Human Gene Patents and Human Dignity

The Case of Gene Therapy for β-Thalassemia Major

Stephanie H. To

Abstract. In Evangelium vitae, Pope St. John Paul II recognized that scientific progress would bring about new attacks on the dignity of the human person. Since that time, remarkable expansion in our knowledge and understanding of the human genome has brought forth questions of ownership rights via patents on human genes and related technology. This article argues that patenting human genes is incompatible with human dignity as it commodifies that which is price-less. In contrast, granting patents to manipulations of human genes does not violate human dignity so long as it is utilized toward the common good. National Catholic Bioethics Quarterly 15.2 (Summer 2015): 265–285.

Never before has biomedical science demanded more focus on human dignity. Stunning bioscientific strides increasingly strike at the strength of humankind—our unique attributes and meaning found in human qua human. The increasing refinement of biomedical technology coupled with a propensity to destroy human parameters strengthen dignity’s role in assessing biomedical challenges to fundamental aspects of humankind.1

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Even before the completion of the Human Genome Project in 2003, whether patents should be granted for genetic discoveries has been hotly debated. Among these debates were such issues as whether it is ethical to allow one to profit from the use of genetic information; whether it fosters or hinders scientific discovery and innovation; whether genetic discoveries can meet the technical requirements of US patent law; whether genetic discoveries fit within the public policies behind US patent law; and whether permitting such patents will effect access to the medical treatments derived from such knowledge. While others have addressed the implications of Catholic principles of property ownership and social justice on gene patents as well as patenting human embryos, the question of whether granting patent rights to genetic technology is consistent with Catholic bioethics and, in particular, with the Catholic understanding of human dignity, has not been addressed in the literature. The matter is further complicated as the Church has not spoken directly to this issue.


This paper will argue that patents on human genes are inconsistent with the Catholic bioethical principle of human dignity because they would commodify the human person, resulting in a perverse understanding of humanity’s relationship with God and in direct opposition to the Catholic view of the human person. The current Phase I clinical trial of gene therapy for β-thalassemia major, an inherited blood disorder affecting hemoglobin production, is one case where this position has been tested. In the first section of this article, a basic background on genetics and gene therapy will be provided. Second, β-thalassemia major and the gene therapy trials will be described. Third, US patent law with a focus on its relation to genetic materials will be surveyed. In the fourth section, the principle of human dignity in Catholic bioethics will be evaluated. Fifth, the disjunction between patent law and Catholic bioethics utilizing the β-thalassemia major gene therapy will be shown. Finally, the gravity of a reasoned approach to human gene patents through the lens of human dignity will be discussed.

Overview of Genetics and Genetic Therapy

A gene is a section of DNA. DNA has alternately been described as mere chemical compounds that form the building blocks of the human person and as the “Holy Grail” to understanding the mysteries of human nature. Genes dictate the inherent properties of a species through the production of specific proteins. Because genes can exist in different forms, called alleles, genes also dictate hereditary variations in a species. Understanding how DNA and genes relate to structure, function, and disease was, for a long time, based on indirect inferences about genes.

4 An in-depth discussion of the structure and function of DNA is beyond the scope of this paper. For additional background on DNA, see Michele Westhoff, “Gene Patents: Ethical Dilemmas and Possible Solutions,” Health Lawyer 20.4 (April 2008): 3–4; see also Anthony J. F. Griffiths et al., Introduction to Genetic Analysis, 7th ed. (New York: W. H. Freeman, 2000), 2.


6 Griffiths et al., Introduction to Genetic Analysis, 2.

7 Ibid.

8 Ibid., 366.
The Human Genome Project, an international and collaborative research program, sought to map and understand all of the genes in the human genome.\(^9\) With the publication of a draft genome sequence in February 2001, new opportunities opened for understanding the functioning of genes and potentially revolutionizing medicine through an enhanced understanding of the molecular mechanisms of disease and target therapeutic treatments.\(^10\) The Nuffield Council on Bioethics has distinguished among four uses of DNA sequences: diagnostic tests, gene therapy, production of therapeutic proteins, and research tools.\(^11\) Diagnostic testing allows detection of a faulty gene based on knowledge of the genes.\(^12\) Gene therapy seeks “to replace a faulty gene with a normal gene.”\(^13\) In contrast, the production of therapeutic proteins as medicines concerns a genetic sequence that has been identified for a specific protein and that has a specific therapeutic use, such as insulin.\(^14\) Finally, research tools encompass a broad category of scientific discoveries that have no immediate commercial value but can guide future research.\(^15\)

Gene therapy can be further divided into four applications. The first is somatic cell gene therapy, which corrects a genetic defect in the somatic cells of a patient.\(^16\) Somatic cells include all cells in the body except for the reproductive. A second application is germ line gene therapy, which inserts a gene into the reproductive cells to correct a disorder in offspring.\(^17\) A third application is enhancement genetic engineering, which inserts a gene for the purpose of enhancing a known characteristic.\(^18\) A fourth application is eugenic genetic engineering, which attempts to improve complicated human traits, requiring modification of a large number of genes.\(^19\)

### β-Thalassemia Major and Gene Therapy

Thalassemia is a group of genetic disorders that affect the body’s production of hemoglobin at normal levels, resulting in various forms of anemia.\(^20\) β-thalassemia

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\(^10\) Ibid., 914.


