

# WHOSE BODY IS IT ANYWAY? HUMAN CELLS AND THE STRANGE EFFECTS OF PROPERTY AND INTELLECTUAL PROPERTY LAW

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*Whatever else I might own in this world, it would seem intuitively obvious that I own the cells of my body. Where else could the notion of ownership begin, other than with the components of the tangible corpus that all would recognize as “me”? The law, however, does not view the issue so neatly and clearly, particularly when cells are no longer in my body. As so often happens in law, we have reached this point, not by design, but by the piecemeal development of disparate notions that, when gathered together, form a strange and disconcerting picture.*

*This Article examines both property and intellectual property doctrines in relation to human cells that are no longer within the body. In particular, the Article discusses the *Bilski* decision, in the context of life science process patents, and the Molecular Pathology case, in the context of gene patents. For patent law, the Article concludes that the problem lies not with the fact that genes constitute patentable subject matter, but rather with the extent of the rights that are granted. For both property and intellectual property law, the Article concludes that a more careful application of basic legal principles would better reflect the interests of society as a whole and the interests of individual human subjects, as well as the interests of those who innovate.*

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## INTRODUCTION

There are many aspects of our lives over which we can exercise what can be called ownership, control, or dominion. However one conceptualizes owner-

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ship, it is clear that people can hold such rights in many things, ranging from more concrete items, such as automobiles, jewelry, or a plot of land, to more abstract concepts, such as our labor, our writings, our innovations, and even our commercial image.

Whatever else I might own in this world, however, it would seem intuitively obvious that I own the cells of my body. Where else could the notion of ownership begin other than with the components of the tangible corpus that all would recognize as “me”?

The law, however, does not view the issue so neatly or clearly. Through the rambling pathways of property and intellectual property law, we are fast approaching the point at which just about anyone can have property rights in your cells, except you. In addition, with some alteration, anyone can have intellectual property rights in innovations related to the information contained therein, but you do not.

I should be clear at the outset that I am talking about property and intellectual property rights to cells when they are no longer in your body. The sanctity of control over one’s body remains reasonably intact, as long as the cells are attached to you.<sup>1</sup> When cells are no longer attached, however, the legal landscape shifts, and the resulting tableau has a strong effect on the choices one can make with those cells that do remain in the body.

As so often happens in law, we have reached this point not by design but by the piecemeal development of disparate notions. Various doctrinal strands have emerged in isolation of each other, each appearing to solve a particular problem in its own domain. When gathered together, however, the doctrines form a strange and disconcerting picture.

Consider a human cell, or a group of cells, being used for research purposes. It could be a blood sample or perhaps a piece of tissue left over from a biopsy. When a researcher is working with a sample of human blood or tissue, the researcher, or the lab, has a property right in those cells. Similarly, if the researcher isolates a protein or a segment of DNA from that sample, the researcher or the lab has property rights in the tangible isolated elements.

Others may ask for a sample of the tissue or the cell lines developed from that tissue.<sup>2</sup> These items are treated under contract law according to agreements related to the transfer of tangible property, commonly called “material transfer agreements.”

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1. *See* *Schmerber v. California*, 384 U.S. 757, 767-68 (1966) (stating that the Fourth Amendment prohibits compelled intrusions into the body for blood to be analyzed for alcohol content if intrusions are not justified in the circumstances or are made in an improper manner). *But see* UNIF. PARENTAGE ACT § 11(a), 9B U.L.A. 445 (2001) (“The court may, and upon request of a party shall, require the child, mother, or alleged father to submit to blood tests.”).

2. A “cell line” is a cell culture that can proliferate indefinitely. *See* BRUCE ALBERTS ET AL., *MOLECULAR BIOLOGY OF THE CELL* 474 (4th ed. 2002).

In addition to property rights, a researcher who isolates something from the sample also may be able to apply for patent rights on that isolated product. If the researcher successfully manipulates the cell, forming a novel cell line or producing a new protein, the researcher may receive a patent on the protein or cell line as a new product.<sup>3</sup> In addition, information from the coding sequences in those cells may help form the basis of a diagnostic or therapeutic patent. In short, a researcher with a human tissue sample may have property rights in that sample. Through observation, isolation, and manipulation of the sample, the researcher may also obtain intellectual property rights.

How about the human who contributed the sample in the first place? The California Supreme Court has refused to grant property rights to individuals in the cells of their bodies when those cells are no longer in their bodies.<sup>4</sup> A federal district court reached a similar result.<sup>5</sup> The discussion in the cases suggests distaste for the possibility of treating human body parts as a form of property, as well as serious concerns about interfering with advancements in medical science.<sup>6</sup> As a result, the person whose body provided the sample has no property rights, although we seem to have no problem giving others property rights in those cells.

The human who contributed the cells has no intellectual property rights either. Patent rights are based on manipulation or use of elements within those cells. The cells as they exist in one's body are in a state of nature and cannot be the subject of patent rights.<sup>7</sup> Thus, although others can end up with intellectual property rights related to those cells, the person who contributed the cells can claim no such rights by virtue of his or her association with the cells.

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3. See *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1321 (Fed. Cir. 2003) (addressing patents on a non-naturally occurring human erythropoietin product made with recombinant DNA technology). "Recombinant DNA technology" refers to techniques to isolate, clone, characterize, engineer, and screen DNA and study gene functions. See ALBERTS ET AL., *supra* note 2, at 492-93; see also *Diamond v. Chakrabarty*, 447 U.S. 303, 310 (1980) (granting patent rights on bacterium produced through genetic engineering and having properties not found elsewhere in nature in that combination).

4. See *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479, 489 (Cal. 1990).

5. See *Greenberg v. Miami Children's Hosp. Research Inst., Inc.*, 264 F. Supp. 2d 1064, 1074 (S.D. Fla. 2003) (noting similarity to *Moore* and holding that donors had no property interest in body tissue and genetic information voluntarily given). In finding, however, that "the property right in blood and tissue samples also evaporates once the sample is voluntarily given to a third party," *id.* at 1075, the *Greenberg* court implicitly suggested that there might be a property right at some point. Otherwise, there would be nothing that could "evaporate."

6. See *id.* at 1076 (noting the potential to cripple medical research); *Moore*, 793 P.2d at 493-94 (expressing concerns over creating disabling civil liability for the infant biotechnology industry); *id.* at 497-98 (Arabian, J., concurring) (noting that the case raises "troubling" questions related to "uplift[ing] or degrad[ing] the 'unique human persona'"); *id.* at 515 (Mosk, J., dissenting) (discussing laws related to slavery, indentured servitude, and debtor's prison in the context of the profound ethical imperative to respect the human body).

7. Cf. *Greenberg*, 264 F. Supp. 2d at 1076-77 (dismissing the claim that a registry of people who had Canavan disease constituted a trade secret).

Human beings do have some rights in relation to the cells of their body when the cells are no longer in the body. Those rights, however, generally are grounded in notions of the fiduciary duty that a doctor owes to a patient and are frequently centered on the doctor's obligation to obtain informed consent.<sup>8</sup> Although the question has not been approached precisely in this manner, humans do not seem to have any particular right to their cells or to the information contained in their cells, outside of their relationship with health care providers.

I have suggested, in a different forum, that the intersection of interests in this area would be well served by a reconceptualization of the relationship between the state and the individual.<sup>9</sup> Much as one might hope for such a paradigm shift, however, I recognize the importance of working with the tools that we have. Significant progress can be made by a more careful and considered application of current property and intellectual property doctrines. Specifically, in our enthusiasm for the truly groundbreaking and spectacular work of the scientific community, we have, at times, granted rights that are far too expansive. In the process, we have lost sight of the interests of the individual and the interests of scientific progress on the whole. Rushing to reward and incentivize, we have created opportunities for patent holders to arrogate to themselves large swaths of territory, well beyond what should be permissible, and they have taken advantage of our invitation. Perhaps it is time to reconsider our approach.

Part I of the Article will examine doctrines of property law in relation to ownership of human cells that are no longer within the body. The Part concludes that under traditional property law concepts, individuals should have a continuing property interest in their own cells. Part II of the Article will examine the more challenging question of intellectual property rights in innovations related to cells and cellular components outside of their natural state in the human body. The Part concludes that modern patent decisions are granting patent rights far too broadly to those who innovate with human cells, cellular components, and cellular information. A more careful and considered application of patent law doctrines would limit the patent rights granted, which would better reflect the interests of society as a whole in maintaining access to the building blocks of science for scientific research and innovation. Although individuals do not have patent rights in their own cells, a proper application of patent law principles would benefit individuals, at least indirectly, through increased competition and access.

