

Intellectual property rights of inventions in biological science

Abstract

Intellectual property rights (IPR) are provided to an author by the government to protect his intellectual credits towards society. It grants the inventor an exclusive right for a certain period of time for proper use of his creation. Intellectual property includes patents, trademarks, copyrights. Since last few years, many controversies have raised on biological patents. Patenting of extracts from indigenous plants, animals and organisms, already known to indigenous people, has been called Biopiracy. Still, people are not aware in terms of what invention or the technology can be protected/patented therefore present review deals with the knowledge that gives us the insight to handle with our intellectual property.

Keywords: patents, intellectual property, biopiracy

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Vikas Pareek, Renu Bist, Hemant Pareek

University of Rajasthan, India

Correspondence: Renu Bist, Department of Zoology, University of Rajasthan, India, Tel +91-74248 52622, Email renu_bist22@yahoo.co.in

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Abbreviations: CBD, convention on biological diversity; CBRs, community biodiversity registers; CSIR, Council of Scientific and Industrial Research; GRAIN, genetic resources active international; HGP, human genome project; IOP, intra ocular pressure; IP, intellectual property; IPC, international patent classification; IPR, intellectual property rights; IVF, *in vitro* fertilization; JP, jaiv panchayat; NISCAIR, national institute of science communication and information resources; PBRs, people's biodiversity registers; PCT, patent cooperation treaty; PIC, prior informed consent; R and D, research and development; RFSTE, research foundation of science technology and ecology; SRISTI, society for research and initiatives for sustainable technologies and institutions; TK, traditional knowledge; TKDL, traditional knowledge digital library; TRIPS, the agreement on trade-related aspects of intellectual property rights; UFAO, united nations and food organization; UNESCO, united nations educational scientific and cultural organization; UP, uttar pradesh; US, united states of america; USPTO, united states patent and trademark office; WTO, world trade organization

Introduction

An intellectual property (IP) is a novel construction of intellect like literature, works of art, mechanical or systematic formation. Intellectual property rights (IPR) is a legal authority provided to the originator for protecting his invention for a particular time period.¹ IP protection is done in different ways such as patents, trademark and copyright. Each industry or organization has its own IPR policies and management style tactics.

The regulations and managerial actions concerning to IPR contain their heritages in Europe. England acted pioneering role and exerted a pull on inventors from elsewhere, as compared to other European countries. The initial identified copyrights were recorded in Italy.² The first law that granted exclusive rights to the inventors appears to have been implemented by the Republic of Venice in 1474, however the earliest IPR was granted by Elizabeth 1 in 1624.^{3,4} Patent act is nearly 150 years old in India. A globally known fact is that IP has an imperative role in the recent financial system. Intellectual efforts linked to the originality need to be provided emphasis as it is necessary

for wellbeing of a community. The first patent to human product was adrenaline and it was granted in the year 1906, March 20.⁵ In 1970s the scientists patented their biotechnological inventions such as recombinant DNA. Until 1980s the patents for whole scale organisms were not permitted. Later on, a bacterium for digesting crude oil was genetically modified (GM) through genetic engineering and then it was patented. Since 1980, it was lawfully approved that genetically altered creatures can also be patented. Genetically modified organisms (GMOs) include viruses, plants, cells, seeds etc.⁶ In the year 1997, for the first time patent was granted to Basmati rice or Rice Tec.⁷ United States Patent and Trademark Office (USPTO) approved a patent claiming "Primate embryonic Stem cells" in 1998.⁸ Then in 2001, another patent was approved with the heading "Primate Embryonic Stem Cells" which mainly focused on Human embryonic stem cells.⁹ A GM mouse called oncomouse, mainly used for cancer research was patented by Harvard University of United States of America. Many companies and organizations have also patented entire genomes of organisms. Agriculture Company Monsanto filed a patent in 2004 for genes of pig.

Significance

IPR is a solid device, to defend stashes of era, wealth and efforts by the originator of an IP. It gives a worker an elite authority to employ his innovation, for a certain phase of time. Society also benefits from IPR. It is mainly grounded on two conventions. First, such a right inspires discoverers to devise, authors to write. Second, the greater the inventions or processes released into the public domain, public benefits and also the quality of life is enhanced. Thus, IPR helps in the financial growth of a nation via vigorous struggle and inspiring formations, inventions and monetary expansion.

Role of confidential information in IPR and controversy

Confidential information or undisclosed information is generally known as trade secrets. It includes formulas, patterns, processes, techniques and methods. Pressure at globalization level led to large investment in research and development by pharmaceutical, chemicals

and other industries. There were difficulties to obtain the profit from discoveries until standardized rules and laws were set. Thus, IPR became a significant component of the World Trade Organization.¹⁰

Over last few years many controversies have raised on biological patents. Patenting of biological extracts from plants, animals and organisms which is previously recognized by indigenous people, is referred as Biopiracy. One among the main purposes of IPR protection is to move a fraction of wet lab investigations to industries. These IPR's deny the right to local population in using these innovations. For example, Myriad Genetics, Inc. (Diagnostic Company) has the patent for BRCA2 gene and many others. In 2009, a case was filed against it by scientists and doctors that patent on genes prohibited patients

from thinking in a different way over their examination reports. In 2013, Association for Molecular Pathology challenged the patent rights of Myriad Genetics. A case appeared in US District Court gave the decision that every challenged assert is not patentable. A DNA or genes of organisms cannot be patented because it is a natural product, but cDNA is patentable because it is modified by researchers and is not an original product of nature.

Types of IPR

IPR is usually considered in three types i.e. patents, trademarks and copyright. People occasionally confuse among patents these three.¹¹ A comparison of patents, trademark and copyright is given in Table 1.