\(^12\) Ibid.

\(^13\) Ibid., 48.

\(^14\) Ibid.

\(^15\) Ibid., 47.


\(^17\) Ibid.

\(^18\) Ibid., 275–276.

\(^19\) Ibid., 276.

\(^20\) Hemoglobin is found in human red blood cells and is a protein composed of alpha- and beta-globins. These globins surround an iron molecule to which oxygen binds, allowing the hemoglobin to transport oxygen throughout the human body. David Surface, *What Is Thalassemia Trait?* (New York: Cooley’s Anemia Foundation, n.d.), 4, available at http://cooleysanemia
is one type of thalassemia and is caused by an abnormality in chromosome 11. The most severe form is β-thalassemia major, also known as Cooley’s anemia, and occurs when both chromosome 11s are mutated. As a result, these patients’ hemoglobin is unable to carry oxygen through the body. Absent treatment, patients’ livers, spleens, and hearts may become enlarged and their bones become brittle or deformed. Patients with Cooley’s anemia require regular blood transfusions. These transfusions can result in iron overload, resulting in damage to the heart and liver, and ultimately shortening the patient’s life expectancy. The only curative treatment is a bone marrow transplant from a matched, related donor; however, such a match is often difficult to find.

Recent discoveries, coupled with knowledge gained through the Human Genome Project, have opened doors for treatment that would correct the genetic code in the patient’s own bone marrow without the need for a bone marrow match. The first US-based clinical trial for this type of gene treatment therapy (CD34+ gene therapy) obtained FDA approval in 2012 and is being led by a team of researchers from Memorial Sloan-Kettering Cancer Center (MSKCC) in New York. The genetic treatment involves collecting stem cells from the patient’s bone marrow and treating them to correct the gene so that the body can make normal hemoglobin. These modified cells are then returned to the patient’s body, making their way back to the bone marrow. Through a process known as transduction, the corrected genes are inserted in place of the incorrect genes in the stem cells, allowing the body to produce corrected red blood cells on its own.

21 Ibid.
23 Ibid.
28 A full description of the science behind this gene therapy is beyond the scope of this article. Further information, however, can be found in Boulad et al., “Safe Mobilization of CD34+ Cells,” 1483–1486.
What is most interesting about the CD34+ gene therapy, and particularly relevant to the current discussion, is that the foundational aspect of the therapy is the insertion of a human globin gene utilizing, as the primary transportation mechanism, the patient’s own stem cells. This therapy is markedly distinct, therefore, from other gene therapies wherein genes or transporters from other organisms are used or where the goal is merely to diagnose or identify the genetic mutation.

Researchers at MSKCC obtained patents in 2009 and 2011, covering the technology utilized in the CD34+ gene therapy Phase I study. Specifically, these patents cover the “corrected” genes to be inserted and the vector transporter as well as the method for creating the therapeutic stem cells. The patents arguably include the genetic sequence that most individuals have on chromosome 11. This genetic technology is thus particularly ripe for discussion here, as it relates to both the patenting of “naturally” occurring genes as well as a method for transporting the corrected genes that does not naturally occur in nature.

**Patent Law Overview**

A patent is a right granted by the government that allows the patent owner to exclude others from practicing the invention for a certain period of time. Patent law in the United States is based on article I, section 8, Clause 8 of the Constitution, which grants to Congress the power “to promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Rights to their respective Writings and Discoveries.” Congress enacted legislation in Title 35 of the US Code. Patent rights in the United States are purely statutory and governed by federal law.

**Basics of Patent Law**

In order for an invention to be patentable, it must meet certain requirements. At its most basic, the invention must be novel, nonobvious, useful, and be patentable subject matter. For the invention to be novel, it must not have been previously disclosed to the public (such as through allowing others to use the invention or through publication) or anticipated by prior art. To meet the nonobviousness requirement,

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30 In light of the Supreme Court’s decision in Assoc. for Molecular Pathology v. Myriad Genetics, Inc., 133 S.Ct. 2107 (2013), the validity of the claim for the correct, naturally occurring chromosome 11 is questionable; however, as of the date of this article, the validity has not been challenged. Regardless of the legal validity of the patent, the question of patentability of naturally occurring genes from a bioethics perspective is still germane.


32 These requirements refer only to the substantive conditions necessary for patentability. In addition to these substantive considerations, there are formal conditions required, including unity of invention (35 U.S.C. § 121), sufficiency of disclosure (Symbol Tech, Inc., et al., v. Lemelson Med., Edu., and Res. Found., L.P., 422 F.3d 1378 [Fed. Cir. 2005]), and enablement (35 U.S.C. § 112[1]), among others.

33 Prior art is all of the relevant inventions, discoveries, and technology that bear on whether an invention is novel and nonobvious. This may include patents, prior applications,
the invention must be more than an obvious advance to the existing state of the art. The nonobviousness is judged in an objective manner: if the claimed invention would have been obvious to a person with ordinary skill in the art when he or she looked at the prior art, then the nonobviousness requirement is not met. The requirement of usefulness means that the inventor must demonstrate that the claimed invention is operable and has a practical, “real world” use; commercial success, however, is not required. Finally, the invention must fall under the category of patentable subject matter as defined by statute. This last requirement, as it relates to genetic material, will be addressed in greater detail below.

