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INTELLECTUAL PROPERTY AND TECHNOLOGY LAW UPDATES

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CONTENTS

AUTHORSHIP AND OWNERSHIP IN COPYRIGHT

-By Tushar Kohli

Law of copyright aims at protecting original works of authors. Copyright law ensures that an author or creator of a work derives benefits from his product of creativity. In other words, copyright law forbids unauthorized use of copyrighted contents. To be eligible for copyright protection, the work must be original, it must be fixed in some material form and it must qualify as a "work of authorship".

As copyright is a property right, this raises important questions about ownership and the mechanisms for exploiting copyright. Authorship and ownership are, in relation to copyright, two distinct concepts, each of which attracts its own peculiar rights: the author having moral rights, and the owner of the copyright possessing economic rights.

Author:

The author is the person who actually writes, compiles composes or draws the work in question, although the idea of the work may have been suggested by another. The word 'author' is defined under s. 2(d) of the Copyright Act, 1957. Author in relation to various categories of works as defined in Sec. 2(d) is as follows:

literary or dramatic work- the author of the work,

- musical work-the composer,
- an artistic work other than a photograph-the artist,
- photograph- the person who takes the photograph,
- cinematograph film- the producer,
- sound recording-the producer,
- literary, dramatic, musical or artistic work which is computer generated- the person who causes the work to be created.

The author of a compilation is the person who gathers or organizes the material contained within it and who selects, orders and arranges that material.[1] The author does not have to be the person who carries out the physical act of creating the work, such as by putting pencil to paper. An amanuensis taking down dictation is not the author of the resulting work. The author of a work does not have to exercise penmanship but something akin to penmanship is required.[2]

Ownership:

Ownership of copyright in a work is quite independent of the ownership of the physical

[1] *Waterlow Publishers Ltd* v *Rose* [1995] FSR 207

[2] *Robin Ray* v *Classic FM plc*.

material in which the work is fixed. As a rule the author of the work is the first owner of the copyright in the work.[3] There are, however, exceptions to this. Since there is no copyright in ideas even if they are original, the originator of a brilliant idea is not the owner of the copyright in the work which gives concrete form to the idea unless he is also the creator of the work. The originator of the idea has no right in the product, for copyright subsists not in ideas but in the tangible form in which it is expressed.[4]

Works of Authorship:

The copyright protection subsists in original works of authorship fixed in any tangible medium of expression. Copyright ownership vests in the author of a work. Determining ownership is critical because the exclusive rights of reproduction, performance, display, and so forth belong to the copyright owner.

Ownership of a physical object is separate and distinct from ownership of the copyright embodied in the material object. Purchasing a manuscript or letters written by a famous person gives the purchaser ownership of those 'physical objects' alone. Unless copyright has been explicitly conveyed with those physical articles, the original authors generally retain all other rights associated with the works, including the rights to perform and reproduce them and any other exclusive rights granted to copyright owners under section14 of the Copyright Act.

Firstly, an author may create a work on his own behalf or at the instance of another person or in the course of employment by another person. In the first case the author is the owner of copyright in the work. Authors who write books, compose music are persons who come under this category. Secondly, an author may create a work at the instance of another person for valuable consideration. Examples: a photographer taking a photo at the instance of another person or a painter drawing a portrait at the request of another person for valuable consideration. In such cases, in the absence of any agreement to the contrary, the person at whose instance the work is made is the owner of the copyright in the work. [5] Thirdly, an author may create a work in the course of his employment under a contract of service or apprenticeship i.e. as an employee for an employer. In such cases the employer in the absence of any agreement to the contrary is the first owner of the copyright.

Joint Authorship:

[3] Section 17.

[4] *Donoghue* v *Allied Newspapers* [1973]3 All ER 503

[5] *Apple Computer* v *Cooper* [1993] FSR 280.

A work may be the result of the efforts of more than one person. Several employees may work together to produce a written report, a team of computer programmers and systems analysts together may produce a computer program. Collaboration between two or more persons will result in a work of joint authorship only if their respective contributions to the finished work are not distinct from each other. That is, the work cannot be broken down so that each author's contribution can be separately identified. A joint work is a work prepared by two or more authors with the intention that their contributions be merged into inseparable or interdependent parts of a unitary whole. Example: book that is coauthored by individuals. It is the intent of the parties at the time a work is created that determines whether it is a joint work. Thus, if two persons sit at a piano and collaborate on a melody and lyrics, the resulting song is a joint work.

Merely making suggestions or giving directions to one creating a work is not sufficient to make one a joint author. For example, giving an architect instruction that a house to be designed by the architect should have a certain amount of living space and giving other directions does not make one a joint author. Although the contributions of coauthors need not be equal, each must make some significant contribution.

If individuals are authors of a joint work, each owns an equal undivided interest in the copyright as a tenant in common, meaning that each has the right to use the work, prepare derivative works based on it, perform it, display it, and so forth, without seeking the other coauthor's permission. Because each coauthor has rights in the work, one cannot exclude another from using the work or exercising the rights of copyright ownership. Nevertheless, if profits arise out of such uses, an accounting must be made so that each author shares in the benefits or proceeds.

If a work such as a book is created by one person who intends it to be complete at the time and illustrations are later added to it by another, the work cannot be a joint work because there was no intention of the parties to create a unitary whole at the time of their creation. In such a case, the new work, consisting of text and illustrations, is a derivative work. The author of the original book has rights only to his or her work and cannot reproduce or perform the derivative work without permission. Similarly, the author of the derivative work cannot create further works based on the original book without permission and cannot reproduce the original

work (or exercise other copyright rights) without permission.

Multiple ownership rights may also arise if separately copyrightable works are compiled into a collection. For example, in case of essays written by various authors, the original authors retain their exclusive rights- such as rights to reproduce, distribute, and perform- in their respective essays. No joint work is created because there was no intent at the time the separate essays were created to merge them into a unitary whole. No derivative work is created because the original works have not been transformed in any way and nothing new has been added to them.

Works Made For Hire:

Although the general rule is that the person who creates a work is the author of that work and the owner of the copyright therein, there is an exception to that principle: the copyright law defines a category of works called works made for hire. If a work is "made for hire," the author is considered to be the employer or commissioning party and not the employee or the actual person who created the work. The employer or commissioning party may be a company or an individual.

There are two types of works that are classified as works made for hire: works prepared by an employee within the scope of employment and certain categories of specially ordered or commissioned works.

Copyright in works prepared by employees are presumptively owned by their employers. For example, if an employee is tasked with creating a computer program by his or her employer, the resulting work is owned by the employee. The general principle is that when something done or produced by a person in the employment of another, and what he does or produces is part of the business or duty assigned to him as that other's employee, the copyright in the work so produced will, in the first instance, be the property of the employer.

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ASTRA ZENECA'S DISPUTED DRUG TRICAGRELOR: DISCLOSURE Vs COVERAGE

- ***By Saipriya Balasubramanian***

In a recent Delhi High Court decision, Astra Zeneca (the plaintiffs) a major biopharmaceutical company, faced a huge setback in its TICAGRELOR (an effective platelet aggregation inhibitor) patent disputes. On 8th August 20196, Delhi High Court passed an order vacating the interim orders that injuncted Micro Labs, Natco Pharma and Dr. Reddy's Laboratories ('defendants') from manufacturing or marketing the generic versions of TICAGRELOR. The three suits filed by the plaintiffs with regards to the infringement of subject matter of three patents namely IN209907 (IN 907/species patent), IN 247984 (IN 984/Polymorph patent) and IN 272674 (IN 674/Formulation patent). The present case deals with two important aspects, ever greening of patents under section 3(d) as well as the issue of 'coverage 'under Markush formula and 'disclosure' of the genus patent and the species patents.

