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## Harnessing Human Potential: Induced Pluripotent Stem Cell Patentability Under the Lens of Myriad

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HARNESSING HUMAN POTENTIAL:  
INDUCED PLURIPOTENT STEM CELL  
PATENTABILITY UNDER THE  
LENS OF *MYRIAD*

DEREK VAN DEN ABEELLEN\*

ABSTRACT

*After the Supreme Court's decision in Ass'n for Molecular Pathology v. Myriad Genetics, previously patentable materials may now be rejected as unpatentable subject matter, specifically because they cover natural products. This presents a problem for businesses performing adult stem cell research and development, because stem cells exist in nature but pluripotency in adult stem cells does not. The United States Patent and Trademark Office (USPTO) and federal courts must recognize that these stem cells are still patentable because there is human intervention that creates a product that could not exist in nature on its own. Neither the USPTO nor any federal courts have yet reached the substantive issue of whether stem cells are patentable post-Myriad.*

*By recognizing the patentability of adult stem cells, the USPTO and federal courts would allow research institutions to recoup their substantial investment into the critical adult stem cell field, while still respecting the standard of patentable subject matter dictated in Myriad. This Note argues for retaining patentability of adult stem cells in the face of certain future challenges to patentable subject matter, at both the examination and appeals stages.*

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## INTRODUCTION

There is a heated debate about whether the medical use of human embryonic stem cells is ethical. Many organizations view such use as a destruction of human life, while other organizations see it simply as an advancement of essential human therapies. Embryonic stem cells are cells taken from early-stage human embryos, usually within four to five days after fertilization.<sup>1</sup> These cells have the ability to differentiate into any type of cell from the three germ layers—an ability called pluripotency.<sup>2</sup> This pluripotency is incredibly important in researching new types of therapeutic technology.<sup>3</sup>

This debate could easily be quelled if advances were made in the development of adult stem cell research. There have been some advances in this field, but each scientific success is met with potential legal roadblocks. Companies looking to develop this technology may find that they have researched unpatentable material, causing them to have invested time and money into a product that is itself now unpatentable, and thus unprotected from competitors. After the Supreme Court's decision in *Ass'n for Molecular Pathology v. Myriad Genetics (Myriad)*, it is clear that natural products are no longer patentable.

In accordance with this ruling, the United States Patent and Trademark Office (USPTO) updated the Manual of Patent Examining Procedure ("MPEP") to exclude naturally occurring substances from being patentable.<sup>4</sup> While pluripotent embryonic stem cells may not be patentable because they are naturally occurring, *induced* pluripotent stem cells are *not* naturally occurring, and

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<sup>1</sup> NAT'L INSTS. OF HEALTH, STEM CELL BASICS: I. INTRODUCTION: WHAT ARE STEM CELLS, AND WHY ARE THEY IMPORTANT?, <http://stemcells.nih.gov/info/basics/pages/basics1.aspx> [<https://perma.cc/JD4S-FVVL>] [hereinafter STEM CELL BASICS I].

<sup>2</sup> *Id.*

<sup>3</sup> *Id.*

<sup>4</sup> See U.S. Patent and Trademark Office, Memorandum on 2014 Procedure For Subject Matter Eligibility Analysis of Claims Reciting or Involving Laws of Nature/Natural Principles, Natural Phenomena, And/Or Natural Products to Patent Examining Corps (Mar. 4, 2014) [hereinafter USPTO Guidance] (naturally occurring substances are ones not markedly different from that found in nature).

are forced to transform into pluripotency through a complex chemical process.<sup>5</sup> Because this process is a step beyond a natural process or product, creating pluripotent adult stem cells should be patentable.

Part I of this Note will provide an overview of the science behind stem cells, and will highlight the differences between embryonic stem cells and adult stem cells. It will lay the groundwork of what stem cells are, and how adult stem cells achieve pluripotency.

Part II will provide the statutory and common law basis for how the USPTO and courts will interpret the law if an invention is considered a natural product. It will identify the current stem cell patent landscape, which developed before *Myriad* was decided. It will also review and analyze the Supreme Court cases that speak to the patentability of natural products. It will look both at how the Supreme Court approached natural products pre-*Myriad*, as well as how this precedent applied to the facts in *Myriad*.

Part III will consider what approaches the USPTO and the courts have taken post-*Myriad* when confronted with questions of subject matter eligibility, specifically when a patent potentially claims a natural product.

## I. INTRODUCTION TO THE SCIENCE OF EMBRYONIC STEM CELLS AND ADULT STEM CELLS AND THEIR DIFFERENCES

To understand the patentability of stem cells, it is necessary to build a foundational understanding of what stem cells are, and to dissect the difference between embryonic stem cells and adult stem cells.

Stem cells are building block cells that have the ability to develop into many different cells and organs throughout the life of a human.<sup>6</sup> Stem cells' importance to research derives from the fact that they "are capable of dividing and renewing themselves for long periods."<sup>7</sup> This differs greatly from other cells found in the body, such as mature muscle cells or blood cells, which do

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<sup>5</sup> NAT'L INSTS. OF HEALTH, STEM CELL BASICS: VI. WHAT ARE INDUCED PLURIPOTENT STEM CELLS?, <http://stemcells.nih.gov/info/basics/pages/basics10.aspx> [<https://perma.cc/DL3U-CD73>] [hereinafter STEM CELL BASICS VI].

<sup>6</sup> STEM CELL BASICS I, *supra* note 1.

<sup>7</sup> NAT'L INSTS. OF HEALTH, STEM CELL BASICS: II. WHAT ARE THE UNIQUE PROPERTIES OF ALL STEM CELLS?, <http://stemcells.nih.gov/info/basics/pages/basics2.aspx> [<https://perma.cc/J444-MEMP>] [hereinafter STEM CELL BASICS II].

not normally self-replicate within the human body.<sup>8</sup> Secondly, stem cells retain the unique ability to become specialized cells with specific functions, such as a brain cell or skin cell.<sup>9</sup>

Embryonic stem cells are stem cells derived from an egg that is fertilized *in vitro*, meaning the egg is fertilized in a laboratory environment or in a fertilization clinic.<sup>10</sup> Despite the fact that women donate these eggs and consent to their use in research,<sup>11</sup> there are still many ethical concerns raised by numerous groups regarding the use of fertilized embryos for research.<sup>12</sup> Such ethical concerns, in turn, could result in hindering important research, such as reduction in government funding towards embryonic stem cell research.<sup>13</sup>

Adult stem cells, on the other hand, are not derived from embryos.<sup>14</sup> Instead, adult stem cells originate within mature tissues and organs.<sup>15</sup> These cells are still undifferentiated, like embryonic stem cells, and can both regenerate themselves and become specialized cells.<sup>16</sup> One of the most common uses of adult stem cell therapy, bone marrow transplants, are not done within a

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<sup>8</sup> *Id.*; see also BRUCE ALBERTS ET AL., *MOLECULAR BIOLOGY OF THE CELL* (4th ed. 2002), available at <http://www.ncbi.nlm.nih.gov/books/NBK26853/> (For myoblasts—the building block cell of skeletal muscle fiber cells—“[o]nce differentiation has occurred, the cells do not divide and the nuclei never again replicate their DNA.”).

