

Chapter Five—Gene Patenting?

The lead story on the front page of *The New York Times* of May 13, 1995, featured a headline reading: “Religious Leaders Prepare to Fight Patents on Genes.” The contents of the story, based on press leaks, described efforts of a broad religious and secular coalition to initiate a nationwide educational campaign in churches, synagogues, mosques, and temples to raise awareness of and an outcry against the patenting of genetic information. The story portrayed the events as a “passionate new battle over religion and science.”¹

The Rev. Herbert W. Chilstrom, presiding bishop of the Evangelical Lutheran Church in America at that time, was among many religious leaders who received from organizers of this campaign an invitation to become a signatory to a statement called the Joint Appeal Against Human and Animal Patenting. Although Bishop Chilstrom did not sign, 180 religious leaders did go on record in support of the following statement released at a May 18, 1995, press conference:

“We, the undersigned religious leaders, oppose the patenting of human and animal life forms. We are disturbed by the U.S. Patent Office’s recent decision to patent human body parts and several genetically engineered animals. We believe that humans and animals are creations of God, not humans, and as such should not be patented as human inventions.”²

Noteworthy

In order to avoid false impressions from a brief description of these events, we should note that religious leaders at the press conference were careful to affirm their support for the biotechnology industry insofar as it seeks to aid human well-being. They also indicated support, in principle, for the legitimacy of the industry’s concern to make a profit. It is noteworthy that scientific voices, for example, the Council for Responsible Genetics, have also been raised in protest of current patenting practices.

Additional statements at the press conference warned that “Marketing human life is a form of genetic slavery,” and “By turning life into patented inventions the government drains life of its intrinsic nature and sacred value. . . .”³

While many religious leaders obviously supported the campaign described above, others countered that the campaign was a well-intentioned effort misconceived. As one writer put it: “During the weeks leading up to May 18, 1995, well-intentioned religious leaders prematurely jumped into water over their heads. While thinking they had a lifeguard watching over them, they were in fact being dragged out to rough seas.”⁴ The result, in this view, was a loss of precious credibility with those in the scientific, medical, legal, and commercial communities.

Introduction

The information above illustrates both the conflicts around the patenting of genetic information and the problems faced by people of faith who want to enter into the ongoing debate. On the one hand, the Joint Appeal initiated some limited, if indecisive, interaction with the legal and biotechnology communities around the issues. On the other hand, it has been critiqued from several quarters as having done more harm than good. Despite these mixed reviews and the campaign’s questionable results (a national campaign never materialized) the Joint Appeal clearly hit upon sensitive nerves and key issues. Whatever one’s final judgment, the event can be instructive and suggests the crucial importance of being well informed. Thus, it can serve the reader as a helpful touchstone.

In order to provide some insight into these important challenges, this chapter seeks to offer information and sketch views on the issues of patent law and genetics from several vantage points. These include perspectives from the legal, biotech, and scientific communities. Some commentators suggest that patenting issues ought to be settled solely on economic or legal grounds, but religious voices insist that humanitarian concerns must also be factored in. Several of these will be explored. The aim is not so much to draw even provisional conclusions as it is to gain a working knowledge of perspectives and concerns in the debate.

GENETICS!

Where Do We Stand as Christians?



Personal Experience and Values

Differing personal convictions and experiences about the question of the natural and the artificial underlie much of this debate. Take a moment to reflect on this question: *What status does nature have in relation to human activity?* When humans alter nature, how does its status change? Are natural events the “acts of God?” What does that mean? Can events involving human activity be acts of God?

The second pre-understanding important to this chapter concerns business practices and the public good. Consider: *At what point should normal business practice be modified for the sake of the common good?* What are the criteria? Have you ever personally experienced being treated as a commodity?

Gathering Input

Multiple Perspectives

Gene patenting is complicated because it entails information and values involving at least four different spheres: law, economics, science, and religion. This section will categorize the issues and introduce the legal background. It will then sketch the concerns of these multiple communities.