There are three different types of patents that the US patent office (PTO) can grant: (1) utility patents; (2) design patents; and (3) plant patents. Utility patents, which are the most common type, can be granted for any new, nonobvious, and useful “process, machine, manufacture, or composition of matter.” Design patents, on the other hand, cover the visual appearance of an article, such as its shape, configuration, or surface ornamentation. Like utility patents, they must be novel, original, and nonobvious. A design patent only protects the article’s overall appearance; it does not protect the utilitarian features. Plant patents protect asexually reproduced plants. Courts have stated that “asexual reproduction is the heart of the present plant patent system: the whole key to the ‘invention’ of a new plant is the discovery of new traits plus the foresight and appreciation to take the step of asexual reproduction.”

Although patent rights were originally grounded in Lockean natural rights theory, the US Supreme Court has defined patent rights in utilitarian terms, with patents based on Lockean natural right theory to the extent that the right to exclude others as a monopoly is necessary to promote invention.

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37 35 U.S.C. §101 (defining the scope of patentable subject matter as any “process, machine, manufacture, or composition of matter” or any improvement of any one of those).
38 Ibid.
41 L. A. Gear, Inc. v. Thom McAn, 1123.
43 Yoder Bros., Inc. v. Cal.-Fla. Plant Corp., 537 F.2d 1347, 1380 (5th Cir. 1976). ( “Asexual reproduction is literally the only way that a breeder can be sure he has reproduced a plant identical in every respect to the parent” ).
being a “reward, an inducement, to bring forth new knowledge.”

Thus, regardless of the amount of labor the inventor invested, “only inventions and discoveries which further human knowledge, and [are] new and useful, justified the special inducement of a limited private monopoly.”

Patents impart a private right to the patent owner. Private ownership is based on the “conviction that encouragement of individual effort by personal gain is the best way to advance public welfare through the talents of authors and inventors in ‘Science and useful Arts.’” The owner of a patent can use this private right offensively against competitors who may try to make and sell comparable products that incorporate the invention. Patent rights may also be used defensively. The patent owner may wait until another entity attempts to sell a product that infringes on the patent. In such situations, the patent owner can commercialize the patent by licensing the patent. The patent owner may also file a patent infringement lawsuit with the goal of obtaining an injunction, lost profits, or reasonable royalties.

Patents are meant to provide a number of incentives. First, patents provide an incentive to invent. Given that invention often requires an enormous investment of time, research, and development, patents encourage this risk-taking with the anticipation that inventions will provide a positive societal benefit. Second, patents provide an incentive for inventors to disclose their inventions, which they may otherwise keep a trade secret. Incentive to disclose is the quid pro quo for the grant of exclusivity. Third, patents create an incentive to design around other inventions in the field; in other words, inventors will create new developments to fall outside the scope of another’s patent. Designing around other inventions brings “a steady flow of innovations to the marketplace.” Fourth, patents create an incentive to commercialize the invention through investment of “risk capital in the commercialization of useful patentable inventions.” Thus, patents introduce “new products and processes of manufacture into the economy, [leading to] increased employment and better lives for our citizens.” In each of these, both the inventor and society as a whole are meant to benefit from the patent.

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45 Ibid.
47 35 U.S.C. §§ 283, 284; *State Indus., Inc. v. Mor-Flow Ind. Inc.*, 883 F.2d 1573, 1577 (Fed. Cir. 1989) (reaffirming that lost profits can be obtained as a remedy for patent infringement).
50 *Kewanee Oil Co. v. Bicron Corp*, 481.
51 *State Indus., Inc. v. A. O. Smith Corp.*, 751 F.2d 1226 (Fed. Cir. 1985).
52 Ibid., 1236.
54 *Kewanee Oil Co. v. Bicron Corp*, 480.
Genes and Genetic Technology as Patentable Subject Matter

As discussed above, patents may be granted on “any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof.” The matter to be patented must be described “with reasonable clarity to those skilled in the art.”

Until recently, the only US Supreme Court decision on the patentability of living creatures was Funk Bros. Seed Co. v. Kalo Inoculant Co. In that case, the patentee claimed a mixed species of bacteria to beneficially infect legumes; previously, such mixtures had been unsuccessful because the bacteria inhibited each other. The patentee had discovered and combined strains of bacteria species that were not mutually inhibitory. The Court, however, held that this claim was not patent eligible as it was just a “discovery of some of the handiwork of nature.”

Although the statute was interpreted by courts for a long time to exclude products of nature or living matter, this changed in 1980, when the US Supreme Court held that patent law does not differentiate between living and inanimate things in Diamond v. Chakrabarty. This case involved the invention of an organism that could digest oil slicks. The Court, however, did find that patent law distinguishes between “products of nature, whether living or not, and human-made inventions.” The Diamond decision appeared to permit the patenting of animals.

Following Diamond, the PTO announced in 1987 that “non-naturally occurring nonhuman multicellular living organisms, including animals, [are] patentable subject matter within the scope of 35 U.S.C. §101.” In 1988, the PTO issued its first patent for animals, commonly referred to as the “Harvard mouse patent.” Over twenty years later, the PTO’s policy that a claim encompassing a human being is not patentable was codified in 2011 in the Leahy-Smith America Invents Act (AIA). Section 33(a) of the AIA states, “Notwithstanding any other provision of law, no patent may issue on a claim directed to or encompassing a human organism.”

