INTELLECTUAL PROPERTY RIGHTS IN BIOINFORMATICS

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Abstract

Intellectual property protection is perhaps one of the key factors for economic growth and advancement in the bioinformatics and biotech sectors. In particular, patents add value to laboratory discoveries, computer coding and in doing so, provides incentives for private sector investment into these sectors. These sectors advocate a strong and effective global intellectual property system.

Bioinformatics is a new field of science that marks amalgamation of life sciences which marks one of the oldest areas of research and deliberation in human civilisations and information technology which is one of the latest and still developing areas. This paper is basically aims to study the field of bioinformatics and application of intellectual property rights to this area.

Keywords: Intellectual Property Rights, Bioinformatics, Genome, Databases, Algorithms

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INTRODUCTION

The bioinformatics industries, as we know, did not exist prior to the landmark decision of Supreme Court in the case of *Diamond, Commissioner of Patents and Trademarks* v. *Chakrabarty*[1] where the Court held that anything made by the hands of man is eligible for patenting. Since this decision, this industry has flourished and continued to grow.

As per the facts of the case, Genetic engineer Ananda Mohan Chakrabarty, working for General Electric, had developed a bacterium capable of breaking down crude oil. A patent application for the said bacterium was filed in the United States listing Chakrabarty as the inventor, but the application was rejected by a patent examiner, because under patent law at that time it was generally understood that living things were not patentable subject matter under Section 101 of Title 35 U.S.C.

The Board of Patent Appeals and Interferences agreed with the original decision; however, the United States Court of Customs and Patent Appeals overturned the case in Chakrabarty's favour. Sidney A. Diamond, Commissioner of Patents and Trademarks, appealed to the Supreme Court. The patent was finally granted by the USPTO on Mar 31, 1981.

The Court emphasised that the patent system should be read broadly to encompass patent regime that would also cover living things.

Hence it is evident that strong intellectual property protection is essential to the success, and in some instances, to the survival of the biotechnology companies. For these companies, the patent system serves to encourage development of new medicines and diagnostics for treatment and monitoring of intractable diseases, and agricultural and environmental products to meet global needs.

The main objective of Bioinformatics is mainly three fold.[2]

- Firstly it organises the data in a way that helps the researchers to access existing information and put it in new entries as they produce.
- Secondly, it helps in developing the tools for the analysis of data.
- Thirdly, to use these tools to analyse the data and interpret the results in biologically meaningful manner.

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

[1] 447U.S.303(1980)

[2] Mcentyre J.and Ostell J. (2005), The NCBI Handbook, Bethseda (MD): National Library of Medicine

healthcare-related applications[3]. 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 world[4].

SIGNIFICANCE AND SCOPE OF BIOINFORMATICS

Bioinformatics involves technologies that can be used to gather, store, analyse and integrate biological and genetic information that can be applied to gene-based drug discovery and development. The science of bioinformatics is essential to the use of genomic information in understanding human diseases and in the identification of new molecular targets for drug discovery. For example, researchers can use bioinformatics tools 'to identify similarity between one gene sequence for which the function is known and another gene sequence for which the function is being investigated. Bioinformatics holds great potential for education, personalised medicine and health care and has increasingly become a competitive business model. With the emergence of bioinformatics and development of genomic databases, an increasing number of companies have gained possession of extensive collections of sequence information and data organised in database formats. The potential commercial value of these data has inspired these companies to effectively protect and leverage them through intellectual property protection.[5]

As more and more DNA, RNA and protein sequences are reported; scientists are developing biological databases to catalogue and store the sequence information. These databases are important if the stored information can be readily searched and analyzed. For example, scientists can use these databases to compare and assign biological functions to particular and characteristics functions. Then, when a scientist obtains a sequence from an unknown DNA, RNA or protein molecule, the scientists can use these databases to identify the unknown molecule and determine its function. Although several databases are available to general public, private companies are not required to make their databases freely

[3] Dennis Fernandez & Mary Chow, Fernandez & Associates LLP, Intellectual Property Strategy in Bioinformatics and Biochips

[4] http://www.bioplanet.com/whatis.html

[5] Singh K.K, Intellectual Property Protection in Bioinformatics and open Bio development

available. For instance, one company working on sequencing the human genome[6], Celera, generally charges for its access to the database, although it provides free access to "qualified academic users".

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 molecules[7]. To be a patentable subject matter an invention should be a process, machine, manufacture, or composition of matter or any improvement[8]. 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.