THE STORY OF BRILINTA

The pharmaceutical formulation containing TICAGRELOR is being sold under the brand name BRILINTA AND AXCER. According to the Plaintiffs, TICAGRELOR is first approved in the US in 2011. The same drug was approved in India in May 2012 and is sold under the same name BRILINTA and AXCER. TICAGRELOR is a platelet inhibitor indicated to reduce the rate of cardiovascular death, myocardial infarction and stroke in patients with acute coronary syndrome (ACS) or a history of myocardial infarction (MI). BRILINTA is protected under three Indian Patents as follows;

IN 907	DISCLOSED CLASS OF COMPOUNDS WITH MARKUSH FORMULA	Ticagrelor is claimed in Claim 5 of this patent.
IN 984	POLYMORPH PATENT	Four Crystalline forms of TICAGRELOR are disclosed in this patent
IN 674	FORMULATION PATENT	pharmaceutical composition of TICAGRELOR

The Plaintiffs received business information from various sources in 2018 that the defendants are planning to launch a generic version of TICAGRELOR under BIGRELOR and TICAFLO in India and hence have filed

[6] http://lobis.nic.in/ddir/dhc/JAN/judgement/08-08-2019/JAN08082019IA39862018.pdf

revocation petition in respect of IN 984 and IN 907 before the Intellectual Property Appellate Board (IPAB). In 2018, the Delhi HC passed interim orders in the plaintiff's interim applications restraining the defendants in three different proceedings from selling, marketing or dealing with TICAGRELOR drug or any other drug violating the plaintiff's above mentioned patents.

INVALIDITY OF THE SUIT PATENTS AS ARGUED BY THE DEFENDANTS:

The Defendants filed written statements to submit that the suit patents have no merits.

- It was pointed that the genus Patent IN 241229 (IN 229) expressly covered TICAGRELOR has expired on 14th July 2018. Form 27 filed for IN 229 also expressly referred to BRILINTA & AXCER products being covered in IN 229.
- The information that the foreign patent equivalents which were held invalid in the contested proceedings (in China, Europe and South Korea) were suppressed by the Plaintiffs which is a clear case of non-compliance of Section 8 of the Act.
- The genus patent of TICAGRELOR expired on 14-July-2018. Therefore, it of mala fide intention of the plaintiffs to seek protection for the same TICAGRELOR subsequently in IN 907 and IN 984 as well. Hence it is a case of patent EVERGREENING.
- Compounds as disclosed and covered in IN 907 are known and anticipated through prior claiming in IN 229. Hence there is lack of novelty and inventive step under Section 64(1)(a) & 64(1)(f), 64(1)(d), 64(1)(k), 64(1)(h), 64(1)(j) and 64(1)(m) of the Act.
- It was submitted by the defendants that the suit patents lack any inventive step as they do not exhibit any therapeutic efficacy over the known substances as disclosed in IN 229. Hence the patent is liable to be revoked under Section 3(d) of the Patents Act, 1970.
- Plaintiffs asserted that the genus patent of TICAGRELOR covers 150 quintillion compounds (1.5 x 1020). The plaintiffs have asserted that the US counterpart application of IN 229, specifically identifies and exemplifies 144 compounds, 134 out of which are specifically disclosed in claim 8 of IN 229. Therefore, a skilled person in the art have to experiment only with 144 or 134 compounds which are readily available for him to further experiment

and create/identify derivatives suitable as drug candidates.

- ⇨ Counter claims for revocation of Indian Patent IN 907, IN 984 and IN 674 was filed by the defendants.
- ⇨ The Plaintiffs has provided no evidence in the plaint that TICAGRELOR is more efficacious than the invention disclosed in IN 229.

PLAINTIFF'S COUNTER ARGUMENTS:

- ⇨ With regards to anticipation, under section 13 (1)(a) of the Act it is stated that IN 229 was published on February 1999 which is after the priority date of IN 907 that is December 1998. Hence IN 229 cannot constitute a prior art document for assessing novelty of IN 907.It was also argued by the plaintiffs that TRICAGRELOR cannot be identified by a person of ordinary skill in the art from the teaching of IN 229. Unless isolated specifically, to show that TICAGRELOR can be derived from the general Markush Formula disclosed in IN 229 is untenable.
- ⇨ On allegations related to Section 3(d) of the Patent Act i.e. ever greening, it plaintiffs stated that the defendants had not specified any known substance from IN 229 of which TICAGRELOR was considered new form or derivative. Mere presence of substances in the examples which are structurally similar to TICAGRELOR did not mean that TICAGRELOR is a new form or derivative. Further, it was submitted that in the affidavit submitted by the defendant Dr.Reddy's Laboratory in which an expert Dr.Robert Riley had stated that TICAGRELOR has a vastly superior metabolic stability. Therefore, hence section 3(d) do not apply.
- ⇨ On allegation of non-compliance under Section 8 of the Act, the Plaintiffs submitted that equivalent of IN 907 was revoked in China but an appeal has been filed. 67 countries granted patent for the same.IN 984 was rejected in Europe and China and patents are granted in 55 countries. IN 674 is subsisting in 60 countries. Hence there is no mala fide suppression therefore Section 8 do not apply.

OBSERVATIONS OF THE COURT

The court observed that the stated compounds as claimed in the suit patents are disclosed in IN 229. The Court further referenced this context to the judgment of the Supreme Court in the case of Novartis

AG vs. Union of India & Ors[7]. The 2013 decision dealt with the dichotomy of disclosure Vs coverage in patent very subtly as it stated that "To say that the coverage in a patent might go much beyond the disclosure thus seem to negate the fundamental rule underlying the grant of patents".

With regards to objections under Section 3(d), the court clearly pointed that the plaint submitted remained silent about any therapeutic efficacy of the suit patents in relation to IN 229. The court also elaborated the strict interpretation of section 3(d) citing the judgment of the Supreme Court in Novartis AGs v. Union of India & Ors.(supra), Section 3(d) was amended to make it even more constrictive than before, we have no doubt that the "therapeutic efficacy" of a medicine must be judged strictly and narrowly. Further, the explanation requires the derivative to "differ significantly in properties with regard to efficacy". What is evident, therefore, is that not all advantageous or beneficial properties are relevant, but only such properties that directly relate to efficacy, which in case of medicine, as seen above, is its therapeutic efficacy."

The court further stated that with regards to the enhancement of therapeutic efficacy, the affidavit of Dr.Riley, stated that the equivalent of IN 907 showed advantages of a lower predicated dose and increased metabolic stability. However, there was no explanation from the plaintiffs as to how the mentioned advantages led to enhancement of efficacy over IN 229. Therefore as noted by the Supreme Court, not all advantageous or beneficial properties are relevant, but only such properties that directly relate to therapeutic efficacy. Therefore, the plaintiffs prima facie failed to establish enhanced therapeutic efficacy of the suit patents over the products and fail the test of section 3(d) of the Act.

Non-Compliance of Section 8

Section 8(1)(a)	Requires an applicant for a patent to file along with his application a statement setting out the detailed particulars of the application filed by such applicant ―in any country outside India in respect of the same or substantially the same invention‖
Section (1)(b)	Requires such applicant to also furnish an undertaking that up to the date of the grant of patent in India he will keep the Controller of Patents informed in writing ―from time to time‖ of detailed particulars as required under

[7] https://indiankanoon.org/doc/165776436/

	clause (a) in respect of such application made in a country outside India.
Rule 12(1)	states that the statement and undertaking to be filed in terms of Section 8 (1) of the Act will be in Form 3.

In the present case, the court observed that there was substantial compliance of the statutory requirements of Section 8 of the Act by the Plaintiffs. The failure of the plaintiffs to mention about the proceedings in China and Europe are not material enough to warrant the vacation of interim orders is what was inferred by the Court.

