

Law of Intellectual Property and Bioinformatics

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Abstract- In this paper there is attempt to portray the law of intellectual property, its statutory framework, rights and liabilities of intellectual property holder with special reference to patentee and protection afforded by intellectual property to bioinformatics. There is also focus on nature of bioinformatics, scope and significance of bioinformatics and how the various components of bioinformatics relate to intellectual property protection, India's position on patent protection to bioinformatics and other branches of intellectual property rights. Whether intellectual property protection should be extended for bioinformatics.

I. INTRODUCTION

Intellectual property (IP) is an intangible right exercisable and asserted in respect of a material or tangible work¹. The term 'intellectual property' was used as a specific legal term in mid-nineteenth century. Random House Webster's Unabridged Dictionary contains this defined entry under 'Intellectual property' Law. Property that results from original creative thought, as patents, copyright material and trademarks (1840-45 Amer)². In the importance of intellectual property has increased because of international trading relations that emphasised during the negotiations that led to the successful conclusion of the GATT³ Uruguay Round on the world trading system⁴. The GATT TRIPS initiative that led eventually to the agreement on Trade Related Aspects of Intellectual Property Rights 1994 that was signed in Marrakesh⁵ was sparked off by a strong desire to eradicate international counterfeiting and piracy, but it became clear at very early stage that the cure against the fake Gucci or Cartier watch, Lactose shirts or even counterfeited fire extinguishing systems in jet engines, for passenger planes, or against what is often described as a plague threatening the worldwide exploitation of intellectual property, required also a harmonisation of national intellectual property laws. Intellectual property is a creative work of the human intellect, human

creativity and innovation⁶. The main idea of protecting IP is to encourage and reward creativity.

The law of intellectual property consists of following distinct branches and governed by the mentioned laws in India:-

Patents	Patents Act, 1970
Trademarks	Trade Marks Act, 1999
Copyright	Copyright Act, 1957
Geographical indications	Geographical Indications of Goods (Registration and Protection) Act, 1999
Industrial designs	Designs Act, 2000
Semi-Conductor chips and integrated circuits	Semiconductor Integrated Circuits Layout-Design Act, 2000
Plant Varieties	Protection of Plant Varieties and Farmers' Rights Act, 2001
Trade secrets	National Innovation Bill, 2008
Biotechnology	Biological Diversity Act, 2000
Bioinformatics	Patents, Copyrights, Trademarks, Trade secrets

There is special reference to Patent which is a monopoly right conferred to the inventor who invented a new product or process through his intellectual efforts which is capable of industrial application.⁷ Novelty, utility (industrial application), non-obviousness, inventive step, are the requirements to be satisfied to get a patent. On demonstration of inventive step and commercial significance patents are granted for twenty years to the inventor to use and exploit the patent.

Rights of Patentees⁸

The owner of the "Patent", i.e. patentee is entitled to deal with such property in the same manner as owner of any other moveable property.

- Patentee has exclusive right to prevent third parties from using his patented article.
- The patentee can sell the whole or part of his Patent.
- He can also grant license to other(s) to use the patented property.
- He can also assign such property to any other(s).

¹ V.J.Taraporevala, Senior Advocate, Law of Intellectual Property, Mumbai, December, 2005

² Second edition Page no.990

³ The General Agreements on Tariffs and Trade, basically the world free trading system which as a structure and organisation was succeeded by the WTO as a result of Uruguay round of trade negotiations.

⁴ Holyoak & Torremans, Intellectual Property Law, Oxford University Press, Fourth edition, 2005.

⁵ The final text of TRIPS was published in 1994 and administered by WTO, which succeeded to GATT.

⁶ Catherine Colstan, Principles of intellectual Property Law, Cavendish Publishing Limited, London, 1991, p.1

⁷ Sahil. K.Roy Chowdary and H.K.Shang, Law of trademarks, copyrights, patents and designs, Kamal Law House, Calcutta, 1999, Second edition, volume II, P.26

⁸ Article 48 of Patents Act, 1970.

Such sale, license or assignment of such patented property naturally has to be for valuable consideration, acceptable mutually.