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8. See *Moore*, 793 P.2d at 483.

9. See Robin Feldman, *Coming to the Community*, in *IMAGINING NEW LEGALITIES* (Austin Sarat ed., forthcoming June 2011).

## I. PROPERTY RIGHTS IN HUMAN CELLS

Henrietta Lacks was a poor black woman who died of a particularly virulent form of cervical cancer in the 1950s.<sup>10</sup> Mrs. Lacks died eight months after she was diagnosed with cancer, leaving behind a husband and five children. Although she would never know, Mrs. Lacks also left an astounding legacy for medical science. Using the aggressive nature of Mrs. Lacks's cancer cells, researchers developed a method for reproducing human cells in the lab. Mrs. Lacks's cells became the first human cells to reproduce prolifically in a laboratory setting, and scientists have reproduced some fifty million metric tons of her cells over time.<sup>11</sup> The so-called HeLa cell line has contributed to major developments in the field of life sciences, including the polio vaccine, cancer treatments, and in vitro fertilization.<sup>12</sup> As one book reviewer noted, Henrietta Lacks became "the godmother of virology and then biotech, benefiting practically anyone who's ever taken a pill stronger than aspirin."<sup>13</sup>

In short, research on Mrs. Lacks's cells paved the way for a wealth of stunning developments in the life sciences industry. Critics have noted, however, that her family has not shared in that bounty.<sup>14</sup>

A similar set of facts formed the basis of *Moore v. Regents of the University of California*.<sup>15</sup> In 1976, John Moore was treated for leukemia at UCLA Hospital. In the course of his treatment, as well as follow-up care for seven years, doctors at UCLA Hospital removed his spleen and took samples of tissue and blood.<sup>16</sup> The doctors told Mr. Moore that the procedures were necessary for treatment of his life-threatening cancer. They did not, however, tell him that his cells were unusual and offered great potential for scientific research.<sup>17</sup>

Working on cells from Mr. Moore, researchers at UCLA established the "Mo" cell line. By the time the case came to trial, UCLA had received hundreds of thousands of dollars in revenue from the cell line, and experts estimated that the value of the line could reach into the billions.<sup>18</sup>

Mr. Moore sued the medical center and his physicians asserting a variety of claims, including ones related to his property rights. In the property claim, Mr. Moore asserted that he had never consented to the use of his cells in potentially

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10. See REBECCA SKLOOT, *THE IMMORTAL LIFE OF HENRIETTA LACKS* 3 (2010); Dwight Garner, *A Woman's Undying Gift to Science*, N.Y. TIMES, Feb. 3, 2010, at C1 (reviewing SKLOOT, *supra*); Lisa Margonelli, *Eternal Life*, N.Y. TIMES, Feb. 5, 2010, <http://www.nytimes.com/2010/02/07/books/review/Margonelli-t.html> (same).

11. See Margonelli, *supra* note 10.

12. See sources cited *supra* note 10.

13. Margonelli, *supra* note 10.

14. See sources cited *supra* note 10.

15. 793 P.2d 479, 480-82 (Cal. 1990).

16. See *id.* at 480-81.

17. See *id.* at 483.

18. See *id.* at 482.

lucrative medical research and that using them in this manner constituted a conversion of his personal property.<sup>19</sup> As described above, the California Supreme Court rejected the claim, concluding that whatever rights Mr. Moore might have had, they did not amount to property or ownership rights.<sup>20</sup>

In reaching its decision, the court essentially used the following logic: When cells are removed from a person's body, the disposition of those cells is limited in that (1) the person cannot sell them under some circumstances, and (2) after the cells are used for research, they must be disposed of according to health department guidelines. With property rights, however, one expects to see an array of rights, including the right to dispose of the property. If disposition rights are missing or sufficiently circumscribed, one must conclude that whatever rights may exist, they are not property rights.<sup>21</sup>

The court did conclude that Mr. Moore's suit might go forward based on causes of action related to a doctor's fiduciary duty to the patient and obligation to obtain informed consent.<sup>22</sup> Although the case settled for an undisclosed sum, experts have estimated that the potential damages from a claim for breach of fiduciary duty would be far lower than the damages Mr. Moore had sought on the basis of property rights.<sup>23</sup>

The logic in *Moore* has been appropriately criticized, beginning with the dissent in the case.<sup>24</sup> It is certainly true that modern property law scholars think of property as a bundle of rights with four key attributes: use, possession, exclusion, and disposition. The extent of those four attributes, however, can vary

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19. *Id.* at 487.

20. *See id.* at 492; *see also supra* note 6 (discussing the dissent in *Moore* and a federal district court decision in *Greenberg v. Miami Children's Hospital Research Institute, Inc.*).

21. *See Moore*, 793 P.2d at 492 ("By restricting how excised cells may be used and requiring their eventual destruction, the statute eliminates so many of the rights ordinarily attached to property that one cannot simply assume that what is left amounts to 'property' or 'ownership' . . .").

22. *See id.* at 483.

23. *See* Maxwell J. Mehlman, *Moore v. Regents of the University of California*, in *PROPERTY STORIES* 41, 53 (Gerald Korngold & Andrew P. Morriss eds., 2004).

24. *See Moore*, 793 P.2d at 506-23 (Mosk, J., dissenting); *see also* E. RICHARD GOLD, *BODY PARTS: PROPERTY RIGHTS AND THE OWNERSHIP OF HUMAN BIOLOGICAL MATERIALS* (1996); Donna M. Gitter, *Ownership of Human Tissue: A Proposal for Federal Recognition of Human Research Participants' Property Rights in Their Biological Material*, 61 WASH. & LEE L. REV. 257, 281 (2004) (criticizing *Moore* and describing the importance of recognizing property rights and providing compensation for research participants); Charlotte H. Harrison, *Neither Moore Nor the Market: Alternative Models for Compensating Contributors of Human Tissue*, 28 AM. J.L. & MED. 77, 81 (2002) (noting three principal objections to *Moore*); Laura M. Ivey, *Moore v. Regents of the University of California: Insufficient Protection of Patients' Rights in the Biotechnological Market*, 25 GA. L. REV. 489, 498 (1991) (discussing Justice Mosk's dissent); Mehlman, *supra* note 23, at 41-56 (discussing the *Moore* holding and how it continues to affect biomedicine); Jeffery A. Potts, Note, *Moore v. Regents of the University of California: Expanded Disclosure, Limited Property Rights*, 86 NW. U. L. REV. 453, 453 (1992) (disagreeing with *Moore's* refusal to allow a cause of action for conversion of property).

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considerably. They are often circumscribed, and this is just as true for disposition rights as for the other attributes of ownership. In fact, the dissent lists a variety of examples in which disposition rights are limited for a particular type of tangible property and yet one would still think of that item as property.<sup>25</sup>

For example, if I have a bottle of prescription medicine, it would certainly be treated as my personal property. I would have the right to possess, use, and exclude others from the medication. My right to dispose of the medication, however, is quite circumscribed. I am not permitted to sell it, and I cannot respond to someone who complains about how boring the Symposium is by saying, "Here, take my Vicodin."<sup>26</sup> I cannot even flush the unused medication down the sink, in some jurisdictions, but would be required to dispose of any unused portion at an appropriate facility. Although the rights of disposition for prescription medicine are severely curtailed, that fact does not preclude treatment as personal property.

In addition, the person from whom the cells have been obtained must have some rights in relation to those cells, and such rights cannot be completely explained through the fiduciary duty of the physician. Mr. Moore could have contracted with researchers himself to explore and exploit the information contained in his cells,<sup>27</sup> regardless of whether those researchers were his physicians. From a more graphic perspective, suppose a man severs his finger while sawing wood in his backyard. One would expect that he has the right to ask that the finger be reattached, as opposed to any other potential uses or modes of disposition, including use for research. The man's priority right to those cells cannot possibly be connected to rights of privacy, nondisclosure, or informed consent. The man would claim the finger, not because it contains information that should be kept private or because he did not properly obtain his own consent before slicing off his finger. He would claim the finger because it is *his*.

