

FRONTIERS IN THE MANAGEMENT OF BIOTECHNOLOGY AND INTELLECTUAL PROPERTY

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Countless issues have arisen over the past twenty years as new forms of property rights have been asserted to protect the products and processes of modern biotechnology. Policy and theory aside, these ever-shifting tides can leave the manager at sea. To properly navigate, the savvy professional must at least know the general contours of the many debates in this crucial field of technology.

Although the multi-national and multi-million-dollar effort to sequence the human genome that is aptly known as the Human Genome Project has successfully yielded a draft of the entire oeuvre, significantly more work must be done before we realize the project's full wealth of promised scientific knowledge and medial applications. Such downstream development and application are inherently cumulative endeavors that require countless exchanges among members of the basic biological science community. As a result, the managers in this community must leverage applicable legal rules, norms to deploy optimal strategies for facilitating such exchanges.

It is generally agreed that this landscape of laws and norms dramatically shifted over the past twenty years, as the assertion of patent rights in the field of basic biological research has become increasingly common since the landmark *Diamond v. Chakrabarty* decision by the U.S. Supreme Court in 1980. The Supreme Court held that there is no *per se* exclusion from patentability for subject matter that merely happens to be living or related to life, like genes, gene products, and even live animals.

It is hotly debated what the net impact of this shift has been. Simply put, the question at issue is how best to manage patents to facilitate and not frustrate the promised developments and applications of modern biotechnology. Members of the basic biological science research community, and those who study that community, are engaged in an intense debate about the impact of patenting on the exchanges of information and material among members of the community that are essential for allowing downstream research to occur. Some – patent critics – argue that the patent right to exclude use will lead to too little use. Others – patent proponents – argue that this right to exclude use is essential for ensuring sufficient use. Within this broader debate, several discrete skirmishes have emerged. Each is reviewed and updated in the book *PERSPECTIVES ON PROPERTIES OF THE HUMAN GENOME PROJECT*,¹ which brings together

¹ F. SCOTT KIEFF, *PERSPECTIVES ON PROPERTIES OF THE HUMAN GENOME PROJECT* (Academic Press, forthcoming 2003) (see www.elsevier.com, www.academicpress.com) (hereinafter "PERSPECTIVES"). Drafts of the manuscripts

manuscripts from leading thinkers in the private, government, and academic sectors, and in the disciplines of law, medicine, science, history of science, economics, and business to offer both a look back at what ground has been covered and a look forward to where future efforts should be focused.

To begin framing the present debate requires at least an overview of the present use and recent history of intellectual property rights in the field of basic biological research. This is the topic of Part 1 of the book, which offers some basic primers on the law and technology in this emotionally and scientifically complex area. Ananda Chakrabarty reviews the past, present, and future of patents in the field, which were first asserted to cover manufactured machines and mass-produced chemical reagents, but which after the Chakrabarty decision were used much more expansively to cover many of the animals, cell lines, and nucleic acid and protein sequences that were the very focus of scientific and medical study.² To be sure, the views expressed by the U.S. Government about such patent rights have evolved over time, as discussed by Gerry Mossinghoff.³ The early government position can best be evidenced by the Patent Office decision to *refuse* patent protection in the Chakrabarty case, which was *reversed* by the appellate court in a decision that was affirmed by the Supreme Court in 1980. Also in 1980, Congress passed the Bayh-Dole Act, which encouraged individual recipients of federal grants to seek patent protection on the fruits of the very research that was funded by those grants. This shift in the federal government's views on biotechnology patents must be seen in the larger context of the parallel shift in the federal government's views on the general interface between patent rights, which confer a type of monopoly, and antitrust laws, which are designed to prevent monopolies, as elucidated by Gerry Sobel.⁴ In contrast, the European Union and its member states, as well as much of the developing world, have each taken a markedly less rosy view towards biotechnology patents, as explored in the comparative analyses by Joseph Straus⁵ and Chuck McManis⁶ – though, as discussed by McManis, the World Trade Organization's ("WTO") Trade-Related Aspects of Intellectual Property Rights ("TRIPS") agreement may be quite influential in this international debate. The theoretical underpinnings for these different approaches are to some extent influenced by larger debates about the limits of capitalism. For example, James Boyle argues that all that a well functioning patent system will deliver is whatever society values most, under a regime in which "value" is determined by ability and

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² Ananda Chakrabarty, *Patenting Life Forms Yesterday, Today, and Tomorrow*, forthcoming in PERSPECTIVES. Ananda Chakrabarty is Distinguished University Professor, Department of Microbiology and Immunology, University of Illinois, and inventor in United States Supreme Court case of *Diamond v. Chakrabarty*.