Table 1 A Comparison between copyright, trademark and patent

	COPYRIGHT	TRADEMARK	PATENT
PROTECTION	Original works of authorship including books, articles, motion pictures and other creative works. An idea itself cannot be copyrighted.	Any name, word, slogan, symbol that identifies a company or brand that distinguishes it from others.	Patent protects inventions with a new or improved function. It includes processes, inventions or chemical compositions.
BENEFIT OF REGISTRATION	It provides a person with legal evidence and public notice of ownership. Copyright owner can sue a person in court in case of infringement.	It gives a person right to ownership. Only registered trademarks can use the symbol.	It gives owner the right to exclude others from making, using or selling the protected invention.
LIFETIME	It is valid for lifetime, plus an additional 70 years. It cannot be renewed.	It can have an unlimited term but must be renewed every 10 ten years.	Non provisional utility patent protects an invention for 20 years and cannot be renewed. A provisional patent lasts for one year.

Trademark

It is a sign, symbol or word used to distinguish products or services of an organization from those of others. No novelty or originality is needed but it must be distinct. For trademarks to be valid, it must be registered. Every country has its own rules and regulations for registration of trademark. It must be renewed from time to time and is usually valid for 10 years. Invitrogen is the first company which is based upon formalized promotion and branding to the Biology with a divergent gaze which was reflected by their products, patterns of packaging, and advertisements. Signs which may serve as trademark are of following categories:-

Words: It includes company names, surnames, geographical names or sets/combination of words.

Letters/Numerals: this category includes letters/ numerals (one or many) or any other combination.

Devices: It includes two dimensional representations of goods.

Painted script: This category includes words, devices and color combinations and color as such.

3-D Signs: A typical three-dimensional signs is in form of the merchandise or their casing method.

Audible marks: It includes sound marks for distinguishing between musical notes and other sounds.

Olfactory Marks: It includes a smell which may be used to attract a customer who gets accustomed to identifying the product by its stink.

Other Signs: by touch.¹²

Trademark rights are aimed to restrict users from using alike symbols, yet they could not prevent others from making the same goods or from selling the same goods or services under an obviously dissimilar spot. Trade Mark Registration Act came into force in 1875, passed and later on from time to time these were amended. In 1946, this act was termed as the Lanham Act. To the infringement of the Lanham Act, "The Trademark Counterfeiting Act" of 1984 was enacted (Chopra and Kumar, 2014).⁴ Any unauthorized use of a trademark identical to a registered trademark is prohibited. It is used and renewed continuously.¹³ Trademark protections is very much significant in pharmaceutical company. Some of the pharmaceutical brands across the world are Ranbaxy Laboratories Ltd., Sunpharma Ltd. and Cipla Ltd etc (Figure 1).

Copyright

It gives the creator right to ownership, has exclusive rights to use and distribution of work. Copyright protection mainly aims for giving the protection to the creativity. The creativity is the consequence of profound investigations and time practices to build up an original article.^{2,4} It gives the legal protection to the appearance of thoughts and not the thought itself. Copyright requires mechanism to be fixed

and need to be updated with time. The protection is specified to the effort and it mainly focuses on originality. There is a provision of fair use. The term usually lasts for life of an author, plus 50 years.¹³

Symbol used for the word copyright is ©. Every single copyright exists in the form of text, graphics, pictures, user interface and many other contents. Copyright laws prohibit one from doubling, replicating, amending, distributing, displaying, acting or transmitting any of the contents of the books or sites etc. Globally, India is at the centre phase of question on IPR, because a few years back legislation had denied a patent to the chemical company 'Novartis' and is not blindly following global trends which have sided with private copyright demands.



Figure 1 Trademarks of pharmaceutical companies of SUNPHARMA and CIPLA.

Patent

The term 'patent' originated from an Anglo-Norman letter patentee, this means an open letter. Patent is a document granted by a government which gives the patentee the exclusive right to his invention and excludes others from creating, using, vending or presenting to sell invention mentioned in the patent. An inventor is answerable for the impression behind the method, tool, material or equipment. In condition, several people are involved, they must share a patent together, and even more than two independent labs are involved (Table 2).

Procedural rules for patenting are different in every country, organization but the criteria for granting patents is similar

worldwide.^{1,11} It is valid for a limited time period and has to be renewed. Companies belonging to Life Science can deliberately use their IP assets to produce returns in a number of diverse ways and developing ventures and strategic alliances.

What can we patent?

There are three basic criteria for patentability:

Novelty – Invention must be first of its kind in the world and must have never been made public.

Inventiveness/ Nonobviouness – Invention must be a new development and should be non obvious to the people working in your field.

Utility – An invention must be of utility in some kind of industry.¹⁴

What we cannot patent?

A method of medical treatment or diagnosis

An idea, abstract or a scientific theory.

Genes, microorganisms, animals etc.

By giving inventors the right to patent their invention or creation promotes creativity and allows inventors to profit financially from their creativity. It gives an attractive offer or incentive for research and development (Mansfield, 1986).¹⁵ Moreover, patent is a document which gives sufficient knowledge about the work carried out in simple language so that it is easily understood and has all the necessary details. It gives information to academicians, researchers, industries and students.¹⁴ A patent given may be an improvement to the existing invention and the original patentee may be still in force. This situation is often resolved by an agreement between the patentees. But now the confusion exists to the true relation of patents to science, because inventors have started using patent rights for commercial purposes ignoring creativity and humanity.

Protecting an IP is a complex process, be it an invention or a process etc. Over last few years IPR has gained special attention. It has helped in reaping the profits of novel creations by creating standardized rules. Human Genome Project (HGP) is a result of IPR.¹⁶

Table 2 Patents published in Life Sciences globally over last few years

Process/ Product	Inventor and Year	Patent Number	Patent
Method of penicillin production	Moyer, ⁷³	US 2442141A	This invention resulted in high production of penicillin. Microbiological assay method used for measuring content of penicillin is very slow, so much of the penicillin disappeared till the assay provided results but due to this process we get correct amount of penicillin and it lasts for longer time.
Microwave oven for treating food stuffs.	Spencer , 1950	US2495429 A	It is an object which provides an efficient method of using electromagnetic energy for cooking of foodstuffs.
Artificial heart	Winchell, ⁸²	US 3097366 A	Artificial heart is placed in the mediastinum in the chest of a human or animal as a total replacement to the original heart.
Laser	Schawlow and Townes, ⁷⁰	U.S. P4,053,845	A laser is a device which emits light through a process of optical amplification based on the stimulated emission of electromagnetic radiation. It is used in DNA sequencing, laser surgery and skin treatments.

