Ilkogretim Online - Elementary Education Online, 2021; Vol 20 (Issue 6): pp. 1209-1216
http://ilkogretim-online.org
doi: 10.17051/ilkonline.2021.06.127

Biotechnological Patents: India'S Perspective And The International Scenario

Ajay Sharma , examiner for Trademarks and GI at IPINDIA , Mumbai.

Introduction:

Biotechnology is not new to human being and since time immemorial it has progressed significantly in its different forms and uses. The process of producing alcohol by fermentation and isolation of antibiotics from microorganisms are the few examples of classical biotechnology. But this technology has gained significance after the revelation of the structure of the DNA molecule and thereby, laid the foundation of modern biotechnology.[1] Biotechnology is an application of science and engineering in the direct use of living organisms in their natural and modified forms.[2] Modern biotechnological inventions include product and/or process of gene engineering technologies, methods of producing organisms, methods of isolation of microorganisms from culture medium, methods of mutation transform ants, plasmids, process for making monoclonal bodies, etc.[3] Though the biotechnological inventions have given tremendous benefits to the humanity yet their close association with the nature often raise issues of patentability. Besides these, there are other issues also which are associated with the biological inventions like morality and public order, environmental protection,issues relating to patenting of EST's (Expressed Sequence Tags) of partial gene sequencing,stem cells cloning of farm animals, gene diagnostics etc.[4] The grant of a patent to a person confers on him two sets of rights.One is the positive right to exploit and use his invention in a desired manner and other is the negative right to exclude others to use and exploit that invention. These sets of rights with their exclusive nature are a problematic concern in the area of biotechnology as it involves the living entities. This is also one of the reasons why the attempts to harmonize patent practices and laws internationally have failed e.g. there is difference of opinions in different jurisdictions regarding features of invention and discovery, that could demarcate the boundaries between the patentable and not patentable subject matter. Thus the patenting of the biological inventions in the field of biotechnology is a challenge to both the applicants for the patent and the patent offices.

India like other jurisdictions in the world was also uncertain over the patentability of biotechnological inventions however the recent amendments in the Patent Act 1970 and the stand taken by Indian judiciary has increased the scope of biotechnological patents .This Paper attempts to set forth India's perspective on the patentability of biological inventions along with the stand taken by the international community on it. The first part of the paper describes the history of Gene patenting and the position on gene patenting of some major jurisdictions in the world like USA,Europe, Canada and Australia. The second part set forth the provisions of TRIPS relating to patentability and

[1]Watson & Crick ,Molecular structure of nucleic acids, Nature 171 (4356) http://www.nature.com/dna50/watson
[2] Section 3(1) Canada Environment Protection Act excerpts from article 'Patenting of Genetic Inventions' by 'Malathi lakshmikumaran'
[3] Introduction' Guidelines for examination of biotechnological patents by Office of Controller General of Patents and Designs of India March 2013
[4] Ibid

meaning of novelty, inventiveness, industrial application in relation to gene patenting.The third part gives the position of Indian patent law on biological patents with the recent amendments, thereby enlarging the scope.The fourth part set forth the stand of Indian judiciary on the gene patenting.The fifth part of the paper set forth some of the guidelines issued by Office of Controller General of Patents and Designs of India for determining biotechnological patents.The last part of the paper set forth the conclusion with brief summarization of moral and ethical aspects of the issues.

Position of International Community on Biotechnological Patents: Some Jurisdictions like USA, Europe, Canada, and Australia

