

PATENT AND SCIENTIFIC PROGRESS

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ABSTRACT

Scientific and economic progress depend upon our shared interest to innovate, which is the key for our development and progress. Scientific world continues to research and develop new therapies, diagnostics, treatments, drugs, alternative fuels, advanced weather information systems, digital solutions, so on and so forth. Such activities lead to growth of scientific knowledge and employment opportunities, besides providing solutions to our complex problems in various fields. Patenting system contributes to innovation by protection or intellectual rights, and by avoiding unnecessary duplication of research & development efforts. It helps in easy dissemination of knowledge and know-how to the society and for further exploration of new technologies. Patent plays a pivotal role in bridging basic science and applied science through protected usage of technology for innovation, and open information and free access to public of new knowledge through publication. Strong patent protection of upstream research tools can severely affect downstream experimentation and validation process in research. However, patenting a new and novel product or a process also encourages scientists to create alternative scientific theories; new research models and thus introduces a paradigm shift in our scientific progress. Taken together, patenting/licensing a novel product or process not only protect the intellectual rights of the owner, but also does not curtail scientific knowledge and hamper scientific research, as the new information will be available for open access to the scientific community and general public and thus, only contributes positively towards the rapid growth and progress in Scientific research. Thus, patents can help accelerate the processes of both protection and open knowledge by driving a paradigm shift leading to the evolution of new scientific theories.

Key Words: *patents, scientific progress, evolution of scientific theory, experimental use, gene patents, and compulsory license.*

1. INTRODUCTION

According to economic theory, policy for innovation must be designed to create a balance between incentives to invest in innovation as well as sharing of knowledge and technology for

societal benefit, that in turn promote efficiency in further development of future innovation. Patents are generally granted for invention, that is either a product or process and that should be new; involve an inventive step; and capable of industrial application. The patent system rewards the inventors and companies, by granting exclusive rights over the intellectual creativity.

Conventional wisdom of patent system proclaims that patents contribute to progress of science and technology. Grant of monopoly through patent rights motivates individuals/companies to invest in research and development, and to innovate.¹ Pharmaceutical and biotechnology research organizations and companies also defend that patent protection is necessary to recover the investment necessary to develop a new drug.² Current estimate of new drug development is around 2.5 billion USD.³ Patent protects the ingenuity, interest and investment of innovative enterprise, that ultimately benefits the society.

There is also a counter intuitive view that states, patents actually deter innovation. Patent conflicts with traditional norms of open sharing of knowledge. It also contents that over proprietization of knowledge and resource may lead to under use of resources.⁴ Increasing patenting of research materials, experimental protocols, tools and equipments deprive scientists and research organizations in carrying out in-depth investigation. Thus stating, a patent can hinder innovation and in turn, the scientific progress.

In this note, we will try to understand the relationship of patents to scientific progress and scientific theory, at the level of basic science and applied science. Also, we will look into the evolution of scientific theory, experimental use, gene patents, and compulsory license.

2. EVOLUTION OF SCIENTIFIC THEORY

The role of patents on evolution of scientific theory has mostly been ignored. Thomas Kuhn in "*The Structure of Scientific Revolutions*" talks about the distinction between "normal science" and "paradigm shifts".⁵ Normal science is accepted the scientific practice like law, theory, applications, and scientific principles, together they provide models and consensus framework that help scientists to infer and analyse their findings. Examples of scientific paradigms in normal science are Copernican astronomy, Aristotelian dynamics, Newtonian dynamics so on and so forth. Traditional belief suggests that science progresses in an accumulative manner; each new discovery builds upon the earlier ones; comprehension of generations of scientific knowledge and findings. Sir Isaac Newton's famous thought, "*If I have seen further it is by*

standing on the sho[u]lders of Giants,” emphasising the wealth of knowledge generated by previous discoveries.⁶

Paradigm shift is a disjointed move from one dominant scientific consensus framework to another. Kuhn emphasized that science mostly advances through nonlinear and incoherent manner. This theory was contrary to popular historiographies of science. Normal science ultimately “generat[es] anomalous results that cannot be explained in terms of the prevailing theory,”^{1,7} and leading to a turning point. This crisis encourages scientists to challenge accepted scientific belief and introduce paradigm shift. For example, Newtonian mechanics was disclaimed by Planck, Einstein and Heisenberg, and it leads to development of quantum mechanics to explain the properties of sub-atomic particles.^{4,7}