In 2012, the US Supreme Court held that processes that encompass the laws of nature are not patentable subject matter unless they include an “inventive concept.” In Mayo Collaborative Services v. Prometheus Laboratories, Prometheus

59 Ibid., 129.
60 Ibid., 130.
61 Ibid., 131.
63 Ibid., 313.
had obtained a patent that covered processes to determine the proper dosage of a drug based on certain metabolite blood levels in a patient’s blood. The Court held that these processes were not patentable.\textsuperscript{68} The Court noted that patent law ought not to “inhibit further discovery by improperly tying up the future use of laws of nature.”\textsuperscript{69} Yet the Court recognized the fine line between application of the laws of nature and patentable developments since all inventions apply the laws of nature to some level.\textsuperscript{70} Indeed, in reaching its holding, the Court emphasized there must be an “‘inventive concept,’ sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the natural law itself.”\textsuperscript{71}

The question as to the patentability of human genes was finally decided by the US Supreme Court in 2013 in \textit{Assoc. for Molecular Pathology v. Myriad Genetics, Inc.} Myriad isolated the BRCA1 and BRCA2 genes. Mutations of these genes can dramatically increase the risk of breast and ovarian cancer.\textsuperscript{72} Myriad then obtained patents, which would give it the exclusive right to isolate BRCA1 and BRCA2 genes in an individual and to synthetically create BRCA cDNA.\textsuperscript{73} More precisely, the patent claims at issue before the Supreme Court were for the naturally occurring DNA segment of BRCA genes. Myriad argued that the act of locating these genes and extracting them for study was a true invention.\textsuperscript{74} The Supreme Court held that the naturally occurring DNA segments were a product of nature and not patent eligible. The Court reasoned that Myriad did not create anything at all but only extracted the naturally occurring genes for study.\textsuperscript{75}

The Court did not hold that Myriad “created an innovative method of manipulating genes” while searching for the BRCA genes a method patent could have been issued.\textsuperscript{76} Moreover, the Court noted that a patent might also be issued for creation of the synthetic form of those genes since they do not exist in nature.\textsuperscript{77}

The Court also held that the cDNA was patent-eligible because it is not naturally occurring.\textsuperscript{78} This holding regarding cDNA was lambasted by commentators who

\textsuperscript{68} Ibid., 1294–1295.
\textsuperscript{69} Ibid., 1301.
\textsuperscript{70} Ibid., 1293.
\textsuperscript{71} Ibid., 1294.
\textsuperscript{72} \textit{Assoc. for Molecular Pathology v. Myriad Genetics}, 2112.
\textsuperscript{73} Ibid., 2113.
\textsuperscript{74} Ibid., 2116.
\textsuperscript{75} Ibid., 2117–2118. It is interesting to note that in 1998, the European Parliament passed a Directive on the Legal Protection of Biotechnological Inventions, stating that “patent law must be applied so as to respect the fundamental principles safeguarding the dignity and integrity of the person.” It explicitly excluded patenting of the human body, including germ cells, embryos, and gene sequences as they are found inside the human body. It, however, does not prohibit patenting of these isolated outside the body for innovation. The European Parliament and Council, On the Legal Protection of Biotechnological Inventions, Directive 98/44/ED (July 6, 1998), n. 16; and Audrey R. Chapman, \textit{Unprecedented Choices: Religious Ethics at the Frontiers of Genetic Science} (Minneapolis: Augsburg Fortress, 1999), 1142.
\textsuperscript{76} \textit{Assoc. for Molecular Pathology v. Myriad Genetics}, 2119.
\textsuperscript{77} Ibid., 2120.
\textsuperscript{78} Ibid.
pointed out that the Court clearly got the science wrong in attempting to distinguish cDNA from “naturally occurring” DNA. Specifically, cDNA is created from “naturally occurring” DNA through the natural base-pairing process, with the omission of “nonsense” DNA. This process, however, is not done by humans; it occurs naturally without any human intervention. It is thus wholly unclear what distinction really exists if natural genetic material like cDNA can be patented.

Overall, the Court’s decision recognized two conflicting possibilities due to their ruling: creating too many requirements for patent eligibility stifling financial incentives to innovate with natural products; allowing broad patent eligibility for natural products, creating a monopoly limiting others from innovating in the field. The emphasis on the commercial environment that surrounds patent rights cannot be missed in the Court’s attempt to carefully balance these two possible outcomes.

From these cases, the current law as to the patentability of genes and genetic technology can be summarized as follows:

- The legal system views DNA as mere chemical compounds, no different from any other chemical substance.
- Whether an organism is living is immaterial as to its patentability.
- Genetic technology may be patentable if it is not naturally occurring. In particular, the US Supreme Court has given a nod of approval to (1) inventions for methods to manipulate genes (beyond natural processes) and (2) inventions of synthetic forms of genes that do not exist in nature.
- What counts as “naturally occurring” remains to be defined more precisely.

In short, it is clear that there are many areas that have yet to be addressed by the Court as to genetic technology’s patentability.

