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Foreword: The Promise and Peril of Biotechnology

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FOREWORD:
THE PROMISE AND PERIL OF BIOTECHNOLOGY

Joan H. Krause*

Recent years have seen unprecedented growth in biotechnology and its potential applications to human health.¹ Genetic engineering techniques such as recombinant DNA technology have made possible the mass production of life-saving pharmaceutical products that previously could only be derived from biological samples.² The identification of the genetic component of many diseases, such as breast cancer, has spurred the development of screening mechanisms for vulnerable populations.³ Advances in pharmacogenetics and gene therapy suggest the tantalizing possibility that drugs can be tailored for specific responsive populations—and that some patients' conditions might ultimately be cured by "repairing" faulty genes.⁴ In light of the recent mapping of the

¹ Biotechnology is defined as "the collection of industrial processes that involve the use of biological systems." ROBERT C. KING & WILLIAM D. STANFIELD, A DICTIONARY OF GENETICS 41 (5th ed. 1997). For purposes of this Symposium, the processes with which we are concerned are those related to health care.

² Recombinant DNA technology describes a variety of "techniques for joining DNA molecules in vitro and introducing them into living cells where they replicate." Id. at 291. In the pharmaceutical context, recombinant technology may be used to create cells that express a naturally-occurring substance, often one that cannot be mass-produced in a synthetic manner. See, e.g., Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd., 927 F.2d 1200, 1203 (Fed. Cir. 1991) (addressing patent dispute over recombinant technology used to produce the red blood cell stimulator erythropoietin, which previously could only be collected by purifying large quantities of human urine).


⁴ See, e.g., Mark A. Rothstein & Phyllis Griffin Epps, Ethical and Legal Implications of Pharmacogenomics, 2 NATURE REV. GENETICS 228 (2001) (describing the uses and dangers of pharmacogenomics); Jesse D. Goldner, Dealing with Conflicts of Interest in Biomedical Research: IRB Oversight as the Next Best Solution to the Abolitionist Approach, 28 J. L. MED. &
human genome—and the recent debate over human cloning—the biotechnology revolution is likely to continue.5

Yet the promise of biotechnology will also bring challenges—challenges to the medical, scientific, and patient communities, and to the legal and regulatory structures that govern the development to the legal and regulatory structures that govern the development of these new biological tools. The ability to identify and manipulate genetic material will stretch our previous assumptions about what can (and should) be protected by patent law, and whether tissue donors have any right to share in the benefal, and whether tissue donors have any right to share in the benefi- 
fits of the discoveries they help create. The necessity of examining large numbers of genetic samples will raise questions regarding patient’s motivations for assisting in research efforts, and whether existing laws adequately protect patient interests. The emerging number of commercially available biotechnology products will force the Food and Drug Administration (“FDA”) to reevaluate its tradi- tion of standardizing approach to pharmaceutical regulation. And in- ternational standardization needs to be more widespread so that it is more competitive, even where the regulation of genetically tai- lored medications will increase pressure on manufac- tured pharmaceutical products will increase pressure on manufactured pharmaceutical products.

The authors in this Symposium address the problems and benefits of biotechnology in the health care fraud, regulatory, and patent law. While recognizing the enormous potential for protection contexts, each author acknowledges the ways in which medical advances stretch the boundaries of traditional health care technology. The boundaries of traditional health care technology. The boundaries of traditional health care technology stretch the boundaries of traditional health care technology stretch the boundaries of traditional health care technology.

The suggestions made by these authors, and their careful analysis of the problems, will go a long way toward helping us achieve that balance.

In 2002 Jenkins & Gilchrist Health Law Lecture, Assistant United States Attorney James Sheehan addresses the challenges fac-

5 See, e.g., National Institutes of Health, Press Release: International Human Genome Se-
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Sheehan, supra note 6, at 18.

6 Sheehan, supra note 6, at 18.

7 Id. at 15-16.

8 Id. at 15-16.

9 Id. at 17. Of course, pursuing such “new fraud” may require the utilization of a broader range of anti-fraud laws than are currently in vogue. For example, the government’s pri-

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avoids clear violations of positive law obligations, this new fraud focuses on breaches of good faith and fair dealing as understood in the community[,] involving a deception or breach of trust.”