2.1 ROLE OF PATENTS IN EVOLUTION OF SCIENTIFIC THEORY

Peter Lee in “*Patents, Paradigm Shifts, and Progress in Biomedical Science*” discussed about the surprising role of patents in evolution of scientific theory drawing on the history, philosophy and sociology of science.⁷

Heavy patenting on upstream research tools makes it difficult to conduct research on downstream application and validation of scientific theories. Higher cost of licensing fee and multiple web of negotiations encourage scientists to avoid patented research tools for their research work. In turn, they try to avoid dominant paradigm and the available research methodology for their experiments and adopt radical theories and models. That consider to be an essential first step in paradigm shift. According to the patent system, patents offer an incentive to innovate, seek new theory and reconceive scientific theories. Adopting new research methodologies helps scientists avoid paying patentee the licensing fee or royalty, and they can bypass exogenous limitations for their research work. These legal and economic considerations add up for challenging dominant paradigms, and thus evolution of new paradigm and scientific theory occurs.

Kuhn’s analysis suggests, patents can limit normal science and provoke paradigm shifts. Landscape of heavy patenting motivate scientists to imagine, formulate, test and develop novel theories that might require completely new set of research tools, encouraging formulation of completely new theories.^{5,7}

3. EXPERIMENTAL USE

In most jurisdiction, patent law permits free use of patented resource strictly for non-commercial, academic and philosophical inquiry. The ‘experimental use exemption’ allows scientists to use a patented invention without violating the rights of patentee, thus safely conducting research without the fear of patent infringement. Without such an exemption, the scientists would be liable for patent infringement. As a result, there is a growing interest in understanding permissible research exemption in patent law, to protect genuine scientific research.⁸

Because of rapid explosion of knowledge in technological innovation, the boundary between commercialisation and basic research has dwindled drastically. Academic researchers are patenting commercially viable discoveries, and companies may fund basic research which may have future commercial implication. As the distinction between basic and applied research is vanishing, the permitted experimental use of patent law is also becoming narrow. Particularly, in the field of biotechnology, as the scientists are looking for more and more products and processes for biomedical applications, they will be patenting significantly at the upstream of product development chain.

At the same time, if public has absolutely no access to use the patent disclosure other than the patentee during the life of patent; it makes little sense to make the patent disclosure available to public from the beginning of patent term.¹

Public innovation policies are designed to achieve a balance between incentive to invest and dissemination of knowledge. Patent plays an important role in technology transfer from universities.⁹ There is a growing pressure on public research organization to patent their research outputs.¹⁰ When more and more research tools are patented, the possibility of patent infringement also increases. So the threat infringement could adversely affect the research projects in both government and private organizations.

Supporter of research exemptions argue that most of the research work is cumulative in nature. If there is no research exemption, there will be multiple license agreements to be negotiated before the actual research takes place, and this process will involve high transaction cost. Afterwards, the actual research might continue up to the point where the transaction cost is less than the research output. In such scenario, important and innovative research projects could not

be pursued. Research exemption is particularly important where the basic research has very less commercial importance but the application may have high commercial implications.⁸

Edmund Kitch has proposed “Prospect theory” of patents, which argues against an experimental use exemption for subsequent research in the field of patented invention. The theory emphasizes on efficiency of future innovation rather than promotion of research on patented technology.¹¹ His argument rests on the fact that patent system promotes efficiency by permitting the patent owner to monitor and control the use of patented technology and resource for future research works. This helps in increasing efficiency of the technology and not overuse of it. Patents will reduce post-grant competition and promote innovation. However, the relationship between competition and innovation is long debated. Contemporary economic theory suggests that innovation is maximum when the market is relatively competitive but not too competitive.¹²

Indian patent law allows the experimental use of patented invention solely for non-commercial purposes.¹³ There is no clear research exemption in US and Australia. Concerns have been raised by scientists and academicians.⁸ The experimental use exemption of patent disclosure is limited in US case laws. There are number of high profile case laws available related to experimental exemption.

