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ARTICLE

RELIGIOUS CONTRIBUTIONS TO THE
DEBATE ON THE PATENTING OF
HUMAN GENES¹

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Whether patents or other forms of intellectual property rights should be granted on living things, particularly human genes, has been debated for more than thirty years. Opposition has proceeded on two levels: some have raised utilitarian and consequentialist questions about the implications of patenting for impeding scientific research and medical applications, and others, primarily in the religious community, have contested life patents on the grounds of their conflict with moral and theological principles. While there has been some public attention on the issue, the “debates” over the appropriateness and impact of genetic patenting have taken place primarily among scholars through publications in ethical and legal journals, papers presented at professional meetings, and panels at academic conferences. Over time the concerns raised have shifted, but criticism of life patents has been persistent, albeit coming in intermittent waves.

The religious community has been involved in discussion of the appropriateness of patenting human genes from the beginning. In 1980, shortly after the Supreme Court issued the landmark *Diamond v. Chakrabarty* decision holding that a genetically modified strain of bacteria was patentable,² the General Secretaries of the National Council of Churches, the United States Catholic Conference, and the Synagogue Council of America sent President Jimmy Carter a letter in which they expressed concerns about the

1. This paper builds upon three previous publications of mine: AUDREY R. CHAPMAN, UNPRECEDENTED CHOICES: RELIGIOUS ETHICS AT THE FRONTIERS OF GENETIC SCIENCE, (1999) [hereinafter UNPRECEDENTED CHOICES]; PERSPECTIVES ON GENETIC PATENTING: RELIGION, SCIENCE, AND INDUSTRY IN DIALOGUE (Audrey R. Chapman ed., 1999) [hereinafter PERSPECTIVES]; Audrey R. Chapman, *The Ethics of Patenting Human Embryonic Stem Cells*, 19 KENNEDY INST. ETHICS J., 261 (2009).

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2. 477 U.S. 303, 313 (1980).

patenting of life. The letter stated that the control of life forms by any individual group posed a potential threat to all humanity:

We know from experience that it would be naïve and unfair to ask private corporations to suddenly abandon the profit motive when it comes to genetic engineering. Private corporations develop and sell new products to make money, whether these products are automobiles or new forms of life. Yet when the products are new life forms, with all the risks entailed, shouldn't there be broader criteria than profit for determining their use and distribution?³

Nevertheless, it is important to note two caveats about religious contributions to the debate over the patenting of human genes. First, religious involvement has been quite sporadic. Periods of activity have been followed by years of silence regarding these issues. Little has been heard during the past ten years from representatives of the religious communities previously interested in the issue or the moral theologians who wrote on the topic. Importantly, only one denomination, the Southern Baptist Convention, submitted an amicus brief to express its views in the sole litigation on the permissibility of patenting unmodified human genes. The case, *Association for Molecular Pathology v. Myriad Genetics*, was decided by the Supreme Court on June 13, 2013.⁴ Overruling the long-standing position of the U.S. Patent and Trademark Office, which had granted some 20,000 patents on isolated and purified genes, all nine justices of the Court held that the segments of DNA that make up human genes are not patentable subject matter under section 101 of the Patent Act⁵ because they are products of nature.⁶ However, the Court ruled that “complementary DNA,” or cDNA, genetic sequences created by stripping away non-protein coding material from naturally occurring DNA, are not a product of nature, and therefore are patentable.⁷

Second, there is no consensus regarding religious positions on genetic patenting. Most religious contributors to the debate have presented their own views rather than representing official denominational positions. Moreover, there have sometimes been stronger and more heated disagreements within the religious community than between members of the religious and secular communities. This was certainly the case when I served as the convener of a multi-sector dialogue group under the aegis of the Program of Dialogue Between Science, Ethics, and Religion of the American Association for the Advancement of Science (AAAS) that brought together representatives of the religious community with scientists, secular ethicists, and

3. Claire Randall, Bernard Mandelbaum & Thomas Kelly, *A Letter to the President of the United States* (June 20, 1980), in *GENETIC ENGINEERING: SOCIAL AND ETHICAL CONSEQUENCES* app. at 48 (1984) [hereinafter *GENETIC ENGINEERING*].

4. 133 S. Ct. 2107, 2107 (2013).

5. 35 U.S.C. § 101 (1952).

6. *Myriad*, 133 S. Ct. at 2109.

7. *Id.* at 2110.

representatives of industry to discuss the appropriateness and implications of patenting human genes. Some of the resources referenced in this paper were written for the dialogue group and published in an edited volume, *Perspectives on Genetic Patenting: Religion, Science, and Industry in Dialogue*.⁸

This paper identifies the various religious contributions over the years to the human gene patenting debate and the context in which these views were presented. It begins with three background sections: the role of law and ethics in human genetic patenting, opposition to human gene patenting in the scientific and legal communities, and an overview of the religious contributions. It then explores five themes on which there have been input by the religious community: (1) the grounds for opposition to patenting of life, specifically human genes; (2) the theological implications of patents on life; (3) the implications of patents for human dignity; (4) the implications of patenting for the commodification of human life; and (5) the ontological and metaphysical status of DNA. The final section evaluates the relevance or lack thereof of the positions taken by the religious community to the *Myriad* case.

I. LEGAL AND ETHICAL PROVISIONS IN PATENT LAW

In 1980, the landmark Supreme Court decision, *Diamond v. Chakrabarty*, overturned some two hundred years of legal doctrine that conceptualized life forms as “products of nature” rather than human inventions and therefore unable to meet the three criteria for patents established by the United States Congress and many other countries: novelty, utility, and non-obviousness.⁹ As interpreted by the United States Patent and Trademark Office (USPTO), to be “novel” an invention must not have been known and available to the public at the time of the application.¹⁰ “Utility” refers to usefulness.¹¹ To qualify, a proposed patent must specify a concrete function, service, or purpose.¹² Under the “nonobviousness” standard, it is not possible to obtain a patent if the differences between its subject matter and the prior art are such that “the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.”¹³ Until 1980 the USPTO did not issue patents for living organisms, but only for composi-

8. See PERSPECTIVES, *supra* note 1.

9. 477 U.S. at 311–12.

10. United States Patent and Trademark Office, General Information Concerning Patents (Nov. 2011), http://www.uspto.gov/patents/resources/general_info_concerning_patents.jsp.

11. *Id.* (“Utility patents may be granted to anyone who invents or discovers any new and useful process, machine, article of manufacture, or composition of matter, or any new and useful improvement thereof”).

12. *Id.*

13. 35 U.S.C. § 103 (1952).

tions containing living things, such as a waste disposal system containing bacteria.¹⁴

In *Chakrabarty* the Court ruled, in a narrow five-to-four decision, that a genetically modified strain of bacteria capable of degrading components of crude oil and thus useful in cleaning up oil spills was patentable as a new and useful manufacture or composition of matter.¹⁵ Although Ananda Chakrabarty, a microbiologist then working at General Electric, acknowledged that he used commonplace methods to exchange genetic material between bacteria, the Court held that “his discovery is not nature’s handiwork but his own” and “the result of human ingenuity and research.”¹⁶ While the decision affirmed that phenomena of nature in their natural state are not patentable, the Court identified a major exception: goods that have been transformed from their natural state through human intervention may be patented. According to the Court, Congress intended that “anything under the sun that is made by man” be patentable subject matter.¹⁷ The courts have continued to affirm, most recently in *Mayo Collaborative Services v. Prometheus Labs*, that “[l]aws of nature, natural phenomena, and abstract ideas are not patentable.”¹⁸ After the *Chakrabarty* decision the USPTO, followed by the European and Japanese patent offices, began to grant new kinds of biotechnology patents. New kinds of biotechnology patents included patents on new plant varieties, non-naturally occurring non-human multicellular living organisms, including animals, such as a mouse genetically altered so as to be susceptible to breast cancer, and eventually, discoveries of naturally occurring human genetic sequences.¹⁹

To justify patenting unmodified human genes, the USPTO had to reinterpret its criteria for patenting. However it did not provide a full legal justification for granting human gene patents until January 2001, when it issued its Utility Examination Guidelines (Guidelines).²⁰ The Guidelines justify patents on isolated DNA by claiming that the raw DNA, whether the whole of a gene or a fragment, becomes a new composition of matter when it is chemically isolated from its natural state and purified.²¹ In the Guidelines the USPTO argues that a DNA molecule that has been isolated in this manner is not a product of nature.²² Even under the USPTO’s reinterpretation, a 2005 evaluation of some 1167 claims contained within seventy-four issued

14. UNPRECEDENTED CHOICES, *supra* note 1, at 132.

15. 477 U.S. at 310–11.

16. *Id.* at 310, 313.

17. *Id.*

18. 132 S. Ct. 1289, 1293 (2012).

19. See Mark Sagoff, *DNA Patents: Making Ends Meet*, in PERSPECTIVES, *supra* note 1, at 245; Mark Sagoff, Report, *Animals as Inventions: Biotechnology and Intellectual Property Rights*, INST. FOR PHIL. & PUB. POL’Y 16, 18 (1996).

20. Utility Examination Guidelines, 66 Fed. Reg. 1092 (Jan. 5, 2001).

21. *Id.* at 1093.

22. *Id.*

patents covering human genetic material found that thirty-eight percent did not meet the then current interpretation of existing statutory requirements under U.S. law.²³

Two developments accelerated the subsequent patenting of genes in this country. The Bayh-Dole Act, adopted in 1980, encouraged the commercialization of federally supported research, including biotechnology, and to that end permitted recipients of federal funding to apply for intellectual property rights for their inventions.²⁴ The inception of the Human Genome Project (HGP) in 1988, a major international initiative to decode the human genome led by the United States National Institutes of Health (NIH), accelerated the pace of genetic discoveries and raised anew the issues related to commercialization of biology. In 1991, well before any of the significant issues regarding intellectual property rights or applications of research and discoveries funded through the HGP were resolved, NIH filed a patent application on 350 human gene fragments that had been identified by one of its scientists, followed by a second patent application in 1992 on an additional 2370 fragments.²⁵ The USPTO turned down NIH's initial patent application on the grounds that gene fragments did not meet the criteria for patenting, but later reversed its policy.²⁶ In 2005 it was estimated that about one-fifth of human gene sequences were patented.²⁷ Genes associated with health and specific diseases are more likely to be patented than other genes.²⁸ More recently however, a new study found that forty-one percent of the genes in the human genome have been claimed.²⁹ If both short and long nucleotide sequences are considered, the study concluded that the entire human genome may be covered by patents held by commercial companies.³⁰

Despite the ethical concerns about the appropriateness of patenting life forms, from the years after the *Chakrabarty* decision to the present day, Congress has refrained from taking up the issue and setting policy. The lack of legislative guidelines left the USPTO free to determine policy on narrow technical grounds. Baruch Brody's review of the development of intellectual property norms applied to biotechnology in the United States offers

23. Jordan Paradise, et al., *Patents on Human Genes: An Analysis of Scope and Claims*, 307 *SCIENCE* 1566, 1566–67 (2005).