Table continue

Process/ Product	Inventor and Year	Patent Number	Patent
Artificial cardiac pacemaker with mercury battery	Greatbatch, ⁵⁹	US3057356 A	Artificial cardiac pacemaker is used for restoring satisfactory heart rhythm to a heart whose functioning is affected by conduction defects in auricularventricularbundle. It is constructed from materials compatible to the body environment.
Wax emulsion	Yokoyama and Araki, ⁴⁹	US20140066685 A1	Wax emulsions are used for water proofing and various other materials. It forms a film which is substantially transparent and smooth and highly cohesive, water resistant and water proof.
Malaria vaccine	Nussenzweig, et al. ⁵⁷	US 4466917 A9	This vaccine provides an antisera and monoclonal antibodies against the sporozoite stage of the malaria parasite.
Human growth hormone formulation	Pearlman and Oeswein, ⁷⁶	US 5096885 A	Human growth hormone is secreted in pituitary hormone. It maintains body structure and metabolism. Its deficiency causes reduced bone strength, depression, lack of concentration and poor memory. It is injected in the body's fatty tissues such as arms thighs.
HIV protease	Dressman et al. 1994	US 5484926 A	HIV protease inhibitor obtained by chemical synthesis inhibits or blocks the activity of protease enzyme, causing replication of virus to terminate. These compounds play an important role in treating HIV patients.
Methods and compositions for pulmonary delivery of insulin	Patton et al. ⁷⁵	US 5997848 A	Insulin is a polypeptide produced by pancreatic beta in healthy person and is necessary for regulating carbohydrate metabolism by reducing blood glucose levels, and its deficiency causes diabetes. Normally it is injected in the abdomen and thighs and it is burdensome and undesirable. Thus pulmonary delivery of insulin is effective alternative of subcutaneous injection.
Hepatitis B Vaccine	Hauser et al. ⁶⁴	US5972346 A	It provides a Hepatitis B vaccine comprising a Hepatitis B antigen in conjunction with 3-D MPL. It is more potent than other medicines.
Extraction of high-purity DNA and RNA	Hurt, ⁶⁵	US 20060199203 A1	It is used for extracting highly purified nucleic acids by minimizing the degradation of these.
Synergistic herbal ophthalmic formulation for lowering intraocular pressure in case of glaucoma	Gupta, ⁶¹	US 20090175972 A1	Glaucoma is a disease caused by high IOP. It may cause temporary or permanent loss of vision. The herbal composition of <i>Withania somnifera</i> and <i>Areca catechu</i> , which reduces intraocular pressure of eyes and is preferred over synthetic drugs because it is economic, non-toxic and safe.
Combination of paracetamol and ibuprofen	Atinkson, ⁵⁰	EP 1781277 B1	This combination of medicines provides enhanced pain relief during first dose of interval and in comparison to the individual taken alone.
Biosensors for detecting allergens	Sarkar, ⁷⁷	251192	It is used for measuring the allergen and dust level in our environment. Allergic individuals have reactions that range from from unnoticeable to life threatening diseases. Skin test does not indicate the specific allergen which specifically affects which organ. So it is necessary to know the level of allergens in the environment.
Method for disposal of radioactive waste	Kata, ⁶⁸	US 20140066685 A1	The primary treatment step is capable of reducing the radiation level of the radioactive waste to a reference value, thereby facilitating transportation to storage. Furthermore, the secondary treatment step is glass granule forming step.

Table continue

Process/ Product	Inventor and Year	Patent Number	Patent
Temperature controlling method for use in in-vitro fertilization (IVF)	Modi and Kale, ⁶⁷	US 20150201609 A1	Cryopreservation of oocyte has been increasing and as it assists in IVF. Cryopreservation of oocyte is very much sensitive to temperature and thus it requires optimal conditions to preserve cell and tissue culture.
Method for screening anti-cancer compounds inhibiting function of TM4SF5 and anti-cancer composition containing chalcone compounds	Park et al. ⁶⁹	United States Patent 9072698	It method for screening an anticancer compound, the method comprising: culturing cancer cells expressing the oncogenic protein transmembrane 4 L6 family member 5 (TM4SF5), treating the cancer cells with an anticancer candidate, and determining that the anticancer candidate is an anticancer substance when the candidate exhibits antagonistic activity against tumor formation and metastasis based on several events through the molecular mechanism of TM4SF5.
Systems and methods for user authentication using eye movement and pupil size change matching	Adhami et al. ⁴⁸	United States Patent 9367677	It includes an ocular sensor that is configured to sense eyes of a user and collects data indicative of the user's eye movement and pupil size changes. When a user's eyes are detected, data is collected by the ocular sensor in order to determine whether the sensed data match data extracted from a template defined by the eye movement and pupil size changes of an authorized user. If it matches than user is permitted to access at least one restricted resource, such as a computer system or room.

Review of literature

Legislations of various countries provide IPR to their creators. Where patent is for inventions, copyright is the IPR for writing books and trademark is a symbol used for distinguishing one company from the other.¹⁷

Considerate the development and utilization of the patents, it is significant to accept policy debate which involves the role of IP in economic enlargement and expansion, the relationship amid IP rules and key public strategy apprehensions, such as health and the atmosphere, and for rising initiative to proceed the efficiency of IPR system.¹²

Among the most powerful IPR tools is the patent which protects those inventions that possess fabulous industrial usages and therefore contain capacity for getting coinage. An invention that claims over anything with novelty but which might be opposing to any regulation, ethics of public or their fitness/ wellness, could not be patented. A scientific theory or a mathematical method and any novel possessions or original employment for a known substance or apparatus unless such known process results in a novel type of creation or employs at least one novel substrate also could not be patented. Any agricultural method or any procedure for the remedial, surgical, therapeutic, disease diagnosis or any additional healing of humans to turn them into state of independence from the disease could not be patented. Traditional knowledge i.e. common practices of indigenous and local communities.² too are non-patentable. Essentially, two types of patents are described, one is for products and other is granted for processes.