Catholic Bioethics and Human Dignity

Central to Catholic bioethics is the concept of human dignity. As philosopher Rev. John Conley, SJ, observed, the definition of human dignity is elusive because

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82 The importance of human dignity has also been recognized in a secular context. See *Cohen v. Hurley*, 366 U.S. 117, 152 (1961) (heralding the “high regard for human dignity” as an aspect of the American legal system).
of the richness of the concept. At its simplest, human dignity is the possession of every human being; it is “about intrinsic worth, rationality, voluntariness, and the capacity to love.” It is more than merely respecting another; rather, human dignity is the motivation behind that respect. The *Catechism of the Catholic Church* defines the dignity of human beings as follows:

The dignity of the human person is rooted in his creation in the image and likeness of God; it is fulfilled in his vocation to divine beatitude. It is essential to a human being freely to direct himself to this fulfillment. By his deliberate actions, the human person does, or does not, conform to the good promised by God and attested by moral conscience. Human beings make their own contribution to their interior growth; they make their whole sentient and spiritual lives into means of this growth. With the help of grace they grow in virtue, avoid sin, and if they sin they entrust themselves as did the prodigal son to the mercy of our Father in heaven. In this way they attain to the perfection of charity.

In this description, the very heart of the notion of human dignity rests in the relationship of the person to God for “the root reason for human dignity lies in man’s call to communion with God.” Humanity is rooted first in a supernatural vocation, that is, in the very life of God. This vocation imparts meaning on our human existence and “reveals the greatness and inestimable value of human life even in its temporal phase.”

The Catholic Church teaches that the meaning and dignity which is the proud hallmark of our law”); *Paul v. Davis*, 424 U.S. 693, 735 (1976) (recognizing “the legitimate expectations of every person to innate human dignity”); *Tennessee v. Lane*, 541 U.S. 509, 537 (2004) (“Legislation calling upon all government actors to respect the dignity of individuals with disabilities is entirely compatible with our Constitution’s commitment to federalism, properly conceived”); Universal Declaration of Human Rights (1948), Article 1 (“All human beings are born free and equal in dignity and rights”); Babylonian Talmud, Berakoth 19b (proclaiming that the attribute of kvod habriot is very precious and there is no virtue more beloved than it); Doron Shultziner, “A Jewish Conception of Human Dignity: Philosophy and Its Ethical Implications for Israeli Supreme Court Decisions,” *Journal of Religious Ethics* 34.4 (December 2006): 663–683; and Mohammad Hashim Kamali, *The Dignity of Man: An Islamic Perspective* (Cambridge, UK: The Islamic Texts Society, 2002).


84 Ibid. This belief is also reflected outside of Catholic teaching. For example, Article 1 of the Universal Declaration of Human Rights states that “all human beings are born free and equal in dignity and rights.”

85 Although some writers seek to distinguish “human persons” from “human beings,” I have chosen to adopt the view of philosopher Teresa Iglesias, recognizing that all human beings are human persons, and utilize the terms interchangeably. See Teresa Iglesias, “Bedrock Truths and the Dignity of the Individual,” *Logos* 4.1 (Winter 2001): 118.


The purpose of each human person’s life is to know, love, and serve God in this world and to be with him in Heaven.\textsuperscript{89} The beginning, end, and purpose of each person’s life are found in God.\textsuperscript{90}

Human dignity is not limited merely to the soul of the person; rather, “the human body shares in the dignity of ‘the image of God.’”\textsuperscript{91} The body truly is an icon to God, pointing to the Incarnation of Christ, our redemption by Christ, and the end times.\textsuperscript{92} St. Paul describes the human body as a “temple,” writing, “Do you not know that you are the temple of God, and that the Spirit of God dwells in you? If anyone destroys God’s temple, God will destroy that person; for the temple of God, which you are, is holy.”\textsuperscript{93} Similarly Paul also writes, “Do you not know that your body is a temple of the Holy Spirit within you, whom you have from God, and that you are not your own? For you have been purchased at a price. Therefore glorify God in your body” (1 Cor. 6:19–20). Paul’s reference to the body as a temple harkens back to ancient Judaism and the centrality of the ancient Jewish temple in that, in a particular way,
it was set apart as the dwelling place of God. Indeed, Pope St. John Paul II defines human dignity as the “sacrum,” or the sacredness, of the person.

Thus, this language of the body as a temple imparts the distinctness of the human body as being different from other types of property or possessions. The temple image “call[s] forth a fundamental disposition of reverential awe toward the ‘sacred space’ of the body, and a sense of both restrictions and responsibilities regarding what may be done with, by, or to that temple by oneself or others.” This imagery requires acknowledgment that one’s body belongs to God and each of us serves as a steward of our bodies; that is, we are particularly accountable for its use or misuse. Put another way, the notion of imago Dei can be understood, at least in part, to be the source of associating humans “as a community of stewards and co-creators in relation to God.”

Bioethicist Daniel Sulmasy has identified four corollaries to the principle of human dignity: (1) biological; (2) given; (3) finite but priceless; and (4) transcendental. First, human beings are biological creatures and thus, being and living are the same. Second, human life is given; we are not the cause of our own coming into existence, which Sulmasy notes is both a biological and metaphysical truth. Third, the value of life is beyond measure; however, this does not mean that it is infinite. While human life can be said to be priceless, Sulmasy contends that this is not the same as having infinite value. A human life has value, but “it is a value unlike other values that can be assigned a price.” Finally, Sulmasy states that what makes human life priceless is that “life has a transcendental, but not a transcendent, value.” Life has value because it is prior to any other possibilities.