24. The Bayh-Dole Act, or Patent and Trademark Law Amendments Act, Pub. L. 96-517 (Dec. 12 1980).

25. Pamela Zurer, *NIH Files Second Human Gene Patent Application*, Chem. Eng. News (Feb. 17, 1992) at 6, <http://pubs.acs.org/stoken/campaign/watchglass/pdf/10.1021/cen-v070n007.p006>.

26. See John J. Doll, *The Patenting of DNA*, 280 *SCIENCE*, 689, 689–90 (1998).

27. Kyle Jensen & Fiona Murtagh, *Intellectual Property Landscape of the Human Genome*, 310 *SCIENCE* 239, 239–40 (2005).

28. *Id.*

29. Jeffrey Rosenfeld & Christopher Mason, *Pervasive Sequence Patents Cover the Entire Human Genome*, *GENOME MED.*, 3 (Mar. 25, 2013), <http://genomemedicine.com/content/5/3/27>.

30. *Id.*

extensive evidence that there were many opportunities, all missed, to modify the traditionally robust system of intellectual property rights to make it more appropriate for living and naturally occurring products.³¹ Nor did the courts or Congress clarify or systematically resolve a series of important issues as they emerged, instead, leaving the patenting landscape to incremental shaping through litigation. As noted, on the central issue of how much change from what is found in nature is required for a product to be patentable, the USPTO and the courts came to accept the view that the isolation and purification of what occurs naturally is sufficient to make the product patentable.³² Congress and the courts also neglected to consider imposing special conditions on the use of genetic material from a particular individual or group of people, for example, to require low-cost licensing when access was important for human welfare.³³

In this country, ethical concerns are not usually seen as relevant to the development of intellectual policy norms. Only once has the USPTO rejected a life patent claim primarily on ethical grounds.³⁴ To bring attention to questions concerning the ethics of genetic engineering and patenting of engineered life forms, two opponents of human gene patents, Stuart Newman and Jeremy Rifkin, filed a patent application in December 1997 for creating human-animal chimeras that could be up to fifty percent human and implanting them into surrogate mothers.³⁵ The patent was rejected by the USPTO in part because “the broadest reasonable interpretation of the claimed invention as a whole embraces a human being.”³⁶ Presumably this ruling reflected the Thirteenth Amendment prohibition against owning another person. Following the filing of the chimera patent application, the USPTO also issued an advisory indicating “that inventions directed to human/non-human chimeras could, under certain circumstances, not be patentable because, among other things, they would fail to meet the public policy and morality aspects of the utility requirements.”³⁷

31. The review was published as a two part article in the March and June issues of the Kennedy Institute of Ethics Journal: Baruch Brody, *Intellectual Property and Biotechnology: The U.S. Internal Experience* (pts. 1 & 2), 16 KENNEDY INST. ETHICS J. 1 (Mar. 2006), 16 KENNEDY INST. ETHICS J. 105 (June 2006).

32. Baruch Brody, *Intellectual Property and Biotechnology: The U.S. Internal Experience – Part I*, 16 KENNEDY INST. ETHICS J. 11 (Mar. 2006).

33. *Id.* at 15–19.

34. See Sander Rabin, *The Human Use of Humanoid Beings: Chimeras and Patent Law*, 24 NATURE BIOTECHNOLOGY 5 (May 2006).

35. Rochelle K. Seide & Carmella L. Stephens, *Ethical Issues and Applications of Patent Laws in Biotechnology*, in WHO OWNS LIFE? 59, 67 (David Magnus, Arthur Caplan, Glenn McGee eds., 2002).

36. *Id.*

37. Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions, 1998 O.J. (L 213) 13, 13–21 [hereinafter Directive 98/44/EC].

In contrast with the situation in this country, European patent law incorporates ethical screens that have discouraged forms of life patenting. Article 53 of the European Patent Convention on exceptions to patentability stipulates that European patents shall not be granted for “inventions the publication or exploitation of which would be contrary to ‘ordre public’ or morality.”³⁸ The exemption language in the European Patent Convention is also incorporated into the World Trade Organization’s Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Building on the precedent of the European Patent Convention, TRIPS allows members to exclude subject matter from patenting “to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment.”³⁹ Although the United States is a member of TRIPS, this provision has not been applied in U.S. courts.

In addition, the Directive on the Legal Protection of Biotechnology Inventions (Directive), approved by the European Parliament in 1998, has a series of exclusions applying to life. In contrast to the absence of restrictions in the policy of the United States, the Directive excludes plant and animal varieties from patenting along with essential biological processes for the production of plants or animals.⁴⁰ Article 5 of the Directive has additional exclusions relating to the human body, including human genes:

- The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.⁴¹
- The industrial application⁴² of a sequence or partial sequence of a gene must be disclosed in the patent application.⁴³

Repeating the language in the European Patent Convention, the Directive also specifies that inventions shall be considered nonpatentable where their commercial exploitation would be contrary to public order or morality,⁴⁴ and identifies the following list as examples:

- (a) Processes for cloning human beings;
- (b) Processes for modifying the germ line genetic identity of human beings;
- (c) Uses of human embryos for industrial or commercial purposes;

38. European Patent Convention, Article 53(a) (Jan. 24, 2011).

39. Agreement on Trade-Related Aspects of Intellectual Property Rights, Marrakesh Agreement Establishing the World Trade Organization, Apr 15, 1994, 1867 U.N.T.S., Annex 1C, section 5, art. 27(2) [hereinafter TRIPS Agreement].

40. Directive 98/44/EC, *supra* note 37, at art. 4(1) a & b.

41. *Id.* at art. 5(1).

42. European patent criteria uses the term industrial application, which is equivalent to the U.S. criteria of usefulness and is stricter about its assessment in evaluations of patentability.

43. Directive 98/44/EC, *supra* note 37, at art. 5(3).

44. *Id.* at art. 6(1).

(d) Processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.⁴⁵

Although the Directive was addressed only to European Union member states, obliging them to amend their national biotech patent laws to be consistent with its provisions, the European Patent Office, which is independent of the European Union, voluntarily incorporated the Directive's rules into its implementing regulations. Article 6(2)c and its moral exclusions became rule 23d(c) of the European Patent Convention.⁴⁶ Significantly, in 2011, the European Court of Justice, when considering a German patent awarded to neuroscientist Oliver Brüstle, ruled that processes and products involving human embryonic stem cells are not patentable in Europe.⁴⁷

II. OPPOSITION TO GENETIC PATENTING FROM THE SCIENTIFIC AND LEGAL COMMUNITIES

Historically, intellectual property regimes evolved to balance the moral and economic rights of creators and inventors with the wider interests and needs of society. A major justification for patents and copyrights is that incentives and rewards to inventors result in benefits for society. The U.S. Constitution, written in 1787, for example, vests the Congress with the power "To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."⁴⁸ Similarly, TRIPS provides the following rationale for intellectual property:

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.⁴⁹

But somewhere along the way, the instrumental character of intellectual property as a means to promote the public good has been lost. In the post-industrial information society, intellectual property has come to be seen as an economic asset in much the same way as material investments once were. In the process, intellectual property has become more a means to

45. *Id.* at art. 6(2).

46. Gerard Porter et al., *The Patentability of Human Embryonic Stem Cells in Europe*, 24 NATURE BIOTECHNOLOGY 653, 653 (2006).

47. Gretchen Vogel, *Dismay, Confusion Greet Human Stem Cell Patent Ban*, 334 SCIENCE 441, 441–42 (2011).

48. U.S. CONST. art. I, § 8, cl. 8.

49. TRIPS Agreement, *supra* note 39, at part 1, art. 7.

encourage and protect investments. Therefore, public policies about patentable subject matter, like other aspects of intellectual property, have been shaped more by considerations of economic competitiveness than social benefit.

A strict reading of the social utility rationale for intellectual property, however, implies that the failure to facilitate scientific research and the development of useful and affordable products undermines the legitimacy of current norms and renders these arrangements subject to fundamental changes that can assure greater benefits. Much of the debate on the patenting of human genes, particularly in the secular community, has revolved around utilitarian and consequentialist ethical issues as to whether the patenting contributes to human welfare through encouraging scientific research and investment, or impedes it. And these factors were raised by the plaintiffs in the legal case over Myriad Genetics' patenting of the BRCA1 and BRCA2 genes.⁵⁰

Patents on human gene sequences have been controversial from their inception. There has been persistent, if intermittently expressed, concern regarding the inappropriateness of genetic patenting and its detrimental impact on scientific advancement.⁵¹ One fundamental question that has been raised is whether genetic patents issued are consistent with the criteria for patenting.⁵² Initial opposition to human gene patenting within the scientific community focused on the failure of the work on which the patent applications were based to provide knowledge of the function of the relevant gene sequences. A second and persistent source of opposition has related to the anticipated negative effects that patenting would have on research and therapeutic applications of the knowledge generated by the HGP. The 1995 statement on the patenting of DNA sequences issued by the Human Genome Organisation (HUGO), an international research consortium coordinating and enhancing efforts in genome research, reflected those concerns and expressed HUGO's dedication to the early release of genome information in order to accelerate widespread investigation of the functional aspects of genes.⁵³

A 1993 opinion from the Group of Advisers on the Ethical Implications of Biotechnology to the European Commission put forward a similar concern. Mindful of the economic value of biotechnology, the opinion found no ethical rationale for opposing the patentability of inventions relating to living matter in principle. But the advisers expressed reservations

50. Complaint at 18–19, *Association for Molecular Pathology v. United States Patent and Trademark Office*, 133 S. Ct. 2107 (2013) (No. 12-398).

