Genomics, Ethics, and Intellectual Property

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ABSTRACT

Ethical concerns and controversies about patenting are playing an increasingly prominent role in the development and applications of the biosciences. Despite the growing importance of ethical issues, there is currently no consensus or clarity on the ethical principles that should guide patenting of human, animal, and plant genes and cells. The three major areas of contention are: (1) whether some or all patents on genes and cells are unethical per se, based on concerns such as commodification, dignity, and similar concepts; (2) how tissue samples are collected, particularly in reference to the principles of prior informed consent and benefit sharing; and (3) how patents are used to restrict access to medical and agricultural use of biotechnology innovations. Given the lack of any agreed guiding principles for navigating these issues, policy-makers, decision-makers, scientists, and users of biotechnology have no choice but to address these contested ethical concerns using a case-by-case approach.

1. INTRODUCTION

Over the past three decades, much ink has been spilt about the ethics of patenting in the life sciences. Unfortunately, these dialogues and debates have produced very little clarity and consensus on the ethical principles and practices that should apply to patenting of biological materials. Policy-makers, decision-makers, companies, scientists, and product end users therefore must navigate through a complex web of unsettled legal principles, moral arguments, social norms, and political influences that collectively represent the ethical landscape for patents in this field. Failure to adequately consider and conform to these influences can result in an eruption of controversy, disruption, and opposition. At the same time, excessive caution and hewing to the most extreme views and positions has the potential to impede the scientific, economic, and developmental benefits of life-science research and innovation.

This chapter does not attempt to fully explicate or resolve the many ethical issues relating to life-science patents. Rather, its more modest goal is to briefly describe the various ethical controversies and landmines related to the patenting of genes and other biological materials, and to discuss how such issues are being resolved or managed in practice. The major controversies can be grouped into the following three categories: (1) whether some or all biotechnology patents are unethical per se; (2) the manner in which the patented invention was obtained or discovered; and (3) how the patent is used.

2. ETHICS OF PATENTS

A threshold question is whether biological patents are per se unethical. Some individuals, groups, cultures, and nations adhere to a position that any patenting of human, animal, or plant genes and tissues is unethical. Various ethical arguments have been advanced against any patenting of genetic or related biomedical innovations. One

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of the most common arguments is that patenting commodifies life-forms. A related critique is that living materials are naturally occurring, and thus isolation and description of "nature's handiwork" should not qualify as patentable subject matter.[1] Other ethical concerns include fears that patenting will facilitate and accelerate applications and commercialization of biotechnology that are themselves viewed to be unethical by some, that patenting will lead to greater animal suffering, and that patenting undermines the dignity of humans and other species by making their genes and cells subject to ownership by others.[2]

A prominent expression of this deontological opposition to biotechnology patents was a statement, issued by almost 200 religious leaders in 1995 opposing any patents of human or genetically engineered animal tissues, that asserted that "*[w]e believe that humans and animals are creations of God, not humans, and as such should not be patented as human interventions.*"[3] Another much-publicized denunciation of gene patenting was the 2000 statement of the French Justice Minister, Elisabeth Guigou, that human gene patents are contrary to the ethical norms of France. The Council for Responsible Genetics issued a Genetic Bill of Rights, which contends that "*all people have the right to a world in which living organisms cannot be patented, including human beings, animals, plants, and all of their parts.*"[4]

While some organizations and individuals denounce patenting of living materials on some or all of the grounds identified above, others defend the patentability of genes and other living materials on ethical grounds.[5, 6, 7] For example, the United Nations Educational, Scientific, and Cultural Organization (UNESCO) International Bioethics Committee concluded that the "*law on intellectual property serves useful purposes, has a foundation in ethical principles and universal human rights, and often contributes to the benefit of humanity.*"[8] Moreover, religious leaders are not unified in their opposition to patents for genes and other living tissues, with many prominent religious organizations and individuals expressly or implicitly supporting such patents.[9]