General Categories

Ultimately, the heart of the gene patenting controversy is the question: *What is the status of the genome (especially the human one) and its components?* Is it merely a chemical compound? Is it sacred? How is it intertwined with human (or other species) identity? The issues in the public arena, however, can be categorized under the following five headings:

1. Should there be patents on human DNA sequences and other living things that occur in nature, even if they have been altered through human invention?
2. What counts as natural and what counts as genetically altered?
3. What is the justification for granting patents on DNA material that is part of humanity’s common heritage?
4. Does patenting human DNA sequences deny the dignity of human beings and human life?
5. What about justice and the common good, insofar as patents put the poor, the ill, and developing nations at a significant disadvantage?

The Legal Background

A patent is a form of intellectual property rights granted to an invention by The United States Patent and Trademark Office (PTO) if it meets three legally established criteria: **1) novelty**; **2) utility**; and **3) non-obviousness**. (See sidebar for explanation.) Until 1980, legal interpretation had denied the eligibility of all life forms for patent rights because their discovery was considered akin to the discovery of an unknown river or a hidden valley. They were *products of nature* rather than human invention, and did not meet the three criteria. This was known as the Douglas Principle.⁶

Significance

The significance of this debate should not be underestimated. In 1999, the U.S. Patent Office granted some 1,800 patents for complete—but modified—genes of humans, animals, and plants. Approximately 7,000 others were being processed. Further, the negative impact of U.S. patenting practice on health care is already evident in the dozens of clinical diagnostic laboratories around the United States that have curtailed the use of certain genetic tests due to high cost or patent barriers. A prominent instance involves the Jewish community of Brooklyn, New York. The international program based there, which screens Jewish couples for potentially deadly Tay-Sachs, has been curtailed because the patent holder of a disease gene is trying to impose licensing fees.⁵

Novel means that an invention must have been previously unknown and unavailable to the public when a patent is filed.

Utility means an invention must serve a specific function or purpose as a useful contribution to the public good.

Nonobviousness qualifies an invention as involving an insight not obvious to a person knowledgeable about the relevant subject matter.



In 1980, the Supreme Court issued a landmark 5-4 decision that altered PTO practice dramatically. In *Diamond vs. Chakerabarty*, the Court ruled that a genetically modified strain of bacteria, useful for oil spill cleanup, could be patented. The rationale for this decision centered on the ingenuity required to modify the bacteria. While acknowledging that life forms in their natural state are not patentable, the Court held that altered life forms (transformed from their natural state through human intervention) were patentable [because] “Congress intended that anything under the sun that is made by man be patentable subject matter.” The Court justified its decision in part on the assumption that a lack of patent protection for genetically engineered organisms would slow down the pace of research and the advancing economy.

In 1987, the PTO extended this justification to an animal that does not occur naturally when the “Harvard oncomouse” was patented (1998) as an invention. (Genes of this mouse were altered for research purposes to be susceptible to breast cancer.) Developments tied to the Human Genome Project (HGP) have exerted great pressures for the patenting of human DNA. Thus, by 1998, the PTO reported granting some 1,500 of 5,000 gene patents to researchers and it expects tens of thousands more as the HGP moves into a phase centered on analyzing the function of DNA sequences.

More on Patents and Genes

Three categories of patenting may be distinguished. All involve genetic manipulation but differ in intent, result, and consequence. The first is the patenting of *genetically altered life forms* (such as the oncomouse). The second concerns patents for *DNA sequences*, primarily human DNA, none of which are life forms. The third has to do with patenting *genetic processes* that involve growing organs and tissues, either in the laboratory or in an agricultural setting, such as pig livers for human transplantation.

Patenting controversies are complicated by ambiguities between two types of patents: **a) process patents**, granted for the process by which a gene is located; and **b) composition patents**, granted for the physical product derived from the process. The difficulty in distinguishing between the two can be illustrated by cDNA (copyDNA). Is obtaining cDNA a process by which a chemical structure is identified or is it a physical composition?