51. Rebecca S. Eisenberg, *Why the Gene Patenting Controversy Persists*, 77 *ACAD. MED.*, 1381, 1381 (2002).

52. See, for example, *id.* at 1381–82.

53. The Human Genome Organisation, *HUGO Statement on Patenting of DNA Sequences*, (Jan. 1995) <https://web.archive.org/web/19970412010739/http://hugo.gdb.org/patent.htm>.

about the patentability of human genes and partial gene sequences on the grounds that identifying genes or partial gene sequences without discovering their function does not constitute an “inventive step” and therefore does not meet the criteria for patenting.⁵⁴ It also reiterated the need to protect human dignity, although it was not specific about the best means to do so.⁵⁵

Rather than being silenced, the level of indignation expressed by opponents of gene patenting in the scientific community has increased over time. In part this reflects the fact that the process of isolating genes has become more mechanized through the use of automatic sequencing machines, and it is argued that this process requires no more than ordinary skills on the part of the inventor.⁵⁶ With this shift, scientists have been able to identify large numbers of genes. In addition, it has meant that the patenting of genes has begun to appear less as patenting end products and more like patenting scientific information.⁵⁷ The uneasiness regarding genetic patents is compounded by the broad claims made in many of the patents that are granted.

Concerns expressed by individual scientists and scientific organizations also reflect their commitment to the norms of academic science promoting open access and circulation of research findings about fundamental discoveries. Until recently, academically based scientists did not seek patents on their discoveries and inventions, but instead sought recognition through publication of their findings. A number of factors, particularly changes in U.S. policy regarding the ownership of publicly funded research and the increasing commercialization of science, have encouraged efforts to secure a legal monopoly over discoveries deemed to have commercial potential.⁵⁸ Nevertheless, as a 2005 National Academies of Science report comments, “Many research scientists who work in public institutions are troubled by the concept of intellectual property protection for DNA-based information, because it seems to be in conflict with scientific norms that dictate that science will advance more rapidly if researchers enjoy free access to knowledge.”⁵⁹

In a much-cited 1998 article in *Science*, Michael Heller and Rebecca Eisenberg warn that the proliferation of gene patents is creating so many concurrent fragments of intellectual property rights by different owners that

54. *Opinion of the Group of Advisors on the Ethical Implications of Biotechnology to the European Commission*, No. 3, 2.2.3 (Sept. 30, 1993).

55. *Id.*

56. Eisenberg, *supra* note 51, at 1381.

57. *Id.* at 1383.

58. Matthew Herder, “Proliferating Patent Problems with Human Embryonic Stem Cell Research?” 3 J. BIOETHICAL INQ. 69, 71 (2006).

59. NAT’L RESEARCH COUNCIL, THE NAT’L ACADEMIES, REAPING THE BENEFITS OF GENOMIC AND PROTEOMIC RESEARCH: INTELLECTUAL PROPERTY RIGHTS, INNOVATION, AND PUBLIC HEALTH 24 (Stephen A. Merrill & Anne-Marie Mazza eds., 2006).

it is likely to create serious problems for future product development.⁶⁰ Heller and Eisenberg argue that the ownership of intellectual property rights is becoming fragmented across institutions in the public and private sectors, requiring researchers to spend a significant amount of time locating a multitude of patent rights to pursue a project. This results in increased legal costs and financial burdens as scientists bundle licenses together in order to conduct research or develop new products. Additionally, as they point out, some researchers and developers, such as academics, may be ill equipped to handle multiple transactions for acquiring rights to research tools and licenses. Faced with this situation, they anticipate that many researchers and companies will choose to invest resources in less promising projects with fewer licensing obstacles and lower initial start-up costs. Because patents matter more to the pharmaceutical and biotechnology industries, they also foresee that corporations in this sector will be less willing to participate in mechanisms like patent pools that can help overcome these problems. They therefore conclude that, unless restrictive licensing practices are minimized, the patent system is more likely to lead to fewer useful products for improving human health than to spur investment and product development.⁶¹

A 2005 survey to evaluate the effects of intellectual property rights on genomic and proteomic research, undertaken for the National Academy of Sciences (NAS), found that “access to patents or information inputs into biomedical research rarely imposes a significant burden for academic biomedical researchers,” but concluded that this situation largely reflects the failure of academic investigators to respect existing intellectual property requirements.⁶² To put the matter another way, academic researchers, perhaps assuming they were protected from liability for infringement by a broad research exemption, tended to ignore and violate intellectual property restrictions. To date, with the exception of gene based diagnostic patents, established companies have been reluctant to take action against most of these academic infringements.⁶³ The NAS report cautioned, however, that in the absence of an established research exemption in this country,⁶⁴ patent holders could become more active in asserting their intellectual property rights, with more “demands for licensing fees, grant-back rights, and other terms

60. See generally Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 *SCIENCE* 698 (1998) (arguing that more intellectual property rights in biotechnology may frustrate the development of useful inventions).

61. *Id.* at 701.

62. NAT'L RESEARCH COUNCIL, *supra* note 59, at 123.

63. *Id.* at 125.

64. The past claims of a research or experimental use exemption protecting scientists from liability for patent infringement were essentially rendered defunct in *Madey v. Duke University*, 307 F.3d 1351, 1361–62 (Fed. Cir. 2002) (“In short, regardless of whether a particular institution or entity is engaged in an endeavor for commercial gain, so long as the act is in furtherance of the alleged infringer’s legitimate business and is not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry, the act does not qualify for the very narrow and strictly limited experimental use defense.”).

that are burdensome to research.”⁶⁵ Moreover, researchers and institutions that infringe on others’ intellectual property could later encounter difficulties in commercializing their inventions. Finally, the NAS report anticipates that as scientists increasingly use the high-throughput tools of genomics and proteomics to simultaneously study the properties of multiple genes or proteins, the burden of securing the intellectual property rights covering them could become “insupportable.”⁶⁶ The NAS therefore called for steps to be taken to anticipate and prevent the emergence of an increasingly problematic environment for research in genomics in the near future as more patent applications are filed and more restrictions are placed on the availability of and access to information and resources.⁶⁷

Concern has also been expressed elsewhere over restrictive licensing of patented genes for clinical-testing services. A 2001 survey of 122 laboratory directors in the United States indicated that twenty-five percent had stopped performing a clinical genetic test because of a patent or license.⁶⁸ In addition, fifty-three percent reported deciding not to develop a new clinical genetic test because of a patent or license.⁶⁹ In 2010 the Department of Health and Human Services Secretary’s Advisory Committee on Genetics, Health, and Society (SACGHS) found that the prospect of patent protection of a genetic research discovery does not play a major role in motivating scientists to conduct genetic research.⁷⁰ Importantly, the SACGHS also concluded that patents can harm genetic research by discouraging follow-on research.⁷¹ Additionally, SACGHS could not identify any cases in which possession of exclusive rights was necessary for the development of a particular genetic test.⁷² It therefore recommended the creation of an exemption from patent infringement liability for anyone “making, using, ordering, offering for sale, or selling a test developed under the patent for patient-care purposes,” as well as an exemption for those who “use patent-protected genes in the pursuit of research.”⁷³ Myriad Genetics’ rigid monopolization of diagnostic testing for susceptibility to breast cancer linked to mutations in the BRCA1 and BRCA2 gene sequences that it has patented—and the detrimental health impact of its doing so by restricting

65. NAT’L RESEARCH COUNCIL, *supra* note 59, at 3.

66. *Id.*

67. *See id.* at 133–49 (conclusions and recommendations).

68. Mildred K. Cho et al., Special Article, *Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services*, 5 J. MOLECULAR DIAGNOSTICS 3, 5 (2003).

69. *Id.*

70. SECRETARY’S ADVISORY COMM. ON GENETICS, HEALTH, AND SOC’Y, DEP’T OF HEALTH & HUM. SERVS., GENE PATENTS AND LICENSING PRACTICES AND THEIR IMPACT ON PATIENT ACCESS TO GENETIC TESTS 1, 1 (2010), available at http://oba.od.nih.gov/oba/SACGHS/reports/SACGHS_patents_report_2010.pdf.

71. *Id.* at 2

72. *Id.*

73. *Id.* at 4, 97.

testing—played a major role in the decision to pursue legal action against Myriad.⁷⁴

As we move into a genomic age, patents on human genes may interfere with new developments, such as the ability to perform whole-genome sequencing. According to Christopher Mason, one of the authors of a study that found companies hold patents on the entire genome, “[t]his means if the Supreme Court upholds the current scope of the patents, no physician or researcher can study the DNA of these genes from their patients, and no diagnostic test or drug can be developed based on any of these genes without infringing a patent.”⁷⁵ He describes the situation as “‘patently ridiculous’” and went on to say that “[f]ailure to resolve these ambiguities perpetuates a direct threat to genomic liberty, or the right to one’s own DNA.”⁷⁶

III. OVERVIEW OF THE RELIGIOUS COMMUNITY’S INVOLVEMENT

The revolution in molecular biology and genetics in the second half of the twentieth century presented the religious community with unique challenges and opportunities to define its social ethics and contribute to public policy formation. In the process, a variety of faith bodies and moral theologians have framed positions on genetics and genetic patenting. Opposition to the patenting of life forms has proceeded intermittently on a variety of symbolic and substantive grounds. Beginning in 1980, when the General Secretaries of the National Council of Churches, the Synagogue Council of America, and the U.S. Catholic Conference wrote to President Carter shortly after the *Chakrabarty* decision,⁷⁷ groups and individuals within the religious community expressed concerns about genetic patenting. Rather than expressing an anti-technology position, this opposition often reflected a religiously grounded conviction that biological patents constitute a threat to the dignity and sanctity of life.⁷⁸

The initiative that drew the most attention occurred in 1995 when leaders of more than eighty religious denominations and faiths in the United States—a broad array including Protestant, Catholic, Orthodox, Jewish, Muslim, Buddhist, and Hindu—held a press conference to announce their

74. See generally E. Richard Gold & Julia Carbone, *Myriad Genetics: In the Eye of the Policy Storm*, 12 GENETICS MED. S39 (2010) (examining Myriad’s business decisions and the context in which they were made).

75. James Foley, *Entire Human Genome Is Patented by For-Profit Companies*, NATURE WORLD NEWS, http://www.natureworldnews.com/home/news/services/print.php?article_id=1059 (last visited Nov. 4, 2013).

