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AReviewonIndia'sbiotechnologypatentingregulationsandchallenges

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Abstract

An inventor who obtains a patent is given the sole authority to commercialise their idea for a 20-yearterm and to safeguard it openly and without restriction. With its significant economic worth, a patentmay be regarded as one of the most significant forms of IP rights. The rules governing patents have along history and have changed throughout time in response to societal needs, the rate of invention, andtheintricacy ofsuchadvances.ThePatentAct,1970andits2005and2006amendments,knowncollectivelyasthePatents(Amendment)Act,governpatentlawinIndia.Formanyacademics,biotechnology has grown to be an essential tool, and the innovations it has inspired. In addition toinspiring the development of several innovators and playing a significant part in enhancing the country'shealth, biotechnology has emerged as a valuable instrument for many researchers. The preservation ofthese inventors' rights becomes inappropriate, therefore several biotechnological innovations includingdrugs, microbes, and transgenic animals have been awarded patent protection globally. This essay seeksto evaluate Indian patent law with a particular emphasis on how it affects biotechnological inventions. Itsheds light on the patent rights of transgenic animals, microorganisms, and pharmaceuticals, as well ashowcompulsorylicensingprevents themisuseof patent law.

Keywords: Patent, Biotechnological Inventions, Pharmaceutical Industry, Micro Organisms, TransgenicAnimals,Compulsory Licensing.

Introduction

A patent is a legal document that the government issues to an inventor in exchange for their creation ofa new item or technique that offers a fresh approach to a problem or new way of doing something. Inexchangeforathoroughpublicdisclosureofthespecificidea,itgrantstheinventortheexclusiverightto use their innovation fora set period of time, often for twenty years. To grantthe creator uniquerights to profit from their inventions is the objective. It provides innovation protection without therequirementfor secrecy.

Until the patent expires, imitators and even independent creators of the same concept are prohibitedfrom using or commercialising the innovation. A patent is a cartel right because it gives the patentee anexclusive monopoly for 20 years before it enters the public domain and is used by others for economicgain. To utilise their innovations, however, third parties may be granted permission or licences by thepatentownerundermutuallyagreed-uponconditions.Theownercanpotentiallytransferownershipof

the patent to another person by selling them the rights to the innovation. In line with the developmentoftechnologyand societal demands,patents haveaverylong history,and thelegislationgoverningthem has also changed through time. In line with the development of technology and societal demands,patentshave averylonghistory,andthelegislationgoverningthemhasalsochangedthroughtime.

RelatedWork

The firststatute on the protection ofinnovations in India, Act VI of 1856, was based on the Britishpatent law of 1852 since the history of patents in India dates back to the time when India was still aprovince of the British empire. Later, in 1859, it was changed to give the inventors some exclusive rights.Subsequently, the Protection of Inventions Act of 1883 and the Patterns and Designs Protection Act of1872wereapproved,andthey wereeventuallycombinedintothe Inventionsand DesignsActof1888.

All prior legislation pertaining to patent law were repealed by the Indian Patents and Design Act, 1911,which also placed control of patent administration in the hands of the Controller of Patents. Once thecountry gained its independence, it was discovered that this act had fallen short of its goal and it wasdetermined that a more comprehensive patent legislation was necessary given the country's significantchangesin thepolitical andeconomic landscape.

To evaluate Indian patent law and make sure the patent system serves the interests of the country, acommittee was established in 1949 under the chairmanship of Justice (Dr.) BakshiTek Chand, a retiredjudgeoftheLahoreHighCourt.TheActof1911wasrevisedin1950basedonthiscommittee'srecommend ations. A committee headed by Judge N. RajagopalaAyyangar was established in 1957 toinvestigate and provide recommendations to the government about the possibility of revising the PatentLaw.

The Patents Act of 1970, which went into effect on April 20, 1972 with the publication of the patentregulations,wascreatedasaresultofthecontributionsandsuggestionsmadebybothofthesecommittee s.Furtherrevisionswere adopted in 1992,2002, and 2005 to make minor changesand putthe Act in accordance with international agreements including the TRIPS agreement. The Indian PatentActcoversboth themethod and the product.

Accordingtosection159ofthePatentsActof1970,whichgivestheCentralGovernmenttheauthorityto create regulations for the Act's implementation and controlling patent administration, the PatentRegulations of 1972 were announced and came into effect on April 20, 1972. After afterwards, theseregulationsweresometimeschangeduntiltheywerereplacedbythe2003PatentRegulationsonMay 20. The Patents (Amendment) Regulations of 2005 and the Patents (Amendment) Rules of 2006 furtheralteredthem.

