must be paid in royalties to the licensors of technologies used in the development of an end product.
27. *Id.* at 61.
28. OECD, *supra* note 20, at 15.
29. The beta carotene in Golden Rice provides dietary Vitamin A, intended to cater to the nutritional needs of peoples for whom rice is the most basic food crop, yet suffer from Vitamin A deficiency. See R. DAVID ET AL., THE INTELLECTUAL AND TECHNICAL PROPERTY COMPONENTS OF PRO-VITAMIN A RICE (GOLDEN RICE): A PRELIMINARY FREEDOM TO OPERATE REVIEW, ISAAA BRIEFS No.20 (2000).
30. *Id.*

Restricted access to upstream technology is a greater concern in the context of downstream research activity. Some of these patents can pre-empt important areas of medical research, and act as legal barriers to the development of a broad category of products. This possibility is particularly strong in the field of biotechnology for several reasons. First, there are many broadly relevant patents. Further, research builds on the use of prior technologies, and solid and clear title to a product is important in the pharmaceutical industry.[31] A researcher must therefore redesign a research program in order to avoid using patented techniques, or obtain licenses from all patent holders.

i. Agricultural Research

The institutional context of agricultural biotechnological research differs from that of biomedical research. The size of the sector and the potential commercial market are much smaller than in the case of medicine. Traditionally, in agricultural research, the public sector carried research right to the farm, whereas, in medicine, commercialisation is an overwhelmingly private sector activity. This landscape is changing.

Traditionally, discoveries in public research institutions and agricultural universities were treated as public goods that flowed freely to farmers and businesses, often through university extension services. This system supported generations of improvements to crop germplasm. Companies adopted and improved upon discoveries from public sector institutions, and turned them into crop varieties for commercial markets. This helped develop a robust seed industry in developed countries and significantly increase food production in developing countries.[32]

However, the biotechnology revolution and the spread of gene patenting changed this scenario. Today, the biotechnology industry is dominated by the private sector. Technology ownership is frequently fragmented between many owners, resulting in encumbrances on the freedom to operate with select technologies. This has forced companies to cross-license technologies, and has led to mergers and acquisitions becoming a means of accumulating portfolios of agricultural patents, and material, such as germplasm. Today, agricultural research, at least in the developed countries, is dominated by a few large companies that control a large proportion of the cutting edge agricultural IP.

31. J.H. Barton, *Research-tool Patents: Issues for Health in the Developing World*, 80(2) BULL. WORLD HEALTH ORGAN. 122 (2002).

32. http://www.pipra.org/en/about.en.html.

Many of the enabling technologies required to carry out agricultural research are patented, and there are concerns on the freedom to operate with technologies, even in India, as many of our institutions carry out research in agricultural biotech.[33] A recent study has suggested that access issues are more serious in agricultural biotechnology than in biomedicals.[34] The study found that in agbiotech research, one quarter of the respondents reported that, in problematic cases, a project or line of research that was part of a project had to be abandoned, or not initiated, due to lack of access to research tools.[35]

Freedom to operate with technologies relevant to research, which leads to increased food production, is significant in the context of developing countries, where agricultural research is still mostly carried out by public sector institutions. If technology induction is a critical component of ushering in a second green revolution, exceptions which facilitate research with patented research tools and enabling technologies will have to be made available to scientists.

ii. Other Emerging Technologies

Early assessments of nanotech patent trends indicate that though the technology is still in its infancy, patent thickets on foundational nano scale particles, tools and processes are already creating barriers to would-be innovators.[36] As a single nano scale application can be relevant for widely divergent applications, across multiple industry sectors, analysts warn that IP roadblocks could severely retard the development of nanotechnology.[37]

The repercussions are felt in stem cell research also. An example is the basic patent involved in the Cellpro case. The discovery made at Johns Hopkins University was of an antibody that selectively binds to an antigen, CD34, found in stem cells. The patent was awarded to Johns Hopkins, having claim on all antibodies that recognise CD34. This patent was licensed to Baxter, which could prevent rival Cellpro's use of the technology.[38]