One could, of course, argue that we should have property rules only for body parts that have the potential to be reattached or reused in some way. At some point, however, the twists and turns necessary to maintain a particular approach undermine the legitimacy of that approach in the first place. The better analysis is to acknowledge the obvious. Cells separated from the human body are tangible property that must, as an initial matter, belong to someone. They cannot simply spring forth as tangible property of a lab or a researcher without having been the property of anyone else prior to that point. The logical person for initial ownership of cells is the person from whose body the cells originated.

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25. See *Moore*, 793 P.2d at 509-10 & nn.6, 8 & 10 (Mosk, J., dissenting) (observing that a homeowner association's right of first refusal over a proposed sale limits the disposition of real property and that a sportsman's right to give away—but not sell—his fish or game limits the disposition of personal property).

26. Vicodin is a narcotic pain reliever available only by prescription.

27. *Moore*, 793 P.2d at 510 (Mosk, J., dissenting).

For public policy reasons, society may want to restrict people from using, selling, or disposing of those cells in certain ways. We take that approach for many different types of tangible personal property, however, from prescription drugs to used motor oil.

Perhaps one of the strongest arguments in favor of property rights treatment for cells outside the human body is that we actually treat them like property. As described above, when research laboratories transfer physical materials, such as cell samples, those samples are transferred subject to contractual arrangements known as “material transfer agreements.” In addition to regulating intellectual property rights that may arise from experimentation with the materials, the agreements treat the physical cells as they would other types of tangible property.<sup>28</sup>

It defies common sense to say that an individual lab can hold property rights in the tangible cells removed from a person’s body while the person whose body supplied the cells cannot. If cells are treated as tangible property for the purposes of material transfer agreements among labs, they should also be treated as tangible property for the purposes of a transfer from the human whose body is supplying the cells.

One could argue that giving individuals property rights in the cells of their bodies when those cells are no longer in their bodies has the potential to endanger basic concepts of human dignity. Treating elements of our body as property could encourage commercialization of those elements, which could erode the reverence for human life that infuses a number of American legal doctrines, particularly those that forbid ownership of human beings in the form of slavery.<sup>29</sup> From a more practical standpoint, treating human cells as property creates a risk that those in financial need will be coerced into selling parts of their body, either by unscrupulous brokers or by the circumstances of their poverty, thereby surrendering or endangering their health.

If our concern truly lies with health risks to those who contribute their cells to research, denying property rights is a remarkably overbroad solution to the problem. If health risk is the concern, the law could forbid individuals from selling or donating their cells if the transfer would endanger their health. Taking a more extreme approach, one could forbid individuals from transferring cells unless those cells are removed as part of a procedure necessary for their

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28. See, e.g., Alan B. Bennett, Wendy D. Streitz & Rafael A. Gacel, *Specific Issues with Material Transfer Agreements*, in 1 INTELLECTUAL PROPERTY MANAGEMENT IN HEALTH AND AGRICULTURAL INNOVATION 697, 698 (Anatole Krattiger et al. eds., 2007) (explaining that a material transfer agreement is a bailment, that is, a transfer of property without a transfer of title, under which the provider maintains ownership of the transferred property); see also Bruce Goldstein, *Overview of Technology Development*, in PRINCIPLES AND PRACTICE OF CLINICAL RESEARCH 291, 299-300 (John I. Gallin & Frederick P. Ognibene eds., 2d ed. 2007) (describing material transfer agreements).

29. See Moore, 793 P.2d at 515-16 (Mosk, J., dissenting) (discussing this type of concern).



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medical treatment. Such restrictions would be consistent with numerous other rules in property law that limit the use or disposition of particular types of property.

Denying individuals property rights in the cells of their body is also a remarkably paternalistic approach to protecting individuals from coercion, particularly in light of the fact that we seem to grant property rights in those cells to research labs. The law, in essence, would be saying: "You have no property rights in the cells of your body when they are outside your body because we must protect you from economic exploitation, but we are perfectly comfortable letting biotechnology companies and research labs profit from the transfer of such cells."

One could always argue that no one should have property rights in human cells. The market solution of material transfer agreements, however, highlights the property-like nature of these substances. Excised human cells are tangible items, and someone must have legal dominion over them.

It is certainly true that giving individuals property rights in the cells of their bodies when those cells are no longer in their bodies may have the effect of giving more valuable remedies to those whose cells are used improperly. Research protocols have adapted to the need for informed consent, however, and they would adapt to this changing environment as well, perhaps by creating indemnification agreements for cells donated. Our enthusiasm and appreciation for the miraculous advances of science should not blind us to the necessity of thinking through the interests of the people whose cells provide the raw materials, nor should it obviate the necessity of ensuring that those raw materials are properly obtained. Perhaps courts in the appropriate jurisdictions will feel moved to revisit these issues, now that we have decades of experience with this type of scientific research.

## II. WHERE DOES NATURE END AND HUMAN INVENTION BEGIN?

The avenue of approach is quite different in the intellectual property realm. In intellectual property, questions normally do not focus on the person from whom the cells originate. Cells are analogous to the raw materials of invention, and patent rights, after all, are granted only to those who take raw materials and create something beyond what nature has provided. Individuals do not engage in this type of creative activity by virtue of simply handing over their cells. Nevertheless, an individual's ability to learn the details of his or her genetic composition, and perhaps even the ability to alter that composition, will be strongly affected by the outcome of current patent debates.

The operative question in patent law concerns the extent to which inventors can tie up human genes and related substances, removing them for a period of

time from that which is free to all and reserved to none.<sup>30</sup> This question is being thrust into the limelight as a result of two cases, *Bilski v. Kappos*<sup>31</sup> and *Association for Molecular Pathology v. United States Patent & Trademark Office*.<sup>32</sup> The cases approach the same question from different angles: where does nature end and human invention begin?

As I will describe below, *Bilski* has already drawn an extraordinary amount of attention. In my view, one of the next chapters in the great *Bilski* saga will involve personalized medicine inventions. This topic is looming on the horizon because personalized medicine cases lie at the difficult intersection of computer science and life science. Such inventions also bring together questions related to proper subject matter for *method* inventions with questions related to proper subject matter for *product* inventions. In other words, the topic implicates the most difficult spot at the center of a number of swirling controversies that require a resolution of things courts have been unwilling or unable to resolve.

Part of the problem in resolving these issues lies in the analogies used. Analogies between mechanical and biological inventions are always risky given the vast differences between the two realms.<sup>33</sup> Consider the basic problem of framing genes in terms of either a product or a process, two basic categories developed in relation to mechanical inventions. Genes are sequences of nucleotides that operate as a set of instructions for carrying out some function in the body. We would normally think of a set of instructions as a process, that is, a method of doing something, rather than as a tangible product. Genes, however, are as concrete and tangible as any machine we might build. It is almost as if one could create a construction manual that operated on its own. Would we treat it as a process or a product?

It takes a certain degree of mental gymnastics to contemplate a thing whose nature is, to some extent, both that of a process and that of a product. The challenge is even greater when that thing must be described in abstract terms in a patent application. It is not surprising that we have run into some difficulties, and those difficulties are exacerbated in the field of personalized medicine when the invention combines genes with computer-related inventions.

*Molecular Pathology* was a personalized medicine case. It involved inventions related to gene mutations that create proteins associated with certain

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30. See, e.g., *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (containing the frequently used language that “manifestations of . . . nature [are] free to all men and reserved exclusively to none” (omission in original) (quoting *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948))).

31. 130 S. Ct. 3218 (2010).

32. 702 F. Supp. 2d 181 (S.D.N.Y. 2010).

33. See Robin Feldman, *Rethinking Rights in Biospace*, 79 S. CAL. L. REV. 1, 2-5 (2005) (describing how an analogy taken from mechanical inventions is wreaking havoc in cases related to biotechnology); cf. ROBIN FELDMAN, *THE ROLE OF SCIENCE IN LAW* (2009) (describing difficulties encountered when scientific definitions are imported into law without a firm understanding of the assumptions inherent in those definitions).

forms of breast and ovarian cancer. The proteins are commonly known as *BRCA1* and *BRCA2*. In a fashion that has become all too familiar in the patent world, the patent holder reached far and wide in drafting claims related to the invention. This Part will focus on a few of the claims that represent the problems with the patent and with the resulting trial court opinion.

DNA is a molecule that carries genetic information and is made up of a sequence of nucleotides. The order of the nucleotides creates a blueprint that the cell will use to perform its functions, including making particular proteins and reproducing itself.

