

An Introduction to Genes and Patents

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The May 1995 statement made by the Joint Appeal Against Human and Animal Patenting and signed by about 185 religious leaders, including 91 Roman Catholic bishops, said the following:

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 [of] humans, and as such should not be patented as human inventions.

The right to exclusive ownership of life forms such as genes, cells, tissues and some animals has stirred debate since the first gene was cloned about 20 years ago.

The patenting of the genome of corn and of rice has had serious impact on the seed production industry and agriculture in the U.S.A. Some would wonder today if such commercial monopolies will result in the patenting processes affecting human genes.

Scientists and corporations are already claiming patents on hundreds of human genes and hundreds of genetically engineered animals. In 1991 the Patent and Trademark Office granted patent rights to a California company for commercial ownership of human bone marrow "stem cells". This patenting was the first of an unaltered part of the human body. The question then arises as to where all of this interest in patenting will lead and how will it be viewed morally and ethically.

The Catholic Perspective

The Church's magisterium has made only occasional statements about the field of genetics. It has not offered a thorough going analysis of the moral concern associated with genetic screening and testing and the use of genetic knowledge, which would include the issue of patenting. Only recently have we begun explicitly to draw on our social justice tradition to address the realm of genetics, using, for example, teachings on the dignity of the human person, the social nature of the person, basic human rights, promotion of the common good and justice—commutative, distributive and social.

Our Holy Father, Pope John Paul II, (1994) in his address to the plenary session of the Pontifical Academy of Sciences observed:

All interference in the [human] genome should be done in a way that absolutely respects the specific nature of the human species, the transcendental vocation of every being and his incomparable dignity. The genome represents the biological identity of each subject; furthermore, it expresses a part of the human condition of being desired by God for his own sake through the mission entrusted to his parents.

The ability to establish the genetic map should not lead to reducing the subject to his genetic inheritance and to the alterations that can be made to it. In his mystery, man goes beyond the sum of his biological characteristics. He is a fundamental unit, in which the biological cannot be separated from the spiritual, family and social dimensions without incurring the serious risk of suppressing the person's very nature and making him a mere object of analysis. By his nature and uniqueness, the human person is the norm for all scientific research. "He is and he ought to be the beginning, the subject and the object..." of all research. (Vatican II, *Gaudium et Spes*, N.25)

Regarding patenting of human genes, Pope John Paul II commented:

...We rejoice that numerous researchers have refused to allow discoveries made about the [human] genome to be patented. Since the human body is not an object that can be disposed of at will, the results of research should be made available to the whole scientific community and cannot be the property of a small group.

In the statement of the Joint Appeal Against Human and Animal Patenting it is important for Catholics to distinguish that there are two different sets of issues to be addressed, i.e., the patenting of human genes distinct from the patenting of animal genes. This distinction flows from the nature and transcendental vocation of the human persons versus the nature of animals. It implies a whole different set of moral principles and theological teachings.

Service Provided by the Joint Appeal Statement

Given the need for the important distinction just mentioned, the Joint Appeal Statement does serve religious leaders with an opportunity to bring the issue of gene patenting more into the open for serious exploration and dialogue. It opens opportunity

for discussion about the distinctive theological perspectives among the various religious traditions to the issue of genetic research, testing, counseling, therapies, pharmaceutical developments, and clinical practices. Perhaps it may even draw the attention of religious leaders to the need for more active interaction with scientists and their academies and professional associations.

The attempts to attract the attention of religious leaders in the matter of genetic research and therapy has not been all that productive in this nation up until now. The results of study by the Pontifical Academy of Sciences; The Institute for Theological Encounter with Science and Technology (ITEST); the National Conference on Genetics, Religion and Ethics; the Program on Ethical, Legal and Social Implication (ELSI) of the National Center of Genome Research; the Pope John XXIII Medical Moral Research and Education Center; and others have not as yet progressed through the discernment processes of religious leaders and theologians to the point wherein the faithful are served with the teachings needed for moral-ethical decisions. The specific issue of the theological and moral-ethical considerations of patenting genes thus suffers as a part of the larger need to further and refine Church teaching on genetics.