10 In order to identify such community boundaries, Sheehan suggests that we look to the broader ethical standards governing science and medicine. Whereas traditional medical fraud has involved issues


2 Id. at 13-14.

3 Id. at 15.

4 Id. at 15-16.

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The authors in this Symposium address the challenges posed by biotechnology in the healthcare environment, focusing on protection of medical advances. Each author acknowledges the ways in which medical advances stretch the boundaries of traditional health care, and the potential for the development of genetic technology already exist, the potential for the development of genetic technology to increase pressure on manufacturers to recoup their investments from a significantly smaller number of customers.

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In Sheehan’s view, however, biotechnology’s promise is compromised by the specter of fraud, a particularly insidious type of fraud posing a threat to vulnerable patient populations. Rather than involving clear violations of the law, this new fraud focuses on “breaches of good faith and fair dealing as understood in the community[,] involving a deception or breach of trust.”10 In order to identify such community boundaries, Sheehan suggests that we look to the broader ethical standards governing science and medicine.11 Whereas traditional medical fraud has involved issues

7 Id. at 13-14.
8 Id. at 15.
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10 Id. at 17. Of course, pursuing such “new fraud” may require the utilization of a broader range of anti-fraud laws than are currently in vogue. For example, the government’s primary method of combating fraud, the False Claims Act (“FCA”), can be invoked only where the defendant submits a monetary “claim” to the government. 31 U.S.C. § 3729(a).
11 Id. at 17-18. However, pursuing such “new fraud” may require the utilization of a broader range of anti-fraud laws than are currently in vogue. For example, the government’s primary method of combating fraud, the False Claims Act (“FCA”), can be invoked only where the defendant submits a monetary “claim” to the government. 31 U.S.C. § 3729(a).
12 Sheehan, supra note 6, at 18.
of billing and reimbursement, Sheehan believes that fraud in the biotechnology era will focus more broadly on what happens to patients in these health care settings.

This new type of fraud will encompass a wide range of impermissable activities, including reckless endangerment of patients and where patient-subjects may be unaware of the dangers, risks, and financial conflicts of interest involved in clinical studies. Despite the difficulties of prosecuting research fraud, Sheehan indicates the importance of full disclosure to patients involved in biotechnology research to achieve legitimacy and to give the researchers the freedom to publish their results in an honest and unbiased manner. In Sheehan’s view, only by proactive efforts on the part of the institutions, and commercial entities involved in research, can the potential for biotechnology fraud be alleviated.

Professor Michael Malinowski addresses one of Sheehan’s initial assumptions—that recent advances in genetic profiling will enable us to determine which patient populations are likely to benefit from individual drugs, and perhaps one day to tailor drugs to individual patients. Malinowski argues that the pharmaceutical industry is under unprecedented competitive pressures due to the growing influence of the generic drug industry and to challenges growing from global patent harmonization. Pharmaceutical companies are devoting an increasing amount of money to research and development (“R&D”) activities, which is leading to significant gaps in our ability to treat individual patients with a new drug. In contrast, recent advances in genetic testing have made it possible to screen large patient populations, offering unprecedented precision in prescription drug delivery.

As Malinowski demonstrates, however, this shift from mass-produced, mass-marketed pharmaceutical products to a “tailored” approach has a number of implications for the relationships between patient-subjects and health care providers. As scientists focus on the intricacies of individual gene function, they are likely to seek access to greater numbers of biological samples and family history in addition to intellectual property disputes, competitive pressures will raise concerns about our ability to protect human subjects from the financial conflicts of interest that entangle researchers and academic institutions. As biotechnology increases the pace of new therapeutic developments, the line between research and treatment increasingly will become blurred.

Outside of the research context, the ability to use genetic testing to profile large patient populations will also challenge health care competency—both of individual health care providers and of the governmental agencies charged with regulating these new products. These advances also will work significant changes to the health care market: drug prices will rise to incorporate the costs of genetic profiling and monitoring activities, and to enable pharmaceutical companies to recoup their R&D costs. Malinowski ends his article with a call for the legal, medical, and scientific communities to work together to develop criteria to guide the development, application, and reimbursement of these new technologies.

Professor Lori Andrews addresses biotechnology from another perspective, exploring one of the difficult intellectual property questions posed by recent biotechnology breakthroughs: should researchers be permitted to obtain gene patents, thereby attaining the right to exclude others from using that genetic material? Andrews grounds her analysis in the basic premise of the patent law: a monopoly is granted to a patent holder only in exchange for the benefit of society.