The debate is not whether genes as they exist in nature should be patented. It is agreed they should not. Rather, the debate involves whether genes that have been altered in some way may be protected by patent. The question is whether new forms of genes, those produced through human intervention, should be. The significant ambiguity here is what counts as human intervention. One example can help demonstrate this ambiguity. It revolves around whether cDNA (copies of expressed DNA material) are considered a natural product or a human invention. Patents for cDNA have been granted on the grounds that obtaining copies involves significant human ingenuity. Critics, however, point out that the information being patented is the *exact* sequence of a human gene as it exists on the genome. This view holds that such information is a common human heritage. Therefore the patenting of human cDNA means that the human genome will be owned, in effect, by a handful of companies or governments as intellectual property.

The Biotech Industry

In defending the practice of patenting DNA and life forms, biotech industry representatives have generally insisted on describing genes and DNA as strictly chemical compounds. The language of the

legal decisions regarding gene patenting reinforces this definition. The importance of such definitions should not be missed in attempting to sort out differences between the industry and its critics.

In line with this view about DNA, patenting is considered the guarantee necessary for the advancement of research and the development of products for the market. This logic is consistent with that of other branches of the biotech industry. John Varian, a biotech financial operating officer, writing in an ELCA publication, explains that any biotech development is a risky business decision for several reasons. He uses the example of a shoe store developer: “None of us would risk the time, money, and effort to develop a new sandal for our shoe store if those other ten stores could immediately copy it and sell it for less.”⁷ Without proprietary position (patents), he suggests, firms fear that others would copy their developments and undercut profitability. Varian also points to the exceptionally high stakes involved in biotech business decisions since they involve huge initial investments and the high possibility of failure. Only patent protection will lure forth the necessary effort and venture capital. Many in the industry thus contend: **a)** that only patents will guarantee the development of genetic products at all, and **b)** this debate impinges on its economic survival.

The Scientific Community and Patents

The scientific community is divided on the question of human gene patenting in regard to research, largely on two counts.

The first is an argument over whether patent applications for most DNA sequences are premature because they comprise gene fragments whose functions are largely unknown at the time and thus fail the utility criterion.

The second source of controversy involves whether patents encourage or discourage the development of research and knowledge. Some hold that gene patents obstruct the practice of shared discovery that makes science possible. Others insist that patent protection is necessary to provide the intellectual space to proceed with painstaking research. Yet another view is that the proliferation of gene patents creates too many overlapping fragments of intellectual property and too many owners. This fragmentation will create serious problems for future research and product development. In short, this view fears that the privatization of information will result in the under-utilization of knowledge, increased price, and restricted use.⁸

Theological Considerations

While the patenting dispute involves social, economic, and scientific concerns, religious voices have insisted that other concerns also must be heard since genetic patents involve human life and well-being. This section will first address the status of DNA theologically, and then sketch the issues of dignity and justice that religious voices have brought to the debate.

Creation and Patents

“We believe that humans and animals are creations of God, not of humans, and as such should not be patented as human inventions.”⁹ This line from the Joint Appeal summarizes an objection to patenting that is often made. But some theologians have pointed out that such logic, even though used by people of faith, misstates the Christian understanding of creation and weakens the case against patenting.

Two points of the Christian doctrine of creation are important here. The first holds that God creates everything from nothing, and the second holds that God’s creative activity is continuous and dynamic. God’s creative activity is thus ongoing with every new moment and did not happen just once “back then.”

These two convictions contradict any viewpoint that sharply divides creation into the natural and the artificial, and assigns God’s creative activity to one, but not the other. These two convictions deny the implication that natural creatures somehow have a God-given dignity that artificial ones do not. In the doctrine of creation, the oncomouse is just as much a creature of God’s creation as is a wilderness field mouse. Both have God-given dignity and both are equally gifts of God’s creative activity. There is a distinction of means between the natural and the artificial, but every living being, whether genetically altered or not, issues from within the activity of God’s creation. The premise here is that human ingenuity is a natural gift of God and that at its deepest level, the artificial is also nature at work. In this sense, divine creativity works through human creativity.