Product patent and process patent

Patents can be issued for a product or a process. A stringent deviation is present between an invention and progression patent regimes. The developed countries go after product patent method whereas process patent system is preferential to the developing countries. Both types of systems provide diverse levels of fortification to scientists.

For a procedure, IP is fixed for a specific industrial method but not for the creation. One might manufacture the same product by other course, adapting several parameters. Patenting methods regime is weak in the way that it gives a reduced amount of protection for the inventor and competitors have opportunities to reconstruct the unique construction by determining a novel method with less strain and venture. There are also benefits of process patent regime as it reduces the element of monopoly.

For product patents, a complete authority is provided to the original worker. No producer can offer the same invention by the same/ modified method. The inference can be taken that there will not be a contestant for the manufacturer since an invention is getting to be patented. The purpose of this is to bring forth the contemporary trade status of India among the the developed countries in terms of patents.^{18,19}

International patent classification (IPC)

A hierarchy of patents categorization scheme is followed by more than hundred nations to organize the content of patents in an identical way. It was created under the Strasbourg Agreement, one of a number of treaties administered by the WIPO. The classification is updated on a regular basis by a committee of experts, consisting of representatives of the contracting states of that agreement with observers from other organizations, such as the EPO and USPTO.²⁰

Patent family

A patent family consists of all those patent documents which refer to precisely the same technical topic. Since the entity "patent" not only comprises a technical but also a legal, territorial aspect, the latter is invariably controlled by a national legal frame work, the same subject-matter has to be filed in all countries for which protection is sought. In simple words it is a set of patents taken in various countries to protect a single invention.

In the year range 2004-2013, 47,591 number of inventors got 81,379 number of patent families granted along with 501,716 no. of patent publications.

Patent number

A patent number includes an eight-character number that is assigned by the USPTO. Patent numbers are formatted by entering the patent number excluding commas and spaces and omit leading zeroes (e.g., Rennnnnn, RE000126 for reissue patents).

Steps to get intellectual property right

Determination of the type of IP protection

To protect any discovery, one might need a patent, trademark, copyright, marketing plan, trade secrets, or some combination of these. Before making a patent application, find out if you truly want a patent or some other form of IP fortification.

Confirmation of novelty of invention

Search to see if your invention has already been publicly disclosed and every country has its own laws and regulations for giving IPR rights. For example, in America, IPR rights are granted by USPTO and Europe has EPO and each has its own website and most of patents are filed online. For making such patent searches, a registered attorney is recommended.

What type of patent you need?

There are three types of patents - Utility, Design, and Plant

Utility patents

Utility patent is granted to anyone who invents a new useful process, machine, manufacture or composition of matter or a new discovery. By far, most patent applications filed at the USPTO are utility applications. It is also referred to as "patents for invention". It is subject to the payment of maintenance. For example contaminant monitoring and air filtrate system or methods for exploration and production of hydrocarbons etc.

Design patent

These patents are issued for a novel, original and ornate design applied to an article of production. It permits its owner to exclude others from making, using, or selling the design. Design patents started to be issued after May 13, 2015 and granted for the term of fifteen years from the date of grant. Design patents are not subject to the payment of maintenance. For example, vases with only minimal configuration differences may be considered a single design concept and both embodiments may be included in a single application.

Plant patent

Issued for a new and distinct, invented or discovered asexually reproduced plant including cultivated sports, mutants, hybrids, and newly found seedlings, other than a tuber propagated plant or a plant found in an uncultivated state, it permits its owner to exclude others from making, using, or selling the plant for a period of up to twenty years from the date of patent application filing. For example, Radcoleome is a patented shrub abundantly forms in clusters and blossoms pink petals and is highly resistant to disease such as dark spot, rust and powdery mildew and exhibits upright and bushy growth.²¹

Reissue patent

Issued to correct an error in an already issued utility, design, or plant patent, it does not affect the period of protection offered by the original patent. However, the scope of patent protection can change as a result of the reissue patent. This step is also called Drafting Stage.

Filing of patent

After determining the type of patent that you need, you can consider your application strategy and whether to use professional legal services. A patent application is an issue to the payment of a basic fee and additional fees including a search fee, an examination fee, and issue fee. Depending on your application, there may also be excess claims fees. Fees may vary depending on the type of patent application.

Prepare and submit your application

Submit your initial application with all the required parts needed for obtaining a filing date and include the correct fee. It is always good to make sure that you read the written description and claims. One cannot add anything new to the filed application. This applying and submitting of application comes under Filing part.

Examination

If application is inadequate, it will be notified to inventors by an official letter from the USPTO, known as an Office Action and a definite time period will be allotted to complete the request filing which may include extra charges. If the omission is not corrected within a specified time period, the application will be returned or otherwise disposed of; the filing fee if submitted will be refunded less a handling fee as set forth in the fee schedule. Once your application has been accepted as complete, it will be assigned for examination. Your examiner will review the contents of the application to determine if the application meets all the necessities.

Approval

If the examiner determines that your application is in satisfactory condition and meets the requirements, you will receive a Notice of Allowance. The notice of allowance will list the issue fee and also the publication fee that must be paid prior to the Patent being issued. Both approval and examining step come under examination stage.

