

# Patent Protection for Genetic Innovation: *Monsanto and Myriad*

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Genetic science is increasingly important to the economy and people's individual lives. Among other things, genetic scientists have contributed to the ongoing Green Revolution that began in the 1950s and continues making agriculture ever more efficient. The study of genetics can also inform people about their risks for disease and develop therapies to treat many of the health scourges of our time. Of course, the genetic research that brings forth such advances (or sometimes endangers our health, according to some critics of genetically modified organisms (GMO)) is complex and costly to conduct. Thus, since at least the 1980s, companies have turned to patents to protect their innovations in genetics.

This term, the Supreme Court ruled on two cases involving patents in the field of genetics. In the first case, the Court upheld a decision preventing a farmer from reproducing Monsanto's Roundup Ready soybeans for subsequent plantings. In the second case, the Court ruled that natural DNA, as it exists in living organisms, is not patentable, but that complementary DNA ("cDNA"), which is produced in laboratories, is patentable even though cDNA is very similar to DNA.

In practical effect, this term the Court maintained protection for genetic crop modifications that are passed on in successive generations of the plants ("self-replicating" genetically modified plants). In disallowing patents on DNA but allowing them on cDNA, the Court decreased the patent rights given to researchers who discover genetic mutations that correlate with disease, but did not fully eliminate them. As to the effects on substantive patent law, the Court explained that the legal doctrine of patent exhaustion does not operate to permit the "making" of new copies of a patented genetic seed,

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even if the method of making the new copy is merely planting the patented seed and letting it grow more seeds that contain the patented genetic trait. The Court also continued to grapple with one of the most amorphous and intellectually unsatisfying areas in patent law—the question of what types of innovation and discovery should qualify for patentability. The Court has not clearly stated a uniform statutory interpretation and policy rationale for what should be patentable, and thus continues to make piecemeal decisions in individual cases without providing clear guidelines or predictability in this area of law. Notwithstanding that, this term the Court probably arrived at a decision that is good policy when it comes to patents on genetic material that occurs in nature.

### *Bowman v. Monsanto*

In *Bowman v. Monsanto*, the Supreme Court upheld a Federal Circuit decision holding a farmer liable for patent infringement for buying and replanting patented seeds.<sup>1</sup> The farmer, Vernon Hugh Bowman, bought seed from a grain elevator deliberately so as to get the advantage of Monsanto's genetically modified soybeans without having to pay Monsanto a patent license fee for each use of a new batch of seeds.

Monsanto created and patented<sup>2</sup> a genetic modification to soybean plants that makes them resistant to glyphosate, which is the active ingredient in Monsanto's herbicide Roundup (as well as many other herbicides). Monsanto markets the seed as "Roundup Ready" seed. Monsanto sells the seed to farmers with a license agreement that allows the farmers to plant the seed and then harvest and consume or sell the crop of soybeans as a commodity, generally to grain elevators who resell to soybean processors. The license agreement is important because the soybeans grown from the seeds purchased from authorized Monsanto retailers are themselves seeds. These soybeans can be consumed, or they can be planted and will reproduce a new crop of Roundup Ready soybean plants. Thus, but for the license agreement, a farmer could buy a single planting's worth of Roundup Ready seed and then replant a portion of the resulting

<sup>1</sup> *Bowman v. Monsanto Co.*, 133 S. Ct. 1761, 1763 (2013).

<sup>2</sup> Monsanto claims its Roundup Ready soybean is covered by U.S. Patent Nos. 5,352,605 and RE39,247E.

crop to produce generation after generation of Roundup Ready soybeans without ever having to buy more from an authorized Monsanto retailer.

Monsanto has seen widespread adoption of its Roundup Ready seed because it saves farmers considerable time and effort in eradicating weeds from their fields. By using Roundup Ready seed, farmers can plant the seed and then spray the herbicide glyphosate on their fields, which kills weeds and leaves the soybean plants intact. This method has been very popular with farmers, who find it a considerable improvement over prior methods of dealing with weeds.

Bowman bought Roundup Ready seed pursuant to a license from an authorized Monsanto dealer for his spring plantings but did not buy it for his fall planting. Instead, he bought soybeans from his local grain elevator at a price significantly lower than Monsanto dealers charge and planted those seeds in the fall. He then treated the resulting plants with glyphosate, which killed the weeds and any non-glyphosate-resistant soybean plants. Because the vast majority of farmers use Monsanto's patented seed, most of his soybean plants survived. Of these surviving soybean plants, all of them contained the patented genetic trait of resistance to glyphosate. Bowman then used some of the soybeans from his fall crop to continue planting soybeans, and he continued in this way for successive generations. By the time Monsanto sued, Bowman had grown eight generations of soybeans containing the glyphosate-resistant trait that Monsanto had patented.