94 N. T. Wright, The New Testament and the People of God (Minneapolis: Fortress Press, 1992), 224 (“The Temple was the focal point of every aspect of Jewish national life. Local synagogues and the schools of Torah in other parts of Palestine, and in the Diaspora, in no way replaced it, but gained their significance from their implicit relation to it. Its importance at every level can hardly be overestimated.”). 1 Kings 8:10–14. E. P. Sanders, Judaism: Practice and Belief 63 BCE–66 CE (Harrisburg, PA: Trinity Press International, 1992), 70, 71 (“The Temple was holy not only because the holy God was worshipped there, but also because he was there . . . . Jews did not think that God was there and nowhere else, nor that the Temple in any way confined him. Since he was the creator and Lord of the universe, he could be approached in prayer at any place. Nevertheless, he was in some special sense present in the Temple.”).


97 Ibid.


100 Ibid., 188.

101 Ibid., 189.
Human dignity is also the source of the right to private ownership of goods. Human work proceeds from the fact that humans are created in the image of God and our dignity is in that identity. The dignity of work arises from human dignity since work confirms humanity’s dominion over the world. Through work, man “makes part of the earth his own, precisely the part which he has acquired through work; this is the origin of individual property.”

However, not only does human dignity support the private ownership of goods, but human labor must also increase human dignity. Private property must always be viewed as a means and not an end. Private property must be used for the common good, in its essence, private property is only an instrument for the universal benefit of all persons. This concept is known as the “universal destination of goods.” The Second Vatican Council’s Gaudium et spes clarifies the meaning of the universal destination of goods:

Whatever the forms of property may be, as adapted to the legitimate institutions of peoples according to diverse and changeable circumstances, attention must always be paid to this universal destination of earthly goods. In using them, therefore, man should regard the external things that he legitimately possesses not only as his own but also as common in the sense that they should be able to benefit not only him but also others.

In particular, new scientific and technological advances must always be placed at the service of humanity’s needs.

The importance of a correct understanding of the person cannot be overemphasized. As Jesuit theologian Rev. Karl Rahner stated, “The notion of person … is of

102 Vatican Council II, Gaudium et spes, n. 34 (“For man, created to God’s image, received a mandate to subject to himself the earth and all it contains, and to govern the world with justice and holiness; a mandate to relate himself and the totality of things to Him Who was to be acknowledged as the Lord and Creator of all.”).


105 John Paul II, Laborem exercens, n. 27; Vatican Council II, Gaudium et spes, n. 35 (“Hence, the norm of human activity is this: that in accord with the divine plan and will, it harmonize with the genuine good of the human race, and that it allow men as individuals and as members of society to pursue their total vocation and fulfill it.”).


108 Catechism, nn. 2401–2404.

109 Vatican Council II, Gaudium et spes, n. 69.

110 PCJP, Compendium of the Social Doctrine, n. 179.
great importance in theology, because it draws attention to those human characteristics which are the necessary condition of his relationship to God and his salutary acts.”¹¹¹ Because of this understanding, the Catholic Church teaches that a person may not be “manipulated for ends that are foreign to his own development” and that are not a means to an end for any project, even under the name of progress.¹¹² To do otherwise would be contrary to the dignity of the other person.¹¹³ Since the other person was also brought into being by God’s love and creative action, and called to an intimate relationship with Him, one does not have the moral authority to treat the other person as one may treat the other creatures of the earth.¹¹⁴

**Commodification of Human Genes**

In 1988, the California Court of Appeals remarked, “In recent history, we have seen the human body assume astonishing aspects of [commercial] value.”¹¹⁵ It is this particular observation that is at the heart of the discussion between the Catholic understanding of human dignity and the values underlying patent law. Commodification of genetic material through the granting of patents is not in harmony with the pricelessness of human beings.

**Ethical Tension between Patent Law and Human Dignity**

Patent law, as discussed above, rests on the notion of creation and ownership of the idea being patented. There is a notion of the sovereignty of the patent-owner via ownership. However, the difficulty with patenting the human genetic code is that it turns the human person into an object, thus subject to market forces. As Patricia Baird noted, “patenting genes is seen as transforming them into a commodity, and this is viewed as being disrespectful of life.”¹¹⁶ Philosopher Baruch Brody observed that “ownership of human genes infringes on human dignity because it is equivalent to ownership of humans, because it commercializes body parts which should not be commodified, because it cheapens that which defines human identity, and because it would lead to inappropriate modifications in our genetic integrity.”¹¹⁷ Genes and gene therapy then become a commodity, something to be objectified and traded. This commodification reduces human life to a commercial

¹¹³ *Catechism*, n. 2295.
¹¹⁴ See Gen 1:24–30.
¹¹⁶ Patricia Baird, “Patenting and Human Genes,” *Perspectives in Biology and Medicine* 41.3 (Spring 1998): 400.
value, focused on marketability. Similar sentiments were previously expressed by bioethicist Paul Ramsey, who stated that the “body is so inseparable from the person that people should not trade in it.”