In U.S. and Europe, the trend of increased patent protection reflects a concerted effort of legislatures, courts and patent offices- potentially the result of governmental pressure to attract biotechnological investment through more liberal patent standards.[5] A recent report of WHO stated that industrialized nations like USA Canada, Europe, and Australia currently hold 97% of patents worldwide.[6] In the field of gene patents US inventors filling more international patents on DNA sequences than any other, including the combined total of all inventors in Europe.[7] In USA the first patent on a recombinant DNA was granted in 1980 which was shared by Stanford University and University of California and it laid down the foundation for using gene sequences to produce wonderful drugs. Till 2013, more than 5000 patents on human genes have been granted in USA .The judgment in 'Diamond v.Chakarbarty'[8] facilitated the expansion in scope of biotechnology by allowing a patent on isolated gene sequences. In this case US Supreme Court overturned the United States Patent and Trademarks office's (USPTO) decision and allowed patenting of genetically modified bacterium for the bioremediation of oil spills.This is considered as the landmark judgment in the history of biotechnological patents as it influenced significantly the patent regimes of other nations and many nations began allowing patents on genes.[9] In another important case of 'Mayo v. Prometheus',the court called the correlation between the naturally produced metabolites and therapeutic efficacy and toxicity an un-patentable 'natural law'.In this case, the court struck down Prometheus's patent claims on method of metabolite levels in the body to thiopurine drugs for stomach disorders. These two cases set forth two different opinions on the patentability of biotechnological inventions. It is due to the expansion in scope of gene patents and with increased number of patent filling in US, the number of parties challenged the validity of gene patents in the courts in the last two decades. Many of these challenges arose out of controversy surrounding 'Association of Molecular Pathology v. Myriad Genetics'popularly has known as Myriad's Genetics case.[10] In this case Association of Molecular Pathology a US nonprofit society of researchers and scientists challenged Myriad's BRCA1 and BRCA2 gene patents along with their patents on diagnostic testing.[11] The court held the isolated human genetic

[5] Biotechnological Patents, Markets and Morality (Peter Drahos), 21 European Intellectual Property Rev. 441, 442-43 (1999)
[6] WHO Human Genetics Program me Genetics, Genomics And The Patenting Of DNA: Review Of Potential Implications For Health In Developing Countries (2005), available at http://www.who.int/genomics/FullReport.pdf
[7] Timothy Caulfield, Gene Patents, Human Clones and Biotechnology Policy: The Challenges Created by Globalization, 41 Alta. L. Rev. 713, 718 (2003)
[8] '*Diamond v. Chakrabarty*' , 447 U.S. 303 (1980).
[9] Williams-Jones, supra note 4, at 125 ("The 1980 U.S. Supreme Court case of 'Diamond v. Chakrabarty' was a landmark decision, and significantly influenced Canadian and international patent law.")
[10] Association for Molecular Pathology v. U.S. Patent & Trademark Office, 669 F. Supp. 2d 365 (S.D.N.Y. 2009)
[11] Ibid

sequences as non-patentable and this judgement had serious effects on earlier granted patents in US. However, the court held that a gene patent application covering nucleic acid chemically different from naturally occurring still patentable. This case has once again drawn international attention to the question of validity of gene patents and like 'Diamond v.Chakrabarty' case,[12] would have significant effect on patent regimes in other nations. In Europe though the patent laws are almost similar with US patent laws however the position taken by European Union is that ii allows patents on isolated gene sequences when a function is identified for the sequence.[13] The European Patent Office invalidated one of Myriad's BRCA gene patents and it was reinstated only after the patent was amended.[14] But still the decision of the EPO has significantly narrowed the scope of gene patenting. In Australia the position is that isolated gene sequences may be patentable as long as it follows other statutory rules of patentability.[15] However the position taken by Australia also remained prone to number of challenges in the last decade and due to this fact, in 2002 the Attorney General Department asked Australian Reform Commission to examine the laws and practices relating to IPR especially the genetics materials with a focus on public health.[16] In a case named D'Arcy v. Myriad Genetics In.[2014] FCAFC , Australia's Federal Court upheld the validity of Myriad's gene patents and said that isolated gene sequence is a valid subject matter for patents.[17] The Court found that there are structural as well as functional differences in isolated genes and natural occurring gene e.g. without manipulation isolated DNA cannot code for a protein or polypeptide, this being a function that occurs naturally within the cell. However the High Court of Australia has accepted an appeal in the matter. In Canada, Myriad Genetics hold four patents in relation to BRCA1 and BRCA2 genes which reflect the position of Canada on gene patents. However Canada's approach of allowing gene patents is also not severed by the challenges, especially on the grounds of growing public health concerns. This is why the Ontario Ministry of Health signed on to a report urging the Canadian Patent Act to exclude broad based genetics patents and include strong public morality issues .[18] As there is diversity of patent regimes and research capacities of developing nations there is difficulty of clear approach towards the patentability of gene sequences in these nations. The developing nations like India, Brazil, China, in spite of having comparatively well-developed biotech industry, differ in their approaches to gene patents.[19] China does not allow patents on life forms but still allows patenting of genes.[20] Brazil on the other hand due to signing of Convention on Biological Diversity disallows genetic resources from patentability .But still its position is not extreme one and plays an important role in plant genetics. Similarly India's position on gene patents according to the Patent Act's provisions and the judicial