<sup>9</sup> STEM CELL BASICS I, *supra* note 1.

<sup>10</sup> NAT'L INSTS. OF HEALTH, STEM CELL BASICS: III. WHAT ARE EMBRYONIC STEM CELLS?, <http://stemcells.nih.gov/info/basics/pages/basics3.aspx> [<https://perma.cc/3HVD-H8K8>] [hereinafter STEM CELL BASICS III].

<sup>11</sup> *Id.*

<sup>12</sup> CTR. FOR BIOETHICS & HUMAN DIGNITY, AN OVERVIEW OF STEM CELL RESEARCH (Aug. 2008), <https://cbhd.org/stem-cell-research/overview> [<https://perma.cc/HRN6-FDPD>] (stating that human embryos are human life, pointing to verses in the Bible that require protecting unborn life).

<sup>13</sup> See Kathleen Gilbert, *Destroying Human Embryos Not Only Unethical, but Unnecessary: Congressmen*, LIFESITENEWS (Mar. 6, 2009), <https://www.lifesitenews.com/news/destroying-human-embryos-not-only-unethical-but-unnecessary-congressmen> [<https://perma.cc/AQ3W-A4EB>] (Pro-life congressional members urged for the defunding of embryonic stem cell research, stating that destruction of embryos is the destruction of human life.).

<sup>14</sup> NAT'L INSTS. OF HEALTH, STEM CELL BASICS: IV. WHAT ARE ADULT STEM CELLS?, <http://stemcells.nih.gov/info/basics/pages/basics4.aspx> [<https://perma.cc/44DV-K9RE>] [hereinafter STEM CELL BASICS IV].

<sup>15</sup> *Id.*

<sup>16</sup> *Id.*

lab.<sup>17</sup> Unlike embryonic stem cells, however, adult stem cells are limited in their ability to differentiate into different types of cells.<sup>18</sup> For example, neural stem cells are only able to differentiate into neural cells (also known as neurons), and astrocytes and oligodendrocytes (two types of cells essential to the central nervous system).<sup>19</sup>

Companies and research laboratories look to harness the possibilities of what stem cells can offer in numerous ways,<sup>20</sup> but one of the hurdles to the cells' effectiveness is a laboratory's ability to differentiate the cells into the desired cells.<sup>21</sup> For example, scientists are still determining the signaling pathways that cause stem cells to differentiate, which are necessary to create the type of matured cells desired.<sup>22</sup>

One of the largest hurdles, specifically for adult stem cells, is the fact that these cells need to first be "genetically reprogrammed to an embryonic stem cell-like state" through complex gene expression and other factors important to maintain a pluripotent stem cell—steps that require human intervention.<sup>23</sup> Researchers are

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<sup>17</sup> *Id.*

<sup>18</sup> *Id.*

<sup>19</sup> *Id.*; see also *Astrocytes*, NETWORK GLIA, <http://www.networkglia.eu/en/astrocytes> [<https://perma.cc/N8KW-Y8CJ>] (stating that astrocytes "are the most numerous and diverse neuroglial cells in the [central nervous system]"); *Oligodendrocytes*, NETWORK GLIA, <http://www.networkglia.eu/en/oligodendrocytes> [<https://perma.cc/6QR4-NMRD>] (remarking that "oligodendrocytes are very well known as the myelin forming cells of the central nervous system").

<sup>20</sup> NAT'L INSTS. OF HEALTH, STEM CELL BASICS: VII. WHAT ARE THE POTENTIAL USES OF HUMAN STEM CELLS AND THE OBSTACLES THAT MUST BE OVERCOME BEFORE THESE POTENTIAL USES WILL BE REALIZED?, <http://stemcells.nih.gov/info/basics/pages/basics6.aspx> [<https://perma.cc/HC32-3C9K>] [hereinafter STEM CELL BASICS VII] (mentioning different uses of stem cells within laboratory research, such as testing safety of new drugs, screening effectiveness of cancer drugs, and replacing destroyed tissues from diseases like macular degeneration and diabetes); see also Catharine Paddock, *Ability to repair cartilage with stem cells steps closer*, MED. NEWS TODAY (Mar. 4, 2015, 3:00 AM), <http://www.medicalnewstoday.com/articles/290298.php> [<https://perma.cc/4KX6-RDSC>].

<sup>21</sup> STEM CELL BASICS VII, *supra* note 20.

<sup>22</sup> *Id.*

<sup>23</sup> STEM CELL BASICS VI, *supra* note 5; see also UCLA ELI & EDYTHE BROAD CTR. OF REGENERATIVE MED. & STEM CELL RESEARCH, INDUCED PLURIPOTENT STEM CELLS (iPS), <https://www.stemcell.ucla.edu/induced-pluripotent-stem-cells> [<https://perma.cc/ZJ2S-WDXT>].

still discerning if there are any major clinical differences between embryonic stem cells and these induced pluripotent stem cells (“iPSCs”).<sup>24</sup> The existence of these challenges shows the major need for further research and development in the stem cell therapy field. Institutions and companies thus need an incentive to invest time and money into such research, which can be provided through patent protection and licensing.<sup>25</sup>

It is clear that these stem cells, both embryonic and adult, exist naturally in the human body.<sup>26</sup> However, in order to induce these cells to proliferate or differentiate, humans must use non-natural processes and introduce non-natural products into the cells.<sup>27</sup> Embryonic stem cells already exist, under correct laboratory conditions, with the ability to proliferate and differentiate into many different types of cells. Adult stem cells, however, require an extra step to become iPSCs, and then can both proliferate and differentiate.<sup>28</sup>

## II. STATUTORY AND SUPREME COURT RESTRICTIONS HAVE BARRED PATENTABILITY FOR NATURAL PRODUCTS

### A. *Statutory Requirements for Patentability*

The United States Constitution explicitly gives Congress the power to grant patent protection to inventors.<sup>29</sup> Under 35 U.S.C. § 101, an inventor may receive a patent for “any new and useful process, machine, manufacture, or composition of matter.”<sup>30</sup> This section is what courts have looked to when interpreting whether an invention is patentable subject matter.<sup>31</sup> Section 112 sets the requirements for specifications for patent applications:

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<sup>24</sup> STEM CELL BASICS VI, *supra* note 5.

<sup>25</sup> See Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1024–26 (1989); see generally Katherine E. White, *Preserving the Patent Process to Incentivize Innovation in Global Economy*, 13 SYRACUSE SCI. & TECH. L. REP. 27 (2006).

<sup>26</sup> See STEM CELL BASICS I, *supra* note 1.

<sup>27</sup> See STEM CELL BASICS VI, *supra* note 5.

<sup>28</sup> See *id.*

<sup>29</sup> U.S. CONST. art. I, § 8, cl. 8 (Congress has the power to “promote the Progress of Science and useful Arts.”).

<sup>30</sup> 35 U.S.C. § 101 (2014).

<sup>31</sup> See *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980).