II. PATENT SPECIFICATION

A patent specification is a document describing the technical details of the invention culminating with one or more sets of claims defining the monopoly sought by the patentee out of the invention. It is the heart and soul of a patent. The validity and monopoly conferred by the patent to the patentee depend on the specification which was filed and successfully prosecuted by the patentee and granted by the Patent Office. Specification is a technical as well as legal document (techno-legal document). It is technical in the sense that the complete specification of a patent provides a scientific explanation and technical workout of a particular invention. It also describes known arts in the field of invention and points out the drawbacks involved in such prior art technology. The specification is a legal document since the rights of patentee are specified in the claim part of the document and many terms incorporated in the document are subjected to legal interpretation⁹.

Every patent application shall be accompanied by a provisional or complete specification¹⁰. There are two kinds of specification:

- Provisional specification
- Complete specification.

The provisional specification describes the nature of invention or the process of involved in the proposed invention. The title of the invention in the provisional specification should give a fair indication of the art or subject to which the invention relates. The complete specification filed after filing provisional specification should substantially the same as that which is described in the provisional specification and it should be written in greater details and with clarity. If adequate drawings have been furnished to clearly illustrate the invention and as per rules 16 to 19 of the Indian Patents Rules, 1972 with the provisional specification, there is no need to repeat the same in complete specification. Parts of the complete specification include¹¹:

- Title of the invention
- Opening description of the invention
- Prior art description
- Objects of the invention
- Statement of the invention(optional)
- Detailed description of the invention
- Claims

Use of Patented invention by the Central Government¹²

The grant of patent confers the exclusive right of use on the patentee for commercial gain but the Act recognises that the Central Government may use any invention even without the payment of royalty to the inventor. The idea is that the invention can be put to use for general public benefit by the government in certain circumstances when the patentee would have to forego his commercial gain in the general public interest.

Some restricted use of patented invention permissible under the law

The essence of a patent is conferring of the exclusive right on the patentee. Yet some restricted use of a patented invention by a person other than the patentee is permissible under the law. For such instance, use of a patented invention is permissible for research or experimental purposes or for imparting knowledge or instructions to pupils¹³.

Infringement of the patent¹⁴

The right conferred by the Patent is the exclusive right to make, use, exercise, sell or distribute the invention in India. Infringement consists in the violation of any of these rights. The act expressly provides that use by a person other than the patentee, patentee's assignee or licensee would be an infringement of the patent and as such illegal. The recent case on the issue of patent is *Apple Inc. v. Samsung Electronics Co., Ltd*¹⁵ was the first of a series of ongoing [lawsuits](#) between [Apple Inc.](#) and [Samsung Electronics](#) regarding the design of [smart phones](#) and [tablet computers](#); between them, the companies made more than half of [smart phones](#) sold worldwide as of July 2012. In 2011, Apple began litigating against Samsung in [patent infringement](#) suits, while Apple and [Motorola Mobility](#) were already engaged in a [patent war](#) on several fronts. Apple's multinational litigation over technology [patents](#) became known as part of the [mobile device](#) patent wars: extensive litigation in fierce competition in the global market for consumer mobile communications. By August 2011, Apple and Samsung were litigating 19 ongoing cases in nine countries; by October, the legal disputes expanded to ten countries. By July 2012, the two companies were still embroiled in more than 50 lawsuits around the globe, with billions of dollars in damages claimed between them. While Apple won a ruling in its favour in the U.S., Samsung won rulings in South Korea and Japan, and the UK. Apple sued its component supplier Samsung, alleging in a 38-page federal [complaint](#) on April 15, 2011 in the [United States District Court for the Northern District of California](#) that several of Samsung's [Android](#) phones and tablets, including the [Nexus S](#), [Epic 4G](#), [Galaxy S 4G](#), and the [Samsung Galaxy Tab](#), infringed on Apple's intellectual property: its patents, [trademarks](#), [user interface](#) and [style](#). Apple's complaint included specific federal claims for patent infringement, [false](#)

⁹ Basic Principles and Acquisition of Intellectual Property Rights, Paper-I, Material for Post Graduate Diploma in Intellectual Property Rights Law, National Law School of India University, Bangalore, at p.44

¹⁰ Section 7(4) of Patents Act, 1970

¹¹ Supra note 9 at p.45

¹² Chapter XVII (section 99-103) of Patents Act, 1970

¹³ Meenu Paul, Intellectual Property Law, Allahabad Law Agency, Faridabad (Harayana), Fourth Edition 2012, p.272-277.