76. Ruth Saunders, *Companies Hold Patents on Entire Human Genome*, BIONEWS, http://www.bionews.org.uk/page_279342.asp (Last visited Nov. 4, 2013).

77. Claire Randall, Bernard Mandelbaum & Thomas Kelly, *A Letter to the President of the United States*, in GENETIC ENGINEERING, *supra* note 3, at app. 47–49.

78. For an analysis of the history and grounding of the religious opposition, see generally UNPRECEDENTED CHOICES, *supra* note 1, at 125–65.

opposition to the patenting of genetically engineered animals and human genes, cells, and organs.⁷⁹ They launched the Joint Appeal Against Human and Animal Patenting (Joint Appeal), a coalition organized by the General Board of Church and Society of the United Methodist Church and Jeremy Rifkin, an anti-biotechnology activist who was the head of the Foundation on Economic Trends. Each of the signatories subscribed to the text of a brief statement:

We, the undersigned religious leaders, oppose the patenting of human and animal life forms. We are disturbed by the U.S. Patent's 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.⁸⁰

An accompanying press release indicated that the signatories planned a nationwide educational campaign in the nation's churches, synagogues, newspapers, and temples to raise critical theological concerns about the patenting of life,⁸¹ but such a campaign never developed.

Although nearly two hundred religious leaders signed the Joint Appeal, the position taken in that statement does not reflect a consensus within the religious community, not even within the majority of the faith communions represented. With the exception of the Methodist bishops, the signatories were not representing the official positions or policies of their respective communions. One indication of the complexity of the situation is that although the U.S. Catholic Conference declined to support the statement, ninety-one Roman Catholic bishops became signatories. At the time of the Joint Appeal few of the participating communions had an explicit policy on the appropriateness of patenting human genes or life forms. Of those that did, the General Conference of the United Methodist Church adopted a position in 1992 that affirmed the understanding of the sanctity of God's creation and God's ownership of life, and identified that claims of exclusive ownership rights to genes as a means of making genetic technologies accessible raised serious theological concerns.⁸² It went on, "[w]e urge that genes and genetically modified organisms (human, plant, animal) be held as common resources and not be exclusively controlled, or patented."

A month after the Joint Appeal, in June 1995, the Southern Baptist Convention adopted a resolution that requested "an immediate moratorium on the patenting of animal and human tissues and genetic sequences until a

79. See UNPRECEDENTED CHOICES, *supra* note, 1 at 125 (citing "Joint Appeal Against Human and Animal Patenting," text of the press conference announcement made available by the General Board of Church and Society of the United Methodist Church, Washington, D.C., May 17, 1995).

80. *Id.*

81. *See id.*

82. UNITED METHODIST CHURCH, *New Developments in Genetic Science, in THE BOOK OF RESOLUTIONS OF THE UNITED METHODIST CHURCH* 325, 332-33 (1992).

full and complete discussion has occurred.”⁸³ The Southern Baptist Convention has remained more actively involved in the patenting issue than other Joint Appeal signatories. It was the only denomination to submit an amicus brief to the Supreme Court to present its view in the Myriad case.⁸⁴

A variety of denominations have developed educational resources on genetics for their own members, a few of which include a discussion of patenting issues. One of the most recent of these, *Genetics! Where Do We Stand as Christians*, prepared in 2001 by the Evangelical Lutheran Church in America, has a chapter on gene patenting.⁸⁵ This resource is unusual in that it includes a brief primer on the legal background and presents competing perspectives on patenting. It is also gently critical of the Joint Appeal and positions taken by others in the religious community on the issue.

It would be erroneous to portray the religious community or specific communions as having a consistent witness or involvement in the discussions related to the patenting of life forms. As with many other scientifically based issues, only a small number of persons within church agencies and theological institutions have paid attention to developments or followed debates among secular experts. Religious statements on patenting have tended to be followed by long periods of silence, often for many years at a time. This is a pattern characteristic of the way many communions have dealt with other issues as well.⁸⁶ Since much of the writing on patenting by moral theologians and ethicists has been reactive to other initiatives in the religious community, there has been little sustained work on the topic by them either.

There has been little apparent interest or involvement related to patenting in recent years. In 2003 a National Council of Churches Exploratory Committee on Human Genetic Technologies report, which was written in response to the mandate to identify the challenges posed by human applications of genetic technologies and to evaluate the merits of long-term efforts in this area, including engagement with the biotechnology industry,⁸⁷ did

83. SOUTHERN BAPTIST CONVENTION, *On the Patenting of Animal and Human Genes*, in ANNUAL OF THE SOUTHERN BAPTIST CONVENTION 91, 92 (1995).

84. Brief of the Ethics & Religious Liberty Commission of the Southern Baptist Convention & Prof. D. Brian Scarnecchia as Amici Curiae in Support of Petitioners, Association for Molecular Pathology, et al., v. Myriad Genetics, Inc., et al., 133 S. Ct. 2107 (2013) (No. 12-398, 2012).

85. EVANGELICAL LUTHERAN CHURCH IN AMERICA, *GENETICS! WHERE DO WE STAND AS CHRISTIANS?* 40–45 Chicago: Augsburg Fortress Publishers on behalf of the Division for Church in Society of the Evangelical Lutheran Church, (2001), ch. 5.

86. This author was the World Issues Secretary of the United Church Board for World Ministries of the United Church of Christ for nearly ten years, where she directed peace, justice, and human rights ministries for the agency, and observed this trend. Her reflections about the public policy ministries of mainline churches are presented in AUDREY R. CHAPMAN, *FAITH, POWER, AND POLITICS: POLITICAL MINISTRY IN MAINLINE CHURCHES* (1991).

87. EXPLORATORY COMMITTEE ON HUMAN GENETIC TECHNOLOGIES, NATIONAL COUNCIL OF CHURCHES OF CHRIST, *REPORT OF THE NCC EXPLORATORY COMMITTEE ON HUMAN GENETIC TECHNOLOGIES TO THE NCC GENERAL ASSEMBLY* (2003).

not propose gene patenting as one potential focus of future initiatives. The report failed to mention gene patenting even though the Chairperson of the Committee, Jaydee Hanson, had played a central role in the Joint Appeal. Religious voices were also not represented in the discussions as to whether human embryonic stem cells should be patentable subject matter. Because human embryonic stem cells are derived from three- to five-day-old embryos (technically blastocysts), allowing patents on human embryonic stem cells has potential implications for human dignity, certainly more so than human genes and gene fragments. The lack of involvement in stem cell patenting might have reflected greater concerns among some of the religious communities with the more fundamental questions about whether it is ethically appropriate to derive human embryonic stem cell lines and engage in embryonic stem cell research.⁸⁸

Another indication of the decline of interest is that of the sixty amicus briefs filed in the legal suit, *Association for Molecular Pathology v. Myriad Genetics*, when it was to be heard by the Supreme Court, only one represented a religious denomination or actor—the *amici curiae* of the Ethics & Religious Liberty Commission of the Southern Baptist Convention.⁸⁹ It is only possible to speculate on why this agency continued its advocacy when other denominations did not. The strength of its convictions may have played a role. Continuity in religious leadership may have been another factor. Another possibility is that someone offered to author the brief on behalf of the Ethics & Religious Liberty Commission so the agency did not have to invest much time or resources in the initiative.

IV. ISSUES RAISED BY RELIGIOUS CONTRIBUTIONS ON HUMAN GENETIC PATENTING

A. *Should There Be Patents on Life Forms and Human Genes?*

One of the fundamental issues underlying the debate is whether there should be patents on life forms and specifically on human genes. Many in the religious community, even those who may not oppose patenting per se, have been uncomfortable with treating DNA as just another commodity that can be owned and controlled by individuals or corporations. Sometimes this discomfort has reflected an assumption or intuition that there are categories of things which by their very nature should not be treated as commodities.

A line of philosophical thinking stresses the moral need to protect certain items from being treated as economic commodities. Michael Walzer's concept of "blocked exchanges" is useful here. He notes that there are categories of items about which society has determined distribution should be

88. See generally Audrey R. Chapman, *The Ethics of Patenting Human Embryonic Stem Cells*, *supra* note 1, at 261 (exploring the ethical issues raised by human embryonic stem cell patenting).

89. Brief for Amici Curiae in Support of Petitioners, *supra* note 84.

on a noneconomic basis.⁹⁰ His list of fourteen such “blocked exchanges” or things which cannot be bought and sold includes human beings; political power and influence; criminal justice; freedom of speech, press, religion, assembly; exemptions from military service, jury duty, or other communally imposed work; political offices; and love and friendship.⁹¹ More recently, Michael Sandel makes a similar argument in his book *What Money Can't Buy*.⁹²

The assumption or intuition that there are categories of things that by their very nature should not be treated as commodities has important implications for understanding the nature of property. As Paul Thompson points out, property and ownership are moral precepts encompassing philosophical beliefs as well as legal, economic, and cultural practices. He distinguishes between two basic approaches to property—an instrumental and an ontological frame of reference.⁹³ As instrumental or utilitarian conception presumes that property itself is a legal fiction, an artifact of a legal code, which is validated to the extent that it is useful in promoting some more fundamental social, political, or economic end.⁹⁴ Most advocates of life patenting have an instrumental or utilitarian conception of property. They justify granting patents on biological organisms on the grounds that intellectual property rights will bring individual or social benefits through promoting research and development of useful medical applications.

In contrast, many of the opponents of patenting biological organisms hold, at least implicitly, what Thompson defines as an ontological conception of property.⁹⁵ An ontological approach bases property status on traits or characteristics alleged to inhere in specific objects and thereby excludes broad categories of objects from private ownership. Each of the three major forms of ontological reasoning Thompson identifies limits property claims in some way. Natural law philosophy stipulates that property must be based on traditional practices deemed justified by their obviousness and noncontroversial nature. Labor theory confines property claims to objects that are the product of human work. There is also broad consensus that ownership of human beings should be prohibited. In addition to excludability, ontological approaches offer two other criteria to consider whether property claims are appropriate. These are the concepts of rivalry (whether the use or consumption of the goods by one person diminishes the availability for others) and alienability (whether a good can be dissociated from one owner

90. MICHAEL WALZER, SPHERES OF JUSTICE 100–03 (1983).

91. *Id.*

92. MICHAEL J. SANDEL, WHAT MONEY CAN'T BUY: THE MORAL LIMITS OF MARKETS (2012).

93. Paul B. Thompson, *Conceptions of Property and the Biotechnology Debate*, 45 *BIO-SCIENCE* 275, 275–78 (1995).

94. *Id.* at 275–77.

