

INTELLECTUAL PROPERTY AND TECHNOLOGY LAW UPDATES

S&A IP-Tech

OCTOBER 2018

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Reforming University research ecosystem can help uplift India's IPR index

Dr. Heena Lamba

Intellectual property rights (IPR) is now a well-accepted concept rightly utilized by creators to protect their intangible creations and enjoy an array of benefits ranging from exclusive rights to gaining royalties from licensees. IPRs usually bring monetary benefits to its creators and consequently also to the nation. Revenue generated from IPRs in the year 2016-17 was estimated to be ₹ 60831.51 lakh as per the Annual Report 2016-17 of the Office of the Controller General of Patents, Designs, Trade Marks and Geographical Indications. Looking at its potential to generate revenues and foster further research and innovativeness, IPRs have now become important indicator for the economic growth of the country.

Major stakeholders in generating IPRs include public and private universities, multinational companies, R&D organizations, scientific institutions, industry, business organizations, SMEs, MSMEs, startups and individuals¹. Among these, Universities are considered to be the prime sites of knowledge creation. It has been shown that academic research carried out by scientists and researchers especially in collaboration with multinational companies and funding

agencies have broader scope, wider field of application across different disciplinary fields and value as compared to non-academic research². This creation of basic research should get commercialized by transferring the technology through various means such as movement of the inventor with knowledge and skills to different institute or sector, publication of invention, inter-institute or institute-industry collaborations, consultation, entrepreneurial activities and licensing³.

Sadly, the reality is different from what is usually expected from a research outcome. While carrying out research in an Institute or University, being novel and inventive is the first criterion that the researchers need to demonstrate over the prior art. Valuable IPs can be generated easily from such research by further modelling it to have industrial applicability. But even after funding and hardships of the researcher, the invention or the conclusion of their work goes in vain. The reason being lack of an ecosystem, which can direct minds of the researchers perpetually toward creating as much IPs from their work as possible⁴. It is well quoted by renowned scientist Prof Roddam Narasimha that 'We don't lack talent or entrepreneurship but we lack the ecosystem'. Because of the present ecosystem, researchers do not seem to be aware of the benefits they could achieve, both

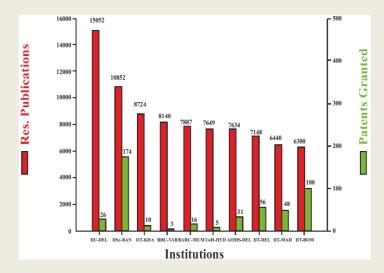
² The Ownership of Academic Patents and Their Impact. Available at https://www.cairn.info/revue-economique-2015-1-page-143.htm

³ The University and the Transfer of Technology: Principal Findings and Recommendations. Available at https://www.nap.edu/read/13001/chapter/2#2

⁴ One US firm files 135% more patents in India than all top labs together. Available at https://timesofindia.indiatimes.com/business/indiabusiness/us-firm-filed-100-more-patents-in-indiathan-all-top-labs-together/articleshow/65110947.cms

in their career and financially, by disclosing their invention legally rather than putting it directly in public domain through research papers.

The basic outcome of research comes in the public domain as a publication or as a commercial product. In 2016, India held 5th rank among all the countries in terms of the number of publications as per Scimago Journal & Country Rank⁵, but its ranking in commercialization especially in terms of generating IPRs was still lagging at 45th rank⁶. This difference in the rankings clearly reflects the unwillingness of Indian researchers to convert their innovation into technologies/products/patents. The same is also evident from the figure shown below, which clearly shows difference in the number of publications and number of patents owned by a University or a research Institute in India⁷.