¹⁴ Chapter XVIII (section 104-115) of Patents Act, 1970

¹⁵ *C 11-1846 & C 12-0630*

[designation of origin](#), [unfair competition](#), and [trademark infringement](#), as well as state-level claims for unfair competition, common law trademark infringement, and [unjust enrichment](#). Apple's evidence submitted to the court included side-by-side image comparisons of [iPhone 3GS](#) and [i9000 Galaxy S](#) to illustrate the alleged similarities in packaging and icons for apps. However, the images were later found to have been tampered with in order to make the dimensions and features of the two different products seem more similar, and counsel for Samsung accused Apple of submitting misleading evidence to the court. Samsung [counter-sued](#) Apple on April 22, 2011, filing federal complaints in courts in [Seoul](#), [Tokyo](#) and [Mannheim](#), Germany, alleging Apple infringed Samsung's patents for mobile-communications technologies. Samsung also filed suits against Apple in the British [High Court of Justice](#), in the [United States District Court for the District of Delaware](#), and with the [United States International Trade Commission](#) (ITC) in Washington D.C., all in June 2011.

The ruling in the landmark patent case raised controversies over the impact on the consumers and the [Smartphone](#) industry. The jury's decision was criticized for being Apple-friendly possibly leading to increased costs for [Android](#) Smartphone users because of licensing fees to Apple. Some raised the question about lay juries in the U.S. patent system. i.e., how qualified the jury members were to determine who was at fault in a complex patent case. It later turned out that the jury foreman, Velvin Hogan, was an electrical engineer and a patent holder himself. His post-verdict interviews with numerous media outlets raised a great deal of controversies over his role as the jury foreman. He told the Bloomberg TV that his experience with patents had helped to guide the jurors' decisions in the trial. A juror Manuel Ilagan said in the interview with CNET a day after the verdict that "Hogan was jury foreman. He had experience. He owned patents himself...so he took us through his experience. After that it was easier." The jury instructions stated that jurors can make decisions based solely on the law as instructed and "not based on your understanding of the law based on your own cases." Hogan also told the Reuters that the jury wanted to make sure the message it sent was not just a slap on the wrist and wanted to make sure it was sufficiently high to be painful, but not unreasonable. His remark does not agree with the jury instructions, which state that "the damages award should put the patent holder in approximately the financial position it would have been in had the infringement not occurred" and "it is meant to compensate the patent holder and not to punish an infringer." Samsung has appealed claiming jury misconduct. If the appeal court finds the juror misconduct, Samsung can be given a new trial. Other questions were raised about the jury's quick decision. The jury had been given more than 700 questions including highly technical matters to reach the verdict and awarded Apple more than \$1 billion in damages after less than three days of deliberations. It was claimed that the nine jurors did not have a chance to read the jury instructions. A juror told in an interview with the CNET that the jury decided after the first day of deliberations that it believed Samsung was in the wrong

Remedy for infringement of patent: An action for infringement must be instituted by way of a suit in any District Court or a High Court having jurisdiction to entertain the suit.

The plaintiff on satisfying the court about infringement of his patent would be entitled to the following relief:

Interlocutory injunction:-The Plaintiff may at the commencement of the action move for an interim injunction to restrain the defendant from committing the acts complained of until the hearing of the action or further orders. The plaintiff should make out a prima facie case and also show that the balance of convenience lies in his favour.

Damages:-In assessing the damages the important question is what is the loss sustained by the patentee. The loss must be the natural and direct consequence of the defendant's acts. The object of damages is to compensate for loss or injury.

Accounts of profits:-Where a patentee claims the profits made by the unauthorised use of his patent, it is important to ascertain how much of his invention was appropriated, in order to determine what proportion of the net profits realised by the infringer was attributable to its use.

III. NATURE OF BIOINFORMATICS

Bioinformatics is the convergence of analytical and computational tools with the discipline of biological research. This has vast influence in biological research as numerous data that are collected through laboratory experiments can be organized, analyzed, or prediction made to reduce the time spent in finding cures to diseases or causes of diseases, biological or other healthcare-related applications¹⁶.

Bioinformatics is the application of computer technology to the management of biological information. Computers are used to gather, store, analyze and integrate biological and genetic information which can then be applied to gene-based drug discovery and development. The need for Bioinformatics capabilities has been precipitated by the explosion of publicly available genomic information resulting from the Human Genome Project. The goal of this project is to determine the sequence of the entire human genome (approximately three billion base pairs). The science of Bioinformatics, which is the melding of molecular biology with computer science, is essential to the use of genomic information in understanding human diseases and in the identification of new molecular targets for drug discovery. In recognition of this, many universities, government institutions and pharmaceutical firms have formed bioinformatics groups, consisting of computational biologists and bioinformatics computer scientists. Such groups will be key to unravelling the mass of information generated by large scale sequencing efforts underway in laboratories around the world¹⁷.