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.<sup>32</sup>

Therefore, a person applying for a patent must sufficiently describe the product or process. After reviewing the patent application, the USPTO can choose to grant a patent if the application fully describes a patent that is novel, useful, and non-obvious.<sup>33</sup>

In 2011, Congress passed the Leahy-Smith America Invents Act (AIA), which created new changes and additions to the patent system.<sup>34</sup> Though some changes were procedural, such as changing the system from a first-to-invent system to a first-to-file system,<sup>35</sup> the AIA also added a section stating that “[n]otwithstanding any other provision of law, no patent may issue on a claim directed to or encompassing a human organism.”<sup>36</sup> Though they did not specifically identify natural products of humans, Congress did indicate here that human organisms themselves should not be claimed as patentable. However, the issue is determining to what extent an invention is considered a human organism. More specifically, the question is whether an invention that encompasses a small component of a human organism—hair, organs, or, as is relevant to this Note, stem cells—is still considered a human organism.

Prior to *Myriad*, there had been no designations in the MPEP stating whether natural products could or could not be patented,

<sup>32</sup> 35 U.S.C. § 112(a) (2014).

<sup>33</sup> *Id.* § 101 (stating that a patent may be obtained for “any new and useful process, machine, manufacture, or composition of matter”); *see also id.* § 102(a) (2014) (reciting the novelty requirement); *id.* § 103 (2014) (“A patent for a claimed invention may not be obtained ... if the ... claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains.”).

<sup>34</sup> Nathan Hurst, *How the America Invents Act Will Change Patenting Forever*, WIRED (Mar. 15, 2013, 6:30 AM), <http://www.wired.com/2013/03/america-invents-act/> [<https://perma.cc/QNY6-FAQ6>].

<sup>35</sup> *Id.*

<sup>36</sup> Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 33(a), 125 Stat. 284, 340 (2011). Section 33(a) was later listed under the notes section, specifically for limiting the issuance of patents, under 35 U.S.C. § 101.

which may be because no statutory requirement for excluding natural products exists. It took a number of Supreme Court cases to shape patentability standards.

*B. The Common Law History Before Myriad*

Over the years, the Supreme Court has heard cases that deal with the subject matter of patents. The Court first clarified that even if certain materials such as naturally occurring gases or chemicals are natural products, they can create subject matter that falls within the scope of patentability when the products are combined.<sup>37</sup> The Court believed that Congress envisioned a broad scope when writing patent laws.<sup>38</sup> The Court, however, did specify that certain types of subject matter could not be patented, mainly because they were not considered new and useful.<sup>39</sup> These exceptions to patentable subject matter were “laws of nature, physical phenomena, and abstract ideas.”<sup>40</sup> Reasons for not allowing people to patent such subject matter mainly point to the idea that “the grant of a patent might tend to impede innovation more than it would tend to promote it.”<sup>41</sup> The Court, however, did recognize that an overly broad interpretation of the exceptions would hinder the ability of people to create new, useful, and non-obvious subject matter.<sup>42</sup>

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<sup>37</sup> *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980) (“[C]omposition of matter’ has been construed consistent with its common usage to include ‘all compositions of two or more substances and ... all composite articles, whether they be the results of chemical union, or of mechanical mixture, or whether they be gases, fluids, powders or solids.’” (citation omitted)).

<sup>38</sup> *Id.*

<sup>39</sup> *Bilski v. Kappos*, 561 U.S. 593, 594 (2010) (“While not required by the statutory text, these exceptions are consistent with the notion that a patentable process must be ‘new and useful.’”).

<sup>40</sup> *Id.* (citing *Chakrabarty*, 447 U.S. at 309); see also *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972) (“Phenomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work.”).

<sup>41</sup> *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1293 (2012).

<sup>42</sup> *Id.* (recognizing that “too broad an interpretation of this exclusionary principle could eviscerate patent law. For all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas.”).

An early Supreme Court case concerning laws of nature was *Funk Bros. Seed Co. v. Kalo Inoculant Co.*<sup>43</sup> Here, the Court reviewed the patentability of two naturally occurring types of bacteria mixed together into one supposedly patentable culture.<sup>44</sup> The claims did not cover a selection or testing process of the strains, but simply the culture itself.<sup>45</sup> The Court found that the culture's benefit—the mixture of bacteria could be broadly used in legume farming without harming the other species of bacteria in the mixture—was something that could not be considered patentable because this characteristic already existed in nature, and there was no inventive step involved.<sup>46</sup>

*Diamond v. Chakrabarty* clarified the scope of *Funk Bros. Seed Co.*, and is one of the most relevant cases to stem cells before *Myriad*.<sup>47</sup> In this case, the Court considered whether a genetically engineered bacterium capable of breaking down crude oil could be considered patentable.<sup>48</sup> No naturally occurring bacteria had this ability, but the patent examiner rejected the inventor's claim because the claims were based on a living thing, which was considered unpatentable under 35 U.S.C. § 101.<sup>49</sup> The Court found that the examiner's conclusion was erroneous, and instead determined that this organism fell into the scope of a "manufacture" or "composition of matter," which § 101 provides is patentable.<sup>50</sup> The Court cited Congress's intention to allow an inventor to obtain a patent for a product that was based on a natural product or process.<sup>51</sup> This bacterium exhibited "markedly different characteristics from any found in nature and one having the potential for significant utility."<sup>52</sup>

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<sup>43</sup> 333 U.S. 127 (1948).

<sup>44</sup> *Id.* at 130.

<sup>45</sup> *Id.*

<sup>46</sup> *Id.* at 131–32 (“[A] product must be more than new and useful to be patented; it must also satisfy the requirements of invention or discovery.”).

<sup>47</sup> 447 U.S. 303 (1980).

<sup>48</sup> *Id.* at 305–06.

<sup>49</sup> *Id.*

<sup>50</sup> *Id.* at 310.

<sup>51</sup> *Id.* at 312 (citing S. Rep. No. 71-315, at 6–8 (1930); H.R. Rep. No. 71-1129, at 7–9 (1930)) (“[Congress] explained at length its belief that the work of the plant breeder ‘in aid of nature’ was patentable invention.”).

<sup>52</sup> *Id.* at 310.

This case is highly relevant to the fact that genetic engineering of a cellular organism is considered to be patentable. iPSCs are similar to the genetically engineered bacterium in *Chakrabarty* because each cell does not necessarily naturally exist in the world.<sup>53</sup> The bacterium in *Chakrabarty* contained a plasmid, creating an organism that had never been seen in nature.<sup>54</sup> Likewise, an adult stem cell—a natural product—that is induced into pluripotency is not natural.<sup>55</sup> Though the cell itself may grow into a tissue that is truly natural, such as a patch of skin or section of liver, that cell would not have come into existence without a human being's inventive step.<sup>56</sup>

As of the writing of this Note, there has been no significant litigation regarding the validity of patents for stem cells. Of the recent litigation that has occurred, these cases involved the issue of whether a researcher used the correct term of “induced pluripotent stem cells” in his patent application<sup>57</sup> or whether the Patent Trials and Patent Appeals Board was correct in affirming the patentability of claims regarding stem cells.<sup>58</sup> However, these cases were simply struck down due to lack of standing.<sup>59</sup>

### *C. Patents on Stem Cells Issued Before Myriad*

There are a number of stem cell patents that the USPTO granted that are still valid. One of the most prominent—and

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<sup>53</sup> STEM CELL BASICS VI, *supra* note 5.