BIOINFORMATICS IN INDIA

Studies have found that India will be a great potential star in biotechnology keeping in mind the factors like biodiversity, human resources, infrastructure facilities and government initiatives.

Bioinformatics has emerged out of the inputs from several different areas such as biology, biochemistry, molecular biology, biostatics and information technology. Specially designed algorithms and organized databases is the core of all informatics system. The requirements for such an activity make heavy and high demands on both the hardware and software capabilities. This sector is the quickest growing field in the country. The vertical growth is because of the linkages between IT and biotechnology, spurred by Human Genome Project. There has already been many start ups in Hyderabad, Bangalore, Pune etc.[9]

INTELLECTUAL PROPERTY AND BIOINFORMATICS INTERFACE: CASE STUDY

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. 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

[6] Meyers T, Patenting and Financing Bioinformatics Inventions
[7] McBride MS, Bioinformatics and Intellectual Property Protection
[8] Kankanala KC, Gentic Patent Law and Strategy, Manupatra (2007)
[9] Naik S, Bioinformatics And Intellectual Property Rights (2014)

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. *Chakrabarty* 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 inoculums 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 include Genomics, Proteomics, Antisense Technology, RNA Inference, Stem and Progenitor Cells, Cell and Gene Therapy, Phramacogenomics.[10]

USE OF IPR IN DIFFERENT STAGES OF RESEARCH

IPR and their use play a vital role in different stages of research and development. In fact the result of research would lead to intellectual property rights which are part of the development of the research. It is felt and recommended that IPR should be considered in a bioinformatics research while:[11]

- Defining a research project

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

[11] Sreenivasulu N.S, Intellectual Property Rights in Corporate World, Edn. 2011

- Arranging collaborations or outsourcing of research
- Performing the research
- Protecting and disseminating the research result
- Transforming the research results to marketable products

BIOINFORMATICS: IS THERE A NEED TO PROTECT IT UNDER IPR REGIME

The employment of these new technologies has led to advances in basic biological processes and, in turn, advances in diagnosis treatment and prevention of many genetic diseases. The possibility of discovery of drugs and cured based on genetic studies that may have the potential to treat diseases has meant investment in huge amounts in the research and development of bioinformatics tools.

It is natural to expect some form of legal framework for protection of the innovations in terms of new bioinformatics tool, which would ensure a return on the investment secured from marauding interests. This is the argument for the application of IPR to the field of bioinformatics, at the most basic level. Thus to put it in the words of Abraham Lincon,

"*The patent system added the fuel of interest to the fire of the genius*."

IPR are seen as catalyst of scientific, technological and economic development. In terms of grant of patent to an innovation, the creation and grant of exclusive and legally enforceable rights ensure that the innovator is awarded. These rights also vest the innovator to market his produce and exclusivity gives him a natural market advantage. Thus the patent system ensures that the innovator has the opportunity to gain revenue at the level of basic marketing and selling of the product, the profit of which can possibly be accrued thorough the market advantage.

This framework of exclusive rights of exploitation coupled with economic gain acts as a motivator to the innovator and others to further innovate. This is the fundamental argument for the perpetuation of IPR. This argument extends to any kind of innovation in the area of research and therefore can be extended to the area of bioinformatics. Technology in bioinformatics consists mostly of programmes and software which would aid in the compilations and updating of extensive databases of information. Seen in this light, there is no reason, whatsoever, to not extend the protection accorded by IPR regime to the field of bioinformatics. The protection of innovation would incentivise further innovations, which would aid the pharmaceutical industry further in its pursuit to discover new cures for diseases.

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 processes.

CLAIMABLE ASPECTS OF BIOINFORMATICS INVENTIONS

Patents can be obtained for such bioinformatics areas as:

The computational and analytical aspects of genomics and proteomics which includes

- Algorithms,
- Sequence analysis techniques,
- Mapping techniques,
- Comparison techniques,
- Primer design,
- Phylogenetic analysis,
- Molecular modeling,
- Protein structure prediction
- Protein function prediction,
- Databases (for example, construction, querying and data mining),
- Biological integrated circuits, micro arrays, and image analysis