[12]447 U.S. 303 (1980

[13]European Patent Office, Guidelines for Examination available at< http://www.epo.org/law-practice/legal-texts/html/guidelines/htm>; see also European Patent Convention (EPC) R. 29.

[14]Myriad Wins European Patent Appeal on Cancer Test, Reuters <http://in.reuters.com/article/2008/11/20/myriad-patent>.

[15]Mead, supra note 32, at 757

[16]Australian Law Reform Commission (ALRC), Genes and Ingenuity: Gene Patenting and Human Health, ALRC Report, available at <http://ww.alrc.gov.au/publications/12-patents-andhuman-genetic-research/impact-gene -patents -research>.

[17]Jamelle Wells, Court Dismisses Second Appeal to Overturn Ruling on Corporate Human Gene Patenting, <https://au.news.yahoo.com/nsw/a/24906725/courtdismisses-second-appeal-to-overturn-ruling-on-corporate-human-gene-patenting>

[18]Williams-Jones, History of Gene patents :Tracing the Development and Commercial Application of BRCA Testing, supra note 4, at 143

[19]Genetics, Genomics and Patenting of DNA,(WHO Human Genetics Program 2005) supra note 27, at 24.

[20] Genetics, Genomics, and Patenting of DNA (WHO Human Genetics Program 2005) supra note 27, at 27.

interpretation is that it may allow patents on gene sequencing if it confirms to the provisions of patentable subject matter.

TRIPS Provisions and their applicability to Biotechnological Patents

The TRIPS Agreement was made to provide a minimum level of protection in the field of intellectualproperty rights to its member states.[21] Section 5 of the TRIPS Agreement provides that patent protection shall be given to those products and processes which are new, involve an inventive step and capable of industrial application.[22] Further Article 27(1) states that patent shall be granted for inventions in any field of technology without any discrimination subject to certain clauses .Though not directly, but it implies that even biotechnological inventions are a valid patentable subject matter.In case of gene patents ,the issue is whether genes which already exist in nature can said to be 'new' and whether they involve an 'inventive step' i.e. it should be non-obvious to the person skilled in art and finally the utility clause i.e. the invention has its industrial application. The novelty of a gene is determined on the facts that the applicant is able to prove that the said gene did not exist prior to the application and the applicant was first to isolate it, characterize it and define its utility .In many countries which are party to TRIPS Agreement, patents are allowed on genes which are purified and isolated from the natural form. The non-obviousness of the biotechnological inventions is determined on the fact that the said claim is not known to person having ordinary skill in art i.e. taking into account the state of knowledge in that field .The US Supreme Court in a case 'Graham v. John Deereco.'[23] mentioned four factors for determining the non-obviousness or inventiveness which are:

a) The scope and content of a prior art,
b) The difference between prior art and claimed invention,
c) The level of ordinary skill in art and
d) Other considerations like commercial success,unexpected results etc.