95. *Id.* at 277–78.

and transferred to another).⁹⁶ Thompson argues that an ontological approach provides strong grounds for rejecting most forms of intellectual property claims. In particular, he concludes that recombinant DNA techniques challenge the natural law bias against alienating goods from previous patterns of ownership and exchange.⁹⁷

Thompson's distinction between instrumental and ontological approaches to property helps illuminate why groups holding different views on the appropriateness of genetic patents frequently talk past one another. Advocates of life patenting sometimes assume that critics do not understand the limited nature of the property rights patenting entails. To correct an assumed misconception about the nature of property, property is characterized not as ownership of a tangible object, but rather as a bundle of rights in an object. In this line of reasoning, patents are conceptualized as very limited forms of property rights. Concurrently, advocates of life patenting underscore that patents do not confer positive right to possess, make, use, or sell anything. Instead, they emphasize patents convey only the right to exclude others from making, using, selling, or importing the patented item or from carrying out a patented process.⁹⁸

But the issue is both different from and more fundamental than a misunderstanding of the nature of intellectual property. Defenders of patents typically have an instrumental approach, offering a consequentialist-incentive rationale. Industry has long held that intellectual property rights are necessary incentives for major investments in research and development needed to commercialize new products that are of benefit to the public. In contrast, religious opponents of patenting usually base their criticisms on ontological principles. Still others try to have it both ways—they attempt to mix an ontological and an instrumental approach to property. On the one hand, they have a moral intuition that it is inappropriate to patent life forms, particularly human tissue and DNA. Nevertheless, they affirm the utilitarian goal of facilitating research and product development and sometimes even the premise that industry is entitled to financial incentives and rewards. Moreover, they are unwilling or unable to critique the claims that patents benefit the public by stimulating investment in research, development, and commercialization of new products.

96. *Id.* at 277–81.

97. *Id.* at 278.

98. Pilar N. Ossorio, *Property Rights and Human Bodies*, in *WHO OWNS LIFE?*, *supra* note 35, at 223, 224–26.

B. *God's Ownership of Life – What is Being Patented*

Some groups in the religious community have put forth the view, perhaps at least in part on symbolic grounds,⁹⁹ that the patenting of life forms implies that human beings rather than God are the inventors of these forms of life. For example, C. Ben Mitchell, then a member of the Southern Baptist Convention's Christian Life Commission, argued in a paper prepared for the AAAS dialogue group that composition of matter patents on living organisms is problematic because these patents impinge on the sanctity of God's creation and God's status as the Creator and therefore the ultimate "owner" of life.¹⁰⁰ By claiming exclusionary property rights in a genetically altered composition of matter, "the human manipulator is assuming a place which belongs alone to God, the divine Artificer."¹⁰¹ Patenting of human body parts is doubly problematic for Mitchell because he believes it also violates human dignity.¹⁰² In an article co-authored by Mitchell and Richard Land, they contend that human genes are sacred and warrant a different status and treatment than non-human genes and cell lines.¹⁰³ They ground this claim on their belief that human beings alone bear the image of God and the *imago Dei* pervades human life in all its parts.¹⁰⁴ The *amici curiae* brief of the Ethics and Religious Liberty Commission of the Southern Baptist Convention to the Supreme Court in the Myriad Genetics case reiterates this theme. It argues that allowing anyone to claim ownership over the material that constitutes the human body "reverses the roles of the Creator and the created" and constitutes a "daring infringement of the law of nature."¹⁰⁵

Without evaluating the specifics of this line of argument, it is relevant to note that other thinkers in the religious community take issue with this perspective. Theologian Ronald Cole-Turner, for example, proposes we understand God's ownership as quite different from human ownership.¹⁰⁶ According to Cole-Turner, God owns all things, not in an exclusive sense, but to give the goodness of creation as gifts to be shared by all creatures. He suggests we conceptualize God's ownership as God reserving the right to

99. The interpretation that these concerns are more symbolic than substantive is put forward in Mark J. Hanson, *Patenting Genes and Life: Improper Commodification?*, in WHO OWNS LIFE?, *supra* note 35, at 161.

100. C. Ben Mitchell, *A Southern Baptist Looks at Patenting Life*, in PERSPECTIVES, *supra* note 1, at 167, 174–76.

101. *Id.* at 176.

102. *Id.* at 177.

103. Richard D. Land & C. Ben Mitchell, *Patenting Life: No*, 63 FIRST THINGS 20, 21 (1996).

104. *Id.* at 20–21.

105. Brief for Amici Curiae in Support of Petitioners, *supra* note 84, at 6 (quoting William Lloyd Garrison, *Declaration of Sentiments of the American Anti-Slavery Convention*, SELECTIONS FROM THE WRITINGS OF W. L. GARRISON, <http://utc.iath.virginia.edu/abolitn/abeswlgct.html> (last visited Nov. 6, 2013)).

106. Ronald Cole-Turner, *Theological Perspectives on the Status of DNA: A Contribution to the Debate over Genetic Patenting*, in PERSPECTIVES, *supra* note 1, at 150, 152.

define their purpose, value, and relationship to other creatures.¹⁰⁷ When it comes to the nonhuman creation, human ownership may therefore proceed as long as it is consistent with God's definition of their purposes. Or to put the matter another way, God's ownership does not exclude but qualifies human ownership.¹⁰⁸ Ownership of a person, however, always violates God's prior claims "because human persons are declared to be in the image of God, which means that God has defined the purpose of every human life to be a free and responsible person able to offer one's life to God in worship and service."¹⁰⁹ Cole-Turner also takes issue with the view of DNA as sacred and equates it with a form of vitalism that equates the sacred with all of life or a life principle.¹¹⁰ In Cole-Turner's view therefore there should be no intrinsic theological objection to biological patents. He concludes that individuals and corporations may claim intellectual property rights in biological components as long as they are exercised in a manner consistent with religious, legal, and business norms.¹¹¹

The Evangelical Lutheran Church in America (ELCA) criticizes the position that patenting demeans God's role as the Creator on other grounds: that it incorrectly sharply divides creation into the natural and artificial and assigns God's creative activity to one, but not the other.¹¹² According to the ELCA, human ingenuity is a natural gift of God and therefore divine creativity works through human creativity. Every living being, whether genetically altered, both the natural and the artificial, have God-given dignity and both are equally gifts of God's creative activity.¹¹³

C. *Implications for Human Dignity*

In making the claim that patenting human DNA and tissue demeans human life and dignity, the religious community echoes concerns raised by some ethicists in the secular community. Moreover, given the commitment to the value of the human person in Western religious tradition, a concern with the implications of patents on human dignity is understandable. Both Christianity and Judaism conceptualize the human person as the *imago Dei*, a representation of the divine creator.¹¹⁴ The affirmation of humanity as the image of God plays an important role in the thinking of at least some of the religious opponents of patenting.¹¹⁵ Some religious opponents of patenting

107. *Id.* at 152.

108. *Id.*

109. *Id.*

110. *Id.* at 155–63.

111. *Id.* at 163.

112. EVANGELICAL LUTHERAN CHURCH IN AMERICA, GENETICS! WHERE DO WE STAND AS CHRISTIANS? 43 (2001).

113. *Id.* at 43.

114. See, for example, the conceptualization of humankind in *Genesis* 1:26–27.

115. See Ted Peters, *Should We Patent God's Creation?* 35 *DIALOG* 117, 122 (1996).

also assume that the protections accorded to persons should extend to human tissue and body parts as well.¹¹⁶

Nevertheless, the affirmation of humanity as the image of God does not in and of itself provide a clear grounding for opposing patenting of altered human tissue or DNA. One of the complexities of this issue is that conceptions and interpretations of the phrase “image of God” have differed dramatically. Theologian Douglas John Hall has shown that, through the centuries, commentators have had a conspicuous tendency to identify those traits or gifts that are valued by their particular culture as the central meaning of the phrase.¹¹⁷ Moreover, the acknowledgement of human dignity and even the sacredness of persons have not precluded religious acceptance of slavery, war, the death penalty, or unspeakable forms of abuse and torture.

The concept of the inherent dignity of the human person is well established in both U.S. and international law and provides the foundation for all current international human rights instruments. The Thirteenth Amendment to the U.S. Constitution also prohibits owning and selling human beings.¹¹⁸ It is relevant here to note that the European Patent Office restricts the subject matter eligible for intellectual property protection so as to eliminate inventions that are inconsistent with protecting human dignity. Provisions of the Directive of the European Parliament and of the Council on the Legal Protection of Biotechnological Inventions exclude inventions from patentability that offend human dignity and ethical and moral principles recognized in member states.¹¹⁹ The Directive, for example, instructs member states that “Patent law must be applied so as to respect the fundamental principles safeguarding the dignity and integrity of the person.”¹²⁰

Proponents of patenting, on the other hand, often distinguish between the status of human material in the body and outside of it. Even if they recognize a moral basis for excluding patenting of human material, they claim that it does not extend to patenting *ex vivo* DNA sequences.¹²¹ European patent law, for example, makes this distinction. Although it excludes the human body at any stage of formation or development—including germ cells and the sequence or partial sequence of a human gene from patent-

116. For example, the Joint Appeal statement objected to the PTO’s decision to patent body parts. “Religious Leaders Prepare to Fight Patents on Genes,” N. Y. TIMES, May 13, 1995, <http://www.nytimes.com/1995/05/13/us/company-news-religious-leaders-prepare-to-fight-patents-on-genes.html>.

117. DOUGLASS JOHN HALL, IMAGING GOD: DOMINION AS STEWARDSHIP, 88–112 (1986).

118. U.S. CONST. Amend. XIII.

119. Directive 98/44/EC, *supra* note 37, at 37–40.

120. *Id.* at 16.