Case law suggests that the experimental use defense may be available only for "pure" research use. In *Roche Products v Bolar Pharmaceutical Co.*, Federal case, Federal Circuit rejected unlicensed use of a patented drug during the patent term to conduct clinical trials. These trials were used to generate data necessary to obtain FDA approval for the generic version of the drug after the expiry of the main patent. The court held that the defence does not permit "unlicensed experiments conducted with a view to the adaption of the patented invention to the experimenters' business," as opposed to experiments conducted "for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry."^{1,14}

3.1 PATENT POOLS

Patent pool is one solution to the problem of heavy patenting of upstream research tools.¹⁵ A patent pool is ‘an agreement among patent owners to licence a set of their patents to one another or to third parties’.¹⁶ More often, these patent pools involve complex technologies and such an arrangement helps in generating efficient solutions. In patent pools, patent owners agree to

use each other's patent in a royalty fee cross licensing or package licensing arrangement. By sharing patent rights, patent owners will reduce their transaction cost for new product development. Benefit of such co-operation is huge; hefty licensing cost and complex web of negotiations can be avoided.^{17, 18}

4. GENE PATENTS

There is a generalized and amorphous public opposition to the concept of gene ownership. Patents on human genes will result in a lack of respect for human life and a devaluation of human dignity. It would restrict free flow of scientific information.

According to 2005 report, 20% of human genes are patented in some way in US patents. This accounts for 4,382 of the 23,688 of genes in the National Center for Biotechnology Information's (NCBI) gene database.¹⁹ Similarly, a large number of human genes are subject of patent claims at the European Patent Office (EPO).

The burst of human gene patenting sparked concerned in legal, health, philosophical and political spheres. Human gene patenting began in 1990, and questions have been raised whether or not gene patenting is in best interest of public. In US, a gene patent can be granted for a claim on a fragment of DNA or RNA sequence, or diagnostic kit or gene chips, or for a method of diagnosing a genetic condition, or for a method of identifying a specific DNA or RNA sequence.^{20,21}

Myriad Genetics, an US based company, was granted patents on two human genes: *BRCA1* and *BRCA2*.^{22,23} Mutations in these two genes are linked to an increased risk of breast and ovarian cancer. Patent right entitled Myriad Genetics to exclude all others from using these genes in breast and ovarian cancer research, diagnostics, and any further treatment. The American Civil Liberties Union (ACLU) and the Public Patent Foundation (PUBPAT) filed a lawsuit in Federal District Court for overturning the Myriad Genetics patents on *BRCA1* and *BRCA2*. The suit states that human gene patents violate the First Amendment and patent law because genes are "products of nature" and therefore can't be patented. These gene patents restrict diagnostic testing and limit women's medical care options.^{21,22}

In June 2013, for *Association for Molecular Pathology v. Myriad Genetics* case, the United States Supreme Court held that naturally occurring isolated human genes cannot be patented,

but that a synthetic DNA sequence, known as complimentary DNAs can be patentable. Myriad genetics case will have far-reaching consequences for the future of personalized medicine.

5. COMPULSORY LICENSE

Indian patent Act has a provision for compulsory licensing. Indian Patents Act 1970, Sections 84, 91 and 100 enlist provisions of compulsory license (CL). The Sections 91 and 100 are provisions for government to issue CL when it is appropriate. Section 84 can be cited by any third party for request of CL.

Section 84:

“(1) At any time after the expiration of three years from the date of the I[grant] of a patent, any person interested may make an application to the Controller for grant of compulsory license on patent on any of the following grounds, namely:— (a) that the reasonable requirements of the public with respect to the patented invention have not been satisfied, or (b) that the patented invention is not available to the public at a reasonably affordable price, or (c) that the patented invention is not worked in the territory of India.”²⁴

Compulsory License is existing since 1830s, and was recognized by Paris convention of 1883. Currently, it is one of the provision in World Trade Organization (WTO) intellectual property agreement in TRIPS (Trade-Related Aspects of Intellectual Property Rights; Articles 30, 31). Patent laws of many countries such as, Canada, USA, UK, France Australia and Thailand, India, Brazil, Ghana have provision for granting CLs.²⁵

India has issued the first compulsory licence in 2013 to Natco Pharma. This allowed Natco to manufacture and sell generic version of Bayer’s kidney and liver cancer drug Nexavar (sorafenibtosylate) in India. The Compulsory License permits NATCO to sell Nexavar at a price not exceeding Rs. 8880 for a pack of 120 tablets against Rs. 284,428, selling of Naxavar by Bayer. The license is valid till 2021, the expiry year of the patent. The ruling says that Natco will pay 7% in royalties to Bayer on the net sales, and NATCO will also supply the drug free of cost to at least 600 deprived patients per year.²⁶

This landmark decision has undoubtedly benefitted the patients. Through CL patients are assured of an affordable and uninterrupted supply of Nexavar.

