Edited by Prabuddha Ganguli,
Rita Khanna, and Ben Prickril

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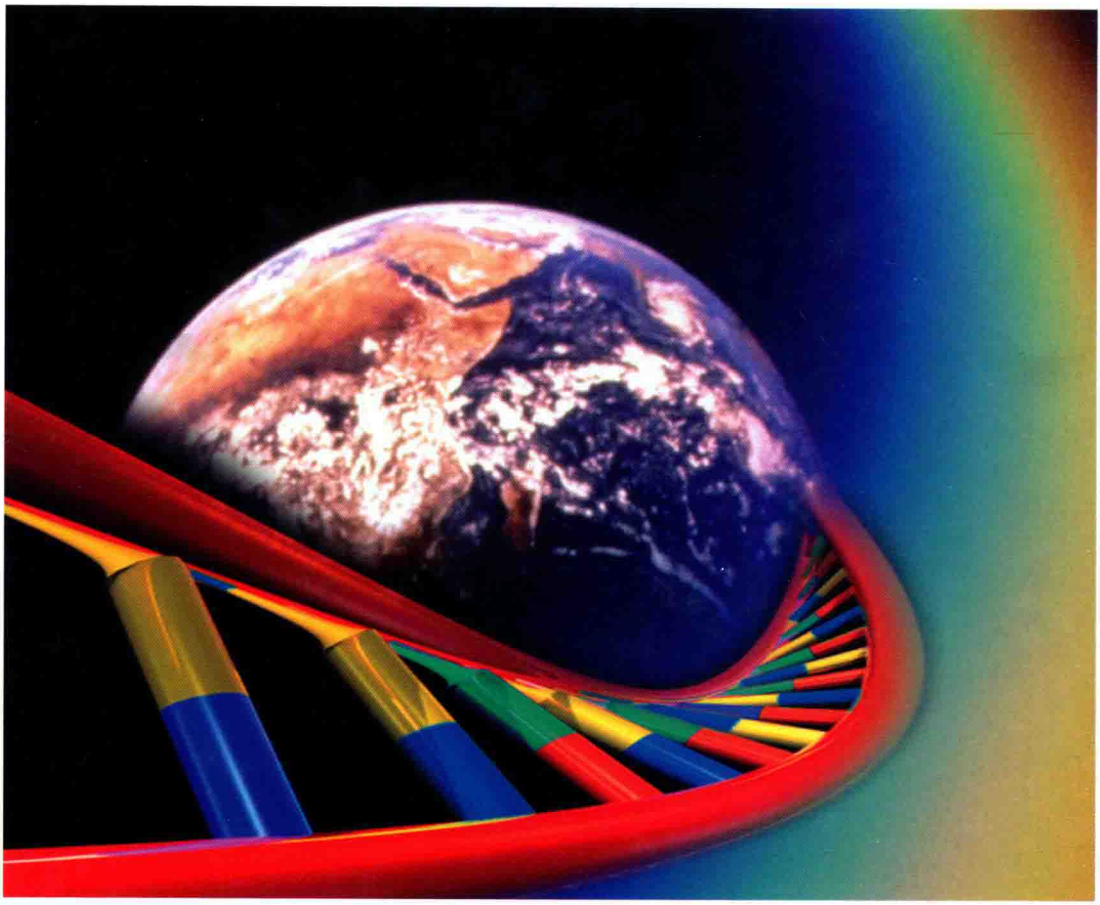
Technology Transfer in Biotechnology

A Global Perspective



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The Editors

Dr. Prabuddha Ganguli
CEO, VISION-IPR, 101-201
Sunview Heights, Plot 262
Shere-e-Punjab
Andheri East, Mumbai 400101
India

Dr. Rita Khanna
International Technology
Transfer Management, Inc.
6533 Kenhill Road
Bethesda, MD 20817
USA

Dr. Ben Prickril
National Cancer Institute
Office of International Affairs
6130 Executive Boulevard, Suite 100
Rockville, MD 20852
USA