³ Gerald J. Mossinghoff, *The Evolution of Gene Patents Viewed From the United States Patent Office*, forthcoming in PERSPECTIVES. The Hon. Gerald J. Mossinghoff is Former Commissioner of Patents and presently is Counsel to the Arlington, Virginia law firm of Oblon, Spivak, McClelland, Maier & Neustadt.

⁴ Gerald Sobel, *Looking Back Over The Patent/Antitrust Interface*, forthcoming in PERSPECTIVES. Gerald Sobel is a partner in the New York law firm of Kaye Scholer.

⁵ Joseph Straus, *Product Patents on Human DNA Sequences: An Obstacle for Implementing the EU Biotech Directive?*, forthcoming in PERSPECTIVES. Joseph Straus is Professor of Law and Director, Max-Planck-Institute for Foreign & International Patent, Copyright & Competition Law, Munich, Germany.

⁶ Charles R. McManis, *Patenting Genetic Products and Processes: A TRIPS Perspective*, forthcoming in PERSPECTIVES. Charles R. McManis is Professor of Law and Director, Program in Intellectual Property, Washington University School of Law.

willingness to pay; and so if we measure value along some other metric then we might not be getting a good deal with patents.⁷ While different governments of the world have adopted quite different approaches towards biotechnology patents, what is certain is that at least in the United States, for at least the twenty years since the Chakrabarty decision, there has been permission, if not encouragement, for a substantial expansion of patenting in this area. Although this reflects a consensus view about what actually has happened, in the descriptive sense, whether it is good or bad is a topic of the great normative debate that is discussed in the remainder of the volume.

The case in favor of a legal system that gives formal property right treatment to the products and processes of the Human Genome Project begins with a set of economic arguments about how markets over such property rights might operate. These arguments, pro and con, are the topic of Part 2. Scott Kieff presents the case in favor of property rights in this area as operating in accord with both the community norms of basic science and the general theory of property.⁸ In response, although Richard Epstein supports the general case for enforcing property rights using strong property rules – backed by a right to exclude – rather than using weaker liability rules – backed only by a take-and-pay requirement – because of what he terms his general preference for “all or nothing solutions,” he suggests that at least for some of the basic biological research tools, such as sequence fragments, the better result is to avoid property rights altogether.⁹ Furthermore, as Rochelle Dreyfuss points out, the economic arguments by both Kieff and Epstein are based to some extent upon assumptions that might not be valid, including for example about rational behavior and about the very goals we should have for our patent system.¹⁰ More specifically, Rebecca Eisenberg argues that a property owner’s effort to reach through to downstream users in this highly cumulative and collaborative field may make negotiations too difficult.¹¹ In response to such concerns about transaction costs, Michael Abramowicz argues that we should use non-property systems, like government grants, as a way to provide the incentives patent proponents say must be provided while at the same time avoiding the costs of negotiating for patent licenses, which are the focus of many patent critics.¹² For those like Justin Hughes, who see indeterminacy in such competing theories, resort may be had to various empirical approaches to better understand the real-world problems facing progress in basic biological research.¹³ When we look to such real-world evidence, we must remember, as admonished by Ed Kitch, to consider the important roles played by the ex ante incentives caused

⁷ James Boyle, *Enclosing the Genome: What the Squabbles over Genetic Patents Could Teach Us*, forthcoming in PERSPECTIVES. James Boyle is Professor of Law, Duke University Law School.

⁸ F. Scott Kieff, *Perusing Property Rights in DNA*, forthcoming in PERSPECTIVES.

⁹ Richard Epstein, *Steady the Course: Property Rights in Genetic Materials*, forthcoming in PERSPECTIVES. Richard A. Epstein is James Parker Hall Distinguished Service Professor of Law, University of Chicago Law School.

¹⁰ Rochelle C. Dreyfus, *Varying the Course in Patenting Genetic Material: A Counter-Proposal to Richard Epstein’s Steady Course*, forthcoming in PERSPECTIVES. Rochelle C. Dreyfuss is Pauline Newman Professor of Law, New York University School of Law.