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12 Id. at 19-21.
13 Id. at 25-29.
14 Id. at 46-52.
15 Id. at 34-42.
16 Id. at 33-59.
17 Id. at 53-59.
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This new type of fraud will encompass a wide range of impermissible activities, including reckless endangerment of patients and financial conflicts of interest involved in clinical studies. Sheehan indicates the difficulties of prosecuting research fraud, stating that legal enforcement officials plan to pursue these cases where patient-subsists may be unaware of the dangers and risks, and emphasizing the need for full disclosure to patients involved in biotechnology research.

In Sheehan’s view, the ability to use genetic testing to profile large patient populations will also challenge the health care competency of individual health care providers and governmental agencies charged with regulating these new products. These advances also will work significant changes in the health care market: drug prices will rise to incorporate the costs of genetic profiling and monitoring activities, and enable pharmaceutical companies to recoup their R&D costs.

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References:

13 Id. at 19-21.
14 Id. at 25-29.
16 Id. at 74-82.
17 Id. at 66-72.
18 Id. at 53-59.
19 Id. at 58-59.
the public receives from the disclosure of the patented invention.\textsuperscript{21} Many substances, such as “products of nature,” are not patentable because the public would not gain any new knowledge in exchange.\textsuperscript{22} While courts have upheld patents of isolated and purified forms of naturally occurring substances, it is not clear that genetic material, standing alone, meets the criteria for patentability. Moreover, restricting access to diagnosis and treatment involving genetic information—the practical effects of patent exclusivity—may have enormous social costs in the health care context.\textsuperscript{23}

Andrews argues that the very exclusivity rights that make patents so attractive pose significant obstacles for the advancement of science and medicine. As a practical matter, the possibility of obtaining patent protection creates an impediment to research by giving researchers incentives to hoard samples and delay publication of results in an attempt to protect their patent rights (and hence their commercial interests).\textsuperscript{24} Similarly, the costs of obtaining a license may prevent others from engaging in further research using a patented gene sequence, including studies needed to confirm the veracity and utility of the original discovery.\textsuperscript{25} Patents also interfere with the traditional scientific process of “cumulative investigation” by forcing researchers to pay for costly access to samples, databases, and other necessary information—costs that will be reflected in the price of the resulting products.\textsuperscript{26} And the pressure to quickly patent new genetic discoveries, long before the functions of the patented sequences can be established, may lead to the granting of “submarine” patents that can unexpectedly derail ongoing research related to those sequences.\textsuperscript{27}

In addition to these broader scientific concerns, gene patents also affect the delivery of health care services. The fact that one company holds the patent on a gene associated with a particular disease may prevent other researchers from engaging in future research involving that disease, particularly where the patent holder refuses to license competing laboratories to test for the gene.\textsuperscript{28} Gene patents also raise the cost of new technology—technology that often is discovered through publicly-funded research.\textsuperscript{29} The high costs of these useful new technologies, including the very patients who once interfered with the physician’s duty to consider the patient’s interest paramount to their own.\textsuperscript{30} Andrews notes several possible policy alternatives for addressing these problems. First, gene patents may be vulnerable to litigation, both by patients who were not informed of their physicians’ patenting genetic material. Second, Andrews argues that it would be possible for Congress to ban gene patents altogether, as it once Congress could enact limited restrictions on patent rights to give treatment, testing, or research purposes. Third, Andrews suggests which researchers and health care providers could purchase blanket licenses for access to certain genetic discoveries.\textsuperscript{31} Similarly, the government might impose a compulsory licensing scheme, forcing patent holders to permit researchers and health care providers to highlights ongoing efforts to strengthen the rights of tissue donors to the possibility that donors should be granted a property interest in the discoveries to which they contribute.\textsuperscript{32} Although being open in patents, Andrews notes that this approach will not resolve the broader controversy regarding gene patents (particularly those de-

\textsuperscript{21} Id. at 67-68.
\textsuperscript{22} Id.
\textsuperscript{23} Id. at 69.
\textsuperscript{24} Id. at 80.
\textsuperscript{25} Andrews, supra note 20, at 81.
\textsuperscript{26} Id. at 83.
\textsuperscript{27} Id.
\textsuperscript{28} Id. at 85.
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\textsuperscript{26} Id. at 83.
\textsuperscript{27} Id. at 85.
\textsuperscript{28} Id. at 86.
\textsuperscript{29} Andrews, supra note 20, at 91. Andrews offers the example of families who participated in a large genetic testing program for Canavan disease, only to have the patent holder later attempt to restrict other laboratories from testing for the gene. Id.
\textsuperscript{31} M. at 93. See, e.g., Moore v. Regents of the University of California, 793 P.2d 479 (Cal. 1990) (refusing to grant leukemia patient a property interest in his cells, which were used by his physician to create a leukemia patented cell line, but finding that patient might have a property interest in his cells).
Regardless of the altered nature of the access, patients are unlikely to be considered "joint" inventors of a discovery (as several litigious patients have already discovered). Id. at 136-37. For similar reasons, patients are unlikely to be considered 'inventors of invention' as several litigious patients have already discovered. Id. at 136-37. The author argues that joint inventorship is a concept that is not always applicable in the context of medical research and development. The author suggests that patients should be able to share in the profits from discoveries that arise from their genetic material.