In order to bridge this gap between knowledge creation and lack of awareness to get it protected commercialized, many or awareness programs are being conducted pan India by government organizations, R&D institutions, universities and NRDC in association with Intellectual Property Offices industry and collaborations with associations like FICCI. CII and ASSOCHAM. Funds have been allocated for this purpose through special projects like Cell for IPR Promotion and Management (CIPAM). But despite fund allocations for awareness creation, a research conducted by Einfolge, an international patent analytics and market research company in 203 educational institutions in Karnataka, Tamil Nadu, Kerala and Telangana revealed the following facts⁸:

• 35% people are not aware of intellectual property rights (IPR);

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India

http://www.scimagojr.com/countryrank.php?year=201

⁶ International Property Rights Index (IPRI) Report-2017. Available at https://internationalpropertyrightsindex.org/countries

⁷ Mapping Patents and Research Publications of Higher Education Institutes and National R&D Laboratories of

 $www.dst.gov. in/sites/default/files/FULL\%\,20BOOK-Chandigarh.pdf$

⁸ Study shows low IPR awareness in India. Available at

https://www.livemint.com/Politics/Rap1LeEuftJTFeh Nt00gTJ/Study-shows-low-IPR-awareness-in-India.html

- design patents, geographical indication (GI) and trade secrets need more attention to spread the benefits of IP rights;
- majority of respondents including students, scholars, teachers and managers were not fully aware about the monetary benefits of acquiring an IP right, commercialization of acquired IP rights, or the legal troubles that one might land in for using a pirated product.

The study clearly shows that a lot more needs to be done than just creating awareness. Need of the hour is 'Change in Research Ecosystem'. Given below are some criteria that can be adopted to bring in some change⁹:

- Academia-industry interactions to improve ability of the researchers to identify correct research problems having industrial applicability.
- Incentives to researchers and/or inventors as a motivation to work hard in their invention and generate IPRs from it.
- Technology transfer offices or IPR departments should be made with knowledgeable IPR professionals to help transfer of invented technology for commercialization.
- IPR department to be made part of every research institute; and personal interactions of the IPR professional with the researchers giving focus on their research area and potential IPRs they can generate.

 IPR to be a part of curriculum in schools, universities and Institutes to give sufficient time and exposure to the coming generation to imbibe the IPR culture.

ups. Available at www.wipo.int/sme/en/documents/academic_patenting .htm

⁹ Academic Patenting: How universities and public research organizations are using their intellectual property to boost research and spur innovative start-

India's tryst with "Evergreening" – An ongoing battle.

Shrimant Kumar Singh

Evergreening is the term used for legal and alternatives technological adopted Pharmaceutical companies to extend their exclusivity of over production and sale of patented medicines beyond the prescribed statutory timeline of 20 years. The said alternatives enable Pharma companies to retain royalties from patented medicines by either taking out new patents over minor incremental innovation. for example, new associated delivery systems, or pharmaceutical mixtures with a hidden motive of extended exclusivity over the main patented medicine beyond the prescribed time.

The main purpose of research and development for a pharma company is to invent an entirely new medicine or a 'blockbuster' drug, which would disrupt the market in a therapeutic domain. This blockbuster drug is aggressively patented for varied compositions. Strictest of patent monopoly is enforced by the company to prevent and more than often killing the competition in such therapeutic domain. Hence, the innovator company gains hugely from the said patented compositions.

To maintain the innovation, and consequently the market dominance, the innovator company needs to again undertake the entire cycle of research, discovery, clinical trials, marketing and distribution, replete with the risk of failure at every step. Also, majority of new drugs developed by the R&D never make it to the market. Therefore, to retain the market dominance a more certain alternative is to somehow extend the said 20 years period for which the company keeps filing applications for patents over minor variants of the parent compound, called secondary

patents. This practice of continued patent protection or prolonged monopoly over the parent compound arising out of minor variants is known as evergreening. To address evergreening, different countries have come up with different standards of qualification of patent grant and protection.

India has been at the forefront of developing an alternative model of patent law which many developing countries have since emulated. To address the issue Indian evergreening, the **Parliament** introduced Section 3(d) by way of 2005 Amendment to the Patents Act, 1970. Section 3(d) categorically excludes the derivatives, salts (trivial tweaks) to the known compound as not being inventions under the Act. The Supreme Court of India, in 2013, held Section 3(d) to be constitutionally valid and clarified that in order to get a patent over derivatives of a known compound, the applicant shall show that the said derivative results in enhanced therapeutic efficacy as compared to the known compound.

Subsequent to the said Supreme Court decision, to overcome Section 3(d) provisions, the applicants had to establish therapeutic efficacy by way of sufficient clinical evidence.