IV. SCOPE AND SIGNIFICANCE OF BIOINFORMATICS

Bioinformatics involve the design and implementation of programs and systems for the storage, management and analysis of vast amounts of DNA sequence data. Such positions require

¹⁶ Dennis Fernandez & Mary Chow, Fernandez & Associates LLP, www.iploft.com Intellectual Property Strategy in Bioinformatics and Biochips.

¹⁷ <http://www.bioplanet.com/whatis.html> last visited on 30-10-2012.

in-depth programming and relational database skills, which very few biologists possess, and so it is largely the computational specialists who are filling these roles. As the bioinformatics field matures there will be a huge demand for outreach to the biological community to separate through gigabases of genomic sequence in search of novel targets. It will be in these areas that biologists with the necessary computational skills will find their position¹⁸. The worldwide bioinformatics value has touched \$ 3.0 billion in 2010, at an average annual growth rate (AAGR) of 15.8%. The application of bioinformatics in drug development is expected to reduce the annual cost of developing new drugs by 33% and time for drug discovery by 30%¹⁹. The pharmaceutical companies are expected to increase their R&D expenditures in the future and a major portion of this is expected to go into Bioinformatics²⁰. Though the IPR laws enforced strictly on territorial basis of countries which offers protection through patents, copyrights, trademarks and trade secrets to invention or creative work, the information technology makes it available throughout the world. As a result, cross-country differences in patent, copyright and other IP laws can result in inadequate protection.

V. BIOINFORMATIC COMPONENTS

Before one can understand intellectual property protection for bioinformatics, it is necessary to understand the nature of the various components that comprise the field of bioinformatics. Bioinformatics involves the acquisition, organization, storage, analysis, and visualization of information contained within biological molecules²¹. To be a patentable subject matter an invention should be a process, machine, manufacture, or composition of matter or any improvement²². Bioinformatics is analyzed according to the following categories:

- (A) Biological sequences such as DNA, RNA, and protein sequences,
- (B) Databases in which these sequences are organized, and
- (C) Software and hardware designed to create, access, organize, and analyze information contained within these sequences and databases.

¹⁸ <http://biinoida.blogspot.in/2007/12/scope-and-needs-of-bioinformatics.html> last visited on 07-11-2012.

¹⁹ Edited by Dr. Sreenivasulu, Chapter by Mr. Sriramamurthy Boppana, Intellectual Property Rights, Regal publications, New Delhi, Second revised and enlarged edition, 2011, p. 268

²⁰ Business Communication Company, Inc. Report.

²¹ M. Scott McBride, Bioinformatics and Intellectual Property Protection

²² Dr. Kalyan C Kankanala, Gentic Patent Law and Strategy, Manupatra, Noida, U.P., First Publication 2007.

Patentability of gene-related subject matter in India, USA, and Europe²³

Subject Matter	India	USA	Country EPC
Genes	Patentable	Patentable	Patentable
Genetically modified Unicellular Organism	patentable	Patentable	Patentable
Genetically modified Multicellular Organism	Not Patentable	Patentable	Patentable
Genetically modified Animals(Excluding Humans)	Not Patentable	Patentable	Patentable (Expect mammals)
Genetically modified Plants			Patentable
Genetically modified Humans	Not Patentable	Patentable	Not Patentable
Gene Therapy	Not Patentable	Not Patentable	Not Patentable but enforceable
	Not Patentable	Patentable	

²³ Ibid at p.27

VI. INTELLECTUAL PROPERTY PROTECTION FOR BIOINFORMATICS

Patents: Companies and entrepreneurs can obtain a legal monopoly to protect their technology from being manufactured and sold by competitors, thus making patents an important incentive for technology development and innovation. In U.S the following types of patent exist: utility patent, plant patent, and design patent. Of those the utility patent is commonly associated with bioinformatics inventions and can be obtained for new and useful, non-obvious process, machine, manufacture, composition of matter, or new and useful improvement of any of the aforementioned.

Trademarks: It can be used to protect trade names, product names, domain names, and service marks/slogans for bioinformatics companies.