Maintenance of patent

Patent can be filed in two steps: 1. Direct Filing: It grants patent in a single country i.e. a patent application filed directly in an international country. This application will be examined in accordance with the particular international country's patent laws and procedures. Examination and approval of a direct-filed application leads to a grant of an international patent in the respective country (Figure 2).²²

Patent cooperation treaty (PCT): It is a multilateral treaty working since 1978. Through PCT, an inventor of a member country contracting state of PCT can simultaneously obtain priority for his/her invention in all or any of the member countries, without having to file a separate application in the countries of interest, by designating them in the PCT application. All activities related to PCT are coordinated by the world intellectual property organization (WIPO) situated in Geneva.²³

Inventors of contracting states of PCT on the other hand can simultaneously obtain priority for their inventions without having to file separate application in the countries of interest; thus, saving the initial investments towards filing fees, translation, etc. In addition, the

system provides much longer time for filing patent application in the member countries.²³

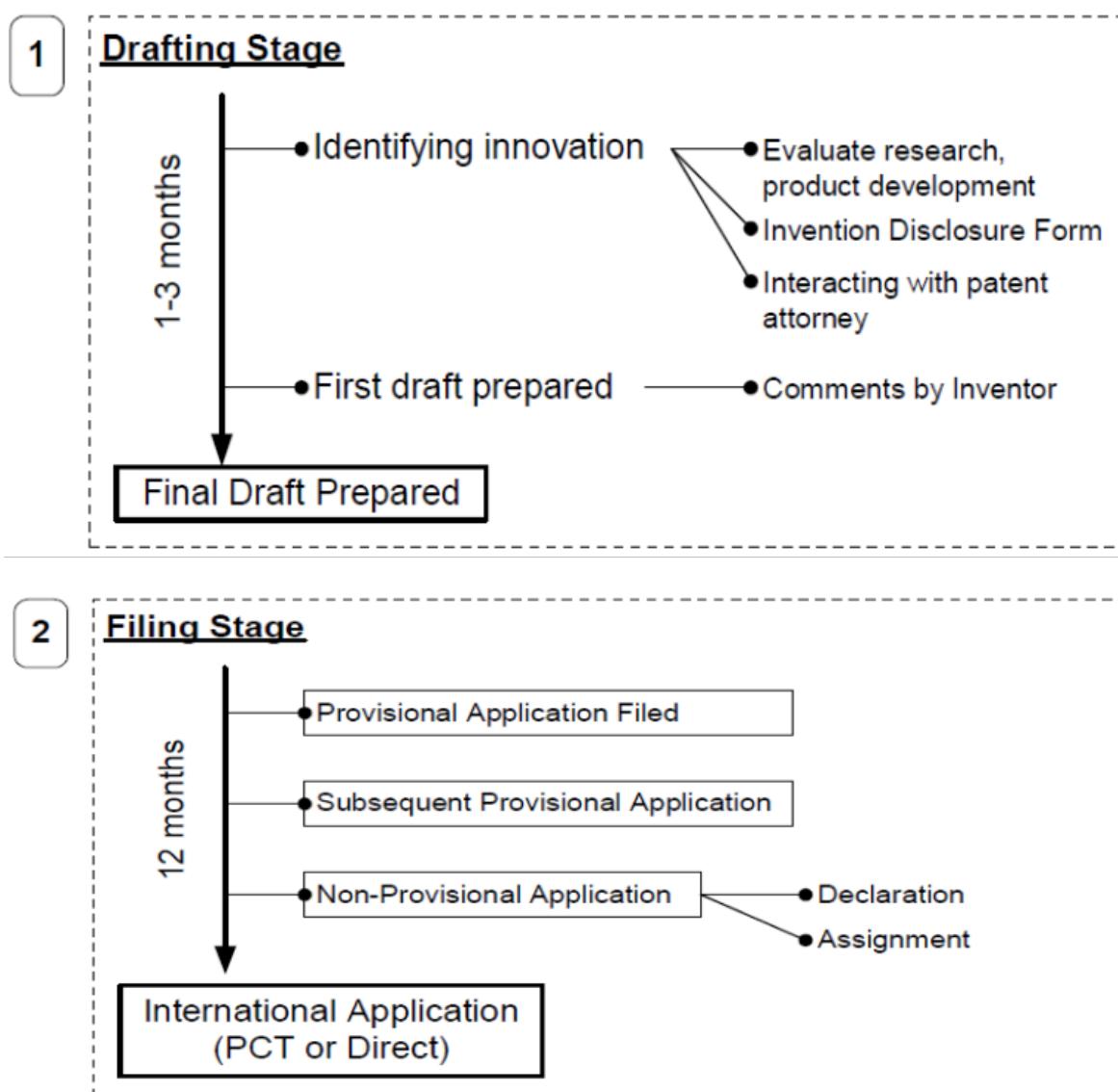
Traditional knowledge (TK)

Traditional knowledge refers to innovations and practices of indigenous and local communities embodying traditional lifestyles and the wisdom developed over many generations of holistic traditional scientific utilization of the lands, natural resources, and environment. It passes down from generation to next generation and is mostly undocumented.²⁴ It has played and still plays an important role

in food security, development of agriculture, medical treatment and also in preparation of drugs.²⁵ It contributes to the future wellbeing and helps in sustainable development.²⁶ Indigenous knowledge also comes under TK, but there is thin line difference between the two.

According to Mugabe.²⁷ Indigenous Knowledge (IK) is that knowledge that is held and used by a people who identify themselves as indigenous of a place based on a combination of cultural distinctiveness and prior territorial occupancy relative to a more recently arrived population with its own distinct and subsequently dominant culture.²⁸ Example of IK is Darjeeling tea.