Finding a relevant sequence is not a simple matter. Researchers begin with a pool of data from a large number of patients. It takes time, diligence, and, most importantly, creativity to sift and sort the data, looking for the genetic mistake that may be relevant to some extent for a particular segment of the patients examined.

It is important to note the limitations inherent in this type of diagnostic technology. First, the variation does not affect all women who have breast and ovarian cancer. Second, the presence of the biomarker does not mean that the patient will definitely develop the disease. Finding the biomarker in a patient suggests no more than an increased statistical probability that the patient will develop the related disease.

Finally, although teasing a genetic biomarker from the data can provide an enormously valuable tool for researching the disease and identifying treatment methods, it would be a mistake to suggest any simple causal relationship between the biomarker and the disease process. A biomarker may provide no more than a clue in a complex and dynamic human puzzle.

The patent holder in *Molecular Pathology* claimed an isolated piece of DNA containing the nucleotide sequence that translates into either the *BRCA1* or *BRCA2* protein. In other words, having developed parameters for a set of proteins that may be relevant to some extent in some set of circumstances, the patent holder identified the sequence that codes for the worrisome proteins and claimed the isolated form of that sequence.

The patent holder did not claim the sequence in its form in the human body. The cell and its components as they exist in the human body constitute a natural product, and the Supreme Court has suggested that the discovery of a natural product is not a patentable invention, even if that product was previously unknown.<sup>34</sup> Thus, the patent holder in *Molecular Pathology* claimed the se-

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34. See, e.g., *Chakrabarty*, 447 U.S. at 309 (noting in a case concerning whether living products constitute patentable subject matter that “a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter”); *Funk Bros.*, 333 U.S. at 130; cf. *Diamond v. Diehr*, 450 U.S. 175, 185 (1981) (noting, in a case related to process patents rather than product patents, that one cannot patent “laws of nature, natural phenomena, and abstract ideas”).

quence in a form outside the human body, isolated and separated from the remainder of the cellular components.

As described above, DNA is made up of a string of paired nucleotides. Separating out a portion of the DNA strand from the remainder of the strand, and from the other cumbersome parts of the human cell, allows researchers to begin working with the strand in a laboratory setting. It is one step in the process of manipulating and combining genes and proteins in ways that, for example, create medications more effective than what the human body can create.

In addition to the isolated segment, the patent holder also claimed a product called cDNA. As a cell goes through the complex process of translating the DNA sequence through messenger RNA and into the proper protein, certain portions of the sequence are spliced away. cDNA is the mirror image of the sequence at the point at which all noncoding regions have been removed.<sup>35</sup>

In other words, think of that wonderful double helix one often sees in illustrations of biology. Imagine opening the double helix like a zipper, and on half of the zipper, separating out the relevant part and then splicing out the noncoding regions. cDNA is the mirror image of that. In simplified form, one can describe cDNA as the mirror image of the uninterrupted coding sequence.<sup>36</sup>

cDNA does not normally exist in the human body, and is naturally created only through the operation of certain retroviruses. Transforming normal DNA into cDNA, however, provides a more efficient tool for researchers and health care professionals who wish to study, diagnose, and treat the disease associated with a gene. In particular, cDNA is tailored to work with bacteria, the organisms commonly used to manipulate human genes and proteins in a laboratory setting. Bacteria do not have the machinery to shorten natural DNA, so we have to create special uninterrupted coding sequences for them. If given an uninterrupted coding sequence, bacteria can translate that sequence into the proper protein.

Another advantage of cDNA over natural DNA is that the shorter length makes many laboratory procedures possible that could not be performed effectively with natural, full-length DNA. In other words, the inventors have created an altered version of DNA that is tailored to work in a laboratory setting in a way that natural DNA would not.

Creating cDNA also may be useful in altering or repairing genes in their natural setting. In the world of gene therapy, which is still in experimental stages, cDNA potentially could be used to bind with the natural gene and render it inactive.

In addition to product claims to isolated DNA and cDNA, the patents in *Molecular Pathology* also included method claims. For example, the patent

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35. While the single-stranded cDNA is a mirror image, it is the double-stranded version that is frequently used in lab applications.

36. In the human body, the uninterrupted coding sequence exists in the form of RNA, not DNA.

holder claimed the method of determining whether a person is predisposed to the relevant form of cancer by comparing the person's gene sequence to the sequence in nature that codes for either *BRCA1* or *BRCA2*.<sup>37</sup> The patent holder also claimed the method of determining whether a potential cancer therapeutic is effective by growing cells containing the relevant gene and determining whether those cells grow more slowly in the presence of the therapeutic.<sup>38</sup>

The proper test for determining whether a method patent satisfies the subject matter requirements of 35 U.S.C. § 101 was the focus of the Supreme Court's recent decision in *Bilski v. Kappos*.<sup>39</sup> In *In re Bilski*, the Federal Circuit had declared that the sole test for determining whether a patent on a method falls within patentable subject matter should be the "machine-or-transformation" test.<sup>40</sup> Under the machine-or-transformation test, a method patent falls within proper subject matter only if "(1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing."<sup>41</sup>

The *Bilski* patent covered a method of hedging risk in the energy commodities industry. Although the case specifically addressed patentability of business methods, the decision had the explosive potential to affect a variety of other method claims, including those related to software and biotechnology. For example, how could the Court limit business method patents, which are essentially a method of doing a business activity, without also limiting software patents, which are often expressed in terms of a method of getting a machine to do something? Moreover, how could the Court limit patents on a method of doing a business activity without also limiting biotechnology therapeutic and diagnostic patents, which are often expressed as methods of diagnosing or treating a disease by doing something? The potential implications of any decision prompted a staggering number of amicus briefs, as well as considerable heartburn in the industries potentially affected.

In a set of divided opinions, the Supreme Court rejected the Federal Circuit's logic and held that the machine-or-transformation test is not the sole test for determining patentable subject matter for method patents.<sup>42</sup> The Court

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37. See *Ass'n for Molecular Pathology*, 702 F. Supp. 2d at 213-14.

38. *Id.* at 214.

39. 130 S. Ct. 3218 (2010).

40. *In re Bilski*, 545 F.3d 943, 959-60 (Fed. Cir. 2008) (en banc).

41. *Id.* at 954.

42. See *Bilski*, 130 S. Ct. 3218. Justice Kennedy delivered the opinion of the Court, except as to Parts II.B.2 and II.C.2. *Id.* at 3221. Chief Justice Roberts and Justices Thomas and Alito joined the opinion in full. *See id.* at 3218. Justice Scalia joined the opinion except as to Parts II.B.2 and II.C.2. *See id.* at 3218, 3221. Justice Stevens filed an opinion concurring in the judgment, in which Justices Ginsburg, Breyer, and Sotomayor joined. *Id.* at 3231. Justice Breyer filed a concurring opinion, in which Justice Scalia joined as to Part II. *Id.* at 3257.

pointed to language in its prior cases suggesting that, while such a test may be an important clue or investigative tool, it is not the exclusive measure.<sup>43</sup>

Perhaps the most striking part of the Supreme Court's decision was its suggestion that the Federal Circuit has been wrong across the board on everything it has said in more than a decade of opinions in this area. Specifically, the Supreme Court declared that "nothing in today's opinion should be read as endorsing interpretations of § 101 that the Court of Appeals for the Federal Circuit has used in the past."<sup>44</sup>

The Court chose very limited language in crafting the *Bilski* decision, which seemed to reflect the Court's concern over the impact that any business method decision might have on other areas, such as software and biotechnology. Cases over the last forty years have tied this area of law into a Gordian knot, making extrication quite difficult.<sup>45</sup> In particular, the Court noted the following:

Rather than adopting categorical rules that might have wide-ranging and unforeseen impacts, the Court resolves this case narrowly on the basis of this Court's decisions in *Benson*, *Flook*, and *Diehr*, which show that petitioners' claims are not patentable processes because they are attempts to patent abstract ideas. Indeed, all members of the Court agree that the patent application at issue here falls outside of § 101 because it claims an abstract idea.<sup>46</sup>

With this language, the Court seemed to limit the *Bilski* decision to abstract ideas. The wording, however, creates some uncertainty over the extent to which the Court is inclined to apply the same logic to software or other types of method cases. One could read the Court's language to convey nothing more than the fact that *business method patents* attempting to block *abstract ideas* are unpatentable based on discussions in *Benson*, *Flook*, and *Diehr* regarding abstract ideas. *Benson*, *Flook*, and *Diehr*, however, concerned computer-related inventions.<sup>47</sup> Thus, one might be tempted to speculate that the Court intends to apply similar logic in software cases, or, at the very least, the Court sees the *Benson-Flook-Diehr* line of cases as offering a viable path for deciding issues related to process patents in general. The broader implication, however, would be troubling. *Benson*, *Flook*, and *Diehr* were decided in the 1970s and early 1980s.