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33. For a more detailed discussion, *see* Z. Thomas, *Agricultural Biotechnology and Proprietary Rights: Challenges and Policy Options*, 8 J. OF WOR. INTELL. PROP. 711 (2005).
34. B. Wright and P. Pardey, *Changing Intellectual Property Regimes: Implications for Developing Country Agriculture*, 2 INT. J. OF TECH. AND GLOB. 93 (2006).
35. *Ibid.* at 102; L. Zhen et al., *Implications of Intellectual Property Protection for Academic Agricultural Biologists*, DEPARTMENT OF AGRICULTURAL AND RESOURCE ECONOMICS, UC BERKELEY, *available at* http://www.are.berkeley. edu/~wright/IJTGWP1.pdf.
36. H. Shand & K.J. Wetter, *Trends in Intellectual Property and Nanotechnology: Implications for the Global South*, 12 J. OF INTELL. PROP. R. 111 (2007).
37. *Ibid.* at 113.
38. Walsh et al., *supra* note 17.

II. PART B

A. Putting TRIPS in Context

Under Article 30, the TRIPS Agreement allows the use of limited exceptions to the exclusive rights granted by a patent.[39] This provision is reflected in many national legislations in the form of research exceptions. Article 31 of the TRIPS Agreement permits compulsory licensing and government use, without the authorisation of the right-holder, subject to conditions aimed at protecting the legitimate interests of the right-holder. These conditions include the obligation not to grant such licenses as a general rule, unless an unsuccessful attempt has been made to acquire a voluntary license, on reasonable terms and conditions, and within a reasonable time period. A compulsory license can be issued to permit exploitation of a patent, which cannot be exploited without infringing another patent. The grant is subject to the requirement of paying an adequate license fee. Such license must be predominantly for the domestic market.[40]

i. Compulsory Licenses

Patent laws of most countries allow governments to issue compulsory licenses on various grounds. The U.K. Patent Act confers such extensive powers, though they are rarely exercised.[41] The United States patent statute does not contain any provision for compulsory licensing. But 35 USC § 203 provides for march-in rights, as part of the Bayh-Dole amendments, where federal funding of an invention is involved.

Section 84 of the Indian Patents Act, 1970 permits the grant of compulsory licenses where (a) the reasonable requirements of the public, with respect to the patented invention, have not been satisfied, or (b) the patented invention is not

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39. Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with the normal exploitation of the patent, and do not unreasonably prejudice the legitimate interests of the patent holder, taking into account legitimate interests of the third parties.

40. The Doha Declaration clarified the compulsory licensing provision to enable members in taking measures to protect public health. It makes it clear that each member-state is free to determine the grounds upon which compulsory licenses are granted, In conditions of national emergency, the usual stipulation that an effort must be made to seek voluntary license would not apply.

41. Section 48(1) of the UK Patent Act allows issuance of compulsory licenses in the event of *"refusal of the proprietor of the patent to grant a license on reasonable terms...the exploitation...of any patented invention which involves an important technical advance of considerable economic significance in relation to the invention for which the patent concerned was granted is prevented or hindered"*. C. Clift, *supra* note 5 at 84.

available to the public at a reasonable price, or (c) the patented invention is not worked in the territory of India. But such licenses can be issued only after three years have expired from the date of grant of the patent.[42] This limits the use of such provisions for research tools since the latest research tools may be required for cutting edge research.

The conditions and stipulations attached to the grant of compulsory licenses, and the procedure prescribed for obtaining such license, are likely to make the procedure lengthy. Where multiple patents are involved, requiring multiple licenses, the compulsory license provision is unlikely to be of immediate help to researchers.

ii. Research Exceptions

Patent laws around the world permit some form of research exceptions. The law relating to research exceptions in some major jurisdictions is discussed below.

a. United Kingdom

In the U.K., the Patent Act exempts acts done privately for non-commercial purposes and acts covering an experimental purpose relating to the invention.[43] The cases that discuss the private purpose exemption include Smith Kline and French Laboratories Ltd v. Evans Medical,[44] and McDonald

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42. *See also* Section 89 which mandates, *inter alia*, that the powers under Section 84 should be exercised to protect the interest of any person for working or developing an invention under the protection of patent are unfairly prejudiced. Section 91 on licensing of related patents enables grant of compulsory license to work any other patented invention could aid researchers.

43. The statutory exemptions for patent infringement that might be of relevance to early stage bio-medical and biotechnological research are contained in the UK Patents Act in Sections 60(5), (a)-(c):

    60(5). 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;

    (c) it consists of the extemporaneous preparation in a pharmacy of a medicine for an individual in accordance with a prescription given by a registered medical or dental practitioner or consists of dealing with a medicine so prepared. *See* F. Bor, *Exemptions to Patent Infringement Applied to Biotechnology Research Tools*, 28(1) E.I.P.R. 5 (2006).