<sup>54</sup> *Chakrabarty*, 447 U.S. at 305.

<sup>55</sup> See *supra* note 23 and accompanying text.

<sup>56</sup> *Id.*

<sup>57</sup> See, e.g., *Xu v. Yamanaka*, No. 13-CV-3240, 2014 U.S. Dist. LEXIS 11772, at \*2 (N.D. Cal. Jan. 30, 2014) (focusing more on state law claims made by the plaintiff rather than federal claims relating to patentability).

<sup>58</sup> *Consumer Watchdog v. Wis. Alumni Research Found.*, 753 F.3d 1258 (Fed. Cir. 2014).

<sup>59</sup> *Xu*, 2014 U.S. Dist. LEXIS 11772, at \*13–14 (finding that the plaintiff had not suffered an injury in fact); see also *Consumer Watchdog*, 753 F.3d at 1262–63. *Consumer Watchdog* attacked WARF's patents as invalid, but the court ruled that *Consumer Watchdog* had not shown it had sustained a “particularized, concrete interest in the patentability of the [WARF] patent, or any injury in fact.” *Id.* at 1263. Unfortunately, the court did not rule on whether the patent was valid, but concerned itself more with the issue of standing. *Id.* The Supreme Court recently denied the writ of certiorari regarding this case, and thus *Consumer Watchdog* will have to find another party that actually has standing to pursue a patent invalidity action. *Id.*, *cert. denied*, 135 S. Ct. 1401 (2015).

controversial—stem cell patent portfolios is that of the Wisconsin Alumni Research Foundation (WARF).<sup>60</sup> WARF is the patent and licensing arm of the University of Wisconsin-Madison, and engages in a broad range of research.<sup>61</sup> Most of the patents in the WARF portfolio cover embryonic stem cells, though a large number apply to stem cells in general.<sup>62</sup> The WARF portfolio was involved in one of the recent cases that was struck down for standing reasons, so there is little risk of challenge to this portfolio.<sup>63</sup>

Researcher, professor, and Nobel Prize winner Shinya Yamanaka also has numerous patents on stem cells, some of which are highly relevant to adult stem cells.<sup>64</sup> Yamanaka's research mainly focuses on the process to produce iPSCs.<sup>65</sup> From this research, he, along with other scientists and research organizations, has obtained a number of U.S. patents that focus on that of iPSCs, as well as a few that cover embryonic stem cells.<sup>66</sup> In particular,

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<sup>60</sup> Brandon Smith, *The Patentability of Human Embryonic Stem Cells in Light of Myriad*, 96 J. PAT. & TRADEMARK OFF. SOC'Y 112, 116 (2014).

<sup>61</sup> *About Us*, WIS. ALUMNI RESEARCH FOUND., <http://www.warf.org/about-us/about-us.cmsx> [<https://perma.cc/LK5H-ED3X>].

<sup>62</sup> *See Pluripotent Cells: Culture*, WIS. ALUMNI RESEARCH FOUND., <http://www.warf.org/technologies/pluripotent-cells/culture.cmsx> [<https://perma.cc/9GZJ-KC3X>]; *Pluripotent Cells: Differentiation*, WIS. ALUMNI RESEARCH FOUND., <http://www.warf.org/technologies/pluripotent-cells/differentiation.cmsx> [<https://perma.cc/GY9B-GPBS>]; *Pluripotent Cells: Related technologies*, WIS. ALUMNI RESEARCH FOUND., <http://www.warf.org/technologies/pluripotent-cells/related-technologies.cmsx> [<https://perma.cc/7KQ7-PVF5>]; *Pluripotent Cells: Tools*, WIS. ALUMNI RESEARCH FOUND., <http://www.warf.org/technologies/pluripotent-cells/tools.cmsx> [<https://perma.cc/PPG4-VP6B>].

<sup>63</sup> *See Consumer Watchdog*, 753 F.3d at 1260 (finding that there was no injury in fact toward the plaintiff to justify standing).

<sup>64</sup> *See* U.S. Patent No. 8,058,065 (filed June 9, 2009); U.S. Patent No. 8,129,187 (filed Feb. 18, 2010); U.S. Patent No. 8,278,104 (filed June 13, 2008). Yamanaka has patents that relate to embryonic stem cells as well. *See* U.S. Patent No. 7,250,255 (filed May 31, 2002); U.S. Patent No. 8,158,766 (filed July 10, 2006); U.S. Patent No. 8,597,895 (filed Mar. 19, 2012). Yamanaka's research also extends to uses of stem cells after their creation. *See* U.S. Patent No. 8,546,141 (filed Apr. 1, 2009) (describing method for preparing blood cells from isolated adult stem cells).

<sup>65</sup> *See, e.g.,* Kazutoshi Takahashi & Shinya Yamanaka, *Induction of Pluripotent Stem Cells from Mouse Embryonic and Adult Fibroblast Cultures by Defined Factors*, CELL (Aug. 25, 2006), [http://www.cell.com/cell/abstract/S0092-8674\(06\)00976-7](http://www.cell.com/cell/abstract/S0092-8674(06)00976-7) [<https://perma.cc/VWL5-YMRZ>].

<sup>66</sup> *See* Smith, *supra* note 60, at 116.

U.S. Patent 8,058,065 covers a method to create iPSCs through reprogramming of the cell's nucleus by the induction of certain genes into the cell's chromosome, and by culturing the cell in certain conditions in order to obtain pluripotency.<sup>67</sup>

All of the patents described herein involved applications that were filed before the Supreme Court handed down the *Myriad* decision. All but one of the patents were granted after the decision, and that patent was a method patent describing how to make particularized blood cells from adult stem cells.<sup>68</sup> However, these patents may now be in question after the *Myriad* decision.

#### *D. The Supreme Court's Decision in Myriad and Its Restriction on Patents*

The Supreme Court directly tackled whether natural products could be patented in the landmark case, *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*<sup>69</sup> In this case, Myriad Genetics, Inc. ("Myriad") had created a process for identifying the breast cancer gene, and had obtained a patent on a complementary DNA ("cDNA") segment.<sup>70</sup>

The Court first stepped through a scientific breakdown of how DNA works. Each "human genome consists of approximately 22,000 genes packed into 23 pairs of chromosomes[.]" which are encoded into a double-helical structure of DNA.<sup>71</sup> DNA is broken up into segments, called nucleotides, which correspond and bond with another nucleotide on the opposing strand of DNA.<sup>72</sup> Together in sequence, these nucleotides code for certain types of amino acids, which the cell uses to create proteins.<sup>73</sup> Importantly, the nucleotide sequences that actually code for amino acids are called exons, while sequences of DNA that do not code for amino acids are called introns.<sup>74</sup> Through a complex process of separating

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<sup>67</sup> U.S. Patent No. 8,058,065 (filed June 13, 2008).

<sup>68</sup> U.S. Patent No. 8,546,141 (filed Apr. 1, 2009). *Myriad* was decided in June 2013, and the patent was issued in October 2013.

<sup>69</sup> 133 S. Ct. 2107 (2013).