121. See OFFICE OF TECHNOLOGY ASSESSMENT, THE HUMAN GENOME PROJECT AND PATENTING DNA SEQUENCES, 4–8 (1994) (discussing “whether, from a moral perspective, human DNA sequences and other things that occur in nature—and hence in that sense part of society’s common trust—should be patentable when isolated and purified *ex vivo*?”).

ing—it adds the caveat that any such element isolated from the human body or otherwise produced by a technical process is patentable.¹²²

Does protecting human dignity require treating human biological materials as blocked exchanges, that is, something that cannot be commodified and thereby be owned and sold? It is relevant to note that there is a tradition, supported by philosophical and ethical thinking, of moral opposition to the ownership and sale of human parts. Beginning with the collection of blood for transfusions, measures have been taken to protect against the development of a market in human body parts and organs. The position that human organs required for transplants should be obtained through donation as a gift is based on the argument that allowing an organ market to develop would place pressure on poor people to sell organs, enabling the affluent to exploit poor and vulnerable individuals, as indeed has occurred in some countries. Claims are also made that allowing a market to develop in human biological material might affect social bonds and diminish human dignity.¹²³ While individuals are sometimes paid for the collection of blood or semen, such payment, from a legal perspective, is considered to be for services rendered and not remuneration for the commodity itself.¹²⁴

The question of whether patenting human genes is wrong because it diminishes human dignity was the subject of an article written by philosopher Baruch Brody for the AAAS dialogue group.¹²⁵ Brody acknowledges that it is perfectly appropriate to limit intellectual property rights in human genes when necessary to preserve human dignity, but he does not believe that most objections to human gene patenting warrant doing so.¹²⁶ He examines and evaluates four sets of claims that patents on human genes infringe on human dignity: (1) ownership of human genes is equivalent to ownership of human beings; (2) patents commodify and commercialize; (3) patents cheapen what defines human identity; and (4) patents will lead to eugenic applications that undermine human integrity. Of the various concerns that have been put forward, he identifies only two that he considers to have potential implications for human dignity. Brody recommends first that applications to patent an entire set of genes should be rejected, if ever proposed, because such patents would entail commodification of that which defines our identity.¹²⁷ His second proposed restriction, related to protecting against eugenics, would disallow the patenting of genetic modifications

122. Directive 98/44/EC, *supra* note 37, at art. 5.

123. *See, e.g.*, THE PRESIDENT'S COUNCIL ON BIOETHICS, ORGAN TRANSPLANTATION: ETHICAL DILEMMAS AND POLICY CHOICES 4–5 (2003) (discussing the policy implications of organ markets).

124. OFFICE OF TECHNOLOGY ASSESSMENT, NEW DEVELOPMENTS IN BIOTECHNOLOGY: OWNERSHIP OF HUMAN TISSUES AND CELLS 11–13, 115–25 (1987).

125. Baruch Brody, *Protecting Human Dignity and the Patenting of Human Genes*, in PERSPECTIVES, *supra* note 1, at 111–26.

126. *Id.* at 123–24.

127. *Id.* at 114–23.

that are incompatible with human dignity.¹²⁸ Otherwise, he finds no sound reasons to reject the patenting of a specific human gene on the grounds that it is incompatible with protecting human dignity.¹²⁹

Theologian Ted Peters concurs with much of Brody's analysis.¹³⁰ His view is that an individual person's dignity is not threatened by patenting knowledge of a portion of DNA that may reside in his or her cells.¹³¹ According to Peters, the concept of intrinsic worth applies to the person as a whole, as an individual, not to any parts or knowledge or parts. Peters also argues that knowledge of a DNA sequence is general knowledge of the physiological make up of humans in general, and not of a particular body.¹³² Considering whether knowledge of the entire genome of a particular person would constitute a violation of human dignity, Peters underscores that one's personal identity is not determined by the genome alone: "Each of us is more than our genome, and dignity applies to who we are as a whole human being. Whether it is ethical or unethical to patent knowledge of an individual's genome, the dignity of that person as a person is not at risk."¹³³

D. *Commodification and Commercialization*

Relatedly, others argue that patenting human genes will demean life by turning it into a commodity with a commercially determined value. This concern is widely shared in the religious community. A statement by Methodist Bishop Kenneth Carder warned that the patenting of genes would relegate the building blocks of life to their economic worth.¹³⁴ He further reflected that the fundamental conflict with which we are confronted is between reverence for life valued as a gift and exploitation of life for its marketability.¹³⁵ Using more colorful language, Richard Land, President of the Southern Baptist Convention's Christian Life Commission, was quoted in newspapers as saying, "Marketing human life is a form of genetic slavery. Instead of whole persons being marched in shackles to the market block, human cell lines and gene sequences are labeled, patented and sold to the highest bidders."¹³⁶ Even Ted Peters, generally an agnostic on the ethical

128. *Id.* at 122–24.

129. *Id.* at 111–26.

130. Ted Peters, *DNA and Human Dignity: A Response to Baruch Brody*, in PERSPECTIVES, *supra* note 1, at 127–36.

131. *Id.*

132. *Id.* at 133–35.

133. *Id.* at 134.

134. Mark J. Hanson, *Religious Voices in Biotechnology: The Case of Gene Patenting*, 27 THE HASTINGS CTR. REP., 9 (1997) (quoting Kenneth J. Carder).

135. *Id.* at 10 (quoting Kenneth J. Carder).

136. Peters, *supra* note 115, at 117.

implications of gene patenting, has written about the danger of commercializing life.¹³⁷

How valid is this criticism? Margaret Jane Radin, a legal theorist, has examined the social process by which something comes to be understood as an appropriate subject of free market transactions from previously being valued in a noneconomic manner.¹³⁸ She distinguishes between literal or narrow and broad or metaphorical senses of commodification. Commodification in the narrow sense describes events in which material goods and economic services are literally bought and sold. According to Radin, commodification also encompasses a worldview that conceives of human attributes as fungible owned objects even where no money literally changes hands.¹³⁹ Much like the religious critics of patenting, Radin believes that the way we conceive of things matters to who we are. She concurs that a commodified view of personhood undermines a Kantian conception of the person as an end-in-itself.¹⁴⁰ Nevertheless, Radin recognizes that commodification is not an all-or-nothing process. She introduces the useful concept of incomplete commodification, which refers to a situation in which only one segment of society accepts a commodified understanding.¹⁴¹ Similarly, she points out the possibilities for the coexistence of commodified and noncommodified understandings in a society.¹⁴²

Mark Hanson uses Radin's categories to show how the genetic patenting debate relates both to Radin's narrow and broad conceptions of commodification.¹⁴³ On one level, patents may be seen as related to the narrow sense of commodification, the actual buying and selling of material goods and economic services, because they literally enable the commercialization of and possible monetary transactions involving genes and other biological material.¹⁴⁴ Religious concerns about a kind of "slippery slope" apparently anticipated that market rhetoric once applied to genes and tissue may be contagious and lead to further literal commodification of human beings. Nevertheless, he quite rightly suspects that what is really at stake in the religious objections to patenting, independent of any claims about God's ownership, is Radin's broader conception of commodification.¹⁴⁵ Here he

137. See TED PETERS, *PLAYING GOD? GENETIC DETERMINISM AND HUMAN FREEDOM* 124–25, 140 (2d ed. 1997) (describing an overlap between divine creativity and human creativity, arguing that ownership of the body cannot rightly belong to humans for reasons such as human dignity, and suggesting that the focus of regulation might better be directed from patent laws to oversight of laboratory research).

138. MARGARET JANE RADIN, *CONTESTED COMMODITIES: THE TROUBLE WITH TRADE IN SEX, CHILDREN, BODY PARTS AND OTHER THINGS* 1–15 (1996).

139. *Id.* at 13.

140. *Id.* at 102.

141. *Id.* at 102–03.

142. *Id.*

143. Hanson, *supra* note 134, at 15–18.

144. *Id.*

145. *Id.* at 21.

notes the criticism of Rabbi David Saperstein, speaking broadly on behalf of religious critics, “that patenting would lead to the most fundamental degradation of all—the turning of all nature, perhaps even humanity itself, into an ownable market commodity.”¹⁴⁶

There is disagreement on whether human gene patenting will promote commodification. Radin acknowledges in her book the potential corrupting influence of market rhetoric.¹⁴⁷ Richard Gold goes further in his book *Body Parts*, arguing that making any commodity, including human biological material, subject to property claims will translate its valuation into a market price.¹⁴⁸ Moreover, he claims that market modes of valuation preempt other, more authentic and meaningful forms of valuation, such as valuing human DNA, blood, or tissue as inherently valuable in themselves and as being instrumentally valuable in aiding human health. According to Gold, property discourse—that is, the sum of the assumptions, conceptions, and language used by judges, lawyers, and legislators in allocating rights of control over goods—promotes economic modes of valuation because it assumes that proprietary goods are best allocated through the market.¹⁴⁹ He therefore concludes that safeguarding noneconomic values related to the human body requires that human biological materials be treated as nonproprietary goods.¹⁵⁰ To this end, he recommends constructing a method of allocating rights of control over these materials that takes both economic and noneconomic modes of valuation into account, but does not offer the specifics of such a scheme.

E. The Ontological and Metaphysical Status of DNA

Is DNA sacred? While labeling something as sacred carries import to people of faith, the concept of the sacred is rarely conceptualized clearly. Life, particularly human life, is widely regarded in Western culture as having intrinsic worth. Virtually all adherents of the dominant Western religious traditions would most likely affirm Bishop Carder’s statement, some perhaps only in reference to human persons, that “life is a sacred gift from God the Creator. As a gift from God, life has intrinsic value.”¹⁵¹ The fundamental principle of the dignity and intrinsic worth of each individual undergirds international human rights norms and the U.S. constitutional and legal systems.

146. *Id.* at 17 (quoting David Saperstein).

147. *See* Radin, *supra* note 138.

148. *See generally* E. RICHARD GOLD, *BODY PARTS: PROPERTY RIGHTS AND THE OWNERSHIP OF HUMAN BIOLOGICAL MATERIALS* (1996) (discussing the ethical dangers of applying an economic analysis of ownership to human biological materials).

149. *Id.* at 5–12.

150. *Id.* at 171–77.

151. *UNPRECEDENTED CHOICES*, *supra* note 1, at 154 (quoting Bishop Carder).

