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INTELLECTUAL PROPERTY STRATEGY IN BIOINFORMATICS AND BIOCHIPS

Dennis Fernandez and Mary Chow

I. INTRODUCTION

What are the fields of bioinformatics and biochips? These are relatively new disciplines that have gained much recognition in the past few years. Basically, 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 and analyzed, and predictions can be made to reduce the time spent in finding cures for the causes and cures of diseases. Additionally, biochips pertain to primarily semiconductor-based devices used for biological or other healthcare-related applications.

The amount of data collected in biological research is tremendous especially in the area of genomics. On June 26, 2000, a group of scientists announced the completed survey of the human genome—the sum total of all the genes in each cell of the human body.¹ The genome is the entire genetic blueprint for a human being written in the alphabet of chemical compounds called nucleotides: adenine (A), guanine (G), cytosine (C), and thiamine (T).² A gene is the specific sequence of the nucleotides that tells the body how to create proteins that maintain cellular structure of the organism and direct the functions of the cell.³ The human cell has some 100,000 genes that are specific sequences of DNA and the sum total of all units of nucleotides results in a mind-boggling 3.1 to 3.2 billion base pairs in the human genome.⁴ However, only 3%–5% of the genome contains genes, which in turn produce four to five proteins. These few protein molecules control all of life's major functions.⁵ Thus,

1. Stephen A. O'Neil, *Mapping the Human Genome*, HILLARDS LYONS EQUITY, Aug. 21, 2000.

2. *Id.*

3. *Id.*

4. *Id.*

5. Stephan Herrera, *Patent Panic*, RED HERRING, July 2000, at 208.

computational technology is required in the sequencing of the database, the studying of the functions of the specific sequence (gene), and the management and dissemination of the genetic information.

With the potential pay-off of finding a blockbuster drug or treatment, a copious amount of funding, both private and public, has gone into the development of bioinformatic tools as well as related biochip applications in the genomic space. With all the money going into these bioinformatic and biochip companies, these companies need to protect their technology. In 1999 alone, for example, 289,448 patent applications were filed in the bioinformatic field and the United States Patent and Trademark Office (USPTO) has created working groups to deal with the influx of bioinformatic applications.⁶ Although patents in these areas have increased and provided an avenue to protect one's intellectual property in this discipline, controversy surrounds the patenting of various technologies in the field. For one, the thought of allowing a company to patent and have a monopoly over a gene sequence that has been around since the beginning of life is quite disturbing. On the other hand, the discovering and developing of a new gene-based pharmaceutical product in the United States requires years of commitment and immense capital resources, possibly in the realm of \$500 million.⁷ Without the protection of the patent system, these companies would have no means of recouping these capital and time investments, and innovation would be put to a halt.⁸

II. INTELLECTUAL PROPERTY PROTECTION IN GENOMIC DISCIPLINE

Within the genomic discipline, companies and research can be divided into three areas: 1) sequencing the genome, 2) functional genomics, which is finding the functions of the genes, and 3) information systems, which is the software tools that manage and present the tremendous amount of data. Additionally, various biochips technologies, such as micro-arrays, are deployed in cooperation with such genomic tools. For each area, different technology is generated and thus, a different intellectual property strategy should be deployed. Often, companies participate in one or

6. Margaret M. Parr, *Patenting Bioinformatics Inventions, The USPTO Comes to the Silicon Valley Slide Presentation* (April 11, 2000).

7. William A. Haseltine, *The Case for Gene Patents*, *MIT TECH. REV.*, Sept.-Oct. 2000, at 59.

8. *Id.*

more of the areas and should pursue a joint strategy.

A. Sequencing the Genome

With the hype surrounding the completion of the Human Genome Project, new technology has been developed for decoding DNA that provided for the rapid discovery of gene fragments known as expressed-sequence tags (ESTs).⁹ Companies such as Incyte Genomics and Celera have generated large databases of expressed sequence (EST) data and have aggressively filed patents on these ESTs. For example, Human Genome Sciences holds patents on 103 human genes and has patents pending on 7,500 genes.¹⁰ Incyte Genomics tops the list with some 400 patented genes, while Celera, which only began decoding DNA last year, has already filed patent claims on at least 6,500 gene sequences.¹¹

To fall within patent protection, an invention must be deemed novel, useful and non-obvious.¹² Often the biological function of these DNA sequences are unknown and companies have tried to fulfill the useful criteria by proposing generic and often frivolous uses, such as forensic probes and sometimes even cattle feed.¹³ Currently, Incyte and similar companies have filed thousands of provisional patent applications with the USPTO for ESTs in hopes that they will someday be able to find the "usefulness" of the sequence.¹⁴ Numerous opponents of these tactics have argued that patent rights should be reserved for whomever uncovers the true biological function of a complete gene.¹⁵ The USPTO is currently developing guidelines that require examiners to reject patents that don't describe a "specific, substantial and credible" use for a DNA sequence.¹⁶ Thus, many experts predict that most of these EST patents would eventually not receive patent protection.¹⁷