<sup>70</sup> *Id.* at 2107.

<sup>71</sup> *Id.* at 2111.

<sup>72</sup> *Id.*

<sup>73</sup> *Id.*

<sup>74</sup> *Id.*

the strands of DNA, transcribing these complementary strands into complementary RNA, removing introns from the RNA strand, leaving only exons, and running the RNA through a structure called a ribosome, amino acids are created, which can form into proteins essential to cellular function.<sup>75</sup>

Scientists are able to isolate and extract DNA from cells, and can also create synthetic DNA that is complementary to the RNA.<sup>76</sup> This new DNA is called cDNA.<sup>77</sup> Changes in the sequence of DNA are called mutations, and are heavily studied by scientists.<sup>78</sup> This type of research is highly impactful because of the harmful effects mutations can have on an organism's functionality.<sup>79</sup>

Myriad discovered the location and DNA sequence of the BRCA1 and BRCA2 genes, mutations of which can increase the risk of certain types of cancer.<sup>80</sup> This discovery was especially important because "[t]he average American woman has a 12 to 13 percent risk of developing breast cancer, but for women with certain genetic mutations, the risk can range between 50 and 80 percent for breast cancer."<sup>81</sup>

In order to protect its discovery, Myriad applied for and received patents, three of which were challenged in this case: U.S. patents 5,747,282, 5,837,492, and 5,693,473 (the '282 patent, '492 patent, and '473 patent, respectively).<sup>82</sup> From these patents, nine claims were presented to the Court.<sup>83</sup> Claim 1 from the '282 patent focused on isolated DNA from the BRCA1 gene that coded for certain amino acids.<sup>84</sup> Claim 2 from the '282 patent was similar

<sup>75</sup> *Id.*

<sup>76</sup> *Id.* at 2112.

<sup>77</sup> *Id.*

<sup>78</sup> *Id.*

<sup>79</sup> *Id.* ("Some mutations are harmless, but others can cause disease or increase the risk of disease. As a result, the study of genetics can lead to valuable medical breakthroughs.").

<sup>80</sup> *Id.*

<sup>81</sup> *Id.*

<sup>82</sup> *Id.* at 2113; see *Ass'n for Molecular Pathology v. United States Patent & Trademark Office*, 702 F. Supp. 2d 181, 211 (S.D.N.Y. 2010).

<sup>83</sup> *Myriad*, 133 S. Ct. at 2113 (claims 1, 2, 5, 6, and 7 of the '282 patent, claim 1 of the '473 patent, and claims 1, 6, and 7 of the '492 patent).

<sup>84</sup> *Id.* ("The first claim asserts a patent on '[a]n isolated DNA coding for a BRCA1 polypeptide,' which has 'the amino acid sequence set forth in SEQ ID NO:2.' SEQ ID NO:2 sets forth a list of 1,863 amino acids that the typical BRCA1 gene encodes." (citations omitted)).

to claim 1, except the sequence was that of the cDNA that Myriad had developed, and only contained exons, and no introns.<sup>85</sup> Claim 5 of the '282 patent covered "isolated DNA having at least 15 nucleotides of the DNA of claim 1" that would identify the BRCA1 gene if searching for specific 15 nucleotide sequences.<sup>86</sup> Claim 6 of the '282 patent was similar to claim 5, in that it focused on a 15 nucleotide sequence of the cDNA referenced in claim 2.<sup>87</sup> The rest of the claims were similar to the previously mentioned claims, and included references to both the BRCA1 and BRCA2 sequences, as well as common mutations found in the sequences.<sup>88</sup>

Overall, Myriad's patents would have given the company an "exclusive right to isolate an individual's BRCA1 and BRCA2 genes (or any strand of 15 or more nucleotides within the genes)" as well as "the exclusive right to synthetically create BRCA cDNA."<sup>89</sup>

In the course of Myriad's litigation, the issue that the lower courts had struggled with was whether the act of isolating DNA was actually inventive or simply a product of nature.<sup>90</sup> DNA is held together by chemical bonds, and these bonds must be broken in order to identify and isolate DNA segments, such as those that were described in Myriad's patents.<sup>91</sup>

In its analysis, the Court established that it is a long held belief that the laws of nature are unpatentable.<sup>92</sup> The Court explained that a strong public policy interest requires such a restriction, as without it, future innovation would be prohibited—a result that conflicts with the very purpose of patents, which is to promote the creation of new inventions.<sup>93</sup> However, the Court recognized that, at a minimal level, all inventions utilize some laws of nature or natural phenomena, so if this exclusion to patentability

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<sup>85</sup> *Id.*

<sup>86</sup> *Id.*

<sup>87</sup> *Id.*

<sup>88</sup> *Id.*

<sup>89</sup> *Id.*

<sup>90</sup> *Id.* at 2114.

<sup>91</sup> *Id.*

<sup>92</sup> *Id.* at 2116 ("We have 'long held that [the 35 U.S.C. § 101] provision contains an important implicit exception[:] Laws of nature, natural phenomena, and abstract ideas are not patentable.") (citation omitted)).

<sup>93</sup> *Id.*; see also *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) ("[M]anifestations of ... nature[] [are] free to all men and reserved exclusively to none.") (internal quotations omitted).

were broadly interpreted, patent law would destroy itself because too many patents would be struck down through this precedent.<sup>94</sup> What was important for the Court to consider, then, was whether there was “any ‘new and useful ... composition of matter,’ or instead a claim of naturally occurring phenomena.”<sup>95</sup>

Myriad did not make any changes to the genetic information that was encoded in the genes, nor did it create anything new, as the gene location and order were already in existence at the time of Myriad’s discovery.<sup>96</sup> The only potentially patentable subject matter was the method by which Myriad had discovered the location and sequence of the genes.<sup>97</sup>

According to the Court, more is needed than just making an unprecedented discovery.<sup>98</sup> In its patent application, Myriad highlighted that locating the gene was the product of extensive research, and that the company had sorted through millions of pieces of DNA to discover the genes it was targeting.<sup>99</sup> Though Myriad detailed how it searched for these genes, the Court rejected this investigative process as insufficient to make the DNA patentable.<sup>100</sup>

The Court also found that simply because Myriad severed the DNA bonds, it did not automatically create a patentable molecule.<sup>101</sup> If Myriad were trying to patent the naturally occurring genetic sequence, a would-be infringer would simply need to make a small change at the end of the sequence to avoid any patent infringement.<sup>102</sup>

<sup>94</sup> *Myriad*, 133 S. Ct. at 2116.

<sup>95</sup> *Id.* (citing 35 U.S.C. § 101 (2014)).

<sup>96</sup> *Id.*

<sup>97</sup> *Id.*

<sup>98</sup> *Id.* at 2117 (“Groundbreaking, innovative, or even brilliant discovery does not by itself satisfy the § 101 inquiry.”).

<sup>99</sup> *Id.* (“Myriad explains that the location of the gene was unknown until Myriad found it among the approximately eight million nucleotide pairs contained in a subpart of chromosome 17.”).

<sup>100</sup> *Id.* at 2118 (“[E]xtensive effort alone is insufficient to satisfy the demands of § 101.”).