Others argue that while there may indeed be important ethical and policy concerns with some biotechnological inventions, the patent office is not the appropriate forum to address those concerns, if only because patent examiners have no specialized training in ethics and policy. Yet another argument is that eliminating patent protections from biotechnology inventions would make those innovations less rather than more ethical, in part by making new technologies less transparent as companies rely more on trade secrets in place of patents and their requirement for public disclosure.[10]

A blanket prohibition on any patents of genes or other biological materials is inconsistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which requires countries to provide IP protection for most biotechnology products. Thus, any existing and prospective nation-state member of the World Trade Organization (WTO) is unlikely to try to adopt or enforce a generic prohibition on biological patents. While advocates against any patenting may advance the political and ethical arguments summarized above against all patenting, such arguments will have little or no legal force and relevance.

More relevant will often be arguments that specific patents or types of patents are unethical. For example, the TRIPS agreement allows WTO countries to exclude bioengineered animals from patentability. Thus, each nation must individually decide whether it will extend its patent laws to animals, and these debates generally focus on ethical arguments about animal rights and commodification of life.

More generally, the TRIPS agreement specifically provides that nations may elect to include a provision in their patent laws that deny patents for specific innovations and inventions that are not ethical. For example, the European Union has an *ordre public,* or public morality clause that denies patent protections to inventions that are contrary to public morality. Other nations, including the United States, have declined to include such a morality clause, and the U.S. Patent and Trademark Office claims that it does not have the authority to deny otherwise valid patents based

on the morality or ethical characteristics of the underlying invention.

The U.S. courts have also disavowed any role in reviewing the ethical or policy aspects of patents. In approving the first patent of a living organism in the United States, the U.S. Supreme Court stated:

[W]e are without competence to entertain these arguments… The choice we are urged to make is a matter of high policy for resolution within the legislative process after the kind of investigation, examination, and study that legislative bodies can provide and courts cannot. That process involves the balancing of competing values and interests, which in our democratic system is the business of elected representatives. Whatever their validity, the contentions now pressed on us should be addressed to the political branches of the Government, the Congress and the Executive, and not to the courts.[11]

In jurisdictions that recognize a morality exception to patents, controversial patents are subject to challenge under such clauses, both during initial application, and in subsequent post-issuance challenges. For example, challenges to European patents for the BRCA1/2 breast cancer genes and the oncogene mouse have been challenged under the ordre public clause several years after the original patents issued, which resulted in the patents being narrowed but not rescinded.[12] The European Union's ordre public clause also prohibits patents related to human cloning, modifying human germ lines, using human embryos for commercial purposes, and genetically engineering animals in ways that cause suffering without a substantial medical benefit to humans. In other cases, challenges under the ordre public clause to biotechnology patents have failed.[13] One criticism of the ordre public provision is that the European Patent Office has failed to articulate a clear definition and criteria for the provision's application, resulting in case-by-case analyses that do not always use consistent approaches.[14]

No issue has generated more outrage and concern than attempts to patent products and processes based on traditional knowledge. The 1992 Convention on Biological Diversity encourages nations to respect and protect traditional knowledge. Any attempts to patent products based on traditional knowledge is likely to generate considerable controversy, as demonstrated by the disputes that erupted over patents issued for basmati rice, neem, and tumeric, all of which were subsequently abandoned or revoked in response to a chorus of objections.[15] The bottom line is that any attempt to patent products that are derived from traditional knowledge are likely to generate considerable opposition and controversy, which may only be avoided if the biological material is collected consistent with the principles of prior informed consent and benefit-sharing discussed in the next section.

3. OBTAINING BIOLOGICAL SAMPLES

Another area of ethical controversy over some biotechnology patents relates to the manner in which the biological samples used for the patentable discovery were collected. In most human genetic research, the prevailing scientific norm is that donors of tissue for research retain no property or other rights in their cells or genes.[16] This means tissue donors receive no financial compensation for their samples (other than reimbursement of their out-of-pocket expenses), are given no share of any profits or revenues that may result from any commercial products developed using the donated tissues, and have no patent rights to any patentable discoveries that may result from research using their tissues. The legal and property rights of local populations and national governments with regard to animal and plant specimens collected within their territory and used for a patented discovery are uncertain and often disputed. At the international level, some of the most inflamed controversies have involved claims of *biopiracy* in which scientists from an industrialized nation seek patents based on human, animal, or plant materials collected from other, less-developed nations. Two specific issues that have been at the forefront of these ethical debates about the collection of biological samples are prior consent and benefit sharing.