To combat the high risk that their patent applications would not be allowed, companies in this area can pursue various strategic options. One of which is to challenge the examiner's rejection by an appeal to the PTO board of appeals. However, if the appeal process is

9. Antonio Regalado, *The Great Gene Grab*, MIT TECH. REV., Sept.-Oct. 2000, at 48.

10. *Id.*

11. *Id.*

12. 35 U.S.C. §§ 101-103.

13. Regalado, *supra* note 9, at 53.

14. Herrera, *supra* note 5, at 210.

15. *Id.*

16. *Id.*

17. *Id.*

not successful, the case can be taken to the Court of Appeals for the Federal Circuit, where the new "usefulness" standard has not been tested.¹⁸ Currently, "usefulness" is defined as something "beneficial in contrast to injurious to the morals, health, or good order of society."¹⁹ Thus, the Federal Circuit would need to justify the requirement of the newly proposed "specific, substantial and credible usefulness standard."²⁰

Another strategic move would be to fortify an application by performing homology studies on the gene sequence in the patent. Homology refers to the establishment of a relationship or common thread between the novel gene sequence in the patent to another gene that has already been discovered, but not patented.²¹ For example, a claim that gene XYZ is related to ABC, which has a known function, thus, making the argument that gene XYZ performs a related function to gene ABC's function. The standard upon which the USPTO relies on is that an expert in the field would agree that the common thread is strong.²² However, as our understanding of genes increases, the existing definition of what is related is constantly shifting and various patents may be invalidated based on these shifts.²³

Another tactic would be to conduct several functional assays in order to better determine gene sequence function. The inventor can submit a declaration on sequences behavior asserting that he or she has a strong notion that the sequence is more likely than not to have some function.²⁴ Even if a DNA discovery claims to encode a protein involved in cancer but later on turns out to be involved in another disease, the courts would allow the new usage and the invention is protected.²⁵ For example, Viagra was originally patented as a heart remedy.²⁶

The most conservative approach would be to go back to the laboratory and perform analysis until the inventor found a definitive function. However, when you do find the function, the genetic sequence probably would have been published already and you will be too late in the game to claim the use of the genetic sequence.

18. *Id.*

19. Herrera, *supra* note 5, at 210.

20. *Id.*

21. *Id.*

22. *Id.*

23. *Id.*

24. *Id.*

25. Herrera, *supra* note 5, at 210.

26. *Id.*

With the controversy surrounding the patenting of just the sequences, companies in this area should explore protecting intellectual property surrounding the tools to sequence the genes and the tools to analyze the genetic data. Patents in this category generally cover computer-implemented methods, computer-based systems, and computer programs for analyzing and annotating voluminous nucleotide sequences.²⁷ For example, protecting a company's proprietary method of locating boundaries between exons and introns would create value in licensing revenue and also, more importantly, the protected intellectual property can be used as bargaining chips in a cross-licensing of another company's technology.²⁸ Many of these analytic tools are embodied in software and thus would get automatic protection from copyright protection for its source code. However, patent protection is a better venue as the functionality of the invention is protected versus the literal source code. For example, if a company obtained a patent for its method of locating boundaries between exons and introns, one who practices one of the steps covered in its patent claims would be an infringer even if a different source code is utilized.²⁹ Under copyright protection, the infringer would need to use the exact source code to infringe.

B. Functional Genomics and Biochips

After acquisition of specific sequences, the functionality of these sequences need to be determined to generate value in creating targets for new drugs and new genetic therapy treatments. Many players compete in this area using bioinformatics and biochip tools, as the monetary and emotional pay-off is tremendous if one is able to be the first to find a cure to a certain disease.

Once again the importance of computational power is put into play as computational methodologies are deployed in comparative genomic,³⁰ the comparing of human genetic data to other organism genomes, which have functions that have been defined. Patent protection would be invaluable in protecting methods and related biosensors for sequence alignments, homology searches, and metabolic pathway modeling.³¹ Protecting these fundamental

27. Wong et al., *Genomics-Based Intellectual Property Portfolios*, MORRISON & FOERSTER, LLP, October 14, 1999, at 3.

28. *Id.*

29. *Id.*

30. Wong, *supra* note 27, at 3.

31. *Id.* at 5.

methods and devices would create more value than patenting a specific software product, as intense competition in this area would create shorter and shorter product life cycles.