Inventions that pass the three precondition conditions are given a patent under the Patent Act of 1970.The innovation must be original and must not have existed before in order to pass the test. Second, theinnovationmustsignificantlyadvancetechnology;asaresult,itmustbenovelandnotjustastraightforward modification of already existing equipment. The last requirement is that the innovationmustbebeneficial, whichcanbe takentomeanthatnopatent canbeissuedforacreation that canonly

beutilised for immoral or unlawful activities. The Indian Patent Act does not specifically say what typesof innovations are eligible for patents; instead, it defines eligibility for a patent in a negative sense,defining a class of inventions that are not eligible for patents under clauses (a) to (p) of section 3 of theact.

One of the most contentious, debatable, and challenging topics a patent attorney must frequentlyaddress in practically every meeting with an ardent Entrepreneur is whether or not an invention ispatentable. Unfortunately, there is no definitive answer to this problem because there are severalpossible solutions. An idea's patentability is not addressed in the Patent Act of 1970. A discovery needsto be new, useful in industry, and obscure to someone skilled in the field in order to qualify for a patent.Anideacan satisfyall threeofthesecriteria.

A patent application may be filed as a provisional or a full specification, according to Section 10 of ThePatents Act of 1970, which also lists the requirements for filing one. Ideas may be patented under thisprovision if they satisfy certain requirements. A provisional application cannot be submitted without theconcept being feasible and having the potential to evolve into a full-scale invention. After a year ofsubmitting the provisional application, one can devise a method for carrying out the concept and thensubmitthecompleteapplicationafterexplainingthe ideaandsubmittinga patentapplication.

ProceduretoapplyPatent

1. Disclosure of the innovation: The initial step is to inform a professional about your idea. By signing anon-
disclosureagreement,thisisaccomplished.Everyinformationregardinganinnovationthatisknownmustbe included,withoutbeing overlooked.

2. Do a search for patentability. A specialist typically charges between INR 10,000 and INR 20,000 for thisphase. The expert will now carry out a comprehensive study to find any past evidence in any availabledatabases.A patentability report basedontheinvention will alsobe createdby them.

3. Choosing whether to proceed with a patent application: This decision can be made after a thoroughanalysis of the (potentially) prior history of the invention. It should be emphasised that for an innovationtoqualifyforapatent,itmustbecomparedtoalready-
existingpriorartworks.Inordertoqualify,itmustbe
"technicallysophisticated,""economicallyimportant,"orbothonanexisting pieceofart.

4. Patent Drafting: The inventor or a professional can draught the application. A professional shouldreceive between 20,000 and 30,000 Indian rupees in payment. One of the most crucial elements in theentireprocedure, itcallsfor expertisein both law andtechnology.

5. Filingthepatentapplication:

One can submit the patent application in the prescribed manner using the appropriate forms, subject toa fee of INR 1,600 or INR 4,000 or 8,000 depending on the type of application. These are payable forfiling the patent application with the Patent Office. If a request is not submitted for an early publication,thepatent application willbe published within18months.

5. Submittingapatentapplication:

Depending on the kind of application, a cost of INR 1,600, INR 4,000, or INR 8,000 must be paid in orderto submit a patent application in the way specified using the proper forms. Fees must be paid in order tosubmit your patent application to the Patent Office. The patent application will be published in 18monthsifnorequest for early publicationismade.

6. Requestforexamination:

In step six, known as "Request for Examination," the applicant must ask the Indian Patent Office toevaluate the patent application within 48 hours. The charge for this step ranges from INR 4,000 to INR20,000.

7. ReactingtoObjections:

Atthis phase,thedraughtand reportthat willbe sentto theauthorities of thePatentOfficearecarefully examined. The inventor now has the chance to include their originality or innovative elementinto anymore worksofartdiscoveredthroughouttheassessment.

8. Grantingofthepatent:

Iftheapplicationsatisfiesallofthestandards,itwillbereleasedforgrantandadvertisedbyapublicationthatis in print.

9. Patentrenewal:

Apatentistypicallygoodfor20years.Theownerisrequiredtorenewthepatentforamodestcostafter20 years.

PATENTINBIOTECHNOLOGY

The term "biotechnological innovation" refers to a process that employs live creatures, or any portion ofthem/components,etc.,tobuildmicroorganismsandorganismsthataredesignedforcertainapplications,ort oconstructorrefinegoodsortomakethembetter.Agriculture,agro-industry,fertilisers, the food business, diagnostics, zoo methods, semiconductors, pharmaceuticals, the trashindustry,fuel,chemistry,etc.arejustafewofthemanyindustriesthatutilisebiotechnologicalinventions.T herulespertainingtothepatentingofinnovationsareappliedforbiotechnologicalinventions, despite everything else being put aside and what has previously been established. Moreover,the pharmaceutical industry and the life sciences have had a significant impact on life expectancy andqualityoflife.Nowadays,biotechnologyisthefoundationofmostcontemporarymedications.