3.1 *Prior consent*

Prior consent refers to the procurement of advance approval from the relevant entities before

taking biological samples. One issue relating to prior consent is who must provide such consent. The consent may need to be given by the specific individuals from whom the tissue is taken (in the case of human samples), from the local community, tribe, or local government in the region from which the samples would be taken, and from the national governmental authorities. Controversies have arisen when only some but not all of these three levels (individual, local, and national) of decision-makers have provided prior consent. For example, the U.S. National Institutes of Health (NIH) sought a patent in 1991 for a cell line derived from a member of the Hagahai, an isolated tribe in Papua New Guinea, that had a high frequency of a gene related to leukemia. The focus of the ensuing international controversy over this patent application, which was subsequently abandoned in response to the pressure, was whether the NIH was required to obtain informed consent separately from the individual donor, the Hagahai tribe, and the Papua New Guinea government.[17, 18]

Another example of an international controversy over the alleged lack of appropriate prior informed consent relates to the Guaymi Indians, the largest indigenous tribe in Panama.[19, 20] Thousands of Guaymi tribal members are infected with an HIV-like virus known as the Human T-Lymphotropic Virus Type 2 (HTVL-II). The U.S. Centers for Disease Control and Prevention (CDC) undertook a research project to investigate infection in the early 1990s, and subsequently the U.S. Department of Commerce applied for a patent claiming a cell line isolated from blood taken from a 26-year old Guaymi woman being treated for leukemia in Panama. The United States claimed that the woman gave oral consent in the hospital (although the woman was reportedly illiterate, unschooled, and quite sick, which raises questions about the effectiveness of the informed consent). However, the focus of the ensuing controversy was that the tribe was never informed of, nor asked to consent to, the removal of the blood sample to the United States, the establishment of cell lines using those samples, or the patent application. The president of the Guaymi General Congress strongly criticized the patent application as "*immoral, contrary to the Guaymi view of nature, and our place in it.*" The United States subsequently dropped the patent application in response to the controversy. The lesson from these examples is that any patent application based on tissues from identifiable populations, such as indigenous tribes, may be subject to significant controversy if prior informed consent is not obtained from the person or persons providing the tissue samples as well as the tribal authorities and, perhaps also, the national government.

The content and form of the information provided in the prior consent has also been controversial. In particular, must the consent process include disclosure that the collected material may be used to secure a patent? According to one critic of current consent procedures, "*over the past thirty years, blood, tissue, and other bodily fluid samples have been collected from individuals and used in genetic research without the person's consent or knowledge. If a lucrative gene was found, it was patented. Once a gene is identified and patented, its availability is often severely restricted, even to the people who provided tissue samples and funding for the genetic research.*"[21]

The European Union's Group of Advisers on the Ethical Implications of Biotechnology has endorsed the need for prior consent before using a donor's tissue to develop a patentable invention:

The ethical principle of informed and free consent of the person from whom retrievals are performed must be respected. This principle includes that the information of this person is complete and specific, in particular on the potential patent application on the invention which could be made from the use of this element. An invention based on the use of elements of human origin, having been retrieved without respecting the principle of consent, will not fulfil the ethical requirements.[22]

In its directive on patenting of biotechnology inventions, the European Union carried forward this recommendation in Recital 26, which provides *"Whereas if an invention is based on biological material of human origin or if it uses such material, where a patent application is filed, the person from whose body the material is taken must have*

had an opportunity of expressing free and informed consent thereto, in accordance with national law"[23] However, because this statement is in the recitals of the directive, it is not legally binding but only hortatory. There are also practical problems with a requirement for prior consent in this context—the original researchers, or subsequent researchers who may have access to the tissue, may not have the intent or knowledge at the time of tissue collection that they will be pursuing a patent application based on that tissue. In addition, except for rare cases (including in *Moore v. The Regents of the University of California* discussed below), most patentable inventions resulting from human tissue are based on findings using large numbers of samples, complicating and attenuating the requirement for prior consent on future patents from each individual tissue donor.