Further the utility or the industrial application of the invention requires that the invention is capable of being made or used in industry. Though Article 27 (3b) of the TRIPS Agreement allows member states to exclude living entities like plants animals from patentability yet isolated living organisms are the exceptions to the clause of non-patentable subject matter.[24]

Indian Patent Law on Biotechnological Patents:

India has amended its laws relating to patents three times in the last two decades to make Indian Patent Act's provisions comply with the TRIPS Agreement. These changes were made in the year 1999, 2002 and 2005. Indian Patent Act disallowed patents for inventions relating to living entities of natural or artificial origin, biological materials or other materials having replicating properties, substances derived from those materials and any processes involving production of living substances or entities including nucleic

[21] Agreement on Trade-Related Aspects of Intellectual Property Rights Art. 27 (1).
[22] TRIPS Agreement, supra note 2, art. 27 n.5 (providing the only language alternatives for patentability: "the terms 'inventive step' and 'capable of industrial application' may be deemed by a Member to be synonymous with the terms 'non-obvious' and 'useful' respectively")
[23] '*Graham v. John Deere'* 383 US 1 (1996)
[24] Agreement on Trade-Related Aspects of Intellectual Property Rights Art. 27(3).

acids till year 2002.[25] But patents for processes of producing nonliving substances by chemical processes, bioconversion, and microbiological processes were allowed .In year 2002 the amendments made to the Patent Act 1970 included biochemical, biotechnological and microbiological processes for the grant of patent.Moreover section 10 of the act was amended after joining Budapest Treaty on the International Recognition of the deposit of Microorganisms for purposes of Patent Procedure on 1st January 2001.[26] The Patent Act 1970 was further amended in year 2005 and set forth the provisions relating to grant of product patent in any field of technology including biotechnology with certain exceptions relating to public interest. The relevant provisions relating to grant of patent on biotechnological inventions according to the Indian Patent Act (Source Indian Patent (amendment) Act 2005 are :

Patentable Subject Matter:-

Section 2(1): products or processes that are newinvolving an inventive step and have industrial application are valid subject matter for patentability.

Non Patentable Subject Matter:-

Section 3 (b): inventions which are contrary to morality or which cause serious prejudice to human, animal or plant life or health or environment are not valid subject matter for patents.

Section 3 (c): discovery of any living thing or non-living substance occurring in nature is not patentable.

Section 3 (d): mere discovery of new form of known substance which does not result in enhancement of known efficacy or mere discovery of any new property or new use for a known substance is not patentable.

Section 3 (j): plants and animals in whole or any part thereof other than microorganisms, but including seeds, varieties and species, and essentially biological processes lack the criteria of patentability.

Patent Application Requirement:-

According to section 10 sub clauses 4 and 5, a patent application must require sufficiency of disclosure, method of performing the invention, clarity, unity of invention, succinctness and support of the claims.

Indian Judiciary on Biotechnological Inventions:

Whether biotechnological inventions are patentable, the question is not directly answered by the relevant provisions of the Indian Patent Act.This is why the judiciary's role is significant to interpret the relevant provisions of the Patent Act thereby giving place to biotechnological patents. In 2002, the judgment delivered by Honorable High Court of Calcutta in a case named 'Dominica AG v. Controller ofPatents and Designs'[27]

[25] 'Brief History of Patenting in India' Guidelines for examination of Biotechnological Patents by Office of Controller General of Patents and Designs of India (March 2013).
[26] Ibid

[27] *'Dimminaco AG v. Controller of Patents and Designs' [*AIR 2002 Calcutta High Court]

where it allowed patent for final product of the claimed process containing living microorganisms is significant in Indian Patent History. In this case a live vaccine protecting poultry against Bursitis infection was refused patent by the Controller of Patents and Designs on the ground that the vaccine involved processing of certain microbial substances and contained gene sequences. Further the Controller of Patent and Designs found that the claimed process was merely a natural process devoid of manufacturing activity. However the honorable court overturned this decision and held that a new and useful art or process and where its new product containing living organisms is a new article, the process leading to its manufacture is an invention. The court stated that as the word manufacture was not defined in the statute but still the dictionary meaning of the word could be accepted in respect to trade and business and especially when the end product is commercial entity. However no appeal was made to the highest court of the country i.e. the Supreme Court of India and as such the highest court is still expected to play a significant role on the issue in the near future.