Legal-Ethical Perspective

Typically, advances in biotechnology precede the development of legal resolutions for the ethical dilemmas that are raised. There does appear to be some applications of law which address the issue of genetic testing by employers to identify persons at risk of disease. This according to Opentlichter (1990) is because the issues raised by genetic testing are analogous to those that have been raised by employer testing for communicable infections (particularly H.I.V. infection), drug use, or disabling health problems. The Americans With Disabilities Act also has applications related with genetic testing and screening in particular. In the overall consideration of what is available from legal guidance in regard to genetic research and clinical practice, it is probably safe to say we have a long way to go in our nation. It would appear we have nothing comparable to the Center for Law and the Human Genome at Deusto University in Bilbao, Spain.

Collins (1993) observed that most legislators in the U.S. know little about genetics, and that public policy is lagging behind progress in scientific technology. Health aides to Congressmen attempt to understand the complexities of the scientific questions and make recommendations to their Congressmen. Perhaps there could or should be a more organized way to achieve good public policy in these matters. Brown (1993) pointed out that there are no policies or regulatory guidelines under which consideration for availability of genetic testing, quality control and test related counseling is regulated. The agency in charge of performing proficiency testing is overburdened, underfunded and undersupervised. Who will set the standards and by what criteria? What are the policy considerations relative to the issue of patenting?

So the question remains, how will the issues pertaining to the ethical and moral considerations of genetic research and clinical practice in general, and the issue of patenting human genes in particular, come more into open discussion?

While the Joint Appeal may in the eyes of some be a less than perfect way to introduce the needed public discussion, it at least involves religious leaders, an ecumenical cooperation, and an invitation to dialogue.

What Is Meant by Patents?

Congressional grants of patents and copyrights are based on Article I, Section 8 of the Constitution. A patent is the grant of a property right to an inventor, excluding others from making, using, or selling his or her invention. The invention may consist of “any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvements thereof...” It also covers ornamental designs, plants and new forms of animal life. The invention must be new. If the patent is granted, it is good for 17 years.

Once a patent is granted, all documents relating to it become available for public inspection, unless they are deemed by the commissioners of the Patent Office as vital to the national security. As with any other property, patents may be sold or assigned in whole or in part to someone else. The patent holder also may license others to use the process or produce the product under specific conditions.

What Are the Main Arguments Offered in Favor of Patenting Genes?

Biotechnology companies maintain that patents have been crucial to their ability to raise capital, because they assure that a company can earn a profit from its research. They state that had it not been possible to patent human genes thousands of patients would already have been denied lifesaving drugs. Some of the most lucrative new drugs on the market, including those that promote human growth, fight anemia and prevent heart attacks, are produced with patented genes and they help many patients. This appears to be a future trend for the development of pharmaceuticals. The benefits to humankind can be enormous, and they outweigh the burden offered by patenting, they assert.

Practical Questions about Patenting

Some of the questions that probably are in the minds of religious leaders who are not privileged to the professional literature in genetics and patenting would be the following:

Is the human body (including a fetus) and the human sex cells and human organs explicitly precluded from patenting? Are

components of the living thing (humans) also regarded as living? Are product patents granted for genes in natural form? Since the naturally occurring human gene and the modified gene both code for immune interferon, is the naturally occurring human gene thus directly covered by the patent claim? In patent applications, is the word gene used in the informative sense, while the specificational formulations of the patent embody corporeal descriptions? Should the entire gene be patented—including the non-protein-coding DNA, which occurs at the start and end of the gene as well as in the gene itself? Will the patenting of a naturally occurring gene entitle one to rights over certain parts of the human body, whose importance to the human as a person and individual is, in principle, not known?

Basic Ethical Considerations and Moral Questions

We have to recognize in ethical considerations that questions of the use of science and technology are always moral and political questions, never simply technical ones. Kass (1981) observed that the “private or public decisions to develop/use biomedical technology—and decisions not to do so—inevitably contain judgments about value. This is true even if the values guiding those decisions are not articulated or made clear, as indeed they often are not. Secondly, the value judgments cannot be derived from biomedical science. This is true even if scientists themselves make the decisions.”