Process Flow for Typical Patent



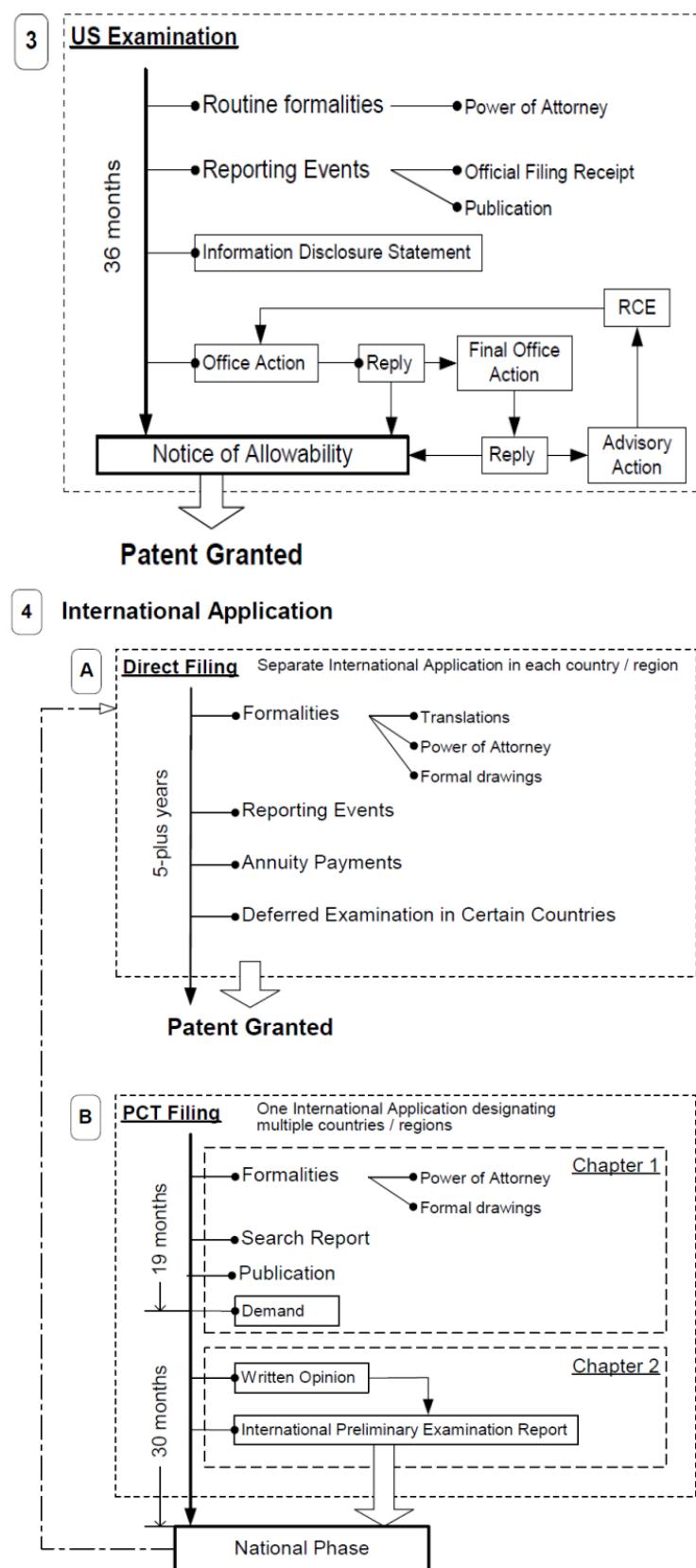


Figure 2 Patent process overview.²²

Importance of traditional knowledge

Traditional knowledge plays an important role in the conservation of biodiversity and its traditional uses:

- a. Indian Systems of Medicine (Ayurveda, Siddha, Unani) are part of the official healthcare system in India, and depend on a diversity of biological resources and traditional knowledge.
- b. Farmers and livestock keepers have improved and nurtured diverse varieties of crops and domesticated animals over generations. This has been invaluable for food security and in providing clothing, healthcare and shelter.
- c. All over India local communities have independently conserved wild areas, including natural ecosystems, sometimes deemed to be sacred e.g. ‘sacred groves’, some thousands of years old, dedicated to a local deity.²⁹

India and traditional knowledge

India is a country which has a tradition of civilization of nearly 5,000 years. India's ancient scriptures consist of 4 Vedas, 108 Upanishads, 2 epics, Bhagavad-Gita, Brahma sutras, 18 Puranas and Kautilya Shastra. It is known for its rich heritage of biological diversity but still has documented very less number of animals and plants. Ayurveda is the oldest and most effective of alternative of medicine. The ancient scriptures of the Ayurveda are full of instances where herbs with medicinal properties were used not only for treatment but also for increasing physical and mental efficiency.²⁶ Nearly 76 species of vertebrates have been found to be useful in tribal medicine.³⁰

Jeevani is a poly herbal drug in a granular form shows restorative, immuno enhancing, anti-stress and anti fatigue properties. The members of the Kani tribe chew fruits of the plant, *Arogyappacha* but since fruits are available in limited numbers, the TBGRI team scientifically validated all parts of the plant including the roots and leaves for possible leads. Eventually they found leaves with the necessary chemical and pharmacological properties.³¹

The knowledge was shared by three Kani tribal members to the Indian scientists who isolated 12 active compounds from *arogyappaacha*, developed the drug “Jevaani”, and filed two patent applications on the drug. Plat his, tribal leaders have customary rights to share or transfer and practice certain traditional and medicinal knowledge.

The technology was then licensed to the Arya Vaidya Pharmacy, Ltd., an Indian pharmaceutical manufacturer pursuing the commercialization of Ayurvedic herbal formulations.

India possesses one of the largest livestock populations in the world, which is more than 484.9million with the top position in cattle (178million), buffalo (98.7million), goat (125.46million) and sheep (64.27million), poultry (505million), and pig (16million). Further, the country has 16.49 percent of the world cattle population and 56.78 percent of the world buffalo population. Out of the total livestock in the country, around 38.2 percent are cattle, 20.2 percent are buffaloes, 12.7 percent are sheep, 25.6 percent are goats and 2.8 percent are pigs.