Guidelines on Biotechnological Patents by Office of Controller General of Patents and Designs:

In India the Office of Controller General of Patents and Designs is the chief authority for grant of patents and designs.It is a statutory body established under the Patent Act.It is due to the fact of change in patent regimes that the Office of Controller General realized the need to enhance the scope of biotechnological patents and consequently issued guidelines specifically dealing with biotechnological patents.Some of the main guidelines relating to the determination of biotechnological patents are as (Source Guidelines for examination of Biotechnological Patents by Office of Controller General of Patents and Designs March 2013):

Prior Art Search:-

For conducting a prior art search the patent examiner is expected to design a comprehensive search strategy and it should involve patent database as well as non-patent database.[28]

Novelty:-

For ascertaining the novelty of the biotechnological inventions the requirement of prior art shall be clearly construed in accordance with section 13 of the act read with sections 29 to 34 of the Act and should be done in the same manner as for other inventions.[29]

Inventive Step:-

An invention shall be supposed to involve an inventive step if it is an advanced to existing knowledge has economic significance and non-obvious to person skilled in art.[30]

Industrial Application:-

[28] Part 6 'Prior Art Search' Ibid
[29] Part 7 'Novelty' Ibid
[30] Part 8 'Inventive Step' Ibid

The guideline says that the gene sequences or the encoded protein cannot be considered for patent until its commercial application, practical significance or usefulness is clearly laid down.[31]

Conclusion:

It is admitted fact that the patent system had benefitted a lot to the human society by encouraging creativity but how far patent on gene sequences remained successful in achieving its goals is debate able. As the development in the field of biotechnological patents has the ability of affecting the whole human society we need to decide collectively on the issue whether any individual, institution or corporation should have right of private ownership of life. A recent study by the University of Toronto's joint center for Bioethics stated that the genetic research such as gene diagnostic test, vaccine, or drugs have the potentiality to find effective solutions not only for the genetic disorders but also for the deadly diseases like cancer, AIDs, Tuberculosis, Malaria etc. It is due to this fact; the foundation of the Human Genome Project was laid down in the beginning of 21st century. The biotechnology promises to deliver a bright future for the developing nations like India, China to tackle the problems of infectious and parasitic deadly diseases; however the legal and ethical concerns of patenting gene need to be addressed amicably. India so far has remained successful in establishing equitable legal framework that allows access to research and therapeutic products and gene patenting is no exception.

Bibliography

BOOKS: Molecular structure of nucleic acids (Watson & Crick)

Australia Patent Law (Bodkin Colin)

WIPO Handbook on Intellectual Property

Mueller on Biotechnological Inventions

Statutes:Agreement on Trade-Related Aspects of Intellectual Property Rights Art. 27,

Indian Patent (amendment) Act 2005

Case Laws: 'Diamond v. Chakrabarty' , 447 U.S. 303 (1980)

'Association for Molecular Pathology v. U.S. Patent & Trademark Office,'669 F. Supp. 2d 365 (S.D.N.Y. 2009)

'D'Arcy v. Myriad Genetics In.' [2014] FCAFC

'Graham v. John Deere' 383 US 1 (1996)

'Dimminaco AG v. Controller of Patents and Designs' [AIR 2002 Calcutta High Court]

[31] Part 9 'Industrial Application' Ibid

Articles:Genetics, Genomics and Patenting of DNA (WHO Human Genetics Program 2005)

Patent harmonization in Biotechnology (Molly Jamison)

History of Gene patents: Tracing the Development and Commercial Application of BRCA (William Jones)

Guidelines for examination of Biotechnological Patents by Office of Controller General of Patents

European Patent Office, Guidelines for Examination of Patents relating to genetic material

Gene Patenting: Gauging Policy by an analysis of the Grants made by Indian Patent Office (Bhavishyani Ravi)

Patenting of Gene Invention (Malathi Lakshmikumaran)

Websites:<http://www.nature.com/dna50/watson>

<http://www.who.int/genomics/FullReport.pdf>

< http://www.epo.org/law-practice/legal-texts/html/guidelines/e/g_ii_4 2.html>

<http://in.reuters.com/article/2008/11/20/myriad patents>

<http://ww.alrc.gov.au/publications/12-patents-andhuman-genetic-research/impact-gene -patents