CONCLUSION

The Court found that in the present case, the defendants has raised a credible challenge to the validity of the patent by raising a serious triable and substantial question that renders it vulnerable to challenge under Section 64(1) and Section 3(d) of the Patents Act. Therefore, the Court denied to grant an injunction due to failure on part of the plaintiffs to establish a prime facie case. Further, the court also stated that the balance of power was in favour of defendants because of the expiry of the original patent in question IN 229 as well as for the reason that drug being sold by the defendants are substantially at a lower price.

Hence, the court vacated the interim generic bans meaning that the defendants Dr.Reddy's, Natco and Micro Labs are free enough to launch their drugs.

The decision rings a loud bell about India's restrictive measures to prevent patent ever-greening, by strong implementation of Section 3(d) that prevents derivative or other forms of the already patented product being granted patent unless the derivatives or other forms "differ significantly in properties in regard to efficacy."9.

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COMPULSORY LICENSING OF PATENTS

-By Shilpi Kumari

Patent provides an exclusive right granted for an invention (either product or process) that provides, in general, a new way of doing something, or offers a new technical solution to a problem.

Compulsory licensing is the authorizations given to a third-party by the Government to make, use or sell patented product or process, without the consent or permission of the patent owner. There are certain pre-requisite conditions which are needed to be fulfilled if the Government wants to grant a compulsory license.

The provisions regarding compulsory licenses are given in the TRIPS (Trade-Related Aspects of Intellectual Property Rights) Agreement at the International level and in the Indian Patents Act, 1970. Although this works against the patent holder/patentee as it kills innovation as getting a patent requires a lot of money, effort and research. However, compulsory licenses are only considered in certain special cases of national emergency and health crisis. Compulsory Licensing of Patents is an exception to the general rule under intellectual property laws that states that the intellectual property owner enjoys exclusive rights that it may license – or decline to license – to others.

The provisions of 'compulsory license' are specifically mentioned under Chapter XVI of the Indian Patents Act, 1970, and the conditions which need to be fulfilled are given in Sections 84-92 of the said Act.

Section 84

At any time after the expiration of three years from the date of the 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.

As per Section 84, any person who is interested or already the holder of the license under the Patent can make a request to the Controller for grant of compulsory license on expiry of the three years, when the above conditions are fulfilled.

However compulsory licenses can be granted on certain other factors as per the Patent Act–

1. Section 92 A- For exports, under exceptional circumstances. In case of national emergency, extreme urgency of public non-commercial use by notification of the Central Government

2. Section 92 A (1) – To a country which has insufficient or no manufacturing power in the pharmaceutical sector to address public health.

Natco Pharma verses Baeyer's Case: India's first case of granting compulsory license

India's first case of granting compulsory license was granted by the Patent office in 2012 to an Indian Hyderabad based Company called Natco Pharma for the generic production of Baeyer Corporation's Nexavar. All the three conditions of Sec 84 was mentioned in the Indian Patent Act,1970 was fulfilled namely a) the reasonable requirements of the public were not fulfilled, and b) that it was not available at an affordable price and c) that the patented invention was not worked around in the territory of India.

A landmark decision, under the amended Indian Patents Act (2005), allows Natco to make and sell in India, a similar version of Bayer's Nexavar, an advanced kidney cancer drug. This medicine is used for treating Liver and Kidney Cancer, and one month's worth of dosage costs around Rs 2.8 Lakh Natco Pharma offered to sell it around for Rs 9000 making this potentially lifesaving drug easily accessible to all parts of the society and not just the rich people. The Government took this decision for the general public benefit. However, it was heavily criticized by the Pharmaceutical Companies as they felt the license should not have been given.

Impacts of Compulsory Licensing

The areas which are impacted by compulsory license are as follows:-

1. Innovation – In the greater part of the underdeveloped and developing nations, the development of pharmaceutical organizations is less as they are progressively subject to nonexclusive medications. They for the most part incline toward getting the obligatory permit to a conventional medication as opposed to subsidizing the Research and Development independently, which is regularly an in all respects expensive thing. In addition, look into based pharmaceutical organizations don't dispatch patent module in the creating nations as there is consistently the danger of losing the patent, and losing cash in research.

2. Patients- Patients will get medications at a fundamentally less expensive rate. Additionally, the huge pharmaceutical organizations regularly acquaint plans like free access with medication to secure their licenses in the creating nations.

3. Competition & Cost- Compulsory authorizing will expand the quantity of organizations creating conventional prescriptions. Consequently the supply will go up, and the cost will descend. This will likewise compel the trend-setter nations to present differential valuing of their patent module so they can remain available.

Global Perspective on Compulsory Licensing- The phenomenon of compulsory licensing is a hugely debated issue. Many developing countries are giving importance to the compulsory licensing because of the unavailability and unaffordability of the medicines due to lack of proper R&D, and they are continuously granting more and more compulsory licenses. The developed countries such as Europe, USA are opposing this view as it hampers and makes innovation difficult for the pharmaceutical companies.

Conclusion

The patent versus patient issue is one of the most significant issues now in the cutting edge medicinal services framework. The quantity of obligatory licenses conceded worldwide is on the ascent because of exorbitance of the medications. The underdeveloped and developing countries want to pass compulsory licenses, and the developed, and the big pharmaceutical companies do not want the compulsory licenses to be passed. The primary reason the enormous pharmaceutical organizations don't want compulsory licenses to be passed as it takes a great deal of money, research and effort to make the medications, and, after it’s all said and done there is no sureness. They need to recover the expenses of the advancement. Consequently, the organizations need to fix the expense of their protected module as per the monetary status of the nation on the off chance that they need to shield their item from necessary permitting.

India, specifically, faces a challenge, owing to the economic condition of the majority population. On one hand, it has to comply strictly with the international standards of patent protection and on the other hand, it has to safeguard public health.

We can say that compulsory licensing has now become the hope for financially challenged patients in underdeveloped countries, and compulsory licensing is now one of the most controversial topics in International Intellectual Property matters.

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PATENTABILITY CRITERIA OF ANTIBODIES AS PER INDIAN PATENT ACT

Nowadays a large number of patents have been granted for antibodies in India. We are also seeing a shift towards antibodies based drugs. After the Addition of section 3(d) in Indian patent act and with growing case-law in this area, the criteria for patentability of antibodies are becoming increasingly strict, with restrictions on the scope of the claims.

ANTIBODIES

Antibodies are Y-shaped proteins produced by B cells of the immune system in response to exposure to antigens. The antigen may include a foreign particle or a pathogen. Antibodies, also known as immunoglobulins (Ig). Each antibody has a paratope which recognizes a specific epitope on an antigen, acting like a lock and key binding mechanism. There are two types of antibodies: (a) polyclonal antibody (b) monoclonal antibody.

Polyclonal antibodies: are a mixture of heterogeneous which are usually produced by different B cell clones in the body. The advantage with polyclonal antibodies is that they recognize and bind to many epitopes of a single antigen

Monoclonal antibodies (mAb or moAb): are identical immunoglobulins, generated from a single B-cell clone. Due to the specificity and selectivity of monoclonal antibodies, they are widely used in diagnostic and therapeutic applications.

TYPES OF ANTIBODY PATENT APPLICATION:

The patents for antibodies may relate to:

- The antibody;
- Compositions containing one or more antibodies;
- Methods of generating the antibody;
- Therapeutic or diagnostic methods involving the use to the antibody; and
- Second medical use of the antibody, depending on the allowable subject matter and patentability criteria of a particular jurisdiction.