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43. *See id.* at 3226-27.

44. *Id.* at 3231.

45. For a detailed history of how various court opinions have slowly tied this Gordian knot and an explanation of how to untangle it, see ROBIN FELDMAN, RETHINKING PATENT RIGHTS (forthcoming) (manuscript at ch. 4) (on file with author) (discussing patentable subject matter in a chapter entitled "Where Do Processes of Nature End and Processes of Human Inventions Begin?").

46. *Bilski*, 130 S. Ct. at 3229-30.

47. *See* *Diamond v. Diehr*, 450 U.S. 175, 187 (1981); *Parker v. Flook*, 437 U.S. 584 (1978); *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972).

Computer-related inventions, not to mention our understanding of those inventions, have progressed significantly in the interim.<sup>48</sup>

Despite a narrowly tailored opinion, the Supreme Court did stress one important point in *Bilski*. In rejecting the patent, the Court noted that “[a]llowing petitioners to patent risk hedging would pre-empt use of this approach in all fields, and would effectively grant a monopoly over an abstract idea.”<sup>49</sup> In other words, it appears that preemption remains important in determining whether a method patent falls within the patentable subject matter described by § 101, at least in the context of the facts of the case. The problem with the *Bilski* patent claim, therefore, is that a patent holder would be able to fully block, that is preempt, an abstract idea. Implicit in the Court’s analysis, of course, is the notion that patent law does not grant rights in abstract ideas.

One will not hear many academics express the following view in regards to the *Bilski* opinion, but I believe the Supreme Court did the right thing. The Court followed a maxim familiar to those in the life sciences that, above all else, one must do no harm. The Justices did not have a good solution for a subject matter test at the crucial intersection of computer software, life sciences, and business methods. Thus, the wisest course of action was to be patient and to allow the conversation to continue.

Personalized medicine cases, like *Molecular Pathology*, can lead us out of the morass, and the notion of preemption is critical to finding the right path. In gene-related inventions, preemption problems can emerge not just in the context of attempts to tie up an abstract idea, but also in the context of attempts to tie up a natural phenomenon. The notion of preemption is important for understanding what is permissible and what is problematic with the claims in *Molecular Pathology* and similar cases.

The Supreme Court has stated repeatedly that one may not patent laws of nature or natural phenomena, noting that these are basic tools of scientific and technological work.<sup>50</sup> Inventions may certainly take advantage of such building blocks. In fact, it would be difficult to imagine an invention that did not use laws of nature to some extent. One should ask, however, whether the patent holder is preempting a natural phenomenon, rather than creating an application of that natural phenomenon and controlling only the application created.<sup>51</sup>

In answering the question, it is important to think about the requirements of patentability as a whole. Patent law has become too segmented in thinking about the elements of patentability, and we risk losing the ability to see the sys-

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48. For an explanation of problems with the *Benson-Flook-Diehr* line of cases, and how to resolve those problems, see FELDMAN, *supra* note 45 (manuscript at ch. 4).

49. *Bilski*, 130 S. Ct. at 3231.

50. *E.g.*, *Benson*, 409 U.S. at 67.

51. *See Diehr*, 450 U.S. at 187 (stating that respondent “d[id] not seek to pre-empt” the use of the well-known Arrhenius mathematical formula but “only to foreclose from others the use of that equation in conjunction with all of the other steps in their [patented] process” in holding that the claim satisfies § 101).

tem as a dynamic whole, with all of the parts working together. In particular, it makes little sense to think about patentable subject matter in isolation from the other elements of patentability and limiting principles of patent law. Rather, one should analyze patentable subject matter in the following manner: considering the limitations of the patent system as a whole, are we likely to have preemption problems with the subject matter of this patent?

For example, early generations of biomarker tests involved a one-to-one relationship between a single physical phenomenon and a disease state. A classic example is the relationship between elevated blood sugar levels and diabetes. Although the discovery of this relationship is tremendously important in the diagnosis and treatment of diabetes, allowing an inventor to patent that phenomenon would raise preemption concerns. Discovering the fact that *A* occurs with *B* is no different from discovering a property of a natural substance or discovering how a biological process unfolds, neither of which would be patentable. Thus, when the invention constitutes no more than the straightforward measurement of a single biomarker, one could easily argue that the invention merely recognizes a natural phenomenon.

At the other end of the spectrum are modern personalized medicine diagnostic methods. These may involve hundreds of biomarkers and complex statistical modeling that identifies patterns or groupings of markers that may indicate the benefit of a particular treatment approach. In addition, the biomarkers are usually selected and statistically modeled to take into account issues such as human genetic and environmental variations.<sup>52</sup> These inventions do not merely reflect nature; they are interpretative models of nature.<sup>53</sup> As I have described in detail elsewhere, patenting such models should not raise preemption concerns, given that they leave plenty of room for the development of other models.<sup>54</sup> In addition, their probabilistic, interpretative approach provides reassurance that the inventions are not preempting anyone's actual natural state.<sup>55</sup>

The diagnostic claims in *Molecular Pathology* fall somewhere between the two extremes. The invention is indeed a correlation involving a single biomarker, and it is one that does not require an extensive amount of processing to read the results. Nevertheless, the presence of the genetic marker creates only a statistical probability, rather than providing a clear one-to-one correlation with a disease state. As such, the inventions fall more on the side of the type of data sifting and interpretation that characterizes the more complex personalized diagnostics and less on the side of a simple fact of nature. Reasonable minds could differ, nevertheless, on this point.

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52. For a detailed explanation of patentable subject matter in the context of personalized medicine, see FELDMAN, *supra* note 45 (manuscript at ch. 4).

53. *See id.*

54. *See id.*

55. Such personalized medicine inventions are a statistical approximation based on an amalgamation of interpretive data; they could not possibly represent the natural state of any individual living being.



Far greater problems exist, however, with the therapeutic research claims. The patent holder in *Molecular Pathology* essentially claimed the method of determining whether a cancer therapeutic is effective, which is described as growing cells carrying the mutation both in the presence and absence of the therapeutic agent and comparing to see if one has a slower growth rate. The process of growing cells and comparing growth rates is not new. Neither is the process of growing cells with genetic mutations and measuring whether a therapeutic slows the growth of the cells. Like the concept of hedging in *Bilski*, the concept of testing a therapeutic against a drug target is well known, and the patent holder offers no novel testing or subtle interpretive information.

The therapeutic research claim is somewhat reminiscent of claims rejected by the Federal Circuit in *Rochester v. Searle*.<sup>56</sup> There, the patent holder tried to claim methods for selectively inhibiting certain enzyme activity in a human patient. The patent holder, however, had not identified an example of a compound that would work. The court rejected the claim under 35 U.S.C. § 112 as a failure to properly describe the invention.<sup>57</sup> My own view is that to claim an entire group of things, it would make sense to require a showing of at least some members of the group, as well as a reason to believe that the entire group is appropriately related to the members demonstrated.<sup>58</sup>

In *Molecular Pathology*, the patent holder has tried to control all potential therapeutic approaches without having provided a single one, let alone a reason to believe that the group is appropriately related to any demonstrated members. Claiming a method of determining efficacy of treatment is simply an attempt to more creatively draft *Rochester*-style claims that would reach an entire category of items whose identity remains undetermined.

The more interesting question involves the claims to particular DNA and cDNA sequences created outside the human body. These are claims for products, rather than the claims for methods described in the prior paragraphs. Given that the DNA sequences occur naturally in some people at particular points

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56. *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916 (Fed. Cir. 2004).

57. *G.D. Searle*, 357 F.3d at 923; see also *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1349-50 (Fed. Cir. 2010) (en banc) (“[A] sufficient description of a genus . . . requires the disclosure of either a representative number of species falling within the scope of the genus or structural features common to the members of the genus so that one of skill in the art can ‘visualize or recognize’ the members of the genus.” (quoting *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1568-69 (Fed. Cir. 1997))). See generally Robin C. Feldman, *The Inventor’s Contribution*, 2005 UCLA J.L. & TECH. 6 (describing the history of the written description requirement and arguing that a separate written description is unnecessary if the enablement requirement is properly construed).