¹¹ Rebecca Eisenberg, *Reaching Through the Genome*, forthcoming in PERSPECTIVES. Rebecca S. Eisenberg is Robert and Barbara Luciano Professor of Law, The University of Michigan Law School.

¹² Michael Abramowicz, *On Prizes and The Human Genome Project in Retrospect*, forthcoming in PERSPECTIVES. Michael Abramowicz is Assistant Professor of Law, George Mason University School of Law.

¹³ Justin Hughes, *Goat-Boy Roams the Halls?*, forthcoming in PERSPECTIVES. Justin Hughes is Assistant Professor of Law, Benjamin N. Cardozo School of Law and former attorney-advisor, United States Patent and Trademark Office.

by legal and social institutions.¹⁴ Moreover, when we gather data and study such data through models, we must remember, as admonished by David Hyman, to keep track of what exactly in the putatively real world can be fairly said to correspond to the data we elect to use and the results our models generate.¹⁵

One approach for bringing real world input to this otherwise theoretical debate might be through comparisons with other technologies and other legal regimes, which are the topic of Part 3. Jerry Reichman proposes to cast the many problems with patents into a broader perspective by evaluating what he sees as the similar but deeper systemic crisis that has overtaken developed intellectual property regimes in the past fifty years.¹⁶ Focusing instead on differences, rather than similarities, Dan Burk and Mark Lemley suggest that important differences exist in the way patent law has been applied to biotechnology as compared with other technologies; and they argue that this is because many of the core principles of patent law simply are not adaptable for use in the field of biotechnology.¹⁷ This proposition is not without its critics. As Pauline Newman¹⁸ and Herb Schwartz¹⁹ suggest, the principles of patent law may not have been applied as Burk and Lemley suggest. Furthermore, according to Polk Wagner, it would not make normative sense to apply the positive law view offered by Burk and Lemley.²⁰

An alternative approach for bringing real world input to this debate might be through comparisons between the actual transactions that we would expect to take place under different laws and norms, such as one in which property rights are allowed and one in which they are not. Part 4 focuses on the details of exchanges over the products and processes of the Human Genome Project and how they actually might take place in both the academic and in business settings under these different regimes. One comparison that might shed some light on the debate shows how patents can distort the scientific research side of the biological community by shifting the boundary between non-commercial and for-profit research in biomedical science, and contributing to the appearance at this interface of a venture funded, for-profit “tool sector” in the biotechnology industry. This is the topic explored by Ian Cockburn.²¹ Another comparison that might shed light on the debate shows how patents can distort the medical application side of the

¹⁴ Edmund Kitch, *Comment on the Tragedy of the Anticommons in Biomedical Research*, forthcoming in PERSPECTIVES. Edmund W. Kitch is Joseph M. Hartfield Professor of Law, University of Virginia School of Law.

¹⁵ David A. Hyman, *An Outsider Perspective on Intellectual Property Discourse*, forthcoming in PERSPECTIVES. David A. Hyman is Professor of Law, University of Maryland School of Law.

¹⁶ Jerome Reichman, *Saving the Patent System From Itself: Informal Remarks Concerning the Real Crisis in Intellectual Property Law*, forthcoming in PERSPECTIVES. Jerome Reichman is Bunyan S. Womble Professor of Law, Duke University Law School.

¹⁷ Dan L. Burk & Mark A. Lemley, *Biotechnology’s Uncertainty Principle*, forthcoming in PERSPECTIVES. Dan L. Burk is Julius E. Davis Professor of Law, University of Minnesota Law School. Mark A. Lemley is Professor of Law and Director, Berkeley Center for Law & Technology, University of California, Berkeley, School of Law.

¹⁸ Pauline Newman, *Do The Cases Really Go That Far?*, forthcoming in PERSPECTIVES. The Hon. Pauline Newman is Circuit Judge, U.S. Court of Appeals for the Federal Circuit.

¹⁹ Herbert F. Schwartz, *Commenting on Biotechnology’s Uncertainty Principle*, forthcoming in PERSPECTIVES. Herbert F. Schwartz is a partner in the New York law firm of Fish & Neave, and Adjunct Professor of Law, University of Pennsylvania Law School.