REJECTION UNDER SECTION 3;

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

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

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

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

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

3 (j): plants and animals in whole or any part thereof other than microorganisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals

[1]REJECTED CASES IN INDIA: The application *6647/DELNP/2007* was rejected for lack of inventive step and for non-patentable subject matter.

In *3411/DELNP/2006* and *6845/CHENP/2010* also claimed antibodies defined only by the antigen [8]of a specific sequence it targeted was rejected.

[1]GRANTED CASES IN INDIA: The application *4823/CHENP/2014* was granted for the antibodies that are produced by isolating the protein from a bacterium recombinantly producing the same. The recombinant protein has differences with respect to the protein naturally produced by the virus.

3155/CHENP/2008: The application fulfills technical criteria of The Patents Act, 1970.

CONCLUSION

The Indian patent office has granted and rejected several patents for antibodies. The correct formation of the preamble is important. While drafting a patent application in India a drafter one should keep in mind the above sections of the Indian patent act.

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[8] https://ipindiaservices.gov.in/publicsearch

PCT AND ITS SIGNIFICANCE

- By Manish Kumar

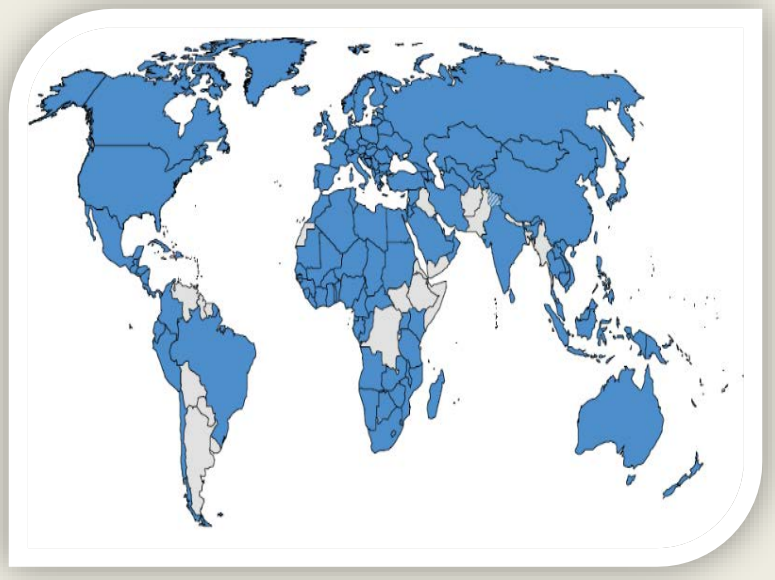
The PCT is an international treaty which provides a system for filing patent applications and assists the applicants in seeking patents in multiple countries around the world on the basis of a single patent application. While, the PCT simplifies patent application filing and processing for the applicants, the ultimate decision to grant a patent rests exclusively with each national or regional patent Office.

Background[9]

The PCT was signed in June 1970, in Washington, D.C., and became operational in June 1978 with 18 Contracting States. The PCT now has 152 Contracting States (*refer below image*), providing you with a worldwide patent filing coverage. The International Bureau of WIPO is responsible for the international coordination and management of the PCT system. This includes the review, communication, processing and publication of PCT applications and associated documents received by WIPO.

Overview of the PCT Process[10]

The PCT process is comprised of the following main steps:



International Phase

(1) Filing of a PCT application

(2) International search

(3) International publication

(4) Supplementary international search (optional)

(5) International preliminary examination (optional)

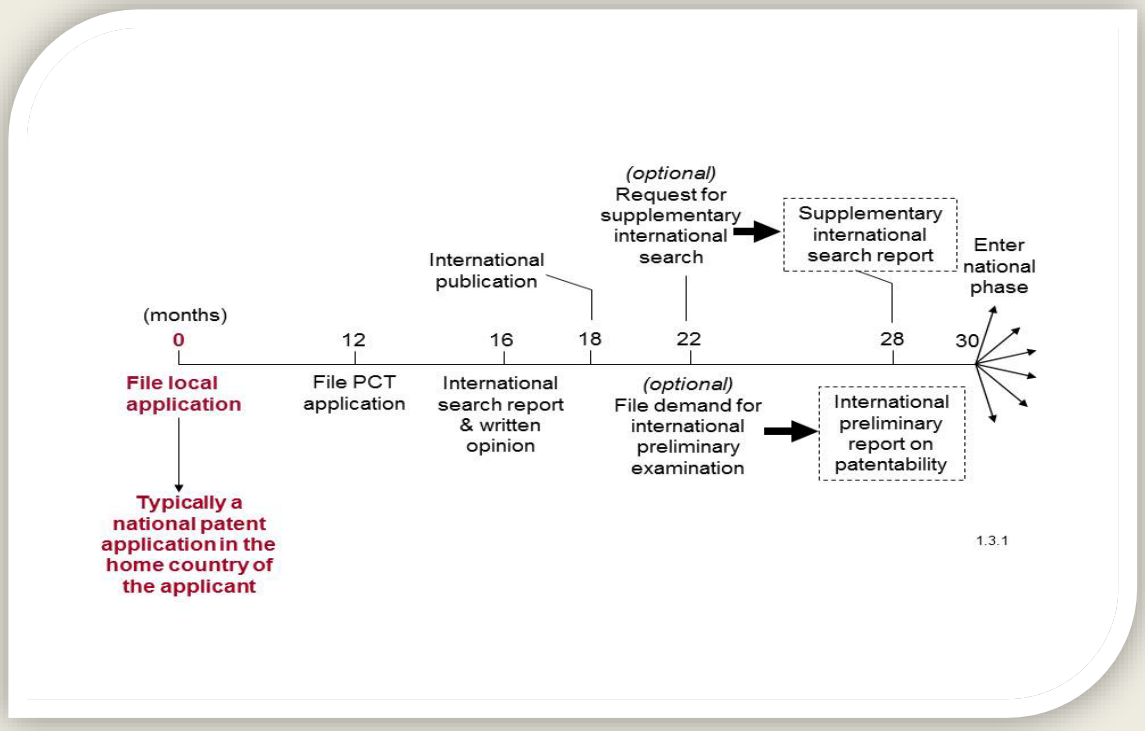
National Phase

(6) Processing of the PCT application before national and/or regional patent Offices

The below image provides the timeline with a graphical representation of the PCT procedure and sequence.

[9] https://www.wipo.int/pct/en/

[10] https://www.wipo.int/pct/en/guide/index.html



Let's understand each step in detail:

1. **Filing of a PCT application**

Based on the contents of the local (first) patent application, the applicant prepare and file the PCT application within 12 months from the local (first) patent application at the receiving office of local/national patent office or with the receiving office of WIPO if permitted by the national security provisions of the national law. Further, the international filing date of the PCT application will have the same effect as a separate application filed in each PCT country.

2. **International Search Report (ISR) and Written Opinion of the ISA**

While filing PCT application the applicant need to choose a competent International Searching Authority (ISA) to perform international searches and to establish written opinions for its invention and the same are available to the applicant by the end of 16 months from the filing date of the local application. Further, the ISR will contain citations of patent documents and other technological references relevant to the potential patentability of the invention. The written opinion complements the ISR by providing a preliminary non-binding patentability assessment of the invention by taking into consideration the references cited in the ISR.

3. **International Publication**

The International Bureau of WIPO publishes the PCT application in the PATENTSCOPE database after 18 months from the priority date of the PCT application. Publication serves to provide technical disclosure of the invention which helps to fuel greater technological progress and development.

4. **International Preliminary Report on Patentability (Chapter I)**

The applicant after considering the written opinion of the ISA may decide not to file a demand for international preliminary examination. In such a scenario, WIPO will attach a cover sheet to this written opinion effectively converting it into the international preliminary report on patentability under Chapter I of the PCT. Further, the report is available for public inspection after the expiry of 30 months from the priority date.