44. Smith Kline and French Laboratories Ltd v. Evans Medical, [1989] F.S.R. 513. The Court held that an act will be exempt if it clears a two-stage test involving: (1) determining whether an act is private or public; and (2) determining whether the act has or has not been carried out for commercial purposes. *See* Bor, *supra* note 43.

v. Graham.[45] The court, in Smith Kline and French Laboratories Ltd, held that the private purpose exemption relates essentially to an individual carrying out scientific experiments at home, with no commercial goal in mind, and does not cover any acts carried out for commercial purposes.[46] But the acts done for experimental purposes, relating to the subject-matter of the invention, even if for commercial purposes, are exempt.[47]

b. European Union

Research exemptions have been incorporated into Art. 31(b) of the European Community Patent Convention, and have been transposed into the patent laws of many European countries.[48] In most of Europe, exceptions exist for acts performed privately, for purposes that are non-commercial, and for experimentation on the subject matter of invention, even if for commercial purposes.[49] In most of Europe, the experimental user right guarantees the freedom, to all skilled in the art, to test and examine patented inventions, without the consent of the patent owner even during the term of protection, in order to establish the invention's utility, working advantages and disadvantages, and above all, to develop, on the basis of the knowledge so acquired, improved (patent-dependent) or new (patent-independent) solutions.[50]

c. United States

In the United States, there is no statutory exception for research uses. But United States Patent law provides for a safe harbour for drug development through an FDA exception, in 35 USC § 271(e)(1).[51]

The common law research exception in the United States has its origins in the 19th century case of Whittemore v. Cutter,[52] wherein the exception was limited

45. McDonald v. Graham, [1994] R.P.C. 407.

46. Bor, *supra* note 43.

47. Bor, *supra* note 43.

48. For example, Section 60(5) of the UK Patents Act, and Section 11 of the German Patent Law, 1981. *See* Bor, *supra* note 43.

49. Clift, *supra* note 5.

50. Bor, *supra* note 43, at 6, quoting Professor Joseph Straus, the managing director of the Max Planck Institute for Comparative Research in Patent Law.

51. 35 U.S.C. § 271(e)(1) states:

> 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.... 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.

52. Whittemore v. Cutter, 29 F. Cas. 1120 (C.C.D. Mass. 1813); Bor, *supra* note 43.

to philosophical experiments with the patented invention. But the ruling in Madey v. Duke University casts considerable doubt on educational use exceptions, if the use has the slightest commercial implication.[53] This ruling had cast doubt on the availability of the common law experimental exception,[54] but recent decisions seem to show that the exception survives. In Merck v. Integra Life Sciences,[55] the U.S. Supreme Court, overturning a plea for a restricted reading, ruled that section 271(e)(1) *"exempted, from infringement, all uses of patented compounds 'reasonably related' to the process of developing information for submission"* to the FDA.[56] In the 2007 ruling by the Federal Circuit in Integra Life Sciences v. Merck KGaA,[57] the court discussed the experimental use exception claimed by the defendant, which had been allowed by the District Court. But this was not the subject matter of appeal.[58] Merck did not rely on the common law experimental use defence, and, in fact, counsel for Merck stated that this defence was not applicable to this case. The natural presumption is that the common law research exception for basic scientific research survives.

Experts conclude from the approach adopted by the US courts that it is apparent that the courts will enjoin the use of infringing research tools only to prevent future infringement and that past infringement may be remedied only by an award of damages.[59] The award of damages itself may be treated as an implied license to use the research tool, precluding injunctive relief. Damages on research tool patents

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53. Madey v. Duke University, 307 F. 3d 171. The Federal Circuit ruled that regardless of whether a particular institution is engaged in an endeavour for commercial gain, so long as the act is in furtherance of an alleged infringer's legitimate business, and is not solely for amusement, or to satisfy idle curiosity or for strictly philosophical enquiry, the act does not qualify for the narrow and strictly interpreted experimental use defence.

54. *"In light of the Madey decision, which instituted the death of the common law research exemption for all practical purposes, scholars are taking a closer look at how research tools fit into the overall picture of patent policy." See* M.D. Walker, *The Patent Research tool Problem after Merck v. Integra*, 14 TEX. INTELL. PROP. L.J. 1, 30 (2005).