Bowman did not deny that the soybeans he was using to plant successive generations of plants contained the genetic trait covered by Monsanto's patents on glyphosate-resistant soybean plants. Rather, Bowman defended himself by invoking the doctrine of patent exhaustion. This doctrine limits patent rights to an initial authorized sale of a patented item.<sup>3</sup> The authorized buyer then has "the right to use [or] sell" the item in whatever way the buyer chooses. The policy rationale underlying the patent exhaustion doctrine is that the patent owner only gets to receive the reward from its patent monopoly at the initial sale of an item covered by the patent. The buyer may

<sup>3</sup> *Quanta Computer, Inc. v. LG Electronics, Inc.*, 553 U.S. 617, 625 (2008) (noting that "the initial authorized sale of a patented item terminates all patent rights to that item").

then use and further convey the item free of the risk of a patent infringement suit to himself or subsequent purchasers.<sup>4</sup>

Patent law gives the patent owner the right to exclude others from making, using, selling, or importing a patented invention.<sup>5</sup> The law is clear that patent exhaustion bars only the assertion of patent rights against successive sales of a patented item after a first authorized sale.<sup>6</sup> The exhaustion doctrine does not allow an authorized buyer to make additional copies of the patented item, or even to reconstruct the item when it has become sufficiently degraded.<sup>7</sup> The policy behind this is simple: to allow a buyer to make copies or reconstruct the patented item “would impinge on the patentee’s right to exclude others from making” the patented item.<sup>8</sup>

Monsanto accused Bowman of making, using, and selling Monsanto’s patented seeds without authorization by his actions of buying soybeans that he knew to contain the patented trait, planting them, applying glyphosate to them, and then planting and reusing subsequent generations of the soybeans. Bowman argued that he had not made copies of the patented soybeans. Rather, he argued that the soybeans were “self-replicating” and that they made copies of themselves when they were placed in the ground. He argued in addition that because soybeans are seeds that naturally reproduce when planted, Monsanto’s initial sale of patented soybean seeds exhausted Monsanto’s patent rights because the only way to use the patented soybean seed was to produce more soybeans.<sup>9</sup>

In a unanimous decision, the Court made short work of Bowman’s asserted patent exhaustion defense. The Court held that Bowman’s planting of new generations of soybean plants definitively qualified as making new instances of the patented plants. In doing so,

<sup>4</sup> See *United States v. Univis Lens Co.*, 316 U.S. 241, 251 (1942) (“[T]he purpose of the patent law is fulfilled with respect to any particular article when the patentee has received his reward . . . by the sale of the article.”).

<sup>5</sup> 35 U.S.C. § 271(a) (“Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.”).

<sup>6</sup> 35 U.S.C. § 154.

<sup>7</sup> *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 365 U.S. 336, 346 (1961).

<sup>8</sup> *Wilbur-Ellis Co. v. Kuther*, 377 U.S. 422, 424 (1964) (internal quotation omitted).

<sup>9</sup> *Bowman*, 133 S. Ct. at 1765.

the Court noted that a contrary holding would leave Monsanto with “scant protection” because Monsanto would only be able to sell its patented seed once, and then the buyer could create and sell successive generations of plants with the patented trait.<sup>10</sup> The Court averred that it was deciding only the case at issue and reserved judgment on other patent exhaustion issues that might arise from self-replicating products, such as self-replication that occurs outside a purchaser’s control, or that is a necessary but incidental step in using the item for another purpose.<sup>11</sup>

The Court also did not have occasion to address a harder question that has remained open since its 2008 decision in *Quanta v. LG Electronics*<sup>12</sup>: the boundaries of patent exhaustion and whether parties can contract around exhaustion. In *Quanta*, the Court held that patent owner LG’s sale of computer chips to chip manufacturer Intel exhausted all patent rights embodied in the chips. Thus, the patentee could not seek license fees from Quanta, which bought chips from Intel and then used them to build computers. The contract at issue in *Quanta* licensed only the manufacturer Intel’s use of the patented chips with other Intel components; it did not authorize the combination of the licensed chips with non-Intel components (such as the data buses and memory that Quanta connected to the chips to build computers). But importantly, the license agreement did not prohibit Intel from selling the patented chips to buyers that Intel knew would combine the chips with other, non-Intel parts, thus exceeding the scope of Intel’s license.

The Court held that LG’s license to Intel authorizing Intel to make and sell chips embodying the patents exhausted LG’s patent rights, and the Court prohibited LG from suing Quanta or other computer manufacturers who bought chips from Intel. Because the license agreement did not prohibit Intel from selling chips to computer manufacturers that LG wanted to separately license, the case left open two questions: First, could a contract claim lie against a manufacturer if the manufacturer’s license agreement with the patent

<sup>10</sup> *Id.* at 1763.

<sup>11</sup> *Id.* at 1769 (citing 17 U.S.C. § 117(a)(1) (“[I]t is not [a copyright] infringement for the owner of a copy of a computer program to make . . . another copy . . . of that computer program provide[d] that such a new copy . . . is created as an essential step in the utilization of the computer program.”)).