6. RELEVANT CASES

Small, start-up biotechnology companies were responsible for many miracle drugs. For example, in 1989 *Amgen* developed erythropoietin (US 5441868 A), used for treatment of anaemia primarily in chronic kidney disease, cancer and dialysis patients. *Chiron Corporation* produced the answer to hepatitis C (WO 1991015771 A1), which has plagued the world for long and challenged scientists for more than three decades. *Cetus Corporation* discovered purified thermostable enzymes used for amplifying genes (US4889818 and US5079352). Individual inventors, and small companies are pioneering and finding important new molecules and insights that are changing the way medicine is practised today.

The DuPont Cre-lox case is the archetypal example of an interesting case on the concerns raised about patenting genes pertained to IP rights and Licensing practices. Cre-lox is a gene-splicing tool patented by Harvard University and under exclusive licence to DuPont Pharmaceutical Co. It allows researchers to make knock-out mice by deleting a single gene from specific cells and is very useful for identifying gene function. DuPont initially asked that public-sector researchers to sign an agreement that would limit their ability to use and share the Cre-lox technique and that would subject their articles to pre-publication review by the company. In addition, DuPont wanted commercial rights to future inventions that might arise from experiments involving Cre-lox animals (i.e. reach-through rights). While at least 150 universities and non-profit organisations agreed to these terms²⁷, some prominent institutions, including the NIH, refused, claiming they created obstacles to biomedical research. The issue was resolved in the United States in 1998 with a memorandum of understanding between the NIH and DuPont (and separate agreements with academic laboratories), which simplified access conditions for the US public sector to this patented research tool²⁸.

In the early 1980s, Professor Philip Leder, recruited as head of the Genetics Department at the Harvard Medical School, developed one of the first genetically engineered mice, dubbed the Oncomouse. Prof. Leder and his post-doc Tim Stewart had used novel transgenic techniques to insert an oncogene into a mouse embryo; the result was a mouse that was highly susceptible to cancer²⁹. Using the mouse to examine the importance of genes in the onset of cancer, Prof. Leder came to recognize that "it could serve a variety of different purposes, some purely scientific others highly practical"³⁰. This research was published in *Cell* in 1984, and, in 1988 a broad patent for the Oncomouse was granted by the U.S. Patent Office (USPTO). The

Oncomouse patent was more controversial than most; not only was the Oncomouse the first living mammal to be patented, but Harvard's licensee DuPont aggressively enforced the intellectual property rights. They made demands for "reach-through" rights on inventions that were made using the Oncomouse, requested early review of publications that used the Oncomouse in further scientific research, and prohibited scientists from freely sharing their mice. The generation of scientific ideas like the Oncomouse ideas that are simultaneously of value as a scientific discovery and as a useful, inventive construct, not a new phenomenon. Stokes described them in view of Pasteur's Quadrant³¹. Louis Pasteur's research on fermentation simultaneously offered fundamental insights that led to the germ theory of disease and was of immediate practical significance for the French beer and wine industry. The production of "dual purpose" knowledge, particularly in the disciplines that underpin modern biotechnology, raises important new challenges for policy makers. The discovery and exploitation of the Oncomouse offers a rather different perspective on the relationship between science and technology and the university-industry divide than traditional policy models. By and large, most policy analysis assumes that science is an important input into the process of technological innovation, and that instrumentation and measurement technologies (such as the computer) can provide important feedbacks (in the form of tools) into scientific discovery itself. In contrast, the Oncomouse highlights the possibility that a single discovery can simultaneously serve as a scientific discovery and a technological innovation. This insight raises questions about how When Ideas Are Not Free: The Impact of Patents on Scientific Research (and those who fund them) manage the collision between the norms of "open science" and the proprietary incentives of commercialization, and the role played by formal intellectual property rights in the development and diffusion of dual-purpose knowledge³².