Nowadays,biotechnologyisthefoundationofmostcontemporarymedications.Theuseofbiotechnology and/or microbiotechnology has made it possible for inventions relating to processes ormethodsofproducingtangibleandintangiblesubstances(suchasenzymes,antibiotics,insulin,interferon,alc ohols,vaccines,etc.)byusingsuchmicroorganismsorbyutilisingtheaforementioned

biologicallyreferredchemicalsubstancesproducedbyusinggeneticallyengineeredorganismsandsubstances moreeconomically.

The Patent Office also gives patents on procedures and techniques for producing things, in addition toitems like pharmaceuticals, DNA, and antibodies. The actions that need to be done in the invention'stechniqueorprocesswillbereflectedintheclaimsofthesepatents.Genes,proteins,andorganisms may now be used for exploitation thanks to biotechnological innovations. It has the ability to alter howillnesses are identified and treated, how food is grown, how energy is created, and how trash is disposedof.Similartootherinnovations,thevalidityofbiotechnologicalinventionsisdeterminedbytheirnovelty,originality, andviability for commercialuse.

Alongwiththingslikedrugs,DNA,andantibodies,thePatentOfficealsograntspatentsonmanufacturing processes and techniques. The claims of these patents will outline the steps that must betakeninordertoimplementtheinvention'stechniqueorprocedure.Thankstoadvancesinbiotechnology, it is now possible to exploit genes, proteins, and organisms. It has the power to changehow diseases are detected and treated, how food is grown, how energy is produced, and how rubbish isthrown away.Similarto other breakthroughs, the novelty,creativity,andcommercial feasibilityofbiotechnologicalinventions determinetheirvalidity.

Anytechnologicaladvancementthatusesbiologicalmaterialtocreateorenhanceproductsorprocedures is referred to as "biotechnology". The pharmaceutical sector is a subset of the economy thatrevolves around the development, manufacture, and marketing of pharmaceuticals. In addition to all ofthis, genes are identified as separate components of a DNA segment that encode the whole individualbody, making DNA a key biotechnological component that cannot be copyrighted. The informationrecordedinaperson'sgenetic codeisprobablytheirfuturediarysinceitdepictsaprivatefuture.

DNA sample collection infringes on three different types of privacy: bodily, genetic, and behavioural.Bodily privacy is when a sample is taken from a person's body; genetic privacy is when a person's DNAsample is used to predict future health and other information; and behavioural privacy is when theinformation is used to determine where a person has been and what he has done. Gene sequencing andgene patenting may violate private rights since they limit a segment of the body. Genes are the basis ofhuman existence and a part of every cell in the body. The right to privacy may be violated if gene patentrightsare allowed.

The inherent privacy infringement in providing ownership rights in which every individual is a part-owner solely for the dignity of a human being is highlighted by opponents of gene patenting. Genepatentingcouldgo againstthe basictenetsof personal and socialprivacy.

PATENTINPHARMACEUTICALINDUSTRY

India has one of the major pharmaceutical industries in the developing world, ranking fourth in terms ofoutput and thirteenth in terms of domestic consumption value. Over the past 30 years, it has evolvedfrom being essentially nonexistent to a world leader in the production of generic medications. Indianpharmaceutical businesses increased the accessibility of less expensive versions of the most widely usedpatent-protected medications worldwide by becoming experts in reverse engineering. The 1970 IndianPatentActmade this feasible.

Despite the fact that section 5 of the act of 1970 provided an exemption by allowing process patents forfoods, medicines, or drug ingredients while expressly excluding product patents for the same, all of thiswas only possible because there was no products patent system for pharmaceuticals and medicines.India was able to copy patented drugs without having to pay a licencing fee as a consequence, enablingthe businesses to distribute the drugs to the general people at reasonable prices. This scenario changedafter the implementation of the 2005 revision to conform with Trade Related Aspects of IntellectualPropertySubjects.

As a result, this amendment increased patent protection for pharmaceutical products and broadenedTRIPS'applicationtocoverallfoods,drugs,andmedicines.Furthermore,it extendedthelength ofpatent protection from the 1970s' legislation's 7 years to 20 years. The creation of product patentswasn't done to stop the cheap mass production of generic pharmaceuticals; rather, it was done toencouragethedevelopmentofnew,moreeffectivetherapiesinIndiaandprovideanalternativestrategyfor theproblemofmedicationavailability.