<sup>101</sup> *Id.*

<sup>102</sup> *Id.* (“If the patents depended upon the creation of a unique molecule, then a would-be infringer could arguably avoid at least Myriad’s patent claims on entire genes ... by isolating a DNA sequence that included both the BRCA1 or BRCA2 gene and one additional nucleotide pair.”).

Myriad asserted that the USPTO had previously allowed for patents on genetic sequences, and thus their specific code should be deemed patentable.<sup>103</sup> However, the Court rejected this assertion, reasoning that the language of the federal statute does not mention genes or isolated DNA, and the fact that the USPTO had previously allowed for genes to be patented does not mean that all genes must be accepted as patentable.<sup>104</sup> Thus, the Court held that the original pieces of DNA that were claimed as patents were not patentable.<sup>105</sup>

However, the Court viewed cDNA differently. cDNA is not a naturally occurring segment, as the BRCA1 and BRCA2 genes are.<sup>106</sup> There are naturally occurring parts within the cDNA—namely the exons that are still left—but in nature, these sections are not readily found.<sup>107</sup> Due to its distinguishability from DNA, this type of cDNA can be patented.<sup>108</sup>

Interestingly, the Court struck down the notion that it was invalidating any ability for Myriad or similar companies to claim a patent over a method of accomplishing gene isolation.<sup>109</sup> Myriad had chosen not to pursue a method patent, however, because the process of isolating DNA was very commonplace in genetic research and a person skilled in the art would have already understood how to accomplish that goal, thus eliminating the requisite novelty.<sup>110</sup>

In the end, the Court chose to strike down patentability of regular gene sequences that are naturally found in human cells, even though they were isolated with human intervention.<sup>111</sup> The

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<sup>103</sup> *Id.*

<sup>104</sup> *Id.*

<sup>105</sup> *Id.*

<sup>106</sup> *Id.* at 2119 (“As already explained, creation of a cDNA sequence from mRNA results in an exons-only molecule that is not naturally occurring. Petitioners concede that cDNA differs from natural DNA in that ‘the non-coding regions have been removed.’” (citations omitted)).

<sup>107</sup> *Id.*

<sup>108</sup> *Id.* (“As a result, cDNA is not a ‘product of nature’ and is patent eligible under § 101, except insofar as very short series of DNA may have no intervening introns to remove when creating cDNA.”).

<sup>109</sup> *Id.* (“Had Myriad created an innovative method of manipulating genes while searching for the BRCA1 and BRCA2 genes, it could possibly have sought a method patent.”).

<sup>110</sup> *Id.* at 2119–20.

<sup>111</sup> *Id.* at 2120.

Court did allow for the patentability of cDNA, which is not something found in nature.<sup>112</sup>

### III. THE AFTERMATH OF *MYRIAD*, BOTH WITHIN THE USPTO AND THE COURTS

#### A. *The USPTO's Response to Myriad*

The day the Supreme Court handed down its ruling in *Myriad*, the USPTO issued a narrow guidance to its patent examiners, explaining that they “should now reject product claims drawn solely to naturally occurring nucleic acids or fragments thereof, whether isolated or not, as being ineligible subject matter under 35 U.S.C. § 101.”<sup>113</sup> The memorandum did not mention the broader holding excluding all natural products, and instead pointed examiners to MPEP 2106 to determine if the subject matter is patentable.<sup>114</sup>

In March of 2014, the USPTO put out its official guidance regarding new procedures for subject matter eligibility in light of *Myriad* and *Mayo* (the “Guidance”).<sup>115</sup> The Guidance expanded on the previous memorandum, and now stated that “all claims ... reciting or involving laws of nature/natural principles, natural phenomena, and/or natural products” require a “marked difference” from nature; otherwise, the application should be rejected.<sup>116</sup>

The Guidance first speaks to the overall process of subject matter eligibility under 35 U.S.C. § 101.<sup>117</sup> The USPTO breaks down the process into three main steps: (1) whether the claim is directed to one of the four statutory categories of process—machine, manufacture, or composition of matter; (2) whether the claim recites or involves potential judicial exceptions—abstract ideas, laws of nature, natural phenomena, or natural products;

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<sup>112</sup> *Id.* at 2119.

<sup>113</sup> U.S. Patent and Trademark Office, Memorandum on Supreme Court Decision in *Association for Molecular Pathology v. Myriad Genetics, Inc.* to Patent Examining Corps (June 12, 2013), [http://www.uspto.gov/sites/default/files/patents/law/exam/myriad\\_20130613.pdf](http://www.uspto.gov/sites/default/files/patents/law/exam/myriad_20130613.pdf).

<sup>114</sup> *Id.* (“Other claims, including method claims, that involve naturally occurring nucleic acids *may* give rise to eligibility issues.” (emphasis added)).

<sup>115</sup> USPTO Guidance, *supra* note 4.

<sup>116</sup> *Id.* at 1.

<sup>117</sup> *Id.* at 2.

and (3) whether the claim recites something significantly different than the exception.<sup>118</sup> This last requirement can be the most unclear, so the USPTO provides guidelines on how to interpret whether something is “significantly different.”<sup>119</sup> Specifically, the USPTO provides six factors for a claim to weigh toward eligibility:

- (a) Claim is a product claim reciting something that initially appears to be a natural product, but after analysis is determined to be non-naturally occurring and markedly different in structure from naturally occurring products.
- (b) Claim recites elements/steps in addition to the judicial exception(s) that impose meaningful limits on claim scope, i.e., the elements/steps narrow the scope of the claim so that others are not substantially foreclosed from using the judicial exception(s).
- (c) Claim recites elements/steps in addition to the judicial exception(s) that relate to the judicial exception in a significant way, i.e., the elements/steps are more than nominally, insignificantly, or tangentially related to the judicial exception(s).
- (d) Claim recites elements/steps in addition to the judicial exception(s) that do more than describe the judicial exception(s) with general instructions to apply or use the judicial exception(s).
- (e) Claim recites elements/steps in addition to the judicial exception(s) that include a particular machine or transformation of a particular article, where the particular machine/transformation implements one or more judicial exception(s) or integrates the judicial exception(s) into a particular practical application.
- (f) Claim recites one or more elements/steps in addition to the judicial exception(s) that add a feature that is more than well-understood, purely conventional or routine in the relevant field.<sup>120</sup>

In addition to these positive factors that weigh towards patentability, the Guidance recites inverse factors that weigh against patentability because the claim is not significantly different from nature.<sup>121</sup>

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<sup>118</sup> *Id.*

<sup>119</sup> *Id.* at 3–5.

<sup>120</sup> *Id.* at 4.