<sup>12</sup> *Quanta*, 553 U.S. at 625.

owner prohibited the manufacturer from selling to buyers who it knew would use the products in prohibited manners (for example, to combine with their components to make computers)? Second, could a patent claim lie against both the manufacturer and anyone who bought from the manufacturer if the license agreement with the manufacturer prohibited sales to those who the manufacturer knew would make unauthorized uses of the patented component? In a nutshell, is patent exhaustion a default that can be contracted around, or is it a hard rule that negates attempts to contract to a different result?

The *Bowman* case does not address these questions because the soybeans at issue were new instances of the patented invention. The logic of *Quanta*, however, suggests that even careful drafting of contracts will not accomplish making successive buyers of patented items infringers, especially if they were not in privity with the initial contract. The Court in *Quanta* disallowed LG from doing just that. LG wanted to license Intel to use its patents for certain authorized uses, but it attempted to draft its contract so that successive users of the patented components would not have the right to use the components without negotiating separate licenses with LG. The Court rejected such restraints on alienation in patent rights, and it seems very unlikely that it would be enough to avoid exhaustion to merely change the contract so that subsequent buyers of components have notice of the purported limited license.

On the other hand, if a contract authorizes a buyer only to use the patents but does not allow the sale of products incorporating the patents to others, could this be enforced in contract and patent law? It would certainly be a breach of contract for a manufacturer to sell components in contravention of the contract. Would patent exhaustion negate the contract claim? Further, if the patent owner only licensed the manufacturer to make and use items embodying the patent, would it be patent infringement for the manufacturer to sell to a third party and for that third party to combine the patented components and resell?

In some areas, courts have upheld license terms restricting the use of patented or copyrighted materials to an initial user. Such license agreements have been widely upheld for computer software. Likewise, courts have generally upheld license agreements that restrict uses of a patented item to a single use. Such restrictions are popular for patented medical devices such as stents, for instance. The

difference between these cases and *Quanta*, however, is that software and medical devices are sold to end users, and thus the license restrictions merely prevent resale to other end users. In *Quanta*, the patents were licensed to chipmaker Intel, and LG knew that Intel would make chips using the patented technology and sell them to other manufacturers for use in computers. Thus, the contract term in *Quanta* acted to disrupt the vertical chain of manufacturing. Are such restrictions in vertical manufacturing chains preempted by patent exhaustion? Again, because *Bowman* deals with a new instance of a patented product, it does not answer any of these lingering questions from *Quanta*. We will have to wait to see how the Court addresses these issues as future contracting arrangements are tried and challenged.

***Association for Molecular Pathology v. Myriad Genetics, Inc.***

In *Association for Molecular Pathology v. Myriad Genetics*, the Supreme Court dealt with a more fundamental question: is DNA patentable? The Court unanimously held that DNA as it occurs in nature is not patentable, even if a particular section of DNA is extracted from an organism and isolated. Yet the Court also held that cDNA, a non-naturally occurring synthetic creation, is patentable. Because cDNA is commonly used in laboratories when working with DNA, the right to exclude others from making cDNA may still give cDNA patent owners substantial control over working with genetic sequences. As more laboratories work with native DNA, however, the practical commercial advantage of cDNA patents may decrease. The Court expressly reserved judgment on whether human-created DNA that does not have a counterpart in nature can be patented.

The patents at issue in *Myriad* claim, in various forms, two human genes, BRCA1 and BRCA2, and some of their common mutations.<sup>13</sup> The claims cover both DNA and cDNA sequences. Myriad's claimed "invention" was not a new genetic sequence, but rather discovering both the location and sequence of the BRCA1 and BRCA2 genes (pronounced "brack-uh one" and "brack-uh two"), as well as mutations of those genes that can significantly increase a person's risk of breast and ovarian cancer. Myriad's patents claimed the genes and portions

<sup>13</sup> *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 1308 n.2 (2008). The patents and claims at issue were claims 1, 2, 5, 6, and 7 of U.S. Patent 5,747,282, claim 1 of U.S. Patent 5,693,473, and claims 1, 6, and 7 of U.S. Patent 5,837,492.

thereof, either in a form extracted and isolated from the human body or in the form of cDNA, which is created in the laboratory from messenger RNA (“mRNA”).<sup>14</sup>

Because the Court’s opinion as to patentability turns on the differences between DNA and cDNA, a brief description of the science is in order. The human genome contains approximately 22,000 genes in 23 pairs of chromosomes.<sup>15</sup> Each gene is encoded as DNA. DNA is made up of four nucleotides: adenine (A), thymine (T), cytosine (C), and guanine (G).<sup>16</sup> DNA occurs in a double helix in which each nucleotide on one side of the helix binds with only one other nucleotide from the other side of the helix. A binds with T and C binds with G.<sup>17</sup> The ordering of the nucleotides in the DNA determines an organism’s genetic