5. **Supplementary International Search (optional)**

Once the application is published, the applicant has the option of requesting that a supplementary international search be conducted on his PCT application (which is an additional search carried out by another ISA). The request for supplementary international search may be filed at any time prior to the expiry of 22 months from the priority date. Normally, the supplementary international search report prepared by the ISA should be available by 28 months from the priority date.

6. **International Preliminary Examination (optional)**

If you wish to amend your PCT application in light of the content of the International search report and written opinion and to have a second patentability assessment carried out on your as-amended application, you may decide to file a demand for international preliminary examination with a national or regional patent Office that has been appointed as an International Preliminary Examining Authority (IPEA) under the PCT. The applicant can file the demand for international preliminary examination at any time prior to the expiry of 22 months from the priority date.

7. **International Preliminary Report on Patentability (Chapter II)**

On the expiry of 28 months from the priority date, the IPEA will send the International Preliminary Report on Patentability under Chapter II of the PCT containing the opinion of the IPEA regarding the patentability of your invention as contained in your (usually) amended application. Further, this report is a non-binding opinion on patentability and is only provided to applicants who have filed a demand for international preliminary examination.

8. **National Phase Entry**

Entry into the national phase represents the end of the international phase of the PCT procedure and the beginning of the national patent procedure. The international preliminary report on patentability (either under Chapter I or Chapter II), which you received during the international phase, will help you evaluate your chances of obtaining a patent in the countries of interest to you. The report will also assist the national and regional patent Offices in their evaluation of whether a patent should be granted for your invention. Further, once the application has reached the national phase, it is subject to the patent laws, regulations and practices of each designated country.

Significance of PCT[11]

The main advantages to the users of PCT are:

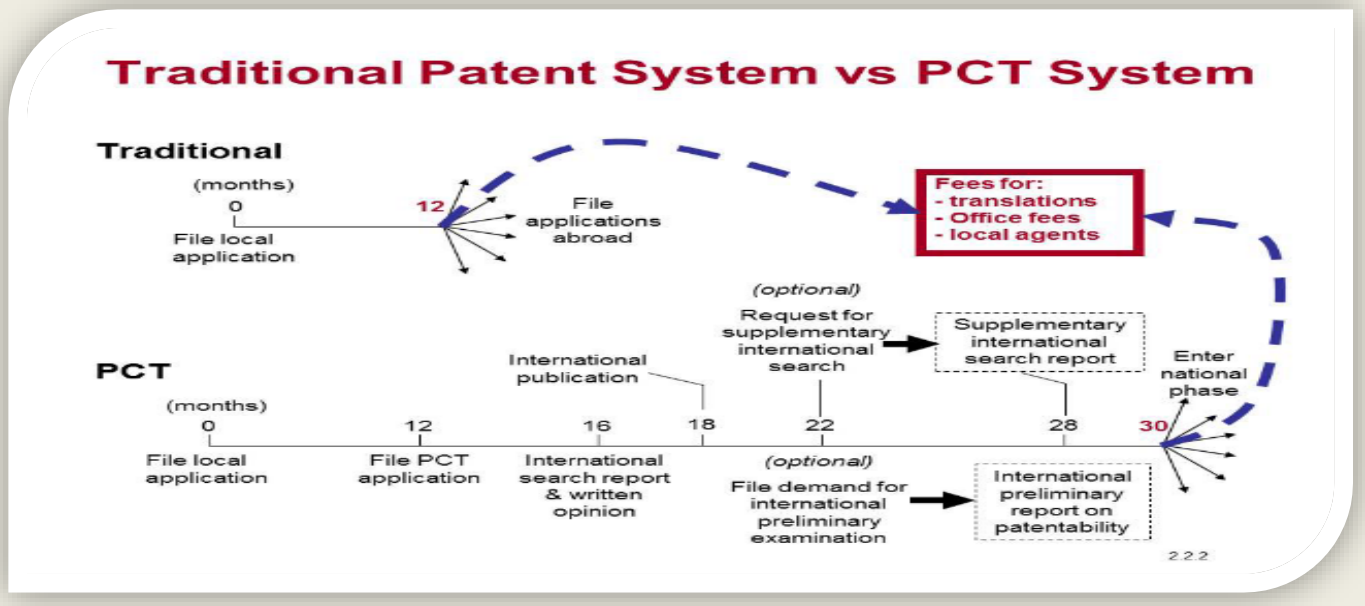
1. **Brings the world within reach**

A single PCT application has the same legal effect as a national patent application in each of the PCT Contracting States.

2. **Cost and Time advantages**

A major feature of the PCT is that it delays cost like: translation of patent application into various national languages, official fees charged by the National Patent offices and Service fees charged by the local patent agents/attorneys.

In traditional patent system, by filing separate patent applications in each country of interest to the applicant, the applicant would incur a significant portion of patenting costs within 12 months from the date of filing a local (first) patent application. In contrast, under the PCT,



[11] https://www.wipo.int/pct/en/guide/ipindex.html

the applicant has up to 30 months from the priority date before having to decide whether to incur those costs, thus 18 months of additional time is available under PCT when compared to the traditional patent system.

In addition to delaying cost, the applicant would also benefits from additional time to:

• Further develop or market the invention;

• consider and explore the various patenting options;

• find investors, partners and secure funding; and

• investigate the commercial possibilities of the invention.

3. **Provide strong basis for Patenting Decisions**

The information received during the PCT procedure on the potential patentability of your invention that can be of great value to you.

a. **International Search Report (ISR) and Written Opinion of the ISA**

Before the international publication of the PCT application, the applicant receive an international search report (ISR) containing information about prior art (documents which have been published) which might challenge the patentability of the invention. Further, it categorize and provide details of each document, and indicate the claims in your application to which each document is relevant.

Together with the ISR, the applicant receive the written opinion established by the ISA, which provides a detailed explanation of the relevance of the references cited in the ISR, analyzing how they affect the potential patentability of your invention. Patentability is assessed against the internationally accepted criteria of novelty, inventive step and industrial applicability.

Hence, once you receive the ISR and the written opinion from the ISA, you will be able to decide on the course of action to take which may include whether or not to file a demand for international preliminary examination with the IPEA in order to be able to amend the application in light of the documents cited.

b. **International Preliminary Report on Patentability (Chapter II)**

After considering the findings in the ISR and written opinion if you wish to amend your PCT application, you may file a demand for international preliminary examination, the result of which will be a second patentability

analysis on the amended version of your PCT application.

Hence, the information provided by the ISR, WO and IPRP will provide the applicant with a well-informed basis on which the applicant can make a decision about entry in the national phase-the countries where the applicant wants to pursue the national procedures for seeking patent protection.

Conclusion

The PCT is the cornerstone of the international patent system. It provides you with a worldwide system for the simplified filing of patent applications. Therefore, it is used by the world's major corporations, universities and research institutions when they seek international patent protection.

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PROTECTION OF INTELLECTUAL PROPERTY IN INDIA – ARTIFICIAL INTELLIGENCE

-By Deepika Dang

The world of technology is changing rapidly, with computers and robots, replacing simple human tasks. AI, in simple terms, is the capability of a machine to mimic intelligent behavior. It is a term that encompassed multiple technologies including deep learning, machine learning, and natural language processing (NLP), computer vision and strong AI. Artificial Intelligence may be best defined by the two components of the term i.e. artificial and intelligence. A definition proposed by Luger and Stublefield, defines AI as the branch of computer science and technology that is concerned with the automation of intelligent behavior.