The author also acknowledges the potential for misuse of genetic information and the need for a policy to address the issue. The author notes that there are several legal issues that need to be addressed, including the protection of patients' rights and the need for a policy to promote positive social advances. The author suggests that a joint inventorship policy is not always applicable in the context of medical research and development.

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rived from more common genetic sources). 26 Regardless of the alter-
native chosen, however, Andrews stresses the need for a policy to
was what rights should patients have in biotechnology inventions based
on their genetic material? 27 Ho argues that patients who contribute
by genetic research may not be aware the research could lead to pat-
tented discoveries that confer exclusive rights on the patent holder.
Professor Cynthia Ho expands on Andrews’ final policy query:
Ho traces the roots of such misconceptions to widespread patient
misunderstanding, including the mistaken assumption that doctors
are immune from commercial interests, and to general
restrictions that make these discoveries possible.

Despite arguments that patients deserve to share in the profits
from these discoveries, Ho argues that the patent laws are not designed
to protect mere sources of scientific information or ideas.
Patents protect “inventors” who make discoveries regarding the
substances they study, such as identifying the function of a particu-
lar genetic sequence (rather than simply identifying the existence of
a genetic anomaly) . 29 Under current law, patients do not engage in
any inventive activities that would grant them a role in the concep-
tion of the patented discovery; their mere genetic material, existing
in its natural state, is not patentable subject matter. 30

Given these restrictions, can patients ever hope to share in the
scientific discoveries made with their genetic information? While ac-
knowledging the policy arguments in favor of amending the laws of
joint invention to recognize a role for patients, Ho argues that
the current legal interpretations regarding the rights of joint inventors—
as well as opposition from corporate interests—make this an un-
likely solution. 31 As an alternative, patients may be able to contract
for ownership (rather than inventorship) rights in a new discovery,
although such contracts raise significant logistical issues. 32 Where
fraud is involved, a patient may also be able to argue in equity that
the patent should be unenforceable. 33 Ultimately, Ho argues that we
need to look to analogous areas of law to find alternatives for pa-
tients. In the area of scientific authorship, for example, scientific
journals have recognized a spectrum of contributions by different
individuals; similarly, efforts have been undertaken to compensate
beneficiaries whose genetic material has been appropri-
ated by large corporations. 34 If similar modifications prove unsatis-
factory, a more radical alternative is available: the issue of patients
rights might lead to a rethinking of our entire approach to the in-
ventorship—and basic patentability—of genetic material.

Although addressing the issue from different perspectives, the
authors in this Symposium confront common concerns: how to as-
sure that biotechnology is used for socially beneficial purposes, and
how to minimize the risks—be they physical, financial, or ethical—
to the patient population. A common theme addressed by these au-
thors is the commercialization of biotechnology, which may create
incentives for scientists and health care providers to place their own
interests above those of the patient-subject population. Yet com-
mercialization has played an extremely beneficial role in biotechnology,
funding expensive R&D efforts and leading to life-changing discov-
10eries that otherwise might never have been made. Rather than de-
crying the role of commercial influences in biotechnology, perhaps
the better approach is to seek mechanisms that better balance the
interests of the varied constituencies of the biotechnology enter-
prise: researchers, health care providers, private industry and,
above all, patients. The articles in this Symposium are an excellent
way to begin this debate.

26 Id. at 105.
27 Cynthia M. Ho, Who Deserves the Patent Pot of Gold?: An Inquiry into the Proper Inventorship
28 Id. at 122-25.
29 Id. at 125.
30 Id. at 153.
31 Id. at 133-37. For similar reasons, patients are unlikely to be considered “joint” inventors of
a discovery (as several litigious patients have already discovered). Id. at 136-37.
32 Id. at 145-47.
33 Id. at 151-52.
34 Id. at 153.
35 Id. at 155-60, 163-66.