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List of Contributors

G. Steven Burrill
Burrill & Company
Chief Executive Officer
One Embarcadero Center
San Francisco, CA 94111-3776
USA

Claudia Ines Chamas
Oswaldo Cruz Foundation
Ministry of Health
Av. Brasil 4365, Gomes Faria, sala 211
Rio de Janeiro, RJ 21045-900
Brasil

Marc Cornelissen
Bayer CropScience
Head of Research Operations–
Bioscience
Technologiepark 38
9052 Gent
Belgium

Carlos Correa
University of Buenos Aires
Center for Interdisciplinary Studies of
Industrial and Economic Law
Av. Figueroa Alcorta 2263
1425 Buenos Aires
Argentina

Prabuddha Ganguli
CEO, VISION-IPR
101-201 Sunview Heights
Plot 260 Sher-e-Punjab
Andheri East, Mumbai 400093
India

Florent Gros
Novartis Pharmaceuticals
25 Old Mill Road
Suffern, NY 10901-4106
USA

Gerald T. Keusch
Boston University
Associate Provost and Associate Dean
for Global Health
715 Albany Street
Boston, MA 02118-2531
USA

Rita Khanna
International Technology Transfer
Management, Inc.
6533 Kenhill Road
Bethesda, MD 20817
USA

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Lita Nelsen
Massachusetts Institute of Technology
Technology Licensing Office
Five Cambridge Center Kendall Square
Cambridge, MA 02142-1493
USA

Yukiko Nishimura
University of Tokyo
Research Center for Advanced Science and Technology
4-6-1 Komaba, Meguro-ku
Tokyo 153-8904
Japan

Ben Prickril
KenGar Consulting
14, Rue Lavoisier
69003 Lyon
France

Mark L. Rohrbaugh
Currently
The REDANDA Group, Inc.
PO Box 305
Monrovia, MD 21770
USA

Formerly
National Institutes of Health
Office of Technology Transfer
6011 Executive Boulevard
Rockville, MD 20852
USA

Brian R. Stanton
Currently
The REDANDA Group, Inc.
PO Box 305
Monrovia, MD 21770
USA

Formerly
National Institutes of Health
Office of Technology Transfer
6011 Executive Boulevard
Rockville, MD 20852
USA

Ashley Steven
Boston University
Office of Technology Development
53 Bay State Road
Boston, MA 02115
USA

Katsuya Tamai
University of Tokyo
Research Center for Advanced Science and Technology
4-6-1 Komaba, Meguro-ku
Tokyo 153-8904
Japan

Michiel M. van Lookeren Campagne
Bayer CropScience
Head of Bioscience Research
Technologiepark 38
9052 Gent
Belgium

Jianyang Yu
Liu, Shen & Associates Law Firm
Hanhai Plaza, 10th Floor
10 Caihefang Road
Beijing 10080
China

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Defining the Future: Emerging Issues in Biotechnology, Intellectual Property Rights and Technology Transfer

Prabuddha Ganguli, Rita Khanna, and Ben Prickril

1.1
Introduction

Since the formation in 1976 of the first modern biotechnology company, Genentech, the biotechnology industry has grown to become one of the major engines of innovation in virtually all developed economies. Indeed, biotechnology's growth in areas ranging from health, agriculture, environment and industrial processes has been phenomenal. This expansion has been paralleled by mounting public concerns because of potential ethical issues and impact on our health, food and the environment.

The importance of innovation in biotechnology and its widespread applications in health, agriculture and commerce has helped bring issues related to intellectual property (IP) rights and technology transfer into sharp focus. The ongoing global debate on IP rights, especially related to health and agriculture, has hinged on proprietorship of knowledge and its ethical and political implications for innovation, knowledge sharing and technology transfer. The means by which knowledge and technologies are moved from basic research up the value chain to become commercial products is critical to the ability of biotechnological innovation to reach those who need it.

1.2
Historical Evolution of Intellectual Property Regime in Biotechnology

There has been a marked paradigm shift in the field of IP rights itself, especially in the areas of patents and copyrights. The modern patent system originated in 1474 as a means of providing inventors the right to block others from using their inventions in return for registering them with the government.