58. *Cf. Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 964 (Fed. Cir. 2002) (noting that a functional description might satisfy the written description requirement if “coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics” (emphasis omitted) (quoting Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1, “Written Description” Requirement, 66 Fed. Reg. 1099, 1106 (Jan. 5, 2001))).

in the DNA strands of their cells, the operative question is whether the product created is sufficiently distinct from nature that it should be considered a human invention. In other words, is this a product of nature or of human invention? As described above, one can certainly take advantage of nature and its properties in creating a new product. Analogous to using laws of nature in a method patent, many inventions rely on nature and natural properties, whether that is bacteria's ability to produce proteins or DNA's ability to serve as a blueprint. The relevant inquiry, however, concerns whether the inventor has created something sufficiently distinct from what nature provides.

The trial court in *Molecular Pathology* analyzed the question according to case law on the purification of natural products. For example, in the 1873 case *American Wood-Paper Co.*, the Supreme Court rejected a product patent for a new version of paper pulp that did not require mechanical treatment before being made into paper.<sup>59</sup> The Court reasoned that although the patent holder might have invented a better process for treating wood with only chemical rather than mechanical means in order to obtain cellulose for making paper, the invention did not constitute a new product. In particular, the Court noted the following in dicta: "Thus, if one should discover a mode or contrive a process by which prussic acid could be obtained from a subject in which it is not now known to exist, he might have a patent for his process, but not for prussic acid."<sup>60</sup> In a similar vein, a group of lower court cases from the 1920s and 1930s held that purification of a product of nature generally does not yield a new patentable product.<sup>61</sup>

Describing gene patents as analogous to purification of a natural product might have made sense in the 1980s and 1990s. In those days, researchers did physically isolate and purify portions of DNA from human cells to obtain a gene. Even cDNA was obtained from purified mRNA.

Although the classic methods are still practiced, "purification" is a description increasingly at odds with what is actually done in the field. In most cases, the modern creation of genetic inventions no longer requires purification. Today's laboratories can use chemical synthesis to build, from the ground up, the

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59. *Am. Wood-Paper Co. v. Fibre Disintegrating Co.*, 90 U.S. (23 Wall.) 566 (1874).

60. *Id.* at 594.

61. *See Gen. Elec. Co. v. De Forest Radio Co.*, 28 F.2d 641, 649 (3d Cir. 1928) (invalidating patent on the grounds that the patent holder had merely produced tungsten in its pure form, and discovered no more than the natural qualities of pure tungsten); *In re Merz*, 97 F.2d 599, 601 (C.C.P.A. 1938) (finding patent holder not entitled to a patent on what amounts to ultramarine produced to a greater degree of purity unless the new product is of such purity that it differs not only in degree but in kind such that there is a new utility); *In re Marden (Marden II)*, 47 F.2d 958, 959-60 (C.C.P.A. 1931) (rejecting patent on purified vanadium which resulted in greater ductility on the grounds that the greater malleability is one of its inherent qualities); *In re Marden (Marden I)*, 47 F.2d 957 (C.C.P.A. 1931) (holding that the appellant was not entitled to a patent on the supposedly new substance, ductile uranium, on the ground that one may not patent a product of nature or the inherent natural qualities of that metal).

physical DNA or cDNA sequence that can be used in the lab. In fact, one can order the required sequence from an outside vendor who will use chemical synthesis to construct the product according to specifications. This is not purification, and we should look to other analogies to determine whether the invention satisfies patentable subject matter.

Constructing a gene through chemical synthesis looks much like putting together mechanical parts to make a machine. One has a variety of nuts and bolts, and the goal is to build a machine that can perform a desired task in the laboratory, in this case, a task that nature performs in the body. To the extent that gene-related inventions are analogous to constructing a machine, they should certainly constitute patentable subject matter.

One should also note that simply attaching nuts and bolts together will not yield a patentable invention. To satisfy all the elements of patentability, an inventor must be able to identify a use for the invention, as well as demonstrate that the invention is novel, nonobvious, and sufficiently described and enabled.<sup>62</sup> One may see many combinations of mechanical parts strewn around a tinkerer's basement, but none will yield a patentable invention unless the inventor can at least identify a use. Similarly, much of the human genome has now been sequenced, which would give researchers the necessary information to construct various gene "machines" in the lab. No researcher could file for a patent on a particular gene machine in a laboratory setting, however, unless the researcher has been able to develop a specific use for it. The same would be true of a genetic mutation. Sequencing projects and databases may contain descriptions of numerous mutations, but those mutations cannot be constructed into a patentable product until a researcher can develop a use that is specific to that mutation. In other words, others in the art may know how to tinker in a way that puts nucleotide pieces together, but the inventor is the one who finds a use for it, in addition to satisfying other requirements of patentability.

Finally, the fact that genes exist in a natural form in the human body should not prevent patenting of genes in laboratory form. Although nature may have offspring that can perform a particular function, one may still make a patentable invention by creating an artificial version of that offspring. Birds can fly, but if an inventor were able to construct an artificial bird capable of flight, that artificial bird would represent an extraordinary and patentable invention, although the patent certainly would not cover nature's own avian version.

These issues are extraordinarily complex and difficult to wrap one's mind around. It is not surprising that courts and commentators are tempted to use a familiar analogy, such as purification, even when the metaphor fits poorly with modern scientific practice. If one were to adopt a purification analogy, however, genetic DNA and cDNA sequences should still constitute patentable subject matter. Purification cases themselves suggest that a product purified from a natural substance can constitute patentable subject matter under certain cir-

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62. See 35 U.S.C. §§ 101-103 (2006).

cumstances. For example, the predecessor court to the Federal Circuit explained in *In re Merz* that although, in general, one cannot get a patent for a product that merely has a greater degree of purity, “[t]he exception is that if the process produces an article of such purity that it differs not only in degree but in kind it may be patentable. If it differs in kind, it may have a new utility in which invention may rest.”<sup>63</sup>

The *Merz* court was echoing a notion that the Supreme Court had hinted at in *American Wood-Paper*. In rejecting a patent on a version of wood pulp, the Supreme Court suggested that a different use could possibly form the basis of a distinction between an unpatentable purification and a patentable new product.<sup>64</sup> The question can be framed in the following terms: is the invention not only new but also new in a way that matters by opening new avenues for humans to do something that could not be done previously?

Judge Learned Hand explored the idea more extensively in *Parke-Davis*, which concerned a patent on a therapeutic product extracted from the suprarenal glands of animals.<sup>65</sup> Judge Hand upheld the patent arguing that while the inventor

was the first to make it available for any use by removing it from the other gland-tissue in which it was found, and, while it is of course possible logically to call this a purification of the principle, it became for every practical purpose a new thing commercially and therapeutically. . . . The line between different substances and degrees of the same substance is to be drawn rather from the common usages of men than from nice considerations of dialectic.<sup>66</sup>

One could argue endlessly over the extent to which Judge Hand’s discussion constitutes dicta.<sup>67</sup> One could also argue that the purification cases are too

63. 97 F.2d at 601; cf. *Am. Fruit Growers, Inc. v. Brogdex Co.*, 283 U.S. 1, 11 (1931) (“Addition of borax to the rind of natural fruit does not produce from the raw material an article for use which possesses a new or distinctive form, quality, or property.”).

64. See *Am. Wood-Paper*, 90 U.S. (23 Wall.) at 594 (“The substance of the products, therefore, was the same, and so were their uses. The design and the end of their production was the same, no matter how or from what they were produced.”).

65. *Parke-Davis & Co. v. H.K. Mulford Co.*, 189 F. 95, 103 (C.C.S.D.N.Y. 1911), *aff’d in part*, 196 F. 496 (2d Cir. 1912).