All other animals account for less than 0.50 percent of the total livestock population. There are unique traits of the farm animals inhabiting Indian sub-continent which hold considerable potential application or utilization through biotechnologies.³²

Under the Central Herd Registration Scheme of the Department

of Animal Husbandry & Dairying, animals belonging to Hariana, Gir, Kankrej and Ongole breeds of cattle and Murrah, Surti, Mehsana and Jaffrabadi breeds of buffalo are registered depending on the conformation to breed characteristics and prescribed milk being misappropriated by others. Until now, the enforcement of IPR in livestock sector is not so rigid in India which reduces the effectiveness of IPR laws and regulations. It also generates a bias towards research outputs primarily marketed in industrialized countries with functional rule of law.³²

Biopiracy

Bioprospectors, depend on the knowledge of indigenous and local communities that have preserved these resources for ages and understand them best for commercialization of valuable genetic resources. This process of “appropriating biodiversity and the knowledge “involved is termed biopiracy.³³ The term can also be used for breach of contract related to access and use of TK. Bioprospectors are those scientists which discover and commercialize new products based on biological resources.

In 2000, the Council of Scientific and Industrial Research (CSIR), India, found that almost 80 per cent of the medicinal plants were granted by United States Patents Office,³⁴ and in that year only 7 medicinal plants of Indian origin were patented. Then again after three years almost 15,000 patents were granted at USPTO, EPO etc. In 2005, this number increased to 35,000, which clearly demonstrated the interest of the developed world in the TK of the developing countries.³⁵ With reference to Yoga, the study conducted by Traditional Knowledge Digital Library (TKDL) team on the international patent databases in February 2004 found 249 patents were granted on Yoga and by May 2005 its number drastically increased to over 2300 patents, 2315 trademarks and nearly 150 copyrights. The reason for this misappropriation at international patent office's is that the traditional medicinal knowledge exists only in local languages, such as Sanskrit, Urdu, Arabic, Persian, and Tamil which cannot be understood by patent examiner.²⁶

A few examples of bio-piracy of traditional knowledge are:

Turmeric (Curcuma longa): *Curcuma longa*, a type of turmeric commonly called Haldi, is an Indian herb which is used for treatment of sprains, inflammatory conditions and wounds. The orange colored root is native to the subcontinent and South East Asia, and for thousands of years has been a one of the major components of Ayurvedic medicine. In 1995, two US scientists from the University of Mississippi were granted US patent 5,401,504 on the use of turmeric. The scientists claimed that turmeric could heal wounds and claiming this to be novel(Bhattacharya,2014).³⁶ The CSIR challenged this patent on grounds of prior art, supporting their claim by documentary evidence of traditional knowledge which includes ancient Sanskrit text and a paper published in 1953 in the Journal of Indian Medical Association. USPTO revoked this patent in 1997 after enquiring that there was no novelty and the innovation has been used in India for centuries.³⁷

Neem (Azadirachta indica): It is derived from the persian name Azad-Darakth, meaning “the free tree”. In India it has been widely used for several decades and is mentioned in Indian texts written 2000 years ago. The remarkable properties of this compound have been used by Indian small farmers and industries in medicine and agriculture in form of insect and pest repellent, toiletries and cosmetics etc.³⁸ In 1994, European Patent Office (EPO) granted a patent to the US

Corporation W.R. Grace Company and US Department of Agriculture for a method for controlling fungi on plant by the aid of hydrophobic extracted Neem oil).²⁶

In May 2000, a coalition of groups successfully overturned the patent held by the United States of America (US) company, WR Grace and the US Department of Agriculture over the Indian neem tree.³⁸

Basmati rice (*Oryza sativa linn*): It is largely produced in many parts of India and some parts of Pakistan. It is evident that basmati is grown in subcontinent for centuries and farmers have developed numerous varieties of rice to meet various ecological conditions, cooking need and taste.³⁹ Texas based Rice Tec received a US patent 5,663,484 on basmati rice in 1997. This patent permitted the company to develop and sell a 'new' variety, which it claims to have progressed under the name of basmati, in the US and abroad. But it was retracted due to the efforts of Indian Agricultural and Research Institute (IARI).²⁶

Nap hal (Wheat): EPO granted a patent to MONSANTO, Seed Corporation. Research Foundation for Science Technology and Ecology (RFSTE) along with Greenpeace and Bharat Krishak Samaj (BKS) filed a petition at the EPO, Munich, challenging the patent rights given to MONSANTO on Indian Landrace of wheat, Nap Hal. The patent was revoked in October 2004.²⁶

Amla (*Phyllanthus emblica*): It is widely grown and used in India and is a main ingredient of triphala which is a traditional ayurvedic formulation used for thousands of years. USPTO has granted 5 patents and one of the patents is claims an invention using extracts of am lain a hair coloring preparation. Four further patents involving Alma have been filed in the Japanese Patent Office.

Karela (bitter gourd): Jamun (blackberry), Gumar and Brinjal, for instance, are commonly known in India for their anti diabetic characteristics. Their uses are so common in India that there is no novelty involved while using them for curbing diabetes. A patent was, however, obtained in the U.S. by three NRIs for their utilization as a cure for diabetes.³⁶

At the indigenous level, it was not until the eighth decade of this century that the subject began to be discussed and became a matter for concern, and only in very recent years that it has been subjected to analysis in various international forums and institutions. This in turn has led to a situation where we indigenous peoples do not agree on concepts, and it has been difficult to conform to the already firmly established precepts of WIPO, owing to the fact that our collective rights are denied to us, or are a subject still unknown to us.⁴⁰

IK is also becoming recognized as a form of rational and reliable knowledge developed through generations of intimate contact by native peoples with their lands which has equal status with scientific knowledge.⁴¹

Some of the International and National initiatives for protecting TK

There are two types of IP protection regarding traditional knowledge:

Positive protection

Positive protection provides traditional knowledge holders the exclusive right to take battle against misuse of their knowledge. It provides protective legal rights over traditional knowledge.²⁶

Defensive protection

It provides safeguard in opposition to unlawful IP rights taken by others over traditional knowledge subject matter. For example some communities have started creating TK databases which can be used as confirmation of prior art to beat a state to a patent and to prevent abuses as biopiracy.²⁶

In wide terms, international interest and labors to protect TK can be traced to the 1960s, when the WIPO and the United Nations Educational, Scientific and Cultural Organization (UNESCO) renowned the need to extend actions to protect expressions of tradition linked to national, cultural and artistic heritage and patrimony.⁴²

A second sign of interest in TK began in the 1980s in the United Nations Food and Agriculture Organization (UNFAO) on farmer's rights and the efforts and intellectual input of small farmers especially in centers of origin and diversification for the conservation and development of agro biodiversity and native seeds.