55. Merck KGaA v. Integra Life Sciences Ltd., 545 U.S. 193.

56. *Ibid.* at 206.

57. Integra Life Sciences v. Merck KGaA, Fed. Cir., 2002-1052,-1065.

58. *Integra Life Sciences*, Fed. Cir., 2002-1052,-1065. The District Court ruled that all but one of the initial studies of angiogenesis inhibition by the first cyclic RGD peptide were of the nature of basic scientific research and within the common law research exemption. No appeal was taken from this ruling, and these early experiments are not included in the subject matter charged with infringement. Although, in the District Court, the defendants had argued that at least some of the ensuing studies were also shielded from infringement by the common law research exemption, this argument was not presented on appeal to the Federal Circuit or the Supreme Court

59. R.K. Seide & M.M. LeCointe, *supra* note 6.

by NIH grants. The guidelines provide that, whenever possible, non-exclusive licensing should be pursued as best practice. The non-exclusive licensing approach favours and facilitates making enabling technologies and research tools widely available and accessible to the scientific community.[69]

The NIH has also been intervening in select cases like that of Harvard Oncomouse, which contained a recombinant, activated oncogene sequence, that permitted it to be used for testing early stage anticancer drugs. Harvard had licensed it to Dupont exclusively. The NIH prevailed upon Dupont to sign a memorandum of understanding that permitted relatively unencumbered distribution of the technology from one academic institution to another.[70]

The universities in the United States have been at the forefront of conducting basic research. The approach of the Stanford University in licensing Cohen-Boyer patents non-exclusively has been widely acclaimed. But it does not seem that many universities followed the Cohen-Boyer example set early in the industry. The Bayh-Dole Act encourages, and most universities in the U.S. practice the grant of exclusive licenses on their patented technologies. The consequence of such exclusive licensing was felt immediately in agricultural biotechnology. Writing in *Science*, the heads of 12 leading U.S. universities observed that they did not have the rights to enabling technologies their institutions had invented.[71] They announced the setting up of the Public Intellectual Property Resource for Agriculture (PIPRA), which aims to mitigate problems arising from the fragmentation of proprietary technologies among different institutions. In their licenses, they systematically retain the rights to use the technologies for research and development of subsistence and speciality crops.

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maintenance, reproduction, and/or distribution of the tool, or because further research and development is needed to realize the invention's usefulness as a research tool, licenses should be crafted to fit the circumstances, with the goal of ensuring widespread and appropriate distribution of the final tool product.

69. http://ott.od.nih.gov/policy/lic_gen.html states:

> "PHS encourages licensing policies and strategies that maximize access, as well as commercial and research utilization of the technology to benefit public health. For this reason, PHS believes that it is important for funding recipients, and the intramural technology transfer community, to reserve in their license agreements the right to use the licensed technologies for their own research and educational uses, and to allow other institutions to do the same, consistent with the Research Tools Guidelines."

70. Walsh et al., *supra* note 17.

71. R.C. Atkinson et al., *Public Sector Collaboration for Agricultural IP Management*, 301 (5630) SCIENCE 174 (2003).

Also, PIPRA member institutions systematically make their current and future technologies known to each other, and to the world.[72]

The experience with impediments to research, posed by exclusive licensing of patented technologies, seems to have altered the approach of some of the universities.[73] Stanford has adopted a licensing policy which enables retention of rights on the licensed technology for non-profit academic research institutions.[74] The University of California retains the right to make use of the licensed invention for itself, and other non-profit educational and other institutions.[75]

Another approach has been to adopt the open source model in patenting. This model licenses patented technologies with an open general license, mandating that further improvements to the technology be made available on the same terms, thus seeking to overcome the access issues of fragmented ownership of technologies. CAMBIA, a non-profit research organisation based in Australia, working in the field of agricultural biotechnology has prepared a model license which enables the sharing of improved technologies.[76]

As a result of the experience with MCH and Canavan's disease, other patient groups have been more active in obtaining agreements on the terms of their co-operation with researchers. *Pseudoxanthoma elasticum* is a genetic disorder in which connective tissues calcify. PXE International is a voluntary organisation which funds

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72. http://www.pipra.org/en/about.en.html.