Genes do not work in isolation. Finding the pattern of gene expression is another great area of interest that requires computational power. Biochip companies, such as Affymetrix and Hyseq, are engaged in developing assays, tools, and computational techniques for detecting, monitoring, and interpreting gene expression profiles.³² For example, a microarray, a collection of short sequences of nucleotide synthesized to hybridize with the genes of interest, are placed in a grid on a glass slide or chip and exposed to a sample of unknown DNA.³³ A fluorescent “signaling” enzyme is attached to the end of the probe that glows when the probe hybridizes with the gene of interest.³⁴ Affymetrix, which pioneered the concept of DNA microarrays based on computer chip technology, can fit 250,000 probes in a matrix only 1 square centimeter in size.³⁵ With an estimated 100,000 genes in the human body, a “universal” microarray is within reach. Incyte Genomics has announced that its Synteni division has intends to make a chip containing the entire human genome in the next few years.³⁶

To protect their intellectual property, companies in this area need to seek patent protection covering the core technology of these devices and methods. However, an even more valuable claim would be to protect the generation of expression data utilizing these methods and devices. In addition, since the design of the microarrays mirrors chip design technology, another method of protection to explore would be maskwork protection. In chip technology, when the chip layout includes an original circuit design, the layout is protectable.³⁷ Specifically, maskworks protect against the unauthorized copying of chip layout information.³⁸ Federal registration is relatively quick and an inexpensive process, but filing must be done within two years of commercialization of the chip product.³⁹ Thus, it is arguable that the

32. *Id.* at 3.

33. CYNTHIA ROBBINS-ROTH, FROM ALCHEMY TO IPO: THE BUSINESS OF BIOTECHNOLOGY 74 (2001).

34. *Id.*

35. *Id.* at 76.

36. ROBBINS-ROTH, *supra* note 33, at 76.

37. Mary Chow & Dennis Fernandez, *Intellectual Property Rights in Bioinformatics*, FERNANDEZ & ASSOCIATES LLP, 1999, at 2.

38. *Id.*

39. *Id.*

layout of the probes for a microarray can avail itself with maskwork protection.

C. *Information Systems and Bioinformatics*

As more information is generated from sequencing tools and functional analysis tools, the managing and sharing of the information becomes increasingly important. The ability to share, manage, and distribute the information is extremely important in this space because ethical issues create an environment that fosters sharing of the information and suppresses the patenting of the information. Already there are advocates who call for an intellectual property free zone for genomic research, a moratorium on gene patenting, and a compulsory licensing scheme.⁴⁰ In March 2000, President Clinton and Prime Minister Blair made a joint announcement that human genome research "should be made available to scientists everywhere."⁴¹ Thus, a company should not concentrate all its intellectual property protection on the information, the genetic sequence, but instead should try to create value in the analytic tools and the management of the information.

Bioinformatics companies, such as Incyte Genomics, Celera, and CuraGen, are developing Internet tools to allow researchers to share the genetic information in their databases. Also, these companies are providing researchers various tools to analyze the data, present the data, and store their research results. This revolution toward content delivery and presentation can be compared to the Internet revolution where content is free but the added value is the presentation. Thus, there is a "silent gold rush in the genomic space" that mirrors the rush to file Internet business method patents, such as Amazon's "one-click" method.⁴² Numerous companies are filing patents to stake out methods for sharing and manipulating the enormous quantity of genetic data being put online. For example, one application claims the idea of using a reward system to compensate scientists with free purchase for posting information and comments to a private gene database.⁴³ However, patenting business methods would bring about the same controversy that surrounds the current Internet patents as opponents are arguing that these methods of manipulating research

40. Seth Shulman, *Toward Sharing the Genome*, MIT TECH. REV., Sept.-Oct. 2000, at 60-67.

41. *Id.*

42. Regalado, *supra* note 9, at 51.

43. *Id.*

data online have been utilized in the research space for a number of years.⁴⁴ Thus, a patent portfolio should include protection of the enabling tools as well as protection of the business methods.

III. CONCLUSION

In its intellectual property portfolio, all companies should aggressively protect their core technology in numerous facets such as patent protection, copyright, trademarks, maskworks for chip design, and trade secrets. This is extremely important in the bioinformatics and biochips arena as ethical issues create an environment against the patenting of genetic sequence data. In addition to a defensive strategy of defending its core technology, companies should also pursue an offensive strategy that includes analyzing emerging standards and competitor focus so that companies could acquire a competitive advantage or entice a cross-licensing of another's technology.

44. Regalado, *supra* note 9, at 51.