<sup>121</sup> *Id.* at 4–5. Items (g) through (l) weigh against patentability and are nearly the same as those listed in (a) through (f). However, the requirements are reversed to show the item is not significantly different. For example, factor (a) states that a product claim may initially look like a natural product, but after further analysis it is determined to be non-naturally occurring and markedly different from a natural product. Item (g) inversely provides that a product claim may look like a natural product, which is not markedly different from a naturally occurring product. *Id.*

Importantly, the USPTO provides that a material or process may still be patent-eligible, even if a natural process was affected by human intervention, as long as there is a marked difference between the resulting product and the product occurring in nature.<sup>122</sup> This statement is significant concerning the production of iPSCs: if human stem cells are considered to be a natural product or a material produced by a natural process, the human intervention that produces an unnatural pluripotency creates a presumption that the method and the iPSCs product must be considered patentable.<sup>123</sup>

The Guidance is helpful in providing examples of situations where a certain product or process may be considered patentable.<sup>124</sup> Though none of the examples speak to stem cells specifically, some do address the significant difference that an induced pluripotent adult stem cell would demonstrate.<sup>125</sup>

Though the USPTO's Guidance provided some instruction about how to approach the *Myriad* decision, courts have yet to apply the decision. The USPTO also has yet to issue its updated guidance on how patent examiners are to incorporate *Myriad* into their examinations. Most importantly, the USPTO provided no guidance on how examiners and the courts should view the patentability of stem cells.

### *B. Court Response After Myriad and the Updated USPTO Guidance*

At the time of the writing of this Note, there have been fewer than thirty recorded court decisions that have cited to *Myriad*

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<sup>122</sup> *Id.* (“The fact that a marked difference came about as a result of routine activity or via human manipulation of natural processes does not prevent the marked difference from weighing in favor of patent eligibility.”).

<sup>123</sup> *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2119 (2013) (stating that although the isolated DNA was not considered patentable subject matter, an innovative process to isolate the DNA could be a patentable method); *see also* *Diamond v. Chakrabarty*, 447 U.S. 303, 309–10 (1980) (extending patentability to “a nonnaturally occurring manufacture or composition of matter—a product of human ingenuity ‘having a distinctive name, character [and] use.’”) (quoting *Hartranft v. Wiegmann*, 121 U.S. 609, 615 (1887)).

<sup>124</sup> USPTO Guidance, *supra* note 4, at 5–18.

<sup>125</sup> *Id.* at 5. The USPTO finds that a simple plasmid is not significantly different from a naturally occurring substance, while the engineered bacterium containing the plasmid can be considered significantly different from what is found in nature. *Id.*

when considering patentability cases, and some of those cases have not been decided based on the analysis of the patentability of the claims at issue.<sup>126</sup>

Some cases, however, have directly concerned patentability of natural products. In the Federal Circuit's case *In re Roslin Institute (Edinburgh)*, patents involved in mammalian cloning were at issue.<sup>127</sup> The patent holders had obtained patents over the method to clone Dolly, the famous sheep,<sup>128</sup> and filed a patent application covering the clones resulting from that method.<sup>129</sup> The method patent was not at issue, but the patent application for the clones was.<sup>130</sup> The challengers to the patent application, with whom the Patent Trials and Appeals Board agreed, argued that the claimed subject matter was simply a natural phenomenon that did not possess any marked difference from that found in nature.<sup>131</sup> The court agreed, and rejected the patent applicant's assertion that the mammalian copies could not be found in nature and required human intervention to come into being, thus allowing the claims to fall under patentable subject matter.<sup>132</sup> Citing *Myriad*, the court found that the patent holder did not alter the genes found in the clones, but used exact copies; therefore, the clones were not patentable.<sup>133</sup>

Although the method patent was not at issue in that case, *In re Roslin Institute* has implications for how stem cell patents may be interpreted in the Federal Circuit, the main court that

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<sup>126</sup> See, e.g., *Consumer Watchdog v. Wis. Alumni Research Found.*, 753 F.3d 1258 (Fed. Cir. 2014) (dismissing Consumer Watchdog's claims due to lack of standing).

<sup>127</sup> 750 F.3d 1333 (Fed. Cir. 2014).

<sup>128</sup> John Whitfield, *Obituary: Dolly the Sheep*, NATURE (Feb. 18, 2003), <http://www.nature.com/news/1998/030217/full/news030217-6.html> [<https://perma.cc/8GLR-4P4Z>].

<sup>129</sup> *In re Roslin Inst.*, 750 F.3d 1333, 1334–35 (Fed. Cir. 2014).

<sup>130</sup> *Id.* at 1334.

<sup>131</sup> *Id.* at 1335.

<sup>132</sup> *Id.* at 1337.

<sup>133</sup> *Id.* (“Here, as in *Myriad*, Roslin ‘did not create or alter any of the genetic information’ of its claimed clones, ‘[n]or did [Roslin] create or alter the genetic structure of [the] DNA’ used to make its clones. Instead, Roslin’s chief innovation was the preservation of the donor DNA such that the clone is an exact copy of the mammal from which the somatic cell was taken. Such a copy is not eligible for patent protection.” (citing *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2111 (2013))).

hears patent appeals.<sup>134</sup> Stem cells may have the same genetic makeup as that of a predecessor, and are simply induced into differentiation or proliferation through external factors.<sup>135</sup> This would likely be covered in a method patent. *In re Roslin Institute* suggests that an exact copy is not likely to be patentable.<sup>136</sup> However, a resulting cell or organism that has the same genetic DNA as a naturally occurring predecessor does not necessarily disqualify the subject matter from being patentable.<sup>137</sup>

Furthermore, some adult stem cell patents require an insertion of specific genes in order to induce the stem cell to proliferate and develop pluripotency.<sup>138</sup> The insertion of new genes non-existent in the original cell would create an organism that is markedly different from the naturally occurring cell, and under *Myriad*, preceding cases like *Chakrabarty*, and the updated MPEP, this new subject matter would be considered patentable.<sup>139</sup> As the Supreme Court pointed out in *Myriad*, method patents are available for inventors who come up with novel ways to produce a material.<sup>140</sup> At the very minimum, inventors must be able to patent novel processes that create iPSCs, assuming that the processes are not natural processes as well. The other cases adjudicated by the Federal Circuit did not involve much analysis into how *Myriad* applies to the issues before them.<sup>141</sup>

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<sup>134</sup> U.S. COURT OF APPEALS FOR THE FED. CIRCUIT, COURT JURISDICTION, <http://www.ca9.uscourts.gov/the-court/court-jurisdiction> [<https://perma.cc/TS4G-H23U>]. The Federal Circuit was formed by the merging of the United States Court of Customs and Patent Appeals with the appellate division of the United States Court of Claims. The court also takes direct appeals from the Patent Trial and Appeal Board.

<sup>135</sup> *See supra* Part I.

<sup>136</sup> *In re Roslin Inst.*, 750 F.3d at 1339.

<sup>137</sup> *Id.* (“[H]aving the same nuclear DNA as the donor mammal may not necessarily result in patent ineligibility in every case.”); *see also* USPTO Guidance, *supra* note 4, at 4. Factor (a) in the Guidance allows patentability for subject matter that appears on its face to be naturally occurring, i.e., has the same genetic makeup as a predecessor and can still be shown to be markedly different in structure or function. *Id.*

<sup>138</sup> *See* U.S. Patent No. 8,058,065 (filed June 9, 2009) (patent claims cover the induction of retroviral vectors, which insert genes into the target cell DNA).

<sup>139</sup> *See* *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2109 (2013); *Diamond v. Chakrabarty*, 447 U.S. 303, 310 (1980).

<sup>140</sup> *Myriad*, 133 S. Ct. at 2119.