If human life is sacred, is it appropriate to confer sacred status to DNA? Some religious critics of patenting imply that DNA is also sacred. The Southern Baptist Convention's amicus brief states that DNA is not simply a chemical sequence that can be manipulated and owned by scientists: it is a divine gift central to human existence.¹⁵² Langdon Gilkey has similarly argued concerning genes that "here, if anywhere, is the locus, principle, or vehicle of the sacred in nature, the principle of vitality for life, what a geneticist friend of mine calls the *icon* of the sacred."¹⁵³ Gilkey also states that genes are in the image of God, implying their worth lies in their relation to God.¹⁵⁴

Or, is DNA merely a complex molecule deserving of no more or less respect than other organic chemicals? Representatives of the biotechnology industry generally describe genes and DNA as mere chemical compounds. Several theologians critical of the Joint Appeal initiative have argued against vesting DNA, even human DNA, with a sacred status. Writing in *Science* magazine, Ronald Cole-Turner asserted "there is no metaphysical difference between DNA and other complex chemicals. Therefore, there is no distinctly religious ground for objecting to patenting of DNA."¹⁵⁵

Here it is relevant to note that the book *The DNA Mystique* documents the ways that the gene has become "a cultural icon, a symbol, almost a magical force."¹⁵⁶ The authors, Dorothy Nelkin and Susan Lindee, conclude that DNA images and narratives of DNA in popular culture convey a message that they term genetic essentialism. Genetic essentialism reduces the self to a molecular entity and equates human beings with their genes. According to Nelkin and Lindee, DNA currently functions in many respects as a secular equivalent of the medieval Christian conception of the soul in that it is considered to contain the essential human self, to be the source of individual difference, and to promise a form of eternal life, either through progeny or through the body reconstituted by scientific manipulation.¹⁵⁷

The paucity of serious theological analysis on the nature of DNA from opponents of genetic patenting makes it difficult to ascertain whether or not their critique reflects an underlying genetic essentialism. Religious critics of genetic patenting appear to vest genes with a special kind of intrinsic value, possibly even a sacred status, which makes patenting inappropriate. But their grounds for doing so are not clear. As Mark Hanson has commented,

152. Brief for Amici Curiae of the Ethics & Religious Liberty Commission of the Southern Baptist Convention and Prof. D. Brian Scarnecchia in Support of Petitioners, *supra* note 84, at 2, 4.

153. LANGDON GILKEY, NATURE, REALITY, AND THE SACRED: THE NEXUS OF SCIENCE AND RELIGION, 96–97 (1993).

154. *Id.* at 143–57.

155. Ronald Cole-Turner, *Religion and Gene Patenting*, 270 SCIENCE 52, 52 (1995).

156. DOROTHY NELKIN & M. SUSAN LINDEE, THE DNA MYSTIQUE: THE GENE AS A CULTURAL ICON (W.H. Freeman ed., 1995).

157. *Id.* at 39.

“the conceptions of DNA that underlie the religious critics’ objections based on ownership—especially the claims that genes are sacred and that even human DNA fragments bear the image of God—are theologically underdeveloped and ultimately problematic.”¹⁵⁸

Of course, one does not have to invest human genes with sacred status to argue that they are fundamentally unique and deserve special treatment on that basis. An amicus brief filed by James Watson, co-discoverer of DNA’s double helix, argued that the United States Court of Appeals for the Federal Circuit, in deciding *Myriad Genetics*, should recognize the “fundamentally unique nature of the human gene. . . It is a chemical entity, but DNA’s importance flows from its ability to encode and transmit the instructions for creating humans. Life’s instructions ought not be controlled by legal monopolies created at the whim of Congress or the courts.”¹⁵⁹

F. *Myriad Genetics Case*

In 2009 the issue of the patentability of human genes finally was brought before the courts. Until this case, no court had addressed whether an isolated human gene is patentable subject matter. The American Civil Liberties Union (ACLU) joined with the Public Patent Foundation at the Benjamin Cardozo School of Law in New York, a series of medical organizations including the American Medical Association and the American Society of Human Genetics, and the American College of Obstetricians and Gynecologists, medical geneticists, advocates for women’s health, and several individual patients to challenge the patents that Myriad Genetics and the University of Utah Research Foundation received for the genes referred to as BRCA1 and BRCA2.¹⁶⁰ By extension, their case attempts to invalidate all isolated but unaltered human gene patents.¹⁶¹ Mutations in the BRCA1 and BRCA2 genes significantly increase the risk of breast and ovarian cancer.¹⁶² Myriad’s patents have enabled this small biotechnology company to exercise monopoly control over diagnostic testing for all mutations in these genes, even new diagnostic tests that the company does not offer.¹⁶³

The suit, filed in May 2009 in Federal District Court in New York,¹⁶⁴ argued that the patents Myriad holds should never have been granted on either the genes or the tests because under U.S. patent law products of nature are not patent-eligible.¹⁶⁵ The plaintiffs also contended that Myriad’s

158. Hanson, *supra* note 134, at 20.

159. Brief for Amicus Curiae James D. Watson in Support of Neither Party, *Ass’n for Molecular Pathology v. United States PTO*, 653 F.3d 1329 (Fed. Cir. 2011) (No. 09-CV-4515).

160. Complaint, *supra* note 50, at 3.

161. *Id.* at 21–22, 30.

162. *BRCA1 and BRCA2: Cancer Risks and Genetic Testing Fact Sheet*, NAT’L CANCER INST., <http://www.cancer.gov/cancertopics/factsheet/Risk/BRCA> (last visited Oct. 22, 2013).

163. E. Richard Gold & Julia Carbone, *supra* note 74, at S42.

164. Complaint, *supra* note 50, at 1.

165. *Id.* at 3.

patents restrict research and scientific progress.¹⁶⁶ The several individual patients involved in the suit stated they suffered harm because Myriad's exercise of its patent rights restricted their ability to receive supplementary testing for cancer-predisposing genomic deletions or duplications or additional confirmatory testing.¹⁶⁷ The plaintiffs had the support, expressed in friend-of-the court briefs, of many parties representing the medical profession, biomedical researchers, and other opponents of monopoly rights on human DNA, but significantly, no organizations or individual representing the religious community submitted an amicus brief.¹⁶⁸

Taking a position typical of industry, the defendants asked the court to dismiss the case on the grounds that the work of isolating DNA from the body transforms it and makes it patentable.¹⁶⁹ They cited the position of the USPTO that human ingenuity is required to create isolated DNA molecules and its 2001 guidelines formally establishing that molecules derived from genetic material can be the basis for a patent.¹⁷⁰ Furthermore, they pointed out that in the thirty years that gene patents have been granted, this was the first case challenging their patent eligibility.¹⁷¹

Although many in the patent field predicted the suit would be thrown out,¹⁷² it was not. In March 2010, much to the surprise of many patent experts, a federal judge invalidated seven patents held jointly by Myriad Genetics and the University of Utah.¹⁷³ Most significantly, United States District Court Judge Robert W. Sweet ruled that Myriad's patents were "improperly granted" because they involved a "law of nature."¹⁷⁴ Specifically, "[b]ecause the claimed isolated DNA is not markedly different from native DNA as it exists in nature, it constitutes unpatentable subject matter."¹⁷⁵ He also ruled that Myriad's method patents, under which it exercised a monopoly to market a diagnostic test costing more than \$3,000 to

166. *Id.* at 2.

167. *Id.* at 10–13.

168. For this author's review of the amicus briefs filed in this case, see generally, *BRCA Resources*, CENTER FOR PUBLIC GENOMICS, <http://www.genome.duke.edu/centers/cpg/BRCA-resources/> (last visited Oct. 22, 2013).

169. See Defendants' Memorandum of Law (1) in Support of Their Motion for Summary Judgment and (2) in Opposition to Plaintiffs' Motion for Summary Judgment at 20–26, *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 702 F.Supp. 2d 181, 232 (S.D.N.Y. 2010) (No. 09 Civ. 4515) (making legal argument for patentability of isolated natural products); Answer by Respondent U.S. Patent & Trademark Office at 12, *Molecular Pathology*, 702 F.Supp. 2d 181 (S.D.N.Y. 2010) (No. 09 Civ. 4515) (requesting dismissal); Answer by Respondent Myriad Genetics at 14, *Molecular Pathology*, 702 F.Supp. 2d 181 (S.D.N.Y. 2010) (No. 09 Civ. 4515) (requesting dismissal).

170. Defendant's Memorandum, *supra* note 169, at 26–28.

171. See *id.* at 1.

172. John Schwartz & Andrew Pollack, *Judge Invalidates Human Gene Patent*, N. Y. TIMES, Mar. 29, 2010, <http://www.nytimes.com/2010/03/30/business/30gene.html>.

173. *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 702 F.Supp. 2d 181, 232 (S.D.N.Y. 2010).

174. *Id.* at 237.

175. *Id.* at 232.

assess mutations in the BRCA1 and 2 genes, were also invalid because they were based on analyzing and comparing DNA sequences and thus did not constitute a transformative act.¹⁷⁶

Myriad Genetics appealed the ruling. The United States Court of Appeals for the Federal Circuit—a court traditionally sympathetic to patent claims¹⁷⁷—came to a different conclusion. It overturned the key ruling on the patentability of genes of the Federal District Court.¹⁷⁸ Instead the court held that isolated and modified DNA molecules can be patented and, on the basis of this reasoning, it upheld Myriad’s patent on the BRCA1 and BRCA2 genes.¹⁷⁹ However, the panel upheld Judge Sweet’s district court ruling that Myriad’s five broadest patents on methods of isolating and modifying DNA were invalid.¹⁸⁰ Like the District Court,¹⁸¹ the Federal Circuit found that genetic diagnostic methods that rely on “comparing” or “analyzing” DNA sequences with corresponding patient DNA samples to identify the presence of mutations are not transformative and hence are not patentable.¹⁸²

In December 2011, the case was appealed to the United States Supreme Court. The Court chose not to issue an opinion at that time. Instead it set aside the Federal Circuit’s decision favoring Myriad and directed the Federal Circuit to review the case in light of a recently issued Supreme Court ruling in a case involving a blood test developed by Prometheus Laboratories.¹⁸³ In that case, *Mayo v. Prometheus*, the Court unanimously reversed a Federal Circuit ruling on the grounds that companies are not permitted to patent observations about natural phenomena.¹⁸⁴

In August 2012, a Federal Circuit panel reaffirmed the Supreme Court’s holding that the process of isolating genes requires human intervention and therefore can be patented.¹⁸⁵ Judge Alan Lourie, writing for the majority, stated “Everything and everyone comes from nature, following its laws. But the compositions here are not natural products. They are the products of man, albeit following, as all materials do, laws of nature.”¹⁸⁶ The

176. *Id.* at 238.