The third phase or period when TK was once again part of international debates began in the late 1980s and culminated with the adoption of the Convention on Biological Diversity in 1992.⁴²

Two international conventions deal with biopiracy:

Convention on Biological Diversity CBD(1992)

TRIPS (Agreement on Trade-Related Aspects of Intellectual Property Rights, 1995).⁴³

CBD is a global conformity which acknowledges the function and contribution of indigenous and local communities in the conservation and sustainable use of biodiversity.

Its main objectives are:

- a) Conservation of biological diversity
- b) Sustainable use of biological diversity
- c) Fair and equitable use of the benefits

Under the CBD, it calls for Prior Informed Consent (PIC), Participation of indigenous and local communities and benefit of sharing.⁴²

The main goal of the CBD is to preserve biological diversity while the goal of TRIPS is to stimulate technological advancement by giving individual rights to the inventor through IPRs.

Recently amended patent law of India contains provisions for mandatory disclosure of source and geographical origin of the biological material used in then invention while applying for patents in India.

Other important initiatives in India towards documentation of indigenous knowledge are:

Preparation of village wise Community Biodiversity Registers (CBRs) for documenting all knowledge, innovations and practices.

The development in Kerala is the production of a benefit sharing understanding between the Tropical Botanical Garden Research Institute and the Kanitribe; based on whose knowledge a drug was made and then marketed.⁴⁴

Gene campaign has documented biodiversity and associated indigenous knowledge in Jharkhand, Madhya Pradesh, and

Uttarakhand. It has focused on three tribal populations: the Munnars of Jharkhand; the Bhils of Madhya Pradesh; and the Tharus of the Terai region. Department of Science and Technology of Indian government supported the documentation. Communities were made aware of the threat of biopiracy, and the implications of IPRs and various national and international developments concerning the protection of biodiversity and indigenous knowledge. Medicinal plants and knowledge related to it was sought to be documented with the help of educated tribal youth.⁴¹

Research Foundation of Science, Technology and Ecology (RFSTE): Initiated a movement called the Jaiv Panchayat (JP) in early 1999.⁴⁵ Activists from RFSTE and Navdanya have been interacting with local villagers in different parts of India to constitute informal community level institutions called JP, comprising volunteers from a village. The first JP to complete the register was in Agasthyamuni village, Garhwal district, UP, where on 5 June 1999, the CBR prepared by the local people was presented.

SRISTI (Society for Research and Initiatives for Sustainable Technologies and Institutions): It is in Ahmedabad and involved in document innovative work done by persons at the rural level. The proposal is recognized as Honeybee Network, which credentials the elements of biodiversity and their uses in particular innovation nearby these elements. Various suggestions to widen shield to information, innovations, and practices include:

- A. Certification of conventional acquaintance.
- B. Registration
- C. Development of contracts.
- D. Grant of IPR under IPR existing systems

Development of a Sui generis system- It means of its own kind or unique. It may consist of some standard form of IP protection with other forms of protections. It is the system that can create legal rights associated with traditional knowledge and promote its access and benefit sharing.⁴⁶

India's latest laws which have repercussion for IK and other bio-resources are given as following:

- i. The Biological Diversity Act, 2002.
- ii. The Patent (Second Amendment) Act, 2002.²⁹

Geographical indicators (GI) - These are the signs used on goods which have a specific geographical origin. It indicates that a product belongs to a certain place and is indigenous to that place of origin and IPR is the only way to protect it.⁴⁷

Traditional Knowledge Digital Library (TKDL)

In India, TKDL is a joint project shared between Council of Scientific and Industrial Research (CSIR), Ministry of Science and Technology and Department of AYUSH, Ministry of Health and Family Welfare. As quad of experts (Ayurveda, Unani, Siddha and Yoga) belonging to Traditional Medicine, patent examiners, scientists, IT experts and technical officers are involved in construction of TKDL for Indian Medicines.⁴⁸⁻⁵⁸

The project TKDL includes credentials of the conventional knowledge available in public domain in the form of literature or prehistoric books related to Ayurveda and Yoga in digital form in five

international languages viz English, Spanish, French, German and Japanese.

Conclusion

IP serves as an incentive for invention, creation and helps in development by tumbling poverty, exciting fiscal growth and improving medical conveniences. Business needs, consumer/ market response and price involved in conversion of an IP into commercial venture are all those factors that affect IPR rights. IPR forms mandate various handling, preparation, planning and appointment of people concerning a variety of domains of acquaintance like life science, medicines, engineering, law, economics, marketing, and finances etc.. All industries ought to evolve their IP regulations, management approach, etc by their own. Moreover, medical and chemical companies should go licensing and commercialization of drugs. Competition among pharmaceutical companies would lead to low cost of medicines and help pharmaceutical industry to grow and improve medical assistance.⁵⁹⁻⁷⁹

IPR has pros and cons both as sometimes it creates differences between scientist's fraternity over patenting of products or processes etc. Sometimes it also affects welfare of human being as some scientists and organizations misuse their IPR rights by patenting useful genes and plants etc. For example, patenting of BRCA 1 genes and neem tree etc.

In developed countries people are well aware of IPR and use it in getting their novel inventions, discoveries etc. for patenting and in getting protection from other forms of IPR but in developing countries scientists and research workers are less aware. Many initiatives have been taken by Nongovernmental organizations and government in creating awareness about IP and its rights. Through this review one get knowledge about IPR and its few types copyright, trademark and patents. For getting patents the invention is cardinal to be original, non-obvious and of effectiveness in industrial sector, whereas symbols and signs can be trademarked by an organization and the authority to use it is copyright.⁷⁹⁻⁸³

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Conflicts of interest

The authors declare no conflict of interest.

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