7. NEW AND NOVEL IDEAS – A PARADIGM SHIFT IN SCIENTIFIC PROGRESS

The creative mind bearing new ideas leading to and new and novel innovative product or process with scientific validity, will attract funds/grants from the governmental agencies or organizations, attracting young generation of scientists, to pursue new research projects in both basic science and applied science. Research in basic science mostly on a process, culminate in publications, and will be a rich source of knowledge for the evolution of scientific theory and progress as represented in the flow chart in **Fig.1**. Good scientific publications and knowledge arising out of basic scientific research in turn fetch new grants leading to further work to develop novel innovations. Also, the knowledge from the basic science research could improve

the current status of the science and helps us in in depth understanding of the subject which forms the basis for furthering science.

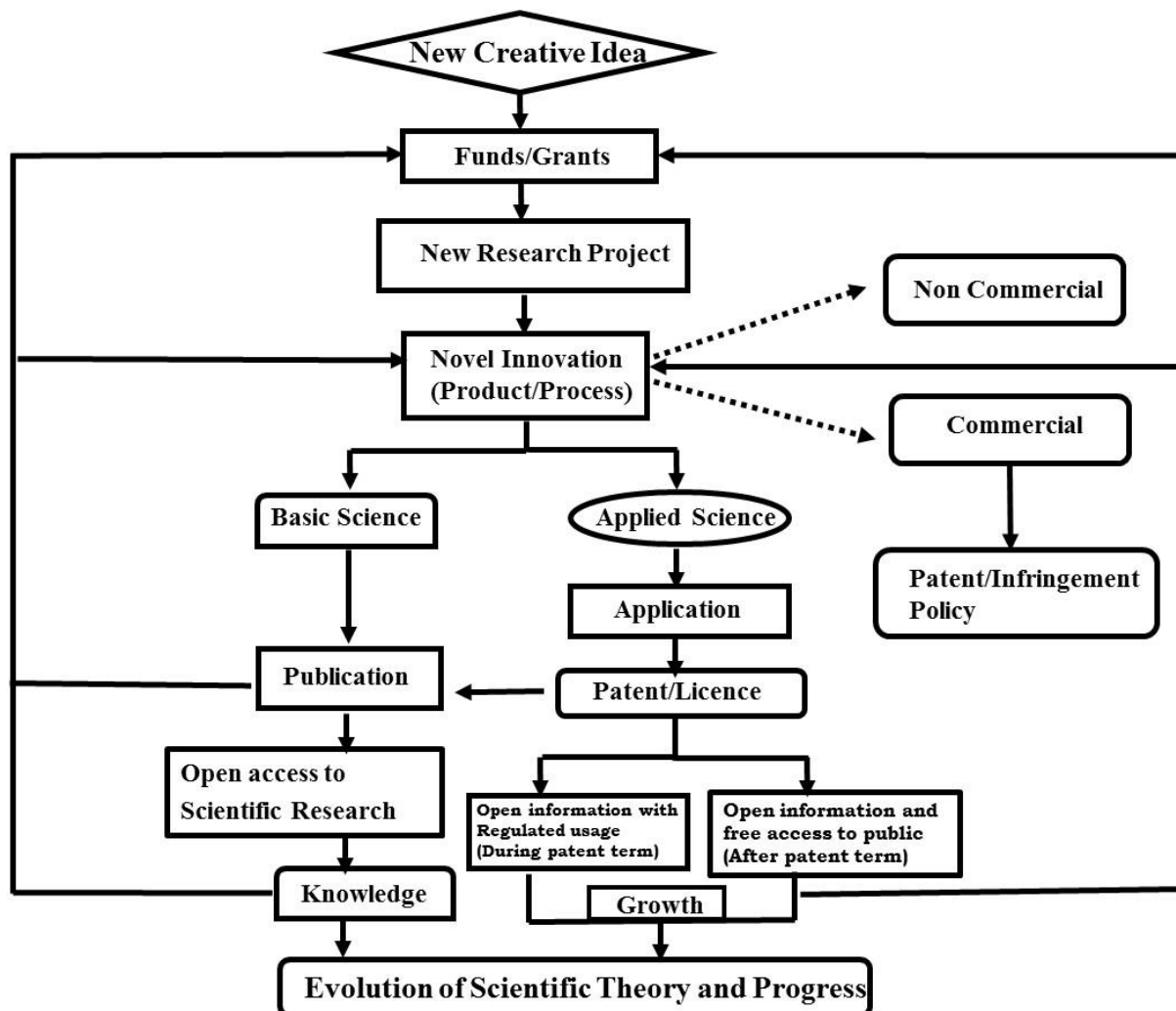


Fig 1. Pathways depicting Creative Ideas leading to Evolution of Scientific Theory and Progress – A New Paradigm Shift: A new and unique creative idea leads to a novel innovation in Product or Process in basic or in applied science, that leads to open access to information either through research publications or publication of patent documents. Scientific knowledge and information grows by the availability of the open access of journals and publications. The patented invention in applied science and technology will have regulated usage of the product/process, but with information open to public during the patent term; and open information and free access to the public after the patent term; both leading to scientific progress. Patenting in upstream tools leads to formulation of new research methods which in turn leads to evolution of new scientific theory.

A deeper insight into the scientific research in technological innovation, leading to a novel product/process which has applications, could be protected by patenting/licencing the same. The patented product/process are published through patent publication, thus making the information freely available to the public, but with regulated usage during the patent term with patent owner having exclusive rights.

Thus, a regulated usage of the patented product or a process should not hamper the scientific progress during the patent term, as many jurisdiction recognize non-commercial research use of patented product and process. Furthermore, after the patent term ends public has free access to patented products and processes. The commercial value of novel innovative product/process should be patented and stringent infringement policy will stake claim for its protection, whereas the non-commercial one will not. Here, policy for research exemption should be stated clearly and protect the rights of researcher/academicians. So, on one hand new and creative ideas leading to novel innovations in science, is strongly protected by patents and licensing. On the other hand, the information about the patent protected product/process will be freely available to the scientific community and general public to make use of, in furthering research on the other.