66. *Id.*

67. The trial court in *Molecular Pathology* claimed that *Parke-Davis* did not address patentable subject matter. See *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 702 F. Supp. 2d 181, 225 (S.D.N.Y. 2010) (“Although Myriad argues that the holding in *Parke-Davis* establishes that the purification of a natural product necessarily renders it patentable, the opinion, read closely, fails to support such a conclusion. The question before the court in *Parke-Davis* was one of novelty (a modern-day § 102 question), not of patentable subject matter (the § 101 question before this Court.”). Judge Hand did, indeed, begin the *Parke-Davis* opinion with a decision relating to whether the claimed form had been anticipated by the prior art. See 189 F. 95 at 101-02. It is in the section on technical objections—that is, things other than novelty—that Judge Hand turned to whether the patent was for a new composition of matter, in other words, whether the invention constituted patentable subject matter. See *id.* at 102-04. Although one can argue over which part of that section

old to be of much use. For example, the most relevant Supreme Court case, *American Wood-Paper*, was written in 1873,<sup>68</sup> *Parke-Davis* was written in 1911,<sup>69</sup> and other purification cases were written three-quarters of a century ago.<sup>70</sup> Our understanding of chemical and biological products has advanced considerably since that time. Nevertheless, one so often finds the wisdom of Learned Hand to be compelling, and *Parke-Davis* is no exception. In the words of the classic Robinson treatise from the late 1800s, “[A]ny frivolous or trifling article or operation not aiding in the progress nor increasing the possessions of the human race, whatever be its novelty, and whatever skill has been involved in its production, does not fall within the class of useful inventions nor become the subject-matter of a patent.”<sup>71</sup> In other words, the hallmark of something worth patenting is that it is useful to society, either by aiding in our progress or helping to bring about an increase in our possessions. One can, therefore, answer by analogy the question of whether something is sufficiently different from its natural counterpart. If one wants to ask whether a difference matters, that is, whether the difference is more than merely frivolous or trifling, that difference should be evaluated in terms of whether the substance allows society to do something new that aids in our progress or helps bring about an increase in

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should be considered precedent and which part should be considered dicta, *Parke-Davis* certainly reached a decision on patentable subject matter. Specifically, Judge Hand said:

Nor is the patent only for a degree of purity, and therefore not for a new “composition of matter.” As I have already shown, it does not include a salt, and no one had ever isolated a substance which was not in salt form, and which was anything like Takamine’s. Indeed, Sadtler supposes it to exist as a natural salt, and that the base was an original production of Takamine’s. That was a distinction not in degree, but in kind. But, even if it were merely an extracted product without change, there is no rule that such products are not patentable. Takamine was the first to make it available for any use by removing it from the other gland-tissue in which it was found, and, while it is of course possible logically to call this a purification of the principle, it became for every practical purpose a new thing commercially and therapeutically. That was a good ground for a patent. That the change here resulted in ample practical differences is fully proved. Everyone, not already saturated with scholastic distinctions, would recognize that Takamine’s crystals were not merely the old dried glands in a purer state, nor would his opinion change if he learned that the crystals were obtained from the glands by a process of eliminating the inactive organic substances. The line between different substances and degrees of the same substance is to be drawn rather from the common usages of men than from nice considerations of dialectic.

*Id.* at 103 (citations omitted).

68. 90 U.S. (23 Wall.) 566 (1873).

69. 189 F. 95 (C.C.S.D.N.Y. 1911).

70. See *Am. Fruit Growers, Inc. v. Brogdex Co.*, 283 U.S. 1 (1931); *Gen. Elec. Co. v. De Forest Radio Co.*, 28 F.2d 641 (3d Cir. 1928); *In re Merz*, 97 F.2d 599 (C.C.P.A. 1938); *Marden II*, 47 F.2d 958 (C.C.P.A. 1931); *Marden I*, 47 F.2d 957 (C.C.P.A. 1931). *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130-31 (1948), is often mentioned in the group of cases. Although it concerned a combination of bacteria rather than a purification, the Court rejected the patent, expounding on the difference between uncovering nature’s qualities and something that constitutes a product of human invention. The Court may have been distracted, however, by the fact that the patent holder tried to claim all bacteria that might behave in a certain way, rather than simply the ones identified in the patent. See *id.*

71. 1 WILLIAM C. ROBINSON, *THE LAW OF PATENTS FOR USEFUL INVENTIONS* § 339 (Boston, Little, Brown & Co. 1890).

our possession. Judge Hand's suggestion that a purification differs from nature when it allows us to do what we could not have done with that which is found in nature makes eminently good sense.

One could argue that the approach mixes questions of utility and novelty into the subject matter inquiry.<sup>72</sup> The elements of patentability are conceptually related, however, and one can easily use the same information for different purposes in different inquiries. For subject matter patentability, the question is not whether the substance is new relative to other invented substances (novelty) or whether it is sufficiently useful (utility). Rather, for subject matter patentability, the question is whether the invented substance is different from a product that nature has provided. In answering that question, we should ask whether the invention allows us to accomplish something that we could not accomplish with the natural product.

Applying that yardstick to isolated DNA and cDNA would suggest that such products should be considered human inventions, rather than the handiwork of nature. Natural human cells, even ones that have been separated from their body of origin, will have many limitations for use in the lab. For example, it is difficult to get the cells to proliferate in culture in sufficient number to support modern biochemical, genetic, diagnostic, and therapeutic techniques.<sup>73</sup>

In addition, cDNA is an artificial DNA that does not normally exist in natural cells but is created by researchers in test tubes. The natural human DNA will not operate effectively with bacteria, the workhorses of modern molecular genetic technologies. Creating an altered version of the human DNA, one that can be used effectively in the lab, facilitates a world of opportunities in biomedical research. It is precisely what Judge Hand was referring to when he suggested that one could find the line between different substances and degrees of the same substance, not by clever wordplay, but by looking at what can be done with the substance that is claimed as new.<sup>74</sup>

I suspect that beneath concerns in the area of patenting isolated genes and gene variations is a question related to preemption. By allowing a patent on DNA segments in laboratory form, even if those segments are entirely artificial, are we indirectly allowing the patent holder to tie up the natural phenomenon of

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72. See Allen K. Yu, *Why It Might Be Time to Eliminate Genomics Patents, Together with the Natural Extracts Doctrine Supporting Such Patents*, 47 IDEA 659, 702 (2007) (arguing that *Parke-Davis* improperly mixed utility questions into subject matter patentability).

73. See ALBERTS ET AL., *supra* note 2, at 470 ("Most biochemical procedures require obtaining large numbers of cells and then physically disrupting them to isolate their components [such as protein, DNA, and RNA]. . . . To obtain as much information as possible about an individual cell type, biologists have developed ways of dissociating cells from tissues and separating the various types[,] . . . result[ing] in a relatively homogeneous population of cells that can then be analyzed—either directly or after their number has been greatly increased by allowing the cells to proliferate as a pure culture."); see also *id.* at 472 (describing how cell cultures "allow[] the number of cells to be greatly increased and their complex behavior to be studied under the strictly defined conditions of a culture dish").

74. See *Parke-Davis*, 189 F. at 103.

the gene itself in the human body? If so, how can we tie up a gene, antibody, or other protein, or even an artificial version of those, when there is so much that we do not understand?

This type of preemption concern is particularly acute in the biological sciences, where elements play more than one role and interact on multiple levels. Consider the case of the patent on the CCR5 receptor. In 1996, Human Genome Sciences applied for a patent on a genetic sequence that coded for a particular protein. The company used computer modeling to compare the sequence and its protein to other known sequences and proteins, in an effort to predict utility.<sup>75</sup> Based on this work, the company filed for a patent predicting the function of the protein from its similarity to a category of proteins known as chemokine receptors.<sup>76</sup> To satisfy utility, the company described the functions of such known receptors, listing them as relating to the very broad fields of “inflammation, immune reactions, allergies, and arthritis.”<sup>77</sup> The patent claims included rights to the genetic sequence and the receptor it codes for.

While the application was pending, AIDS researchers independently were researching CCR5, a receptor that the HIV virus uses to enter and infect cells.<sup>78</sup> Having fewer than both copies of the CCR5 gene can increase resistance to HIV infection: having only one copy can slow infection and having no copies at all can create strong resistance to infection.<sup>79</sup> The Human Genome Sequence’s receptor turned out to be CCR5. Once the patent issued, it covered nearly all uses of the CCR5 receptor.<sup>80</sup> Critics have charged that the patent effectively precluded research, diagnosis, and treatment of AIDS in ways related to the CCR5 receptor without a license from the company.<sup>81</sup>

The Patent and Trademark Office would be much less likely to grant Human Genome Sequence’s patent today, given current utility rules. Current rules require that an inventor articulate a more particularized use for an invention

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75. See Donna M. Gitter, *International Conflicts over Patenting Human DNA Sequences in the United States and the European Union: An Argument for Compulsory Licensing and a Fair-Use Exemption*, 76 N.Y.U. L. REV. 1623, 1625 n.11 (2001) (describing the CCR5 patent application and homologous sequencing).