The creation of new technology is often followed by protection of intellectual property, and in the case of AI, patents seem to be the most obvious form of protection. As the development in the field of artificial intelligence and machine learning grow steadily, the increasing number of patents filed is an indication of the growing prevalence of these emerging technologies. India is emerging as a new target for patent filing in the field of Artificial Intelligence and is among the top countries for publications in specific categories such as natural language processing and computer vision according to a UN report. According to the World Intellectual Property Rights (WIPO) technology trends reports 2019, which studies AI patents across the world to get a comprehensive picture pertaining to the development in the field, almost 50% of the AI patents have been filed only after 2013, with the number totaling up to 170,000. The report briefs about how India has become one among the top 10 countries to file AI patents. India, according to the report, was ranked eighth for the first filings in year 2015 and has enjoyed a high rate of annual growth during recent years (with an average of 33% in the three years up to 2015). The report said that while major patent office's receiving patent filings in the AI field are France, Germany, The Republic of Korea and the UK, India is emerging as a new target for patent filing. The greatest number of patent applications are filed in the patent office of U.S and China, followed by Japan, Korea, Australia, Germany and India. India ranks fourth in scientific publications (ahead of Japan), Italy which ranks ninth, and Spain, which is 10th. India ranks third in fuzzy logic and fourth in machine learning, whereas it is eighth or lower in patenting activity. Also in March 2018,

India launched a plan to have enabling policies for socially relevant projects, a data policy to include sharing rights, ownership, and usage policies, as well as tax incentives for income generated through the adaption of AI technologies and applications.

Fig. Top geographical affiliation by number of scientific publications for different AI techniques

AI led the emerging technologies patent race both in terms of number of patents as well as growth over the period 2015-2018. India domiciled companies filed over 4,600 patents in the US between 2015- 2018, a majority of which were from technology domain, according to the report by industry Nasscom. The National Association of Software and Services Company (NASSCOM), revealed that more than 50% of patent applications of Indian companies in the United States are in the area of emerging technology like Artificial Intelligence (AI), cybersecurity, cloud computing and Internet of Things (IOT). The report also revealed that AI leads the emerging technologies patent race both in terms of a total number of patents. From 2013 to 2018, some 330 AI patents were filed in the US by Indian Companies. The top filers were top Indian companies, namely Welspun Steel, Reliance Industries Limited, Mahindra, Wipro, TCS, Bharat Petroleum, HCL and Infosys. NASSCOM believes that India is on course to become one of the leading hubs for innovation, research and development.

How can AI be patented in India

Software and Computer related innovations can be patented in India under the Indian Patent Laws. However, according to Section 3(k) of the Indian Patent Acts, computer programs, mathematical formulae, and even business methods are regarded as non-patentable inventions. As per Computer related Inventions (CRIs), India also excludes computer programs or algorithms from getting patented. Hence the patents can only be granted if they pass the software eligibility test and are combined with hardware aspects to be registered under Indian Patent Law. Few guidelines should be followed by the companies which want to claim IP protection:

1. Describe the hardware, for example servers, sensors and the computer system besides AI algorithms in the patent.
2. Refrain from shining the spotlight only on programming codes or algorithms of the AI applications
3. Define the process or working methodology used for developing AI applications

There is a perpetual debate on whether awarding the patent rights to CRIs can encourage investment in software- related

technology and thereby promote innovation. It is a simplistic approach to suggest that patents should not be awarded AI- based inventions, which would eventually fall under CRIs. The Indian Patent Office should look for a middle ground which is more sensible option. The government must ensure that AI's impact on patents is dealt with systematically and to the benefit of the technology community, especially if India is to become a creator of AI, and not a mere adaptor.

It is important to revisit the Intellectual Property Laws to conformity with the present technological developments which are defining the future of this world. Assigning inventor-ship and authorship to non-humans is a novel way to promote the growth and development of AI, which will boost the appetite of the world for more inventions. The Patent laws considering AI can have profound impacts on innovation, the society and economy which make it imperative for the people associated with Intellectual Property to find ways for the patent system to encourage innovation while minimizing any adverse consequences. Apart from encouraging creativity, there should be a cohesive effort to regulate and organize the growth of this humongous field. The idea of creating a humanoid or the concept of human intelligence replacement machines and robots may sound futuristic and brazen, but will ultimately have a lasting impact on the mankind as a whole.

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CONCEPT OF DECEPTIVE SIMILARITY IN TRADEMARKS

-By Ishan Sambhar

One of the questions that frequently arise in trademark litigation is whether two marks are 'deceptively similar'. The concept of deceptive similarity, in general can be understood as "two marks, when placed side by side, may exhibit many and various differences, yet the main idea left on the mind by both may be the same. A person acquainted with one mark, and not having the two side by side for comparison, might well be deceived, if the goods were allowed to be impressed with the second mark, into a belief that he was dealing with goods which bore the same marks as that with which he was acquainted."[12] The definition of the term deceptive similarity is given under the Trade Marks Act, 1999, which is as follows-

> "*A mark shall be deemed to be deceptively similar to another mark is it so nearly resembles that other mark as to be likely to or cause confusion.*"[13]

Relevant sections of Trademark Act, 1999:

- Section 9(2) (a), which provides for absolute grounds for refusal of registration.
- Section 11(1) and (2), which provides for relative grounds for refusal of registration.
- Section 11(1) and (2), determination by Registrar of likelihood of applicant being restrained by a court under a law of passing off[14] or copyright[15]; which requires determining hypothetical deceptive similarity of the applicant's mark with that of the opponent.
- Section 57, Rectification of Registered applications.
- Section 134 or 135- Infringement and passing off proceedings based on Sec. 27(2) and 29.

The Test for Determining Deceptive Similarity

The test for determining deceptive similarity is whether the mark in contention resembles the protected mark in such a way so as to be likely to confuse the average consumer as to the source of the goods or as to the connection between the users of the similar marks. In other words, a mark is considered "confusingly similar" if it is so similar to the

[12] David kitcin, David LLewelyn, et.al., Kerly's Law of Trade Marks, and Trade Names 456 (Sweet and Maxwell, London, 14th edn.)
[13] Section 2 (h), The Trade Mark Act, 1999
[14] S.11(3)(a) of the Trade Marks Act, 1999
[15] S.11(3)(b) of the Trade Marks Act, 1999

protected mark that a substantial number of average consumers are likely to be confused or misled as to the source of the goods sold under the second mark, as they may believe that such products originate from the same owner which owns or uses the protected mark.

The ***Court of Appeal of New-Zealand*** in ***Pioneer Hi-Bred Corn Company v. Hy-Line Chicks Pty Ltd***[16] has observed that the test of likelihood of deception or confusion does not require that all persons in the market are likely to be deceived or confused. But it is not sufficient that someone in the market is likely to be deceived or confused. A balance has to be struck. Terms such as 'a number of people', 'a substantial number of people', 'any considerable section of the public', and 'any significant number of such purchasers' have been used. As *Cooke J* put it:

> 'That varying terminology in the judgments is a reminder that it is not always necessary that a large number of people should be, or should probably be, of the state of mind in question; rather it is a question of the significance of the numbers in relation to the market for the particular goods.'[17]

In ***The Pianotist Company Ltd***[18] case ***the High Court of Justice- Chancery Division (UK)*** has observed thus: "You must take the two words [or marks]. You must judge of them, both by their look and by their sound. You must consider the goods to which they are to be applied. You must consider the nature and kind of customer who would be likely to buy those goods. In fact, you must consider all the surrounding circumstances; and you must further consider what is likely to happen if each of those trademarks is used in a normal way as a trademark for the goods of the respective owners of the marks. If, considering all those circumstances, you come to the conclusion that there will be a confusion— that is to say, not necessarily that one man will be injured and the other will gain illicit benefit, but that there will be a confusion in the mind of the public which will lead to confusion in the goods—then you may refuse the registration, or rather you must refuse the registration in that case".