A second basic ethical consideration that applies in the question of patenting is how to distribute scarce resources justly. Questions of distributive justice come into play also in the earlier decisions to acquire new knowledge and to develop new techniques. How will the balances be struck: prevention vs. cure; delivery vs. research; power vs. service?

Kass observed that our “greatest problem will increasingly be one of voluntary self-degradation, or willing dehumanization. What happens when our desires outrun defensible goods?”, he asks. This leads one into having to wrestle with the notion of what is “distinctively human,” a topic which promotes much discussion and which goes beyond the scope of this particular reflection.

Practically speaking, the burden of the proof needs to be carried by the proponents of a new biomedical technology, says Kass. Concepts of “risk” and “cost” need to be broadened to include some of the social and ethical consequences of patenting.

The Presidential Commission on Genetic Engineering and Genetic Policy (1983) concluded that “increased private funding for bioengineering research has sparked questions about conflicts of interest and about the import of commercialization on

academe more generally.” A fair question to be asked could well be “what has happened in the last twelve years?”

The Human Genome Initiative’s (HGI) Working Group on Ethical, Legal and Social Implications (ELSI) (1991) earmarked among the nine very complex topics worthy of their particular attention questions raised by the commercialization of the products from the HGI in areas of intellectual property rights, e.g., patents, copyrights, trade secrets, the impact on scientific collaboration and candor, and accessibility to data and materials.

Caplan (1992) observed in a workshop for American bishops that:

from the public policy point of view, patenting is desirable only to the extent to which it’s going to serve the social goal of generating the [genetic] information quickly, reliably, accurately. If the incentive needed is to make some money doing it, I don’t find that offensive. I simply would find it offensive if the patenting got in the way of serving the public interest.

In the Catholic tradition the promotion of the common good would require as a minimum practices, structures and institutions that foster the dignity and development of human beings, foster justice and protect the human rights of all.

At the present time the knowledge about such structures involved with genetics remains in the hands of a few. Moreover, we do not know about what fundamental fairness exists in the agreements and exchanges involving patenting of genes. Is there respect for the equal human dignity of all persons in contracts, commitments and economic transactions? What precautionary measures monitor possible genetic research/product firms becoming subject to corporate buyouts—friendly or not—which can lead to conglomerates and monopolies?

Additional questions of a more practical nature which should be entered into the dialogue are the following: What will gene patenting do to foster future research? Will pure research continue to flourish independently? How will academic centers be involved? Who will make the critical decisions and by what criteria? What exactly will be owned? Who will own mutations of the patented gene? What will be the long term fallout biologically, in family life, and in society? What will be the international impact of gene patenting? How will we know when germ-line gene research arrives at the point to be included in patenting of genes? What moral-ethical considerations will be forthcoming in the patenting of that which results from transgenic animals and human genes interacting? While animals have in our tradition served to assist human life, will their genetic alterations be done with a sense of good stewardship, respect natural selection processes, employ reasonable standards and employ a reasonable benefit-harm rationale?

Independently of the biological, cultural, social or religious differences that distinguish human beings, every individual has a natural right to be what he or she is and to have sole responsibility for his or her genetic inheritance. How will this be protected? How will informed and free consent come into play in the use of genetically patented medications and therapies?

While there are thousands of questions, such as these just mentioned, we must caution against a blanket rejection of newer technological possibilities on the grounds of more artificiality. The compassion of the Church for the sick has encouraged the development and application of technology in the pursuit of God-given, truly human goals. (Donum vitae, 1987)

Gene patenting and the even larger picture of genetics and genetic research and therapy command more of our attention as church leaders than is given presently. Our development of pastoral guidelines remains wanting.

Perhaps the courageous move will be made soon to address in more realistic terms the questions which pertain to genetics and the theological, ethical-moral, and philosophical questions associated with this aspect of God's wonderful creation and human discovery and invention.

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