Early inventions usually dealt with the creation of inanimate and tangible objects, but as understanding of basic phenomena progressed, inventions relating to intangibles became fairly common. The field of biotechnology IP rights is

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often intangible and became even more so when the field was transformed by the advent of molecular biology in the 1960s and 1970s. The tools of molecular biology began to enable production of completely new therapeutic drugs, vaccines, diagnostic tools and plant breeding methods starting at the level of individual genes. The seminal US Supreme Court Case *Diamond v. Chakrabarty* was the turning point in the history of IP rights related to biotechnology. Since the Supreme Court's ruling in *Diamond v. Chakrabarty*, certain non-naturally occurring organisms are eligible for patent protection and the patent system has played a critical role in stimulating an emerging biotechnology industry. This decision led the way to patenting life forms provided they were created by human intervention, and met the requisite criteria of novelty, inventive step and utility. Patent exclusivity for biotechnology inventions catalyzed further investments in R&D in biotechnology and marked the dawn of a new biotechnology industry. The tremendous development of this industry and the concomitant increase in the proprietorship of knowledge through IP rights has raised contentious issues in knowledge transactions in a competitive environment.

1.3 Issue of Patentability of Gene Sequences, Antibodies, Early-Stage Technology/Platform and 'Insufficient Support for Claims'

The growth of biotechnology has presented new challenges to the patent system. As noted above, right from the outset issues of what is patentable and how it should be patented have been particularly important and contentious in the biotechnology field. Some aspects have been clarified and resolved, while others still remain to be addressed and new issues continue to emerge. This section will review the history and remaining issues with respect to the patentability of genes, antibodies, research tools and platform technologies.

A subject in biotechnology that has attracted critical attention is the subject matter of erythropoietin. A 2004 UK House of Lords Decision invalidating Kirin–Amgen's erythropoietin patent questioned the patentability of gene sequences as the court observed that 'gene sequences are to be assessed as "discoveries" or just "information about the natural world"'. This decision suggests that the bar to patentability in matters related to gene sequences needs to be regularly reassessed.[1)]

The patentability of antibodies has also been questioned in several recent decisions as in *Noelle v. Lederman* [355 F.3d 1343, 1349 (Fed. Cir. 2004)] and *Smithkline Beecham v. Apotex* [403 F.3d 1328 (Fed. Cir. 2005)]. In the case of *Noelle v. Lederman*, the court observed that the written description of the specification did not provide sufficient support for claims to a human antibody because it failed to disclose the structural elements of the human antibody or antigen. In the *Smith-*

1) Crespi, R.S. (2005) Erythropoietin in the UK: a setback for gene patents? *Nature Biotechnology*, **23**, 367–8.

kline Beecham v. Apotex matter, the court observed that there was 'inherent anticipation'.[2)]

The ongoing case of *Novartis Pharmaceuticals Corp. v. Teva Pharmaceuticals USA, Inc.* [05-1887, 2007 WL 2669338 (DNJ 6 September 2007)][3)], addressing issues related to obviousness, provides insight regarding the importance of references that teach away from an invention. The question being addressed is whether a specific article teaches away from penciclovir, but the prior art 'as a whole' did not teach away from using penciclovir as a lead compound.

Patenting of early-stage technologies such as target identification, pathway analysis, platform technology development and even generation of putative biotherapeutic compound leads have also been subject to debate. In several cases that have come before the courts especially in the United States, such as *The University of California v. Eli Lilly* [119 F.3d 1559, 43 USPQ2d (BNA) Fed. Cir. 1997), cert. denied 523 US1089 (1998)], *Amgen v. Chugai* [927 F.2d 1200, 18 USPQ2d (BNA) 1016 (Fed. Cir. 1991)] and *Fiers v. Revel* [984 F.2d 1164, 25 USPQ2d (BNA) 1061 (Fed. Cir. 1993)], it has been clearly shown that when such patents are challenged, they have not stood the test of validity regarding an adequate written description of the invention.[4)]