Proponents of the patent system, including the PTO, have made the point that patents do not confer the full bundle of rights of ownership; instead, it confers only a limited right to exclude others from commercial exploitation of an invention for a certain period of time. Further, patents do not grant ownership of genetic material inside a person. Therefore, there is no argument, at least from a legal perspective, that an inventor owns any of the genes inside of my body.

Even if this position is correct, it does not account for the practical implications of patents. Patents are very often the gateway to commercial viability. The right to exclude others from utilizing the patented technology provides the patent holder a tremendous advantage in acquiring market share and profits. It also provides the patent holder the opportunity to license the invention to others to use, providing another avenue of profits. Particularly in the area of genetic technology, patents are intimately linked to market forces. As Mary Taylor Danforth noted, research with human cells with an eye toward profit “tends to treat the human body as a commodity—a means to a profitable end. The dignity and sanctity with which we regard the human whole, body as well as mind and soul, are absent when we allow researchers to further their own interests without the patient’s participation by using a patient’s cells as the basis for a marketable product.”

Just as important as the notion of ownership is the rhetoric that attaches once genes are thought of in a commercial sense. Commodification of human genetic material introduces economic language to the understanding of genes. Law professor Margaret Radin writes that “in market rhetoric, the discourse of commodification, one conceives of human attributes (properties of persons) as fungible owned objects (the property of persons). One conceives of human interactions as ‘sales’ with ‘prices’ even where no money literally changes hands.”

This notion is opposed to human dignity. As discussed previously, Sulmasy’s corollaries to human dignity further elucidate this point. Human beings are priceless because their value is beyond anything that can be assigned some numerical value. To

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121 See Assoc. for Molecular Pathology v. Myriad Genetics.
utilize rhetoric suggesting price, sale, or commodity is diametrically opposed to the pricelessness of human beings. This holds even when discussing a part of a human being because of the unity of the human person.\textsuperscript{124}

Moreover, the problem is that application of rhetoric associated with the marketplace objectifies the human person and encourages an attitude of disposability. There is a sense that if it can be bought and sold (or at least that that language can be utilized in the discourse), it becomes fungible. This can be seen in the case law’s discussion of genes and DNA merely as another material, seemingly no different than a piece of plastic or metal.

At an even deeper level, this ownership language leads to an even more fundamental rift, namely, the nature of who God is and who we are as humans. For if each human person is “the temple of God” whose purpose is communion with God, then the question of whether patenting genetic material and genetic technology is in accord with Catholic theology ought to be whether it fosters the relationship between the person and God.\textsuperscript{125}

The difficulty, then, is once again the problem of viewing the patented technology as property. To say that a person or institution “owns” a specific sequence of DNA or even the ability to manipulate existing vectors to transport the DNA seems opposed to God as the Creator and source of all life. Richard Land and C. Ben Mitchell of the Southern Baptist Convention’s Christian Life Commission articulated this position in this way:

Human beings are pre-owned. We belong to the sovereign Creator. We are, therefore, not to be killed without adequate justification (e.g., self-defense) nor are we, or our body parts, to be bought and sold in the marketplace. Yet the patenting of human genetic material attempts to wrest ownership from God and commodifies human biological materials and, potentially, human beings themselves. Admittedly, a single human gene or a cell line is not a human being; but a human gene or cell line is undeniably human and warrants different treatment than all non-human genes or cell lines. The image of God pervades human life in all of its parts. Furthermore, the right to own one part of a human being is \textit{ceteris paribus} the right to own all the parts of a human being. This right must not be transferred from the Creator to the creature.\textsuperscript{126}

Put another way, there is one ideal owner, one who is the owner in relation to every other thing. That owner is God. This understanding is derived from the Lord being

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\item \textsuperscript{125} \textit{Catechism}, n. 2294 (“Science and technology by their very nature require unconditional respect for fundamental moral criteria. They must be at the service of the human person, of his inalienable rights, of his true and integral good, in conformity with the plan and the will of God.”).
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the Creator of all things, bringing all into being out of nothing (Gen 1–3). Only God, therefore, can exercise pure ownership. As humans, we can only share in or imitate God’s ownership of his creatures in an imperfect manner.127

Thus, we see that the body is “a witness to creation as a fundamental gift, and therefore a witness to Love as the source from which this same giving springs.”128 The body bears to the visible world a witness of God’s love. As Philip Hughes stated, “It is the image of God in which man was created, rather, which pervades his existence in its totality and is the cause of his transcendence over the rest of God’s creation.”129 This image of God thus has its imprint on all aspects of the human person, beginning obviously with human genes. Respect for the whole body must also be reflected in the smallest component of the body.

In summary, the fundamental difference between the US patent system and Catholic bioethics is how the human body and its components are viewed. Patent law permits assigning an ownership right to certain naturally occurring genetic material such as cDNA. This ownership right reduces human beings to small pieces to which a price can be assigned by science and the free market. In stark contrast, Catholic bioethics is rooted in the human body as something worthy of reverence, a “sacred space” in which humans are able to have a relationship with God and strive toward their ultimate goal. In this light, it follows that there is a pricelessness of the human body that is incompatible with commodification of the human body.