It does not follow that every human decision about genetic alteration is consistent with God’s loving intentions, but the doctrine of creation does set the proper framework. There may indeed be reasons not to patent DNA and genetically altered life forms, but such a decision should not be based on a faulty distinction about creation. We shall now turn to several of these arguments.

Dignity and Commodification

Many in the religious community contend that the God-given dignity of life is the basis on which to challenge some forms of genetic patenting. This is a moral argument rather than a philosophical question about being natural. This challenge to patenting is often pursued under the heading of *commodification*. Again, a statement from the May 18, 1995 press conference may serve as a starting point. “The patenting of genes, the building blocks of life, tends to reduce it to its economic worth.”¹⁰

What exactly is commodification?

A commodity is anything that someone is willing to sell or another is willing to buy. Commodification is the process by which something previously valued in non-economic terms (in this case, knowledge about genes) comes to be understood as a market commodity. A complaint about the commercialization of Christmas or Valentine’s Day is about commodification, albeit a less profound issue.



It is important to note that the charge of commodification in a narrow sense—the actual buying and selling of goods or services—is not the concern here. Patents on genetic material or genetically altered animals do not represent ownership of that life. Rather, they represent the right to ideas or information that may be developed for sale.

The concern of religious voices (and some non-religious as well) in this debate is about commodification in the broad sense of the term. These voices have argued that the God-given dignity of life forms—an inherent one—is degraded by subjecting fundamental information about them to monetary transaction. This occurs whether or not they are actually traded in the marketplace. Commodities are not accorded inherent dignity for what they are in themselves, but are valued only for what price they can bring or the uses to which they can be put. The fear about commodification in this broad sense is really a fear of encouraging a mindset that reduces everything to a one-dimensional economic value. This charge of commodification registers a clash of mindsets more than an objection that patents commodify genes in a narrow sense.¹¹ The fear is that the patenting of life forms and of DNA will edge society closer to their abuse. For example, the concern is that we are moving toward a world in which a person's patented cell line (that of a sports star, for instance) would be valued rather than the person.

Justice

Besides commodification concerns, religious voices (as well as humanitarian ones) have raised concerns about justice. This concern results from the monopoly of power over products gained by holding patents. These voices insist this is an appropriate concern since these genetic products are predominantly medical in nature and beneficial to human health and well-being. Christian voices support this challenge to current patenting practice by pointing to the biblical message of God's special concern for the poor. This is buttressed by pointing to Christ's compassion for the ill and concern for "the least of these." These voices note that current practices increase medical costs for everyone. Such practices also penalize the ill who are poor or who live in developing countries with fragile economics. For these reasons, these voices argue that some exception to patenting and traditional market mechanisms should be sought out. They urge either that patents not be granted or that special economic arrangements be developed.

Conclusion

As promised in the introduction, we have only been able to suggest the competing perspectives at work in the patent dilemma. No resolution is attempted. Yet, Christian attention to the debate is important since practices being shaped today will likely have long-term impact. Religious voices do add a distinctive contribution if carefully and effectively exercised.

Deliberation

The following set of principles (a reduced version) for guiding religious voices in the patenting debate is taken from the work of theologian Ted Peters, who has written several times on these issues. He issued these recommendations specifically with the Joint Appeal controversy in mind.¹² As an exercise in theological and moral deliberation, consider the usefulness of these for the patenting debate.