Copyrights: It can be used to protect bioinformatics related materials such as scientific articles, books, software code, manuals, web pages, graphic artwork, multimedia works, and compilations of facts/databases.

Trade secrets: It is used to protect bioinformatics related materials such as software code, manuals, and compilations of facts/databases, formulas and processes²⁴.

VII. INTELLECTUAL PROPERTY AND BIOINFORMATICS-INTERFACE

Intellectual property protection is the key factor for economic growth and advancement in the bioinformatics and biotech sectors. The patents add value to the laboratory discoveries, computer coding and in doing so provide incentives for private sector investment into bioinformatics and biotech sectors and for their development.²⁵ Intellectual property laws are the driving force for innovation and progress in the contemporary society. Different forms of IP such as patents, copyrights, trademarks, trade secrets, can be used to protect the products of invention and innovation. Patents provides for development of new products, improvement over the existing product, employment opportunity for people around the world. There was no application of IP in biotechnology until the landmark decision in *Diamond v/s Chakrabarty*²⁶ by the United States Supreme Court where the court held that anything made by hand of man as eligible for patenting.

In 1972, respondent Chakrabarty, a microbiologist, filed a patent application, assigned to the General Electric Company. The application asserted 36 claims related to Chakrabarty's invention of "a bacterium from the genus *Pseudomonas* containing therein at least two stable energy-generating plasmids, each of said plasmids providing a separate hydrocarbon degradative pathway. This human-made, genetically engineered bacterium is capable of breaking down multiple components of crude oil. Because of this property, which is possessed by no

naturally occurring bacteria, Chakrabarty's invention is believed to have significant value for the treatment of oil spills.

Chakrabarty's patent claims were of three types: first, process claims for the method of producing the bacteria; second, claims for an inoculum comprised of a carrier material floating on water, such as straw, and the new bacteria; and third, claims to the bacteria themselves. The patent examiner allowed the claims falling into the first two categories, but rejected claims for the bacteria. His decision rested on two grounds: (1) that microorganisms are "products of nature," and (2) that as living things they are not patentable subject matter under 35 U. S. C. §101. Chakrabarty appealed the rejection of these claims to the Patent Office Board of Appeals, and the Board affirmed the Examiner on the second ground. Relying on the legislative history of the 1930 Plant Patent Act, in which Congress extended patent protection to certain asexually reproduced plants, the Board concluded that §101 was not intended to cover living things such as these laboratory created microorganisms.

Bioinformatics is the science of storing, managing and analyzing biological data using computational tools. It uses multiple and diverse disciplines of Mathematics, Statistics, Biology, Chemistry, Computer Mathematics and Physical Sciences, etc. Bioinformatics within a short time by means of computational tools has us to understand the function and structure of genes and proteins. The recent technologies includes Genomics, Proteomics, Antisense Technology, RNA Inference, Stem and Progenitor Cells, Cell and Gene Therapy, Phramacogenomics²⁷

VIII. CONCLUSION

Bioinformatics comprises a wide array of components, and it follows that a wide array of protection might be available, depending on the particular nature of the bioinformatics component and its intended use such as from patent, copyright, trademark, trade secret protection. Because of the tremendous growth and investment in the field of bioinformatics, it is important to consider whether IP protection is available to offset the cost of development and create new efficiencies.

With regard to bioinformatics software, the inventor can obtain patent protection on the method within the program, provided the method produces tangible results; and the author can obtain copyright protection, but only for the literal elements of the bioinformatics software code. Although trade secret protection is available for bioinformatics software, again, like many bioinformatics components, the owner runs the risk that the code will be reverse engineered and the trade secret will be lost to the public domain. With regard to biological sequences, trade secret protection may be the only practical protection. This holds best where the owner effectively maintains confidentiality agreements or does not intend to commercialize the corresponding biological composition, because sequences can be easily determined or "reverse engineered" where compositions are available. Likewise, trade secret protection may provide the

²⁴ Supra note.19 at p.270

²⁵ Supra note 19 at p. 263

²⁶ 443 U.S.303 (1980)

²⁷ Philip W. Grubb, *Patents for Chemicals, Pharmaceuticals and Biotechnology*, Oxford University Press, Fourth Edition 2004, First Indian Edition 2006 p.265-268.

best protection for biological databases, but only if adequate security measures can reliably limit access and the owner effectively maintains confidentiality agreements. Copyright protection for databases is minimal and is unlikely to extend to the information contained within the database.

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