73. A pivotal catalyst for change in the approach of universities was forced by a student of Yale Law School (Amy Kopzynski) in early 2001, in connection with the stavudine vaccine for AIDS, jointly patented by Bristol-Myers Squibb (BMS) and Yale University (trademarked Zerit by BMS to whom Yale had licensed the patent exclusively). This vaccine was found to be too expensive for those in the poorest regions of South Africa and in Sub-Saharan Africa. The protests led Yale and BMS to conclude an agreement to make this treatment available at no cost in South Africa. *See* A.J. Stevans, *Valuation and Licensing in Global Health, in* INTELLECTUAL PROPERTY MANAGEMENT IN HEALTH AND AGRICULTURAL INNOVATION: A HANDBOOK OF BEST PRACTICES (A. Krattiger et al. eds., 2007).

74. *See Stanford Exclusive License Agreement, available at* http://otl.stanford.edu/industry/documents/revstagmt3-08.pdf. ("Retained Rights: Stanford retains the right, on behalf of itself, and all other non-profit academic research institutions, to practice the Licensed Patent and use technology for any non-profit purpose, including sponsored research and collaborations. Licensee agrees that, notwithstanding any other provision of this Agreement, it has no right to enforce the Licensed Patent against any such institution. Stanford and any such other institution has the right to publish any information included in the Technology or a Licensed Patent.")

75. OECD, *supra* note 20.

76. http://www.cambia.org.

research and provides support to affected families and supports physicians.[77] They created a tissue and blood bank which scientists could access to study this genetic disorder. Access to the bank was conditional on the signing of a contract, which included a provision for joint ownership with PXE of any resultant intellectual property. The PXE gene was jointly patented with the scientists at the University of Hawaii. The patient group developed this strategy to ensure that future licenses for any genetic tests will be inexpensive and widely available.[78]

Another approach is the potential use of patent pools, which has been adopted successfully in the electronics industry.[79] However, an OECD report observed that the pharmaceutical sector is fundamentally different from the electronics industry. Universal standards and interoperability are not the norm in the pharmaceutical sector. A company is tightly tied to its IP, which fosters a 'bunker mentality'.[80] The report pointed out that the dominant players may have little incentive to join the pool. Doubts have also been cast on the interplay of competition laws and patent pools.

A recent study finds that on average, there are more patents and more patent holders than before, involved in any commercial invention in biomedicine, and many of these patents are on research tools.[81] However, despite this increased complexity, none of the commercially or scientifically promising projects has been stopped because of Intellectual Property rights on research tools. This is attributed to the abilities of industrial and university researchers to develop working solutions that allow their research to proceed, some of which have been narrated above. Further, changes in the institutional environment, particularly USPTO guidelines on patenting of genetic inventions, some shifts in the approach of the courts towards research tool patents, as well as pressure from powerful actors like the NIH, also appear to have warded off the problem.[82] The study suggested the development of standard contracts and templates, by institutions like the NIH, to license technologies. In other words, they recommend a licensing policy that enables access to research tools from public funded projects.

77. http://www.pxe.org.

78. OECD, *supra* note 20.

79. U.S.P.T.O., in a 2000 report on patent pools and biotechnology, had suggested the formation of patent pools in the biotechnology field, which could serve the interests of both the public and the private sectors. Such pools have worked successfully in the electronics industry.

80. OECD *supra* note 20.

81. Walsh et al., *supra* note 17.

82. Walsh et al., *supra* note 17.

The Government of India is likely to enact a law to create a uniform legal framework for government-funded research and to give universities and research institutions ownership, and patent rights, for their innovations.[83] A Bill has been drafted on similar lines as the U.S. Bayh-Dole Act.[84] From what has been reported, it appears that India is moving in the same direction. As India aspires to be a hub of biotechnological research, lessons learnt from the American experience are relevant. Indian institutions may have to formulate appropriate responses so that research will not be stifled on emerging technologies, and so that publicly funded research serves its intended purpose. The initiative of the Council for Scientific and Industrial Research (CSIR), to move to open source drug discovery and open source pharmacogenomics shows that Indian institutions are alive to this issue and are responding appropriately.[85]