177. *Federal Circuit Dubbed a “Rogue Appeals Court” Seen as Biased in Favor of Patent Holders*, LIFE SCI. & TECH. LEGAL BULL. (Shook, Hardy & Bacon, Kansas City, Mo.) Oct. 3, 2012, at 1–2.

178. *See Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 653 F.3d 1329, 1358 (Fed. Cir. 2011).

179. *Id.* at 1350–54.

180. *Id.* at 1358.

181. *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 702 F.Supp. 2d 181, 238 (S.D.N.Y. 2010).

182. *Molecular Pathology*, 653 F.3d at 1357.

183. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012).

184. *Id.* at 1305.

185. *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 689 F.3d 1303, 1333 (Fed. Cir. 2012) *cert. granted in part*, 133 S. Ct. 694 (U.S. 2012) and *aff’d in part, rev’d in part sub nom.*, *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013).

186. *Id.* at 1331.

Circuit also affirmed its decision that the Myriad method patents did not meet the threshold for patentability.¹⁸⁷

After the second decision was issued, the ACLU again asked the Supreme Court to hear the case. In November 2012, the Supreme Court granted a writ of certiorari. Of note, the Court limited the appeal to a single issue, the most contentious one raised in the case: whether human genes are patentable.¹⁸⁸ Other issues decided by the Federal Circuit will therefore stand.

One of several surprises in the case was the decision of the Solicitor General to enter the case when it was appealed to the Federal Circuit by filing an amicus brief on behalf of the U.S. government.¹⁸⁹ The Solicitor General submitted a similar brief to the Supreme Court.¹⁹⁰ Both briefs took a position contrary to the longstanding policy and practice of the USPTO, arguing that isolated but otherwise unaltered genomic DNA is not patent-eligible subject matter under the U.S. patent code.¹⁹¹ The briefs state that an isolated gene is not a new and useful composition of matter, but instead, genomic DNA is a product of nature and as such ineligible for patent protection.¹⁹² The briefs argue that methods of identifying, isolating, and using such DNA molecules may be patented as well as new and useful alteration of these molecules, provided they meet current patent standards for qualifying as an invention.¹⁹³ The intervention by the Solicitor General may have encouraged the Supreme Court to accept the case and may have influenced the nature of the decision it rendered.

The Supreme Court issued its decision on June 13, 2013, some four years after the case was initially filed in the Federal District Court. A unanimous Court held that “[a] naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated.”¹⁹⁴ According to the decision, “laws of nature, natural phenomena, and abstract ideas are basic tools of scientific and technological work that lie beyond the domain of patent protection,”¹⁹⁵ and the Myriad DNA claim falls within the

187. *Id.* at 1336–37.

188. *See* Ass’n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 694, 695 (2012) (mem.).

189. Brief for the United States as Amicus Curiae in Support of Neither Party, Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office, 689 F.3d 1303 (Fed. Cir. 2012) (No. 2010-1406), 2012 WL 2884115.

190. Brief for the United States as Amicus Curiae in Support of Neither Party, Ass’n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107 (2013) (No. 12-398), 2013 WL 390999.

191. *See* Brief for the United States, *supra* note 189; Brief for the United States, *supra* note 190.

192. Brief for the United States, *supra* note 189, at *4; Brief for the United States, *supra* note 190, at *20–26.

193. Brief for the United States, *supra* note 189, at *6–8; Brief for the United States, *supra* note 190, at *3.

194. Ass’n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2111 (2013).

195. *Id.* at 2116 (internal quotations omitted).

law of nature exception.¹⁹⁶ According to the decision, “Myriad’s principal contribution was uncovering the precise location and genetic sequences of the BRCA1 and BRCA2 genes, [but] Myriad did not create or alter any of the genetic information encoded in the BRCA1 and BRCA2 genes . . . [or] the genetic structure of [the] DNA.”¹⁹⁷ While the Supreme Court acknowledged that Myriad found an important and useful gene, it determined that a groundbreaking, innovative, or even brilliant discovery does not by itself satisfy the requirements of the patent code.¹⁹⁸

This ruling has obvious implications for thousands of other claims on naturally occurring DNA sequences, but some analysts believe the impact will be relatively modest.¹⁹⁹ According to this line of reasoning, the most valuable biotechnology patents are not based on such naturally occurring DNA sequences.²⁰⁰ Since 2005, fewer companies have sought to patent naturally occurring gene sequences, while claims on DNA that has been engineered have been on the rise.²⁰¹ Some companies also found it more difficult than expected to profit from these genetic patents.²⁰² However, the decision importantly expresses strident judicial opposition to patents on methods claims for detecting genetic sequence alterations and thereby diminishes the prospects of Myriad or another company claiming monopolies on a genetic diagnostic test without a linkage to a therapeutic agent or a modification of DNA molecules.²⁰³

Complicating its decision, the Supreme Court also held that “complementary” or cDNA genetic sequences created by stripping away non-protein coding material from naturally occurring DNA can be patented.²⁰⁴ The Court reasoned that a cDNA sequence constitutes “an exons-only molecule that is not naturally occurring.”²⁰⁵ The Court’s split judgment has been criticized by some analysts because cDNA itself can occur naturally.²⁰⁶ Others have pointed out that the ruling that patents can be claimed on modified DNA has confused and puzzled observers because it creates a “bizarre rheostat about the amount of change that would need to take place chemically in order to justify a patent.”²⁰⁷

196. *Id.* at 2117.

197. *Id.* at 2116.

198. *Id.* at 2117.

199. Aaron S. Kesselheim et al., *Gene Patenting—The Supreme Court Finally Speaks*, 369 *NEW ENG. J. MED.* 869, 873 (2013).

200. Robert Cook-Deegan, *Law and Science Collide Over Human Gene Patents*, 338 *SCIENCE* 745, 747 (2012).

201. Kesselheim et al., *supra* note 199, at 873.

202. *Id.*

203. *Id.*

204. *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 1229 (2013).

205. *Id.*

206. John M. Golden & William Sage, *Are Human Genes Patentable? The Supreme Court Says Yes and No*, 32 *HEALTH AFF.* 1343, 1345 (2013).

207. Heidi Ledford, *Myriad Ruling Causes Confusion*, 498 *NATURE* 281, 281 (2013).

In the end, the Supreme Court's decision was rendered on narrow technical grounds ignoring the ethical, theological, policy, and human welfare concerns that animated much of the opposition to patents. As one article commented, "It is interesting that although the Supreme Court decision concerns human genes, humanness had no bearing on the decision. Nor does the law allow courts to consider whether patenting human genes—or anything else—should be disallowed on grounds of morality."²⁰⁸

G. Reflections

For years members of the religious community were lonely voices "crying in the wilderness" about the problems with issuing human gene patents. In doing so, they raised significant issues about the appropriateness of patenting human genes and other life forms and its potential implications for denigrating respect for life and human dignity, albeit often in an inadequate manner. The religious critics argued that to embark on a course of promoting commercialization and privatization of biology without meaningful public debate regarding the morality and wisdom of such acts constitutes a violation of the implicit social contract between the government and the governed in a democratic society. The religious community thus highlighted issues often neglected by secular critics.

However, at the same time the religious community neglected other important issues. The religious community did not discuss the detrimental impacts of genetic patents on scientific and medical research. Nor did it take up the concerns so central to the plaintiffs in the *Myriad* case that the willingness to extend life patents restricted the availability of needed genetic testing and obstructed patient care. If it had done so, it might have been possible for some religious actors to collaborate with secular critics.

In retrospect, the various communions that put forward positions seemed to do so more as an act of witness than as a serious effort to influence the course of U.S. patent law. Their interventions were not timed to coincide with, or react to, relevant initiatives in the patent field. Nor did they refer to the specifics of patent law or to policies of the USPTO with which they took issue. Instead the issues identified and the manner in which those issues were addressed appear to be primarily symbolic. Moreover, the religious witness on patenting fell far short of a well-formed public theology. The religious actors could have offered a more careful theological and ethical analysis with specific proposals without undermining the force of its critique. It is particularly problematic that the one amicus brief filed on behalf of a religious agency did not raise broader ethical issues, such as the impact of genetic patents on human welfare and medical treatment.

John Evans contends that religious critics of patenting have been disadvantaged in the discussion of the issue because they are attempting to

208. Kesselheim et al., *supra* note 199, at 874.

make a “prophetic” argument while supporters of the current patent regime had the advantage of the status quo on their side.²⁰⁹ Evans characterizes the prophetic approach as an effort to expose the roots of what is perceived to be fundamentally and systematically right or wrong.²¹⁰ However, opting for a prophetic approach does not excuse imprecise and inadequate theological and ethical reasoning.

Like the work of the religious community on some other issues, interest in patenting has been intermittent, possibly because relevant staff persons went on to other positions or because the denomination developed other priorities. More thoughtful, informed, and in-depth reflections on patenting issues written by individual ethicists and moral theologians, such as the work of Ronald Cole-Turner and Ted Peters,²¹¹ were often reactions to the positions taken in these acts of witness, particularly the Joint Appeal, or were solicited through their participation in projects like the AAAS dialogue group and a similar group sponsored by The Hastings Center. So although the religious community did make a contribution to the patenting debate, it was less than it might have been.

When the Supreme Court made its landmark decision on the patentability of genes there was little religious involvement or reflection of its concerns in the various briefs and positions of the litigants, with the exception of the poorly written *amicus* brief filed on behalf of the Southern Baptist Convention. It might have been otherwise.

209. See John H. Evans, *The Uneven Playing Field of the Dialogue on Patenting*, in PERSPECTIVES, *supra* note 1, at 60–68.

210. *Id.* at 60–61.

211. See generally Cole-Turner, *Theological Perspectives on the Status of DNA; A Contribution to the Debate over Genetic Patenting*, in PERSPECTIVES, *supra* note 1 (arguing that a robust understanding of divine ownership of nature can augment our understanding of human ownership of nature); *DNA and Human Dignity: A Response to Baruch Brody*, in PERSPECTIVES, *supra* note 1 (arguing that the locus of human dignity extends beyond the genome).