Religious voices should operate according to the following guidelines:

- Disregard the attempt to draw a connection between divine creation and a ban on patents as proposed by the Joint Appeal Against Human and Animal Patenting. There is no warrant for treating nature prior to human technological intervention as the sole domain of divine creation. Nature is not less sacred after being influenced by human ingenuity. Rather, pursue a theological vision that affirms continuity between humanity and the rest of nature, and affirms our divine call to be stewards. The goal of stewardship is to relieve suffering and make the world a better place.
- Avoid simplistic and misleading rhetoric that confuses the present controversy. In addition, seek increased precision regarding the term *gene patent*. If the word *gene* refers to what exists naturally in the human genome, then no patent should be issued. If *gene* refers to a copied sequence—that is, cDNA—that matches the original genome, then, likewise, no patent should be issued. If, however, *gene* refers to an altered or engineered DNA sequence that is novel, useful, and non-obvious, then intellectual property protection should be considered.
- Take seriously the concern expressed by the Joint Appeal Against Human and Animal Patenting that the dignity and integrity of life be safeguarded. Affirm the enormous difference between a patented

cell line and a living human being, and remain alert to any reduction of the latter to the former. Ever present is the temptation to “thingify” or commodify. Develop guidelines so that animals and persons with genetically modified cells retain the dignity and integrity they deserve.

- Treat all living animals, even those genetically engineered, with a level of dignity that lifts them up above mere inanimate things. Encourage research practices to minimize suffering to the extent possible in each situation. Animals are not things, even if their genetic makeup results from a technological process.

Taking the Conversation Further

Ask someone in your group to investigate the current controversies involving genes and patents by re-searching the media or using the Web. Are religious voices involved? This report could be followed by an invitation to both sides of the controversy to speak to your group. In many communities, helpful resources for this include local members of the legal profession, biotechnology industry, or activist groups. If one is available, invite a theologian or ethicist as well.

For Further Investigation

Chapman, Audrey. *Unprecedented Choices: Religious Ethics at the Frontiers of Genetic Science*. (Fortress Press, Minneapolis, 1999). Chapman’s fine overview of religious ethics and genetic science overlaps several topics in this study guide. It is referenced here because one entire chapter is devoted to questions about patenting.

Genetic Science Task Force of the United Method Church. *United Methodist Church Genetic Science Task Force Report to the 1992 General Conference*. (General Board of Church and Society of the United Methodist Church, Washington D.C., 1992). The United Methodist Church has taken an active role in this debate. This report marks one of their earliest explorations of the issues.

Peters, Ted. *Playing God?: Genetic Determinism and Human Freedom*. (Routledge, New York, 1997). Peters’ chapter on gene patenting is a revised version of an essay that has been published in several places.

Willer, Roger A., ed. *Genetic Testing & Screening: Critical Engagement at the Intersection of Faith and Science*. (Kirk House Publishers, Minneapolis, 1998). The chapter by John Varian provides a fine overview of the financial and economic issues from the perspective of the biotech industry.

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Citations

1. “Religious Leaders Prepare to Fight Patents on Genes.” *New York Times* (New York), May 13, 1995, A1.
2. Ted Peters, *Playing God?: Genetic Determinism and Human Freedom*. (New York: Routledge, 1997), 117.
3. *Ibid.*, 116.
4. *Ibid.*, 115.
5. Robert Kotulak, “Taking License With Your Genes.” *Chicago Tribune* (Chicago), September 13, 1999, 1.
6. So named for Justice Douglas, who held in a 1948 ruling (*Funk Brothers Seed Co. v. Kalo Inoculant Co.*) that “patents cannot issue for discovery of the phenomena of nature . . . [Such] are manifestation of laws of nature, free to all men and reserved exclusively to none.”
7. John Varian, “Genetics in the Marketplace: A Biotech Perspective.” *Genetic Testing & Screening: Critical Engagement at the Intersection of Faith and Science*, ed. Roger A. Willer. (Minneapolis: Kirk House Publishers, 1998), 66.
8. Audrey Chapman, *Unprecedented Choices: Religious Ethics at the Frontiers of Genetic Science*. (Minneapolis: Fortress, 1999), 136.
9. *Playing God?*, 117.
10. *Ibid.*, 125.
11. Mark J. Hanson, “Religious Voices in Biotechnology: The Case of Gene Patenting.” *The Hastings Center Report* 27, November/December 1997, 36.
12. *Playing God?*, 139f.