The most famous—some would say infamous—court case on this issue is *Moore v. The Regents of the University of California* decided by the California Supreme Court in 1991.[24] Moore had his spleen removed by doctors at the UCLA Medical Center as part of his treatment for cancer, but unbeknownst to him, his doctors used the removed tissue to create a potentially lucrative patented cell line. The doctors did not disclose their intentions to Moore that they would patent his cells without sharing any of the proceeds, nor did they request his permission to do so. Even more egregiously, they affirmatively misled Moore into returning to the hospital on several subsequent occasions to collect additional tissue. The California Supreme Court rejected Moore's argument that he continued to own his cells after they were removed from his body, but the court refused to dismiss Moore's claim that his doctors failed to provide adequate informed consent by not disclosing their potential financial interest in Moore's cells.

A more recent U.S. case raised similar issues, but this time in the research context rather than the clinical setting. Parents of children with the inherited Canavan disease convinced a medical researcher to attempt to isolate the gene responsible for the disease, and provided tissue samples from affected children and their families and helped to raise funds for the research.[25] The researcher successfully identified the gene, but, without informing the parents who had donated tissue samples to the research, the researcher's employer (Miami Children's Hospital) patented the gene, and the genetic test based on the gene, and began charging a modest licensing fee to clinics that had starting using the newly discovered genetic test. The families and various support organizations were outraged by these actions and sued the hospital alleging various legal claims including conversion, failure to provide informed consent, unjust enrichment, and breach of fiduciary duty. The federal district court dismissed most of the families' claims, but concluded that the unjust-enrichment claim was sufficiently viable to go forward, and the case subsequently settled.[26] This case, like the *Moore* case before it, demonstrates that a physician or researcher may have a legal duty to inform tissue donors of their intent to pursue patents using the donor's tissue, but even if such disclosure is not legally mandated, the failure to obtain prior informed consent from tissue donors runs the risk of provoking ethical controversies that can result in bad publicity and expensive, time-consuming litigation.

The ethical duty of informed consent is less established in the context of plant and animal samples compared to human tissue collection, but there has been considerable momentum toward recognizing such a duty in recent years. The 1992 Convention on Biological Diversity requires informed consent from the appropriate national authorities as a condition of access to plant or animal genetic resources. Several nations have adopted their own laws requiring prior informed consent to the collection of plant and animal resources.[27] Several recent international studies and proposals have been published on this subject in recent years, but the legal and ethical status of informed consent requirements for nonhuman biological materials continues to be hotly debated and uncertain.

3.2 *Benefit Sharing*

A second major issue is whether entities that collect tissue samples that are used to patent a product are ethically obliged to share the economic benefits of their discoveries with the individuals

or population from whom the samples were taken. The Human Genome Organization (HUGO) adopted a Statement on Benefit Sharing with regard to human genetic research in 2000, which states: "*in the interest of justice, the last decade has witnessed an emerging international consensus that groups participating in research should, at a minimum, receive some benefit.*"[28] The statement suggests that profit-making research institutions "*should dedicate 1-3% of their after-tax net profits to healthcare infrastructure and/or humanitarian efforts to benefit communities donating genetic samples.*" For nonprofit institutions, "*immediate health benefits as determined by community needs could be provided.*" Similarly, Article 19 of the International Declaration on Human Genetic Data provides that: "*Benefits resulting from the use of human genetic data, human proteomic data or biological samples collected for medical and scientific research should be shared with society as a whole and the international community.*"[29]

An important precedent for benefit sharing in human genetic research is the ill-fated Human Genome Diversity Project (HGDP), which sought to collect genetic samples from as many human populations as possible on the planet. Although the project was never implemented, largely because of ethical critiques and controversies about the project,[30] it did adopt precedent-setting ethical guidelines that recognized an ethical duty for benefit sharing. [31] The guidelines specify that "*a fair share of the financial rewards shall return to the sampled populations*" when the research results in commercial products. The suggested mechanisms for returning such payments to the donors include (1) paying "*a set percentage royalty … for the benefit of the sampled populations*" or (2) negotiating "*a reasonable financial payment with a trustee for the sampled populations, with the proceeds for the population's benefit.*"