²⁰ R. Polk Wagner, *(Mostly) Against Exceptionalism*, forthcoming in PERSPECTIVES. R. Polk Wagner is Assistant Professor of Law, University of Pennsylvania Law School.

²¹ Iain M. Cockburn, *O’ Brave New Industry, That Has Such Patents In It! Reflections On the Economic Consequences of Patenting DNA*, forthcoming in PERSPECTIVES. Iain Cockburn is Professor of Finance and Economics, Boston University School of Management.

biological community by contributing to the explosion of the pharmacogenetics and genetic test sectors of the healthcare market. This is the topic explored by Michael Meurer.²² Yet, as James Davis and Michele Wales point out, despite potential distortions from the theoretical optimal, patents have made vast contributions to both these sides of the biological community.²³ Moreover, as shown by Ed Lentz, the lawyers who have to structure the actual legal arrangements that are entered into in this area when patents are in play can deploy strategies that would facilitate, not frustrate, such exchanges for both the academic and the private sectors in ways that can offer real and positive achievements for the agendas of both the private, self-regarding licensor and even a skeptical social ethicist.²⁴

While comparisons about transactions can shed some light on the debate, a full analysis also requires comparisons about dispute resolution under the same alternative regimes. Part 5 explores the details of the disputes that inevitably occur over the products and processes of the Human Genome Project and how they actually can and might take place in both the academic and business settings under different regimes. One such comparison is between a regime in which disputes are resolved by someone with technological expertise and one in which disputes in even this technologically complex area are resolved the same way typical commercial disputes are resolved. This is the topic explored by Robin Jacob, who questions the merits of a one-size-fits-all approach, as is used in many respects by U.S. District Courts in civil cases.²⁵ Roderick McKelvie responds with an analysis of some empirical evidence about how technologically complex issues are actually decided in U.S. District Courts.²⁶ Scott Kieff then offers a theoretical explanation for why the ordinary judges and juries of U.S. District Courts might be best suited for deciding technologically complex questions in patent cases, even for those seemingly complex technological issues that arise when determining patentability over the prior art.²⁷ In comparison, Horace Judson unpacks some of the complex problems the academic science community itself has experienced when it has been forced to have its own technologically trained members conduct legal-type decision making over its own internal disputes.²⁸

This collection of manuscripts from different perspectives is designed to educate and stimulate the further work needed before the complex issues in this important field can be fully

²² Michael Meurer, *Pharmacogenetics, Genetic Tests, and Patent-Based Incentives*. Michael Meurer is Associate Professor of Law, Boston University School of Law, forthcoming in PERSPECTIVES.

²³ James F. Davis & Michele M. Wales, *The Effect of Intellectual Property on the Biotechnology Industry*, forthcoming in PERSPECTIVES. James H. Davis is Senior Vice President and General Counsel, Human Genome Sciences. Michele M. Wales is Associate General Counsel, Human Genome Sciences.

²⁴ Edward T. Lentz, *Are Real Business People So Easily Thwarted?*, forthcoming in PERSPECTIVES. Edward T. Lentz is a patent attorney in New York.

²⁵ Robin Jacob, *One Size Fits All?*, forthcoming in PERSPECTIVES. The Hon. Mr. Justice Robin Jacob is High Court Judge of England and Wales and Judge of the Patents Court of England and Wales.

²⁶ Roderick R. McKelvie, *Some Empirical Evidence on How Technologically Complex Issues Are Decided in Patent Cases in U.S. District Courts*, forthcoming in PERSPECTIVES. The Hon. Roderick R. McKelvie is presently a partner in the Washington, D.C. office of the New York law firm of Fish & Neave and was formerly U.S. District Judge, U.S. District Court of the District of Delaware.

²⁷ F. Scott Kieff, *How Ordinary Judges and Juries Decide the Seemingly Complex Technological Questions of Patentability Over the Prior Art*, forthcoming in PERSPECTIVES.

²⁸ Horace Freeland Judson, *The Difficult Interface: Relations Between the Sciences and Law*, forthcoming in PERSPECTIVES. Horace Freeland Judson is Research Professor of History, and Director, Center for History of Recent Science, The George Washington University.

understood. The savvy professional can leverage the survey it provides to best manage commercialization in the Biotech arena today. It is hoped that the efficient targeting of tomorrow's frontiers will benefit from this survey of the ground already covered through today.