It has been seen in a recent study titled 'Pharmaceutical Patent Grants in India' that the Indian Patent Office has allowed nearly 72% for secondary patents in the pharmaceutical field which could have been checked under Section 3(d) of the Act. The said study states that the secondary patents granted by the Patent Office were in contravention of the anti-evergreening provisions contained in the Patent Act, which also included Sections 3(e) and 3(i), apart from Section 3(d).

On further evaluation of the cases in question, the study reports that patent applicants repeatedly blunted the effect of Section 3(d) by claiming incorrect application of Section 3(d) by the Patent Office. The applicants would often divert the attention of the Patent Office to Section 3(e) which stipulates that a mere admixture resulting only in aggregation of the properties of the components thereof is not considered as invention under the Act. To overcome Section 3(e), the applicant had to simply show synergistic effect of the components forming the compound which was much easier in comparison to the requirement of Section 3(d), i.e. to establish the enhanced therapeutic efficacy of the new compound. Accordingly, by showing the synergistic effect (a relatively much easier standard), applicants would steer argument away from the evidential requirements that a Section 3(d) citation would warrant. Therefore, patent applicants overcome the requirement exhaustive clinical data to establish enhanced therapeutic efficacy and directed their legal arguments towards the application of Section 3(e) thereby switching to simpler test of synergistic effect.

The big pharma companies have been criticizing India's Section 3(d) as being too oppressive on them and against the TRIPS principles. They have been arguing that Section 3(d) is a discouragement to the inventors towards incremental innovations in the pharmaceutical field. The Indian Government counters that patent exclusivity is to incentivize innovation and not for tweaking known compounds without any advancement in efficacy.

Biotechnology Patent and Related Moral Issues

Monika Shailesh

"Biotechnology can transform humanity provided humanity wishes to be transformed" Geoffrey Carr-

Biotechnology inventions are important for human development. It is the broad area of biology involving living systems and organisms to develop or make products, or any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific uses.

Thomas Jefferson the man behind the first Patent Act did not have even slightest idea that the life forms can ever become a subject of Patent protection. The most famous case of Diamond v Anand Chakrabarty where a biochemist at GE developed a genetically modified organism that had the ability to decompose crude oil. At first his patent application was rejected which on further appeal was granted by the court with order stating "His claim is not to a hitherto unknown natural phenomenon, but to a non-naturally occurring manufacture or composition of matter-a product of human ingenuity".

Biotechnology Patent and India

Patent Act in India was enacted in 1856. It has been modified several times since then; one major amendment being in 1970 which the international satisfied norms patentability covering novelty, inventive step and industrial application. But this version specific had nothing concerning Biotechnology invention and protection. At the same time, since the patent offices and courts in US and EU were seeing increasing number of biotech inventions and patent application, the demand for amendment of Indian Patent Act to introduce biotech patentability gained voice in India. The

amendment came in 2002 to explicitly include biochemical, biotechnological and microbiological processes within the definition of potentially patentable process. Statutory obstacles to patentability

The criteria for fulfilling patentability requirements are novelty, inventiveness, and industrial application. Apart from this, some inventions are also excluded from patentability under section 3 of the Patent Act, 1970.

What Is Not Patentable In India:

- Section 3 (b) . As per the section an invention would not be patentable if it is immoral or against public order, harmful to human, animal or plant life or harmful to environment
- Discovery of living things or non-living substances in nature Section 3 (c)
- Plants and animals in whole or any parts thereof other than micro-organisms but including seeds, varieties and species Section 3 (j)
- Essentially biological processes for the production or propagation of plants and animals—Section 3 (j)
- Any Process for the medicinal, surgical, curative, prophylactic, diagnostic or therapeutic or other treatment of human beings or animals to render them free of disease or to increase their economic value or that of their products Section 3(i)
- Methods of agriculture or horticulture
 Section 3(h)
- Traditional knowledge Section 3(p)

Deposition of biological material

Under Section 10(4) and rule 13 (8)of the Patent Act, an applicant must deposit the biological material mentioned in the specification if it is unavailable to the public and cannot be described adequately as per the

provisions of the act. The material must be deposited with an international depository authority under the Budapest Treaty.

The international depository authorities in India are the Microbial Culture Collection, Pune and Microbial Type Culture Collection and Gene Bank, Chandigarh. It is the duty of the applicant to give information w.r.t biological material used in specification.

Time period - The deposit must be made no later than the filing date of the patent application in India. Mentioning of the deposit must be made in the specification within the prescribed period (i.e. three months from the filing date).

Sequence listing

Sequence listing is the most important part of any bilological invention. It pertains to the listing of nucleotides and amino acids. The details of nucleotides and/or amino acids shall be filed in electronic form. However, the fee with respect to the equivalent number of pages shall be payable. In the case of Biotechnology related inventions, relevant numbers of the sequence listing shall be mentioned at appropriate place in the specification. Sequence listing should also be given in electronic form.

Moral Issues

It is true that necessity propels any invention. In this new era our necessities are increasing fuelling inventions but again it is our responsibility to protect our rights too.

- I. Organ Transplantation Organ transplantation is a big moral issue for biological based invention. It possess a big moral issues. The biological invention facilitate the organ transplantation is opposed by numerous intellectual based on religious faith. Also it is anticipated by some that it may give rise to illegal Human trafficking.
- II. Biological Weapons Biological weapons are the most dreaded ones today, far more dangerous than nuclear, chemical or conventional weapons. Discussion on this issue is most crucial.
- III. Bioinformatics- It is a methology of biological studies implemented with the help of computer programme. It is generally used for gene identification and prediction of upcoming diseases. Many believe that this could bring legal turmoil in the society. Also it may hamper the natural living of humans.

Conclusion

It can be seen that the Biotechnology and life form patentability is a subject of exploration in India. With more and more research and innovation going on in this field and keeping in view the rich bio-diversity that India enjoys, there is a real need to protect the interest of inventors. India needs to enable its inventors and inventions to compete in the global scenario, although few claims are considered but they are more on case-to-case basis and there is a lack of tidy guidelines.

BOLAR EXEMPTION IN INDIA

Aayush Sharma

Section 107A of the Indian Patent Act is known as India's Bolar Exemption. The fundamental objective of Section 107A is to delineate certain acts which are not to be considered as infringement.

The relevant section has been reiterated below-

"For the purposes of this Act- (a) any act of making, constructing, using, selling or importing a patented invention solely for uses reasonably related to the development and submission of information required under any law for the time being in force, in India, or in a country other than India, that regulates the manufacture, construction, use, sale or import of any product;

(b) Importation of patented products by any person from a person, who is duly authorized under the law to produce and sell or distribute the product, Shall not be considered as an infringement of patent rights"

India is the largest producer of generic medicines. The huge demand for cost-effective medicines is one of the most important factors behind the establishment of generic manufacturing companies in the country. In a recent notification by the Indian Government, it has been clearly informed to the Medical Association of India and their registered doctors that only generic medicines need to be prescribed to the patients. The cost of any generic medicine is very less compared to the parallel patented drugs. In order to prepare a drug, most of the generic companies rely on the patented drugs. A patented drug is protected for 20 years by way of rights conferred under section 48 of the Indian Patents Act, 1970, where the patent holder has the monopoly rights to make, use, sell or distribute his patented products for protection period. Bolar exemption is applicable within this protection period wherein patented drug is used by third or interested parties for further research and development.

Bolar Provision is a defense used against patent infringement. When an invention is made, it is either used or sold by a third party for certain purposes for further research and development. Thus. this provision assumes extreme importance because the generic manufacturers, who seek to boost their business in the market soon after the expiry of the innovator company's patents, through the application of Bolar provision have the necessary time and opportunity for conducting research on the product while the patent being still valid.

In simple words, we can say that the exemption that enables generic manufacturers to experiment with patented drugs and produce them in limited quantities for research, is known as the Bolar exemption. The exemption enables generic drug manufacturers to use an inventor's pharmaceutical drug before the patent expires, which not only aids in the early launch of generic versions of the drug once the innovator drug's patent term ends, but also promotes further R&D.

<u>Comparison of India's Bolar provision with</u> United States

In India, the Bolar provision is comparatively broader than its US equivalent. In the US, the Bolar provision restricts the safe harbour available to generic manufacturers to making, using, offering for sale or selling the patented invention solely for uses that are reasonably related to the development and submission of information under US federal law in the United States only. But its Indian counterpart does not specify such territorial limits. Thus, a sale, even if outside India, will fall within the sweep of

Section 107A, if it is reasonably related to the development and submission of information required for regulatory approval under the law of the country in which the sale takes place.

Are marketing authorizations and clinical trials, also part of the Bolar exemption?

The Bolar exemption in India is broader in terms of scope of coverage and provides greater liberal provision(s) when compared to its counterparts. When viewed from the perspective of the definition of S.107A of the ,'....development submission and information required under any law for the time being in force in India....'; since the clinical trials and marketing approvals/ marketing authorization application would come under information required under the Indian Drug regulations viz. Drugs and Cosmetics Act, 1940 and Rules, 1945, it would be safe to interpret that generic manufacturers can use this pathway for clinical development (conduct of clinical trials) filing of marketing authorization and applications for their generic products of Invented Drugs / Patent Protected Drugs.

It is pertinent to mention here that there is paucity of cases regarding Bolar exemption in India, India has only one case regarding this provision wherein clinical trials have been mentioned as part of Bolar exemption, the case being *Bayer Corporation vs. Union of India & Anr.* It can be concluded that due to limited precedence of usage of Bolar exemption for the marketing authorizations and clinical trials by pharmaceuticals companies so far in India, we interpret marketing authorizations and clinical trials are also part of Bolar exemption.

The concept of Bolar exemption is highly relevant to the Indian scenario. In one of the statements by an Indian Pharma company it was said that, "Bolar exemption was provided to encourage competition. The greater the competition, the better it is for the protection of

public health". India being one of the developing nations, should bring in laws favouring R&D. Further, the Bolar provision should be clearly explained by the supreme authority so that the rights of the patentee are never harnessed. Furthermore, the apex court should also assess whether the infringement has been caused due to R&D or for profit or for academic purpose.

Industrial Design Protection in India: The Designs Act, 2000

Suchi Rai

Introduction

The Designs Act, 2000 ("the Act"), is a complete code in itself and protection under it is wholly statutory in nature. It protects the visual design of objects that are not purely utilitarian. Section 2(d) of the Act, defines a Design as:

"design" means only the features of shape, configuration, pattern, ornament or composition of lines or colours applied to any article whether in two dimensional or three dimensional or in both forms, by any industrial process or means, whether manual, mechanical or chemical, separate or combined, which in the finished article appeal to and are judged solely by the eye; but does not include any mode or principle of construction or anything which is in substance a mere mechanical device, and does not include any trade mark as defined in clause (v) of sub-section (1) of section 2 of the Trade and Merchandise Marks Act, 1958 (43 of 1958) or property mark as defined in section 479 of the Indian Penal Code (45 of 1860) or any artistic work as defined in clause (c) of section 2 of the Copyright Act, 1957 (14 of 1957).

The pre-requisites for a design to qualify for protection are as follows

- It should be novel and original.
- It should be applicable to a functional article.
- It should be visible on a finished article.

• There should be no prior publication or disclosure of the design.

Locarno Classification

Designs are registered in different classes as per the Locarno Agreement. It is used to classify goods for the purposes of the registration of industrial designs which further helps in Design searches. These classes are mainly function oriented

Protection term

The Copyright on a registered design is in total for 15 years. Initially the Copyright in Design is registered for 10 years, which can further be extended by 5 years on making an application for renewal.

Design Rights

As in case of any other IP rights, the design registration also bestows a monopolistic right to the Proprietor by which he/she can legally exclude others from reproducing, manufacturing, selling, or dealing in the said registered design without his/her prior consent. The design registration is particularly useful for entities where the shape of the product has aesthetic value and the entity wishes to have exclusivity over the said novel and original design applied to its product(s) or article(s).

In addition to the above, the design sought for protection must be new or original, i.e., not disclosed to the public in India or elsewhere in the world by prior publication or by prior use or in any other way. The design should be significantly distinguishable from designs or combination of designs that are already registered or pre-existing or disclosed to the public. Furthermore, the design should not

include any scandalous or obscene matter or any feature that is purely functional in nature.

Remedies

- It is submitted that as per Section 19 of the Designs Act, 2000, at any time during the subsistence of the Design registration, any person can seek cancellation of design registration by filing a Petition before the Controller, on the following grounds: [ra1] "...(a) that the design has been previously registered in India; or
- (b) that it has been published in India or in any other country prior to the date of registration; or
- (c) that the design is not a new or original design; or
- (d) that the design is not registerable under this Act; or
- <u>(e)</u> that it is not a design as defined under clause (d) of section 2..."

Further, an appeal against the order of the Controller can be made to the High Court.

Piracy of Registered Designs

Section 22 of the Designs Act, 2000, provides that any fraudulent or obvious imitation of a registered design without the consent of the proprietor is unlawful and also prohibits the import of such material which closely resembles a registered design. The section very specifically provides that in a civil case compensation payable shall not exceed Rs. 50,000/- in respect of infringement of one registered design. As the compensation payable is statutorily limited, it is a good ground for insisting an interim injunction even before the commencement of trial.

Comparison of Design Registration against different IPs

- Design registration versus Patents registration: A patent protection is granted over a novel product or process comprising inventive step (technical advance) and exhibiting industrial applicability. One of the prime differentiators for design vis-à-vis patent protection is that contrary to designs, patents must contain a functional and/or structural feature of technical significance. While a design is judged on aesthetics only and not functionality/technicalities of the shape/pattern of an article, the patents on the other hand are judged solely on the functionality and not the aesthetics of the feature/shape.
- Design registration versus Copyright:
 Both design and copyright protections relate to aesthetic features of the article.
 The differentiating factor is clearly provided under Section 15(1) of the Copyright Act, 1957, which states that:
 - 1. Copyright shall not subsist in any design registered under the Designs Act, 1911, or
 - 2. Copyright in any design capable of being registered under the Designs Act, shall cease as soon as any article to which the design has been applied to has been reproduced more than fifty times by an industrial process.

Therefore, by virtue of Section 15 of the Copyrights Act, a design registration and copyright over the article cannot co-exist, both forms of IP protection are mutually exclusive.

• Design registration versus Trademark registration: ¹⁰A registered design and a trademark (not yet registered) may have an overlapping area. Say if a unique shape is a registered design and the said unique shape of the article attains such level of popularity leading to brand recognition amidst available articles in the same classification of goods, the same may fall under consideration for a

trade marks registration by the proprietor/company. Accordingly, unique industrially applied shape or pattern shall be registered as design, and if and when the design becomes indicative of the origin of the article/products of the company, the company may consider applying for registration of the shape/pattern as a trademark.

¹⁰ Refer Section 2(zb) and Section 9(3) of the Trade Marks Act, 1999

National Workshop On Intellectual Property Rights (IPR): Current Status And Future Prospects organized by Department of Botany, Maitreyi College, University of Delhi in association with Singh & Associates, Founder: Manoj K. Singh, Advocates and Solicitors

Department of Botany, University of Delhi Associates. Founder: & Advocates and **Solicitors** Workshop On Intellectual Current Status And Future October, 2018 at Maitreyi Delhi. The workshop aimed knowledge sharing among the participants on the future prospects ofRights. Besides this, the envisioned to inspire students to benefit from the IPR rights.

The workshop opened with a Dr. Haritma Chopra, College, University of Delhi. various interactive sessions Information *Technology* Property Rights, Industrial *Biotechnology* Related Rights, Property Plant Intellectual Property Rights. presentations analyzed in



Maitrevi College, association with Singh Manoj K. Singh, organized a "National Property Rights (IPR): Prospects" on College, University of facilitating at raising IPR awareness current status and Intellectual **Property** workshop also and research scholars

welcome address by Principal of Maitreyi The program had Patents & on Intellectual Based Design and Aspects of Intellectual Genetic Resources and The technical detail about the

different IPR rights including Patent, Design, Trademark, Copyright and Plant Varieties Act. Apart from the technical presentations, there were hands-on session on Patent & Trademark searches and live demonstration of e-filing system in India for Patent filings.

The participants at the workshop comprised graduation students, research scholars, guest faculties from the reputed institutions across the country and faculty members of Department of Botany, Maitreyi College, who were also the organizers of the workshop.

The key speakers presenting the sessions on different topics were Mr. Shrimant Singh, Senior Principal Associate, Singh & Associates, Ms. Suchi Rai, Senior Principal Associate, Singh & Associates and Dr. Arun Kumar Maurya, Assistant Professor, CCS University, Meerut, U.P.

Memories of the Work Shop