76. See *id.*; *The Fate of Gene Patents Under the New Utility Guidelines*, 2001 DUKE L. & TECH. REV. 8, ¶ 6.

77. *The Fate of Gene Patents Under the New Utility Guidelines*, *supra* note 76, ¶ 6.

78. See Lori B. Andrews, *The Gene Patent Dilemma: Balancing Commercial Incentives with Health Needs*, 2 HOUS. J. HEALTH L. & POL’Y 65, 87 (2002); see also *The Fate of Gene Patents Under the New Utility Guidelines*, *supra* note 76, ¶ 6 (describing the CCR5 receptor). Receptors are themselves proteins. TEXTBOOK OF BIOCHEMISTRY WITH CLINICAL CORRELATIONS 936 (Thomas M. Devlin ed., 5th ed. 2002). Thus, descriptions of the CCR5 controversies can be confusing to those without a science background because the descriptions use the term “protein” to refer to both the thing that the CCR5 sequence creates and the thing that the creation binds to.

79. See Andrews, *supra* note 78.

80. Shanshan Zhang, *Proposing Resolutions to the Insufficient Gene Patent System*, 20 SANTA CLARA COMPUTER & HIGH TECH. L.J. 1139, 1161 (2004).

81. See *id.*

than something as broad as “a wide variety of uses . . . including inflammation, immune reactions, allergies, and arthritis.”<sup>82</sup> The solution is important for understanding the extent to which problems flow from setting the appropriate reach of a patent, rather than from patentable subject matter. As I suggested above, one should analyze patentable subject matter with the following question: considering the limitations of the patent system on the whole, are we likely to have preemption problems with the subject matter of the patent? From this perspective, the problem with CCR5 and similar examples lies not with the fact that the patent system allows inventors to patent genes, proteins, receptors, and the like, but rather with the extent of the reach that is allowed.

I have argued in the past that rules allowing patent holders to reach beyond the state of knowledge at the time of the invention are wreaking havoc across disparate doctrines, as courts struggle to avoid the uncomfortable implications of those rules.<sup>83</sup> For example, the notion that an inventor who creates a machine can control that machine regardless of how it is made or how it is used may make sense for mechanical inventions, but it makes little sense in the context of uncertain arts such as biotechnology.<sup>84</sup> It is this discordance that is creating distortions across a number of patent law doctrines, and it would be unfortunate to allow that discomfort to distort patentable subject matter as well.

The solution lies in properly limiting the scope of the allowed claim. In a case like *Molecular Pathology*, this limitation could be accomplished through the disclosure requirements of 35 U.S.C. § 112. Perhaps a properly drawn patent in this arena would say something to the effect that the inventor claims an isolated sequence of DNA (or a sequence of cDNA) containing the nucleotide sequence that transmits information for the creation of either the *BRCA1* or *BRCA2* protein for the purposes of breast cancer diagnosis in a designated patient population. In other words, the inventor would not control anything that the sequence might relate to outside of this population or for reasons other than this purpose. This would limit the inventor to the state of knowledge in the art at the time of the invention plus anything that the inventor has contributed, but no more. This may not satisfy all critics, but it respects the need for providing incentives in this exciting and robust industry while limiting those incentives to the inventor’s actual contribution.

I should address the concern that the types of limitations I propose are field-of-use restrictions, and field-of-use restrictions are problematic. In particular, the Supreme Court has suggested, in decisions related to process patents, that field-of-use restrictions are of no benefit in deciding whether an invention

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82. *The Fate of Gene Patents Under the New Utility Guidelines*, *supra* note 76, ¶ 6.

83. *See generally* Feldman, *supra* note 33.

84. *See id.* at 2-3 (“A doorknob is a doorknob, regardless of whether it is made of wood or glass. Can we really say . . . that an antibody is an antibody, no matter how it works or what materials it is made out of? . . . [A]re we prepared to say that an antibody is an antibody at a time when our knowledge of why particular antibodies arise in the body and how they fit into the body’s overall organic processes is limited?”).



constitutes patentable subject matter.<sup>85</sup> The logic is that one cannot save an attempt to patent a law of nature by asking for the right to apply the law only in a particular field. For example, one could not claim the law of gravity by limiting it only to uses in the field of bridge building.

Resistance to field-of-use restrictions may be wrapped up in an improper line of logic that began to emerge during the early computer cases.<sup>86</sup> The logic is as follows: Computer programs are mathematical formulas; mathematical formulas are laws of nature; laws of nature are not patentable and cannot be rendered patentable by limiting their application to a particular field of use. Therefore, computer programs cannot be rendered patentable by limiting their application to a particular field of use.

There are significant flaws in this logical progression. For example, we are accustomed to seeing laws of nature expressed in mathematical language, such as  $E = mc^2$ . This does not mean, however, that everything expressed in mathematical language is a law of nature, or even a formula. In particular, the fact that computer programs are expressed in a formulaic language that looks somewhat like math to the layperson does not answer the question of whether the concepts underlying the computer program are analogous to laws of nature or even formulas. One must not confuse the content of something with the language in which that content is expressed, but must look at what the language represents. Comic books and the Constitution may both be expressed in English, but their content is quite different.

The type of restrictions I am suggesting should be understood as distinct from the field-of-use restrictions characterized by the bridge-building example. Proper claims limitations are an understandable extension of the notion that while inventors may make use of laws of nature and natural phenomena, they may only patent a particular application of that law or phenomenon. Claims drafted in the manner I suggest provide assurance that we are allowing patents on an application of a law of nature or a natural phenomenon. They should not be swept into the category of improper field-of-use restrictions.

Taking this approach also provides a bridge between product claims and process claims in inventions related to genetics. The reach of product claims, when limited as I have suggested, would harmonize with the reach of process claims I suggested earlier in this Article.<sup>87</sup>

One could argue that the reach of all product and process claims should be harmonized as a general matter. It is particularly appropriate to do so with gene claims, in light of their nature as a product that has echoes of process. In short,

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85. See *Bilski v. Kappos*, 130 S. Ct. 3218, 3231 (2010).

86. This logic is described in detail in FELDMAN, *supra* note 45 (manuscript at ch. 4).

87. See *supra* text accompanying notes 51-54; see also FELDMAN, *supra* note 45 (manuscript at ch. 4) (providing a detailed explanation of the proper delineation of process claims in personalized medicine inventions in light of concerns regarding patentable subject matter).

with properly limited claims, genes as the subject matter of patents would be unproblematic, given their limitation to the state of the art and the state of disclosure by the inventor.

If genetic patents are limited in the manner outlined above, how would the individual from whom the cells originated stand to benefit? Even if court rulings had the effect of allowing an individual to isolate a particular gene from his or her own cells and compare that gene to known mutations without fear of infringing a patent, few individuals could do it themselves.

The benefit to individuals would be indirect. Limiting genetic patents as described above would maintain incentives for genetic research, while preventing individual patent holders from preempting natural phenomena. Such limitations leave more territory open for researchers who want to study genes and for those who want to develop competing approaches and downstream products. Those effects would increase the avenues available to individual patients who wish to understand, respond to, and perhaps even change their genetic profile.

I do want to be clear that I am not suggesting here that individuals should be given rights related to the information in their individual cells, regardless of whether those cells are inside the body. That would truly require a paradigm shift, and although I have proposed such a shift in a different forum, this Article is intended to suggest a more modest and practical approach.<sup>88</sup> A careful curtailment of patent rights, however, should better reflect the interests of society as a whole in maintaining access for scientific research and innovation, interests that should redound to the benefit of the individual.

#### CONCLUSION

Scientific research related to the components of human life continues to produce astounding insights and therapeutic treatments. Our understandable enthusiasm for these advances, as well as our piecemeal approach, has yielded a strange patchwork of doctrinal rules. It is worth considering how the pieces fit together as a whole and whether the resulting picture properly emphasizes the interests of society and of the individual. A careful and more considered application of both property and intellectual property doctrines should provide more appropriate respect for the disparate interests in a way that is consistent with the doctrinal and theoretical roots in both areas. Perhaps in the end, it is our body, anyway.

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88. For an approach that would involve a more paradigmatic shift, see Feldman, *supra* note 9.