With regard to food and agricultural products, the 1992 Convention on Biological Diversity clearly recognized that sovereign states have the authority to regulate the collection and use of genetic resources within their territory by providing in Article 15 that "*the authority to determine access to genetic resources rests with the national government and is subject to national legislation.*"[32] The Convention also recognizes in Article 1 the principle of "*fair and equitable sharing of the benefits*" of biodiversity. The Treaty on Plant Genetic Resources for Food and Agriculture, negotiated under the Food and Agriculture Organization (FAO) of the United Nations and concluded in 2001, goes further and establishes the principles of "facilitated access" and "sharing of benefits" for the commercial or scientific uses of the nation's resources by out-of-country entities.[33] Of course, these treaty obligations are only mandatory for nations that have ratified the treaty, and many prominent nations including the United States and some European nations have yet to ratify the 2001 treaty. In addition, many individual nations have adopted their own laws restricting access to biological materials within their borders that usually require some form of benefit sharing and prior consent. By one recent count, more than 40 nations have enacted such laws since 1993.[34]

Despite the endorsement of benefit sharing in the various statements and international agreements described above, benefit sharing remains a controversial and uncertain principle. One practical problem is that many scientific researchers are not provided funds in their research grants for providing economic compensation to individuals or populations providing the tissue samples. Another problem is that there is uncertainty in many cases in identifying who should decide how the benefits are allocated within populations. When the samples are taken from a discrete community or tribe with a recognized governance structure, the allocation of the benefits is usually not problematic in that the existing local government can take responsibility for using and distributing the benefits, but when the population is more dispersed or more difficult to clearly define, the distribution of benefits becomes more difficult. Finally, there is an ethical objection that paying significant financial benefits to individual tissue donors may unduly induce some individuals to participate in research.

In sum, while some legal rules and precedents address the issues of prior consent and benefit sharing in certain limited contexts, these issues are primarily ethical issues at the present time, in the absence of applicable laws. At their core,

the largely unresolved ethical debates on these issues represent a concern with the fairness and distributional aspects of biotechnology research and commercialization, and are important factors that should be considered in the context of any research project or program involving the collection of biological samples from plants, animals, or human populations.

4. USE OF PATENTS

The final major area of controversy associated with patents of biological materials is the use (or misuse) of such patents after they have issued. Perhaps the most common concern is that the availability of the patented invention is unduly restricted or costly due to high licensing fees, exclusive licensing, or similar access-limiting strategies by the patent owner.[35] Such practices may inhibit access to the benefits associated with the patented technology by entities with limited funding, including public research institutes, patients, farmers, some healthcare providers, university researchers, and similar entities. This restricted availability could adversely affect, in particular, subsistence agriculture, medical research, and health care.

For example, critics allege that Myriad Genetic's patents on the BRCA1 and BRCA2 breast-cancer genes, and the nearly US$3000 licensing fee per use it charges, adversely affects scientific research and health care.[36] This high licensing fee and monopoly prevent some nonprofit and other clinical-care units from offering a genetic test for these mutations, particularly for patients without health insurance or the means to pay for such tests, and may also burden or restrict scientific research related to hereditary breast cancer, although the company provides a substantial discount in the license fee to university and nonprofit researchers.[37]

A 2003 survey of 132 directors of diagnostic laboratories found that 25 percent had stopped performing a medical test because of a patent or license and 53% stopped research efforts because of a patent or license.[38] The practice of exclusive licensing also limits access to important scientific tools, materials, and procedures. A survey in the late 1990s found that out of 27 disease gene patents studied, 14 had been licensed, and all the licenses were exclusive.[39] The American College of Medical Genetics has adopted a position statement advocating broad licensing of patents on genes with clinical implications and that "*[l]icensing agreements should not limit access through excessive royalties and other unreasonable terms.*"[40]