Are the Patents Related to the CD34+ Gene Therapy Ethical?

As an initial matter, it is important to note that the CD34+ gene therapy is morally licit. Gene therapy was addressed in Dignitas personae, and distinctions were made between the different types of gene therapies. It stated that “procedures used on somatic cells for strictly therapeutic purposes are in principle morally licit” as they “seek to restore the normal genetic configuration of the patient or to counter damage caused by genetic anomalies.”130

A separate question arises, however, as to whether patent ownership is in accord with Catholic bioethics. As discussed above, the CD34+ gene therapy and

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128 John Paul II, General Audience (January 9, 1980), in Man and Woman, 14:4, original emphasis.


the associated patents are comprised of two parts: the patent for the normal gene configuration on chromosome 11 and the method by which the normal gene configuration is delivered to the stem cells. I would argue that granting patent rights to the normal genetic configuration is not in conformity with the Catholic understanding of human dignity, but that granting patent rights to the method of delivering the normal genes to the stem cells does not contradict Catholic understanding on human dignity.

Patenting of the normal gene configuration is the easier aspect to address. The normal gene is found in nature, as the US Supreme Court noted. Does it make any sense to confer an ownership right to the pattern of a human body, that is, a head, body, two arms, and two legs? To confer ownership over normal, naturally occurring genes makes no more sense than conferring ownership for a pattern to formulate the physical body parts of humans. Permitting ownership of such naturally occurring patterns expands the dominion of humans over nature to an insufferable extent. Dominion over nature, as understood in the Catholic tradition, involves both a recognition of humans as the summit of the hierarchy of creation and a respect for natural law as a foundation for moral action.131 The patent type of ownership results in a view of the human person as a disposable item. An ownership interest being granted to humans over the patterns inherent in the body creates a distorted view of God as Creator and humans as part of the created order. Viewing the human body has being owned by humans instead of by God offends human dignity.

In contrast, patenting the method for insertion of the normal gene is not objectionable. The reason why a different result is reached with regards to this aspect of the CD34+ gene therapy is because the method is not a natural component of the human person like genes. Instead it is a tool for restoring normal human function. The method is not found in nature and work is invested to develop the specifics of the vector in a way that is effective and safe for humans. This is more akin to a farmer growing and harvesting apples from a tree. It is also more than an attempt to own principles of nature because, although it relies on common scientific principles, it requires manipulation and recombination. It is congruent with human dignity for humans to own technologies to restore right functioning to other persons as a product of their labors.

It should be noted, however, that even patent rights for the therapy’s process are only in conformity with human dignity if the patent rights are being utilized toward the common good, namely, for the benefit of those needing the medical treatment.132 Like one’s ownership of his or her own body, owners of goods such as the CD34+ gene therapy are “steward[s] of Providence, with the task of making it fruitful and communicating its benefits to others.”133

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131 See *Catechism*, nn. 343, 346, 353, 354.
133 *Catechism*, n. 2404.
Moving Forward

Through the example of the CD34+ gene therapy, it can be seen that whether patent rights are in accord with the Catholic principle of human dignity varies based on the specific aspect of the genetic technology sought to be patented. Patenting, and thereby conferring an ownership right, to naturally occurring genetic code is contrary to human dignity as it results in the commodification of the very fundamental aspects of the human person and distorts the relationship between God and humanity. Moreover, to attribute some conception of ownership to human genes heightens the notion that humans, or at least portions of them, are disposable, capable of being purchased, sold, or destroyed at will.

In contrast, patenting a method for inserting normal genes into a person does not create such offenses since they honor the work of the person in discovering and developing solutions not found in nature. Permitting a claim of ownership rights in this latter situation is consistent with God’s command to humanity to have dominion over the earth.\textsuperscript{134} So long as such ownership is not selfish but instead allowed to be accessed by all who need it, the dignity of humanity is upheld.

Although, as of the Myriad decision, it appears that the courts are in accord with this view of human dignity, the judicial toehold may be wearing thin. Since the Myriad ruling was grounded in a tenuous view of what is “natural” as the defining feature, there will undoubtedly be future challenges that may cause the courts to reconsider the fine hair-splicing maneuver to conclude genes are not patentable. A better line of reasoning along the Church’s understanding of human dignity would permit a strong rationale for not permitting gene patents, while still allowing patents on truly novel discoveries.

As questions related to ownership of genetic technology, along with issues related to disposal of human embryos and other human tissues, loom on the horizon, it remains imperative to hold fast to a moral vision of who we are as human beings, namely, our dignity through our relationship with God. If we lose this center, we are liable to replace it with something less than concern for other persons, such as progress for its own sake, market-forces, or even a sense of divine power over other humans. As John Paul II noted, “When the sense of God is lost, there is also a tendency to lose the sense of man, of his dignity and his life; in turn, the systematic violation of the moral law, especially in the serious matter of respect for human life and its dignity, produces a kind of progressive darkening of the capacity to discern God’s living and saving presence.”\textsuperscript{135} In other words, the push toward a reductionist view through the commodification of the very physical foundation of the human person is a result of a failure to understand and appreciate the dignity of every human person, and ultimately, an understanding of who God is.

\textsuperscript{134} See Gen 1:28–30.
\textsuperscript{135} John Paul II, Evangelium vitae, n. 21.