<sup>141</sup> *See* *Consumer Watchdog v. Wis. Alumni Research Found.*, 753 F.3d 1258 (Fed. Cir. 2014); *In re Bentwich*, 566 Fed. App’x. 941, 943 (Fed. Cir. 2014)

Other courts have taken different approaches to *Myriad*. In an interesting development, two separate district courts reviewing the same patent returned different verdicts after deeply analyzing the patent at issue.<sup>142</sup> The patent in contention was a method for amplifying DNA.<sup>143</sup> The plaintiff filed six suits in different district courts,<sup>144</sup> but its motion for centralization of the claims was denied,<sup>145</sup> even though the motion alleged that various companies had infringed on its patent.<sup>146</sup> The District Court of Delaware ruled that the method was so closely tied to natural laws that it could not be found to be patentable, and thus granted the defendant's motion to dismiss that claim.<sup>147</sup> Conversely, the Northern District of California found that the claim was valid because the defendant could not show with clear and convincing evidence that the patent claims were mere applications of natural laws.<sup>148</sup> Ironically, the Multidistrict Litigation Judicial Panel that had denied centralization of the claims expressly hoped that this type of result would not occur.<sup>149</sup>

#### CONCLUSION

When *Myriad* was defending its patents in front of the Supreme Court, the company faced opposition from many amicus

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(patent applicant already conceded that the claimed product at issue, a viral nucleic acid, was naturally occurring, and thus the court made no ruling on how *Myriad* applied to the claim).

<sup>142</sup> *Genetic Techs. Ltd. v. Agilent Techs., Inc.*, 24 F. Supp. 3d 922 (N.D. Cal. 2014); *see also* *Genetic Techs. Ltd. v. Bristol-Myers Squibb Co.*, 72 F. Supp. 3d 521 (D. Del. 2014).

<sup>143</sup> *Bristol-Myers Squibb Co.*, 72 F. Supp. 3d at 521.

<sup>144</sup> *Agilent Techs., Inc.*, 24 F. Supp. 3d at 925; *see also* *Bristol-Myers Squibb Co.*, 72 F. Supp. 3d at 523–24.

<sup>145</sup> *In re Genetic Techs. Ltd. (179) Patent Litig.*, 883 F. Supp. 2d 1337, 1338 (J.P.M.L. 2012) (denying centralization of venue for the patent infringement claim against the six defendants in four different venues).

<sup>146</sup> *Agilent Techs., Inc.*, 24 F. Supp. 3d at 925; *see also* *Bristol-Myers Squibb Co.*, 72 F. Supp. 3d at 523–24.

<sup>147</sup> *Bristol-Myers Squibb Co.*, 72 F. Supp. 3d at 523.

<sup>148</sup> *Agilent Techs., Inc.*, 24 F. Supp. 3d at 931.

<sup>149</sup> *In re Genetic Techs. Ltd. (179) Patent Litig.*, 883 F. Supp. 2d at 1338 (“Though we are denying centralization, we nevertheless encourage the parties and involved courts to pursue various alternative approaches, should the need arise, to minimize the potential for ... inconsistent pretrial rulings.”).

curiae briefs.<sup>150</sup> The argument that pervaded many of these amicus briefs alleged that patents like Myriad's restrict innovation in important areas like cancer research, and extend the timeline of treatment development.<sup>151</sup> Although keeping an eye on the public interest is important for all areas of the law, patent law specifically addresses the public interest when considering the patent bargain.<sup>152</sup> The idea behind the patent bargain is that the public wants to induce inventors to tell us about their inventions and, in exchange, we give them a period of exclusivity for that specific invention.<sup>153</sup> The patent bargain is a foundation of the Intellectual Property Clause in the Constitution,<sup>154</sup> and was important to Thomas Jefferson in his consideration of how patents should be treated in the United States.<sup>155</sup>

Of course, patents should not be given to inventors whose inventions do not meet the criteria of patentability. But if an inventor does create a novel, useful, and non-obvious invention, and meets the other factors of patentability required by the USPTO or the statute, then she is entitled to receive a patent that excludes others from making, selling, and using the invention for a limited time. Myriad had created something patentable in its cDNA invention, and has the right to exclude others for uses of this invention.<sup>156</sup> In return, Myriad disclosed what the invention was, including the best mode for a person skilled in the art to create the invention.<sup>157</sup>

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<sup>150</sup> See, e.g., Brief for Am. Med. Ass'n et al. as Amici Curiae Supporting Petitioners, Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107 (2013) (No. 12-398).

<sup>151</sup> See *id.* at 10.

<sup>152</sup> 35 U.S.C. § 2(a)(2), § 2(b)(2)(E) (2012).

<sup>153</sup> Kevin E. Mohr, *At the Interface of Patent and Trademark Law: Should A Product Configuration Disclosed In A Utility Patent Ever Qualify For Trade Dress Protection?*, 19 HASTINGS COMM. & ENT. L.J. 339, 344 (1997).

<sup>154</sup> U.S. CONST. art. I, § 8, cl. 8.

<sup>155</sup> Letter from Thomas Jefferson to Isaac McPherson (Aug. 13, 1813), in 13 THE WRITINGS OF THOMAS JEFFERSON 326–27, 334 (Albert Ellery Bergh ed., 1907) (An inventor has “no right to obstruct others in the use of what they possessed before.” Jefferson later states that “[s]ociety may give an exclusive right to the profits arising from [inventions], as an encouragement to men to pursue ideas which may produce utility, but this may or may not be done, according to the will and convenience of the society, without claim or complaint from anybody.”).

<sup>156</sup> See *supra* note 108 and accompanying text.

<sup>157</sup> See U.S. Patent No. 5,747,282 (filed June 7, 1995).

Adult stem cells and methods for creating stem cells are extremely important for the future of scientific research. Many different types of important adult stem cell therapies are currently undergoing extensive research. Such innovative research is not the only reason adult stem cells should be used; ethical concerns surrounding embryonic stem cell research can cause public outcry or potential reduction in government funding,<sup>158</sup> and thus research using adult stem cells instead can quell these issues. To incentivize this forward-thinking and ethical research, inventors should receive patent protection for taking novel approaches to developing both adult stem cells and methods for inducing adult stem cells that do not naturally occur. Patent protection should be afforded because adult stem cells are likened to the bacteria found in *Chakrabarty*.<sup>159</sup> Although the initial adult stem cells are found in nature (like the bacteria in *Chakrabarty*), the final product can be something that would never actually occur on its own.<sup>160</sup> This is markedly different from the isolated DNA in *Myriad*. Adult stem cells are not merely isolated from their environment. Instead, they are transformed into completely new material. This type of research should be encouraged by the public, and patent protection should incentivize these researchers to devote time and money to creating such landmark therapies. Though embryonic stem cells present problems regarding achieving patentability, adult stem cells and the methods to create them are different enough from nature to allow for patent protection.

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<sup>158</sup> See Gilbert, *supra* note 13.

<sup>159</sup> See STEM CELL BASICS VI, *supra* note 5; *Diamond v. Chakrabarty*, 447 U.S. 303, 305 (1980).

<sup>160</sup> See STEM CELL BASICS VI, *supra* note 5.