Other commentators are concerned that the "upstream" patenting of research tools and genes will create a "tragedy of the anticommons" that will result in excessive and overlapping proprietary hurdles that will impede scientific research.[41] A recent survey of 1,240 university geneticists found that patenting and commercialization of research may be impeding the scientific ideals of openness and sharing, with 73% of respondents claiming that withholding of data by colleagues is slowing progress in their field.[42]

Yet another argument is that some biotechnology patent holders are exploiting their patent rights to provide greater market power and profits, to the detriment of patients, farmers, and other potential end users of the patented technologies. For example, some farmers and public interest groups have alleged that Monsanto's patents on genetically modified crops such as the herbicide tolerant Roundup Ready® technology are being used to promote sales of Monsanto's Roundup herbicide through license agreements that requires farmers who buy Roundup Ready® seeds to also use Monsanto's Roundup® rather than competing brands of the herbicide glyphosate. In several cases, lawsuits have been filed against Monsanto for "patent misuse," but to date these legal claims have been unsuccessful,[43] leaving the issue to be debated in the ethical realm.

As with all other ethical issues relating to biotechnology patenting, the alleged harmful effects of patenting on scientific research and healthcare are not uncontroverted. Many biotechnology and pharmaceutical companies consider their patents to be the lifeblood of their business, without which they could not raise and invest the substantial amounts of money needed to develop innovative products that can enhance human health. Some independent analyses have concluded, contrary to some of the arguments summarized above, that

the benefits of patenting outweigh the costs in the context of both scientific research and health care,[44] or that the problems feared from biological patents have largely not manifested.[45]

Some commentators have suggested that companies and other patent holders can take steps to minimize these consequentialist arguments against patenting, including not enforcing patents against university researchers and charging reduced licensing fees for clinical testing by nonprofit clinics and hospitals.[46] Other policy approaches that have been suggested for addressing these concerns include requirements for compulsory licensing, prohibition of exclusive licensing, liability exemptions for clinical uses of patented materials and tests, an expanded experimental-use exemption, the development of patent pools, and open-source approaches to biomedical research.

A related and relatively new issue is the use of patent rights to promote certain ethical or political objectives. For example, Myriad Genetics, which has the exclusive patent rights to the BRCA1/2 breast-cancer genes in the United States and some other jurisdictions, refuses to allow the patent to be licensed for prenatal testing for these genetic markers.[47] This is an example of the patent right being used to achieve a policy outcome—that is, preventing prenatal testing (and presumably follow-up abortion in some cases) for cancer-susceptibility traits.

One group of researchers has suggested that patent licensing could be used as a "moral tollbooth" to ensure the ethical use of biotechnology technologies.[48] Under this proposal, patent holders could be held liable for the unethical use of genetic inventions. The authors suggest "*that a patent holder could be expected to ensure that a licensee of that invention be required to meet emerging legal and ethical norms associated with the use of the technology, such as the requirement to provide fully informed consent or genetic counseling where appropriate.*"[49]

5. CONCLUSION

Ethical issues and controversies about biotechnology patents are a significant, and growing, factor in the development and implementation of biomedical and agricultural technologies. In a few limited contexts, ethical concerns have been translated into legal rules that specify a clear course of conduct, but those situations are the exception. In most cases, ethical concerns about gene patents have not been incorporated into laws, and the ethical issues remain largely unresolved and hotly debated. The lack of clear ethical principles and guidelines creates a problem for actors in this field. As the U.S. Office of Technology Assessment recognized many years ago:

Uncertainty about how courts will resolve disputes between specimen sources and specimen users could be detrimental to both academic researchers and the infant biotechnology industry… [R]egardless of the merit of claims by the different interested parties, resolving the current uncertainty may be more important to the future of biotechnology than resolving it in any particular way.[50]

In the absence of greater ethical consensus and clarity, decision-makers must navigate the ethical minefields of biotechnology patents on a case-by-case basis, seeking to avoid the ethical hot spots that will likely trigger controversy, disruption, and opposition, while avoiding being paralyzed into inaction by the matrix of conflicting ethical viewpoints and positions that exist. ■

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