ELSEVIER

Technology in Society 25 (2003) 337–349

Technology In Society

www.elsevier.com/locate/techsoc

Preemptive patenting, human genomics, and the US biotechnology sector: balancing intellectual property rights with societal welfare

Thomas A. Hemphill *

Department of Strategic Management and Public Policy, School of Business and Public Management, The George Washington University, Monroe 203, 710 21st Street, NW, Washington, DC 20052, USA

Abstract

Within the biotechnology sector of the US economy, aggressive patenting, i.e. preemptive patenting, of human genomic research results are practiced by private-sector firms, the academic community, and non-profit organizations. Preemptive patenting has traditionally been practiced by the private sector as a competitive strategy, being driven by economic considerations. Recently, academics and patients/consumers have instituted preemptive patenting strategies as a way of ensuring access to genomic sequences for, respectively, research study purposes and life-enhancing access to diagnostic gene testing. To reduce this non-economic motivation for preemptive patenting by these nontraditional competitors, it is recommended that the biotechnology industry initiate a strategy of its own which will: (1) relax firm patent enforcement of genomic sequences that are essential for academic researchers to use in their studies; and (2) provide for a 'means-test' approach that incorporates a 'staggered' fee-schedule for academic researchers to charge their subjects, i.e. patients, for gene tests and diagnostic results.

Keywords: Biotechnology; Competitive advantage; Competitive strategy; Intellectual property; Preemptive patenting; Sleeping patents

* Tel.: 202-994-6677.
E-mail address: tomhemphill@comcast.net (T.A. Hemphill).

0160-791X/$ - see front matter © 2003 Elsevier Ltd. All rights reserved.
doi:10.1016/S0160-791X(03)00050-2

1. Introduction

Biotechnology is defined as "the use of the cellular and molecular processes to solve problems or make products" [1]. Broadly speaking, this definition includes firms or organizations that employ cells and biological molecules for applications in medicine, agriculture, and environmental management [2]. Often cited as the genesis of the biotechnology industry, the 1980 United States (US) Supreme Court decision *Diamond v. Chakrabarty* held that "anything under the sun that is made by the hand of man" was eligible subject matter for patenting.[1] In this particular case, Dr. Ananda Chakrabarty's invention of new microorganisms ('genetically engineered bacterium') which do not exist in nature were deemed a new "invention" and therefore patentable.

Over the last two decades, the biotechnology sector of the US economy has flourished with hundreds of new biotechnology drugs, vaccines, medical diagnostic tests, foods, and environmental-related products entering the marketplace.[2] By 2001, there were 1379 US biotechnology companies employing 174,000, of which 339 firms are publicly held. Financially, revenues for the biotechnology industry have increased by over 300%, from $8 billion in 1992 to $25 billion in 2000. Biotechnology is also one of the most research-intensive industries, with US companies having spent $13.8 billion on research and development (R&D) in 2000. To place this industry expenditure in perspective, the top five biotechnology companies spent an average of $89,400 per employee on R&D in 1999, compared to an average of $37,200 per employee spent by the leading pharmaceutical companies the same year.

Within the medical subfield of biotechnology, human gene (or genomic) research has been in the forefront of a decade-long national effort called the Human Genome Project (HGP) begun in 1990 and jointly funded by the US Department of Energy and the National Institutes of Health. A gene is the fundamental physical and functional unit of heredity and consists of tightly coiled threads or polymers of deoxyribonucleic acid (DNA). In contrast, a genome is the complete set of genetic instructions carried within a cell or an organism. An international research program, HGP is designed to construct detailed genetic and physical "maps" of the human genome to determine the sequence of 3 billion chemical bases (i.e. nucleotides) in human DNA, to localize the estimated 50,000–100,000 genes within the human genome (although more recent estimates are closer to 40,000 [4]), and to perform similar analyses on the genomes of several organisms used extensively in research laboratories as model systems [5]. The discovery of new genes is anticipated to provide invaluable tools for improving disease prediction, diagnosis, and treatment. Along with Celera Genomics, a private corporation, HGP announced a completed working draft of the human genome on June 26, 2000.

Genomic research in the private sector, while sharing many of the same goals as the publicly funded HGP, further seeks to use this genetic map to commercially

[1] See *Diamond v. Chakrabarty*, 447 US 303 (1980).

[2] This section on industry financial and market statistics draws on information provided by the Biotechnology Industry Organization [3].