Chapter 16
Intellectual Property Protection for Synthetic Biology, Including Bioinformatics and Computational Intelligence

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ABSTRACT

Since the completion of the Human Genome Project, biologists have shifted their efforts from understanding biology to modifying it. Synthetic biology is a rapidly growing interdisciplinary field that includes developing and manufacturing synthetic nucleotide sequences, systems, genomes, and medical devices. Gaining patent protection represents an imperative and significant tool for business development in synthetic biology. Without IP protection, investors most likely will not commit necessary resources for progress. While there have been many important breakthroughs in biotechnology, recent case law rulings and legislative statutes have created obstacles for inventors to gain patent protection of novel synthetic biology inventions. These issues cause hesitation in license agreements and postpone creation of synthetic biology start-up companies. Nevertheless, inventors still can gain patent protection in many branches of synthetic biology. This chapter examines the issues, controversies, and problems associated with patent protection in synthetic biology. It then gives solutions, recommendations, and future directions for the field.

INTRODUCTION

Synthetic biology is an emerging field that combines the disciplines of biology, engineering, and computer science. It encompasses parts (or genes), pathways (or multiple genes), genomes, devices, and systems (Rabinow, 2009). In the past 15 years, advances made in bioinformatics and computational intelligence have led to its quick expansion and success. Specifically, developing

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new algorithms and statistics to assess relationships among members of large data sets, reading large nucleotide or protein sequences, and utilizing tools for efficient access to and management of healthcare have allowed for researchers and healthcare professionals to expand diagnostic and treatment options related to synthetic biology. For example, researchers at SUNY at Buffalo recently teamed up with IBM to identify efficiently patients with genetic variations associated with a higher risk of multiple sclerosis (Ramanathan, 2012). SUNY researchers have been able to reduce the time to conduct the analysis from 27.2 hours to less than 12 minutes (Ramanathan, 2012).

Because of the exponential increase, venture capitalists and business professionals have invested significant time and money into this field. Patent protection represents one important aspect of business development and success in synthetic biology. However, due not only to the diversity of involved arts but also to recent Supreme Court and Federal Circuit rulings, intellectual property protection in synthetic biology is a complex, yet poorly researched, topic. This chapter will discuss an overview of synthetic biology and provide evidence for recent successes in the field. It will then discuss recent legal cases that affect this industry. Finally, this chapter will include recommendations on how to patent synthetic biology successfully based on recent legislation and case law.

BACKGROUND

Synthetic biology is a unique way to study life that combines the arts of life science, engineering, and computer science to promote human health and preserve the environment. Since the completion of the Human Genome Project in 2001, the scientific field has learned the function of many gene products. These advances have led to assembly of biological parts, such as DNA, plasmids, promoters, and translational units, into registries. Most notably, the International Genetically Engineered Machine (iGEM) Foundation (https://www.igem.org), which developed out of Massachusetts Institute of Technology, has cataloged the Registry of Standard Biological Parts which supports this goal by indexing biological components and offering assembly services to construct new parts, devices, and systems (Trafton, 2011).

A patent in the United States is an exclusive property right that protects inventions, including any process, machine, manufacture, or composition of matter, or any improvement thereof, that is novel, useful, and non-obvious (http://www.uspto.gov/patents/resources/general_info_concerning_patents.jsp). For a period of 20 years (depending on the type of patent), an inventor and/or assignee has a monopoly over making, using, licensing, or selling the invented property in exchange for full disclosure of the invention. This process promotes economic growth and progress by disclosing knowledge to both individuals skilled in that particular field and laypersons who are interested in the process or invention. Patent protection in synthetic biology has increased rapidly in the past 25 years. In 1990, only 13 patents associated with technologies in synthetic biology were filed. Since then, there has been a 600% increase worldwide in the number of filed patents (van Doren, 2013). Activity in the United States is the most dynamic, as the number of patents filed has increased by over 400%.

Interest in understanding the function of each gene product has grown rapidly since the completion of the Human Genome Project. (Venter, 2001) To expedite this process, researchers have invested time and effort into identifying gene sequencing methods that are more affordable. To this effort, one company that specializes in DNA sequencing, Illumina, Inc., has reported a machine that would decrease the cost of sequencing an entire genome from $3 billion in 2001 to only $1000 today (Young, 2014; http://www.illumina.com/systems/hiseq-x-sequencing-system.ilmn). This low cost will aid researchers not only in understanding gene product function,