As a result, this amendment provided patent protection for pharmaceutical products and increasedTRIPS' overall scope to cover foods, medicines, and other therapeutics. In addition, it extended thelengthofpatentprotectionfromthe1970s'7-yearlawto20years.Nottostopthecheapmassproduction of generic pharmaceuticals, the introduction of product patents was intended to encouragethe development of new, more effective therapies in India and provide an alternative strategy for theproblemofmedication availability.

However, the product patent raises issues regarding increased drug costs for the general public andpatent holders abusing their rights by failing to commercialise or produce their innovation in developednations in order to increase profits. In order to prevent such patent rights abuses and to stop the use ofthe innovation due to concerns about public morals, the TRIPS (Agreement on Trade Related Aspects ofIntellectualProperty Rights) provides for theissueofacompulsorylicence.

SCOPEANDCHALLENGES

Given that Indian patent law and practise are still developing, they are not yet completely establishedand/or standardised with regard to the patenting of biological materials. The substantive legislation stillhas a number of issues that need to be resolved. Biotech goods must disclose biological content, receiveprior clearance from the Biodiversity Board, and deal with access and benefit concerns within the IndianPatentsystem in addition to thestrict rulesforpatentability.

While TRIPS prohibits the exclusion of inventions that are novel, non-obvious, and broadly applicable toindustry,Indianlawhasalonglistofexceptionstothepatentabilityrequirement,includingthefollowing:

a. TRIPS consistent - living or inanimate naturally occurring components derived from biologicalmaterialortheirportions;proceduretoproducesuchcomponents;separationoflivingorganisms, genetically altered or transgenic organisms, and cell components; separation andmodificationprocesses; use ofbiologicalmaterial;
b. Consistent with TRIPS, plants and animals as a whole or in part; different species of plants andanimals;seeds; basically biologicalmeansof propagation;
c. Criteria not contained in TRIPS, such as frivolous or a straightforward arrangement of well-knowncomponents;
d. Criteria that are inconsistent with TRIPS, including as inventions based on business techniques,curative and preventative treatment procedures, or traditional knowledge that are not deemedpatentable.
e. Newrequirement:absent from TRIPS - new uses of well-known substances are not thought tobe patentable. Salts, esters, ethers, polymorphs, metabolites, pure forms, particle sizes, isomers,mixturesofisomers,complexes,compositions,andderivativesarealsonotconsideredpatentable unless they"do not resultin the enhancement of known efficacy of the substance"or"differsignificantlyin properties with regardtoefficacy."
f. Newrequirement:simpleadmixture,suchasthebacteriapresentintheroot-nodulesofleguminousplants,isnotfoundinTRIPS anddoesnotimprovenaturalfunctioning;
g. Additional disclosure of source and origin biological materials for patent grant is now requiredand is not covered by TRIPS (further amendments to Sections 25 (j) and 64 (p) of the 1970 Actexpand grounds for opposition and revocation to include nondisclosure of source and origin ofbiomaterials).
h. LimitationsonPatentability-Includingbiochemical,biotechnological,andmicrobiologicalprocessesinchemicalprocessesas anexplanation forthepurpose ofproductpatent.

Conclusion

As previously said, India is still learning about the challenges surrounding the patenting of biologicalmaterial. Regarding the patenting or non-patenting of biological innovations, standardisedpractise hasnot yet been adequately established. However, the Patent Office typically accepts such inventions aspatentableifaclaimofaninventionrelatestoanovel,inventive,andmodifiedgeneticmaterial,whereinsuchgeneticmaterialisidentifiedbyitsproteinoraminoacidsequencesatleastinthedescriptionandintheclaims,andsuchgeneticmaterialiscapableofindustrialapplication.Asaresult,

theinnovationsmustmeetavarietyofquitewiderequirements.Itisimportanttohighlightthatbiologicalmaterial patentingin Indiais stillfrequently decidedon acase-by-case basis.

A number of elements in India'spost-TRIPS patent rules make biotechnologypatenting more desirableas a foundation for competitive advantage. The Dimminaco ruling also represents a rise in judicial andadministrativeunderstandingofthesignificanceofbiotechnologypatenting.Itisclearfromthepermittedclaimspreviouslyrevealedthatbiotechpatentscanbeobtainedinavarietyoffieldssolongasthedescription/enablementconditionsaremetandtheprosecution isconductedclearly.

Additionally, since India is one of the nations with a high level of biological diversity, it would be wise toprotect biotechnological inventions as this would enable Indian biotechnology research to competeinternationally. With an enabling mechanism for patent protection in biotechnological advances andinventions,India canbettercapitaliseonits abundantbioresources.

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