The patent system represents a powerful tool to this purpose, as well as a great source of information about the nature of the patent itself, i.e., it discloses the invention in a manner sufficiently clear and complete for it to be carried out by a skilled individual trained in the art. Further, the patent system is continuously changing, to try to comply with the developing technologies, as in the field of biotechnology and other emerging technology. Therefore, people involved in research, especially in emerging cutting edge technology, should be aware of this essential and strong tool, the IP rights, and hopefully use it for the betterment of the mankind.

8. CONCLUSION

The patent system tries to strike a balance between promotion of scientific and technological progress and granting monopoly for new invention. But the enforcement of exclusive rights may act against subsequent researchers, and thus interfere with scientific progress. The

philosophy of science believes that free access to previous discoveries might be more meaningful and effective for scientific progress. There should be a regulated and permissible exemption of patent usage of products and processes for experimental use. The distinction between basic and applied research is vanishing. Guarded access to patented resource could result in increased competition, more collaboration, development of new technologies, falling cost of kits, and greater benefit for society. So, a carefully formulated ‘experimental use exemption’ policy is an important first step in that direction. That will encourage scientists to pursue essential reach projects without the fear of patent infringement.

Recent ruling of gene patent cases has given hope to biotechnology start-ups, universities, and scientists, to research and develop new therapies, diagnostics, drugs, methods of isolating biomolecules and other inventions, based on genetic information and sequence. Broad claims on gene sequence pose serious concerns, and should be regulated.

Provision of ‘compulsory license’ in patent law a beautiful mechanism to protect the interest of basic health care needs of patients, especially in developing countries. Public should not be deprived of essential lifesaving drugs and therapies. At the same time, exercise of compulsory licensing must be use judiciously to balance the rights of innovative pharma companies and also the society.

Patents can stimulate and impact paradigm shifts. Experimental use exception with a generally strict patent regime facilitates both the *normal science* that evaluates theories and *paradigm shifts* that produces new alternative hypothesis. In this manner, patents can help accelerate the processes driving paradigm shifts and the evolution of new scientific theories. Policies concerning intellectual property must recognize this, otherwise policy regime will be inadequate. Moreover, science is not insulated from society rather science progress through influence of civilization and culture. So, scientists working with basic science should resist unreasonable pressure from over propertization.

Therefore, it is obligatory for policymakers, scientific communities and legal scholars to recognize that law impacts scientific progress, so the intellectual property right policies must be structured accordingly. Taken together, the overview of patenting of one’s own intellectual rights, be it in scientific or technological know-how, should be open but regulated, to cater the needs of the scientific community for the benefits of the mankind in order to stand on par with the developed countries in this modern world.

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