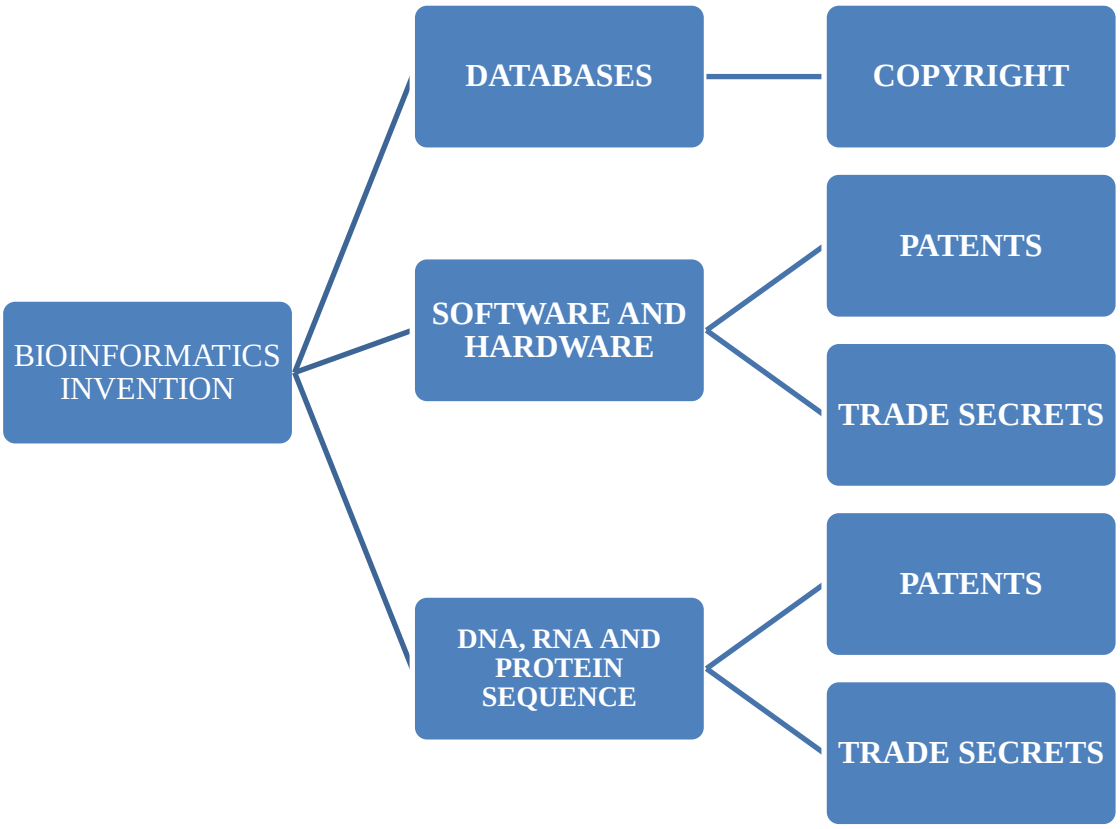
ISSUES IN THE PROTECTION OF BIOINFORMATICS

There are various intellectual property rights issues in bioinformatics field. Since these fields are considered to be fusion between the fields of biotechnology, chemical sciences and information technology, there is a growing significance of these fields. The following are the key issues involved and be considered in the intellectual property protection:

- Internet collaboration
- Types of IPR in bioinformatics

- Revenue from databases
- Employees and ownership
- Database ownership
- Access to databases

BIOINFORMATICS IN THE WORLD OF INTELLECTUAL PROPERTY RIGHTS



ARGUMENTS AGAINST IPR PROTECTION TO BIOINFORMATICS

There have been objections raised against the extension of IPR protection to the field of informatics on the ground that the protection would act to enclose the commons in the very ethically sensitive realm of human genome and gene related studies. The introduction of profit motive in this field of study would tie up ethical balance in an unfavourable manner. The realm of human genomic science should be common and assessable to all humanity and should not be truncated and severed and owned absolutely by a few individuals by virtue of being the first claimants.[12] This strain of argument is further developed wherein it is contended that the main motive behind innovations in bioinformatics is to further medical treatment and rule against patenting of other medical procedure should also apply here.[13]

[12] Gopalan R, Bioinformatics: Scope of Intellectual Property Protection, *Journal of Intellectual Property Rights*
[13] McBride MS, Bioinformatics and Intellectual Property Protection, *Berkley Technology Law Journal*

Given the complex nature of bioinformatics, it is difficult to offer best form of IP protection. The form of IP protection to bioinformatics depends upon the technology used such as algorithms, databases, software, etc. There is enormous confusion as to the viability of a particular form of the IP protection such as patent, copyrights and trade secrets in protecting bioinformatics databases or software as all forms of IP protection have certain inherent limitations.[14]

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 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.

[14] Singh K.K, Intellectual Property Protection in Bioinformatics and open Bio development