B. A Legal Challenge

Historically, research or educational exceptions in patent law were formulated in the 19th century. One of the philosophical foundations of the patent law is that it encourages inventors to find alternative ways to achieve the same end. According to Chisum, one of the objectives of the patent system is to provide an inducement for inventing around the patents, on successful inventions, to bring more innovations to the public.[86] By giving protection to existing patents, the patent system acts as a teaser to an inventive mind to bring about new inventions. Such new inventions may include new ways of achieving the same result. These may generally be described as work arounds. The 19th century courts constructed a narrow exception based on current technologies which enabled such 'work around' inventions. A diversity of similar, but not identical approaches represents the hallmark of innovation.[87] It generates competition, drives innovation and leads to

83. K. Pathak, *supra* note 3.

84. P.T.J. Datta, *Public Funded Research May Pay Dividends for Scientists*, BUSINESS LINE (Mar. 17, 2008). The Bill encourages public-funded institutes to patent inventions and explore avenues for commercialisation. It proposes that the inventor gets 30 per cent of the revenue from commercialising the patent, while 10 per cent is ear-marked for the institute's IP Management Cell. Rights to the product remain with the institute, while assignment rights are jointly held between the scientist, the institute and the government. Commercialisation plans require consent from all the three.

85. *See Interview with Dr. S.K. Brahmachari, DG CSIR, available at* http://spicyipindia.blogspot.com/search?q=Brahmachari.

86. D. CHISM, PRINCIPLES OF PATENT LAW: CASES AND MATERIALS (2002).

87. K.N. Cukier, *Navigating the Future(s) of Biotech Intellectual Property*, 24(3) NATURE BIOTECHNOLOGY 249 (2006).

subsequent 'creative destruction' that is the cornerstone of capitalism. The impossibility of a workaround was never anticipated in patent law.[88]

The courts have traditionally interpreted these exceptions strictly. In the U.K., courts restricted it to the acts of an individual carrying out research for non-commercial purposes, while in the U.S. it was limited to the satisfaction of idle curiosity. The statute in India reflects the traditional strict approach.

This traditional approach creates unique problems in genomics. Genes and genetic sequences have unique informational content, making it impossible for researchers to invent around them.[89] For example, genes detecting disease susceptibility, or encoding therapeutic proteins, are not amenable to workarounds since substitutes are not possible by nature.[90] Lack of potential for workarounds represents an enormous problem for the patent system to operate in biotech research.[91]

Hence, the traditional research exceptions have an inherent inadequacy to deal with genomic inventions. This lack of workarounds was probably not contemplated in patent law. Hence, the approach to traditional research exceptions, based on the classical philosophy behind research exceptions, seems insufficient to handle the issues posed by genomics. The courts and the policy makers have to now remodel the exception, which was originally tailored to the needs of the nineteenth century, to address the challenges posed by 21st century technologies.

In the Indian context, the provisions of the statute which reflect the traditional, strict approach to exceptions do seem to require modification in the context of the challenges posed. Also, Indian scientists do not have the common law research exceptions available in jurisdictions like the U.S. Viewed in the context of research exceptions available in the European Union and Japan, there is a case for modifying the provisions of research exceptions as available in section 47(3) of the Patent Act.

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88. *Id.*

89. G. Matthijs, *Patenting Genes may Slow Down Innovation and Delay Availability of Cheaper Genetic Tests*, 329 B.M.J. 1359 (2004).

90. *Id.*

91. Matthijs, *supra* note 89.

IV. Conclusion

So, is there clear evidence of the anti-commons in research tools thwarting social welfare? There is little evidence yet. But most commentators agree that the patenting of research tools has made the research landscape more complex. The 19th century philosophies of research exceptions in patent law are insufficient to accommodate the challenges of the nature of science in biotechnology, nanotechnology or stem-cell research. Appropriate responses are being tailored by leading players in the field.

As per the Supreme Court of India, the 'object of patent law is to encourage scientific research, new technology and industrial progress'.[92] To meet this objective, Indian policymakers need to analyse the experiences of the U.S. and other countries, and frame appropriate responses, both from the legal and policy angles. The response may be at least two fold. On the legal side, the existing provision on research exceptions in Indian law is inadequate, as compared to the provisions of the laws of Europe or Japan. The law may require fine tuning, as India does not have the common law exception which exists in the United States. Institutions which are involved in managing and overseeing research may have to formulate appropriate policies on technology invented with their funds, to retain rights to use the technology for research and other related purposes, by that institution or by others, while licensing its technologies.

92. M/s Biswanath Prasad Radhey Shyam v. M/s Hindustan Metal Industries, A.I.R. 1982 S.C. 144.