The field of genomic diagnostics and IP rights is also becoming embroiled in controversy. Most debates have centered around the patents on *BRCA1* and *BRCA2*, questioning the intent of the patent holders to unreasonably restrict access to the important diagnostic tests. In an article titled 'Emerging patent issues in genomic diagnostics',[5)] Barton raises several questions especially on the problem of royalty stacking. There could be a series of patents claiming the use of a specific gene sequence to identify a specific biological property that may make it difficult for the integrator of a microarray/chip device to assemble the rights to use the different patented sequences that are relevant to the clinical or research application. In principle, each holder of a patent on a diagnostic sequence marker used in the array could traditionally block marketing or the use of the array. Similarly, patents may be issued on sequences that might identify drug efficacy or side-effects. Such patents may cover sequences as biomarkers of an effect on drug metabolism, or the use of sequences to make decisions about drug regimes. Barton suggests that the patent law needs to be assessed keeping in mind such developments in the field of biotechnology and to improve access to the pool of available knowledge.

Another issue that is gaining prominence is the question of 'patenting race'. An article by Khan[6)] raises issues related to the strategic use of race as a genetic category to obtain patent protection and drug approval as they are increasingly

2) Lu, D.L., Collinson, A.M. and Kowalski, T.J. (2005) The patentability of antibodies in the United States, *Nature Biotechnology*, **23**, 1079–80.
3) Lu, D.L., Collission, A.M. and Kowalski, T.J. (2007) Patentability issues surrounding antivirals, *Nature Biotechnology*, **25**, 1403–4.
4) Suster, M.J., Su, H. and Blaug, S. (2003) Protecting rights to early-stage technology, *Nature Biotechnology*, **21**, 701–3.
5) Barton, J.H. (2006) Emerging patent issues in genomic diagnostics, *Nature Biotechnology*, **24**, 939–1.
6) Kahn, J. (2006) Patenting race, *Nature Biotechnology*, **24**, 1349–51.

being evoked in biotechnology patents. Between 1976 and 1977 there were no issued patents in the United States that mentioned racial and ethnic categories. However, during the period 1998–2005, there were a total of 12 instances in issued patents in which race and ethnic categories were mentioned. Further, in patent applications from 2001 to 2006, there were 65 instances in which race and ethnic categories were mentioned. In June 2005, BiDil became the first drug approved by the US Food and Drug Administration (FDA) with a race-specific indication. Underlying BiDil's New Drug Application for FDA approval is a 2002 race-specific patent specifying use of the drug for treatment of heart failure in an African-American patient (US 6465463). Interestingly NitroMed, BiDil's corporate sponsor, also holds an earlier patent (US 4868179) to use BiDil in a general population, regardless of race. The earlier patent expired in 2007, whereas the race specific patent expires in 2020.

Similarly in Europe, in June 2005, the European Patent Office upheld a patent owned by Myraid Genetics relating to the testing for *BRCA2* genetic mutation for 'diagnosing a predisposition to breast cancer in Ashkenazi Jewish Women'.[7] Such patents will have profound sociological and economic consequences in due course.

1.4 Scope of Patent Claims

As in other areas of IP rights, the appropriate term, breadth and specificity of patents has been a continuing and, indeed, a growing concern. The number of patents issued has grown exponentially. Proponents of more stringent IP rights have stressed the importance of a robust system of patents for biotechnology. On the other hand, many have raised concerns about the excessive number and breadth of patents, and their growing complexity of knowledge sequestration is discouraging efficient diffusion of knowledge and undermining research. Striking a balance between adequate IP rights protection and the efficient availability of knowledge with spillover effects remains a continuing challenge.

Patenting of research tools has been at the center of an important debate over the last decade, without much clarity of date. These tools are generally recognized as embracing the full range of resources that scientists use in the laboratory, including such items as cell lines, animal models and reagents.[8]

Several areas such as patenting of expressed sequence tags (ESTs), which are essentially research tools, have been perceived to severely restrict research, while being unlikely to result in discrete commercial products. One means of addressing these concerns has been to raise the bar to utility, as was done through the

7) Kienzien, G. (2005) *The Scientist*, **July 1**, http://www.the-scientist.com/article/display/22719.

8) NIH (1998) *Report of the NIH Working Group on Research Tools*, June 4, NIH, Bethesda, MD. Available at http://www.nih.gov/news/researchtools/.