[16] [1978] 2 NZLR 50 [New Zealand]

[17] Ibid.

[18] (1906) 23 RPC 774 [UK]

DETERMINATION OF LIKELIHOOD OF CONFUSION OR ASSOCIATION

-By Ishan Sambhar

The courts have laid down certain guidelines to be followed while deciding the likelihood or association. The **Twin Test** in this regard is- 'Competing Mark and Reaction of Purchaser'. The Supreme Court of India in the case of ***National Sewing Thread v. James Chadwick***[19] held that-

"*….in deciding whether a particular trade mark is likely to deceive or cause confusion that duty is not discharged by arriving at the result by merely comparing it with the trade mark which is already registered and whose proprietor is offering opposition to the registration of the mark. The real question to decide in such cases is to see as to how a purchaser, who must be looked upon as an average man of ordinary intelligence, would react to a particular trade mark, what association he would form by looking at the trade mark, and in what respect he would connect the trademark with the goods which he would be purchasing.*"

In ***Interpace Corporation v. Lapp Inc***.[20], the Court observed that over the years the courts have identified a number of factors to aid in determining likelihood of confusion in non-competing products cases. Those factors are:

- the degree of similarity between the owner's mark and the alleged infringing mark;
- the strength of the owner's mark;
- the price of the goods and other factors indicative of the care and attention expected of consumers when making a purchase;
- the length of time the defendant has used the mark without evidence of actual confusion arising;
- the intent of the defendant in adopting the mark;
- the evidence of actual confusion;
- whether the goods, though not competing, are marketed through the same channels of trade and advertised through the same media;
- the extent to which the targets of the parties' sales efforts are the same;
- the relationship of the goods in the minds of consumers because of the similarity of function;
- other facts suggesting that the consuming public might expect the prior owner to manufacture a product in the defendant's market, or that he is likely to expand into that market.

[19] AIR 1983 SC 357
[20] 721 F.2d 460 [USA]

These factors are not a mechanical checklist, and 'the proper weight given to each will vary from case to case.' At the same time, although no one factor is decisive, the similarity of the marks, the intent of the defendant, and evidence of actual confusion are the most important considerations.[21]

How to Compare Two Marks

The Delhi High Court in the case of ***United Biotech Pvt. Ltd*** (supra) has laid down following rules of comparison-

- Meticulous Comparison not the correct way.
- Mark must be compared as a whole.
- First Impression.
- Prima Facie view not conclusive.
- Structural Resemblance.
- Similarity in Idea to be considered.

In this process, the plaintiff is required to prove the following:

- The business consists of, or includes selling a class of goods to which the particular trade name applies;
- That the class of goods is clearly defined & is distinguished in the public mind from other goods;
- Because of the reputation of the goods, there is goodwill in the name;
- The Plaintiff is a member of the class selling the goods is the owner of goodwill which is of substantial value;
- He has suffered or is likely to suffer damage.

In ***Hiralal v. Ganesh***[22] Lentin J., has summarized 9 principles for determining deceptive similarity and 7 factors for comparing the marks, whether in registration proceedings or infringement/passing off. The principles are as follows:

- The main idea or salient features of the mark must be considered.
- Marks are remembered by general impression or by some significant details rather than by a photographic recollection of the whole.
- Overall similarity is the touchstone.
- Marks must be looked at from the view and first impression of a person of average intelligence and imperfect recollection.
- Overall structure, phonetic similarity and similarity of idea are important and both visual and phonetic tests must be applied.

[21] *Eli Lilly & Co v Natural Answers Inc*., 233 F.3d 456 [USA]

[22] AIR 1984 Bombay 218

- The purchaser must not be put in the state of wonderment.
- Marks must be compared as a whole, microscopic examination being impermissible.
- The broad and salient features must be considered, for which the marks must not be placed side by side, to find out differences in design, and
- Overall similarity is sufficient. In addition the nature of commodity, the class of purchasers, the mode of purchase and other surrounding circumstances must be considered.

The question of similarity between two trademarks or the likelihood of deception or confusion arising from the use of the trademarks is not to be decided in vacuum but is to be determined always in the background of the surrounding circumstances.[23] The following factors must be taken into consideration:

- The nature of the marks i.e., whether they are words (coined or descriptive or non-descriptive), surname or geographical name, devices, letters or numerals r a combination of one or more of the above;
- The degree of resemblance between the marks- phonetic, visual as well as similarity in idea;
- The nature of goods in respect of which they are used or likely to be used as trademarks;
- The similarity in nature, character and purpose of the goods of the rival traders;
- The class of purchasers who are likely to buy the goods bearing the marks, their level of education and intelligence, and the degree of care they are likely to exercise in purchasing the goods;
- The mode of purchase of the goods or of placing orders for the goods;
- Any other surrounding circumstances.

Conclusion

On the basis of aforementioned discussion, it can be concluded that the factors to be taken into account while dealing with two trade marks for the purpose of appreciating the presence of deceptive/confusing similarity between the two. The test in, nutshell, is *firstly*, consider the mark as a whole, *secondly*, such determination is a question of first impression and *lastly*, the two competing marks are to be considered from the point of view of 'common man with average intelligence and imperfect recollection

[23] Ashwani Kumar Bansal, *Law of Trade Marks In India* 642 (Thomson Reuters, 3rd edn., 2014)

(imperfect recollection as in not photographic recollection)'. If one mark is so similar to another mark as is likely to cause deception/confusion among public, the aforementioned mark is not allowed to be registered absolutely. If such deceptively similar mark is used in the market, the proprietor of prior mark is eligible to bring an action for passing off or infringement, as the case may be. Such is the importance of this concept of 'deceptive similarity' in trademark law.

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INTELLECTUAL PROPERTY PROTECTION OF TRADITIONAL KNOWLEDGE

- ***By Anjana Viswanath***

Traditional knowledge (TK) is a living body of knowledge that is developed, sustained and passed on from generation to generation within a community, often forming part of its cultural or spiritual identity[24]. For centuries, TK has played and continues to play a major role in the lives of indigenous peoples all over the world[2]. It is well known that TK forms an important component of the cultural heritage of indigenous peoples and is fundamental to their sustainable development[25].

However, in recent times, there has been a growing concern with regard to the misuse of traditional knowledge for deriving commercial benefits. For example, the intellectual property (IP) system for patents and copyright has helped the multinational companies to obtain and use TK for commercial purposes. Such a scenario has left the indigenous communities with no remedies available to tackle the misappropriation of these knowledge resources[2]. This has led to renewed focus globally on the need for protecting TK through the enactment of appropriate legal instruments. The importance of TK and the need for providing IP protection to TK are being discussed here.

Traditional knowledge

Traditional Knowledge (TK) generally refers to any information, knowledge, innovation, or practices of the indigenous communities that is of relevance in ensuring their sustainable development[2]. TK may be developed and passed on through generations in the form of stories, songs, cultural values, traditional laws, local languages, rituals, healing arts, and agricultural practices. Such passage of knowledge within the communities is important to ensure the collective good of the communities. TK is developed through observations on the environment and from the experience acquired over time and across generations[26].

Traditional knowledge and current IPR system

[24] https://www.wipo.int/edocs/pubdocs/en/wipo_pub_tk_1.pdf

[25] https://acadpubl.eu/hub/2018-119-17/2/105.pdf

[26] http://nopr.niscair.res.in/bitstream/123456789/33984/1/IJTK%2015%282%29%20304-312.pdf

The international IP system prevalent as of now was formulated to suit the needs of the industrialization era[1]. This system has been modified subsequently over the years as per the needs of the technologically advanced societies[1]. Unfortunately, this has placed most of the knowledge and practices of indigenous people and less technologically advanced communities outside the current IP framework. However, in recent years, the awareness about the IP laws and the need for IP protection is on the rise. Consequently, indigenous peoples, local communities, and governments in developing countries, have started pursuing equivalent protection for TK[1]. World Intellectual property organization (WIPO) member states carry out negotiations within the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC). The aim is to develop international legal instruments for protection of traditional knowledge, genetic resources and traditional cultural expressions (folklore) [1].

Two types of IP protection exist for TK.

1) **Defensive protection**: For stopping people outside the community from acquiring IP rights over TK[1]. India has compiled a searchable database of traditional medicine. Patent examiners can use this TK database for collecting evidence of prior art when assessing patent applications. Prevention of Trademark registration of sacred cultural manifestations is also another aspect of defensive strategies for TK protection[1].

2) **Positive protection:** Involves the granting and exercise of rights to enable indigenous communities to promote their TK and to control its uses and benefit from its commercial exploitation[1]. This type of protection can be achieved through the existing IP system, whereas specific legislations were developed by some countries. However, it is obvious that legal protection provided by a national law may not be applicable for other countries. Hence, there is a need to formulate appropriate international legal instruments[1].

WIPO is addressing these issues pertaining to traditional knowledge IP with emphasis on three distinct aspects: traditional knowledge, cultural expressions or folklore and genetic resources[1].

Initiatives for protecting traditional knowledge

For innovations within the TK framework, the indigenous community members can obtain patents to protect their innovations. However,

traditional knowledge in the strict sense is of ancient origin. Most of such knowledge is informal and oral and hence is not protected by the conventional IP systems. Hence, some countries are trying to develop their own *sui generis* systems for protecting their TK[1]. Attempts are being made worldwide to document TK but more often the motive is to preserve the information for their own use rather than for obtaining IP protection[1]. It is imperative that the documentation of TK should not occur in a policy or legal vacuum but should follow a well-defined IP strategy[1]. The components of the existing IP system, such as copyright, geographical indication, trademark and design can be used for protection of traditional cultural expressions. Copyright protection may be obtained for contemporary adaptations of folklore, whereas traditional music, dance or theater performances may be protected under the WIPO Performances and Phonograms Treaty or the Beijing Treaty on Audiovisual Performances[1]. Trademark protection can be obtained for authentic indigenous arts[1].

Genetic resources are not creations of human mind and hence are not considered "intellectual property" in the strict sense. However, in recent times, the IP protection of genetic resources has gained widespread attention. The first occasion on which the value of TK received wide recognition was the United Nations (UN) Conference on Environment and Development in Rio de Janeiro in 1992[3]. There exists an international legal framework comprising of the Convention on Biological Diversity (CBD), and its Nagoya Protocol, and the International Treaty on Plant Genetic Resources for Food and Agriculture of the United Nations Food and Agriculture Organization (FAO). This framework regulates the access to, and the sharing of benefits arising out of the utilization of genetic resources worldwide[1]. There are provisions within the CBD, that the member States should respect and promote TK and should make it generally accessible. However, the access to TK knowledge should be based on the consent of the knowledge holders and equitable participation of holders in the benefits arising from the use of their knowledge should be ensured[3].

In addition to this, WIPO is directing its efforts towards IP protection of genetic resources in accordance with the existing international framework. IP protection can be obtained for the inventions based on or developed using genetic resources by plant breeders' rights. However, there are concerns raised about grant of IP rights over such inventions, which do not fulfill the

conventional requirements of novelty and inventiveness[1]. The setting up of genetic resources and TK databases is proposed to help patent examiners find relevant prior art and to avoid erroneous granting of patents[1].

An international legal instrument is needed because the existing international IP system is inadequate to protect TK and cultural expressions. Discussions are ongoing to develop an instrument for providing *sui generis* protection. The proposed legal instrument would clearly define traditional knowledge and cultural expressions, define the rights holders, procedure for resolving competing claims, and the rights and exceptions ought to apply[1].

Traditional knowledge digital library

The Traditional Knowledge Digital Library (TKDL) is a collaborative project between the Council for Scientific and Industrial Research (CSIR) and the Ministry of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy (AYUSH)[27]. TKDL is a pioneer initiative of India to prevent misappropriation of the country's traditional medicinal knowledge at International Patent Offices. The genesis of TKDL could be attributed to India's successful efforts for the revocation of USPTO granted patent on the wound healing properties of turmeric[4]. In 2005, it was estimated that about 2000 wrong patents concerning the Indian systems of medicine were being granted every year at the international level. Since, India's traditional medicinal knowledge exists in local languages, it was not accessible or comprehensible for international patent examiners[4].

By converting and structuring the available contents from ancient texts into five international languages, TKDL has successfully overcome the barriers of language and format. Currently, the access to TKDL is available to nine International Patent Offices including the European Patent Office and the United State Patent & Trademark Office. Such access is granted under an access (non-disclosure) agreement. The patent examiners can utilize TKDL for search and examination purposes only but are prevented from revealing its contents to third parties except for citation purposes. Furthermore, pre-grant oppositions are being filed at International Patent Offices, with the help of prior-art evidences from TKDL[4].

27 http://www.tkdl.res.in/tkdl/langdefault/common/Home.asp?GL=Eng

Conclusion

Traditional knowledge forms an important aspect of the identity of many indigenous people and communities. There is a growing concern on the lack of Intellectual property protection for traditional knowledge and cultural expressions. In the ongoing negotiations for developing an appropriate legal instrument, many argue that use of traditional knowledge ought to be free, subject to prior informed consent. However, others are concerned that granting exclusive control over TK could curb innovation. There are others who are apprehensive of whether IP rights are appropriate instruments for protecting traditional forms of innovation and creativity. This is a complex issue with divergent views and reaching a consensus through discussions and negotiations between all stakeholders is the ideal way forward.

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THE PATENTS (AMENDMENT) RULES, 2019

The Government of India, Ministry of Commerce and Industry (Department of Industrial Policy and Promotion) has notified the Patents (Amendment) Rules, 2019 in the Official Gazette with effect from 17th September, 2019.

The following amendments have been incorporated in the Patent Rules, 2003.

1. **Leaving and Serving documents:**

- Rule 6 (1A) is now amended to be read as:

  "*(1A) Notwithstanding anything contained in sub-rule (1), a patent agent shall file, leave, make or give all documents only by electronic transmission duly authenticated:*

  Provided that any document, if asked to be submitted in original, shall be submitted within a period of fifteen days, failing which such documents shall be deemed not to have been filed."

2. **Document for Small Entity and Startup:**

- Rule 7 (1) is now amended for second proviso, wherein now Startup is also included along with Small entity for the filing of Form 28:

  "Provided further that in the case of a small entity, or startup, every document, for which a fee has been specified, shall be accompanied by Form-28."

3. **Expedited Examination of Applications:**

- Rule 24 C (1) (b), is now amended to include eight new types of applicants for applying expedited examination.

  - Small entity
  - Female Applicant
  - Department of the Government
  - An institution which is owned or controlled by the Government
  - Government company
  - An institution wholly or substantially financed by the Government
  - A sector which is notified by the Central Government
  - Applicant eligible under an arrangement pursuant to an agreement between Indian Patent Office and a foreign Patent Office.

4. **The First schedule:**

- Entry 48 A is included after entry 48, wherein Transmittal fee for International application (for e-PCT filing) is no longer payable.
- Entry 49 A is included after entry 49, wherein the Fee for preparation of Certified copy of priority document and e-transmission through WIPO DAS is no longer payable.

5. The Second schedule:

- Form 18 A, para 3 has been amended to include the eight new types of applicants for applying expedited examination as mentioned above. Further description of documents to be mandatorily submitted as evidence of eligibility for availing expedited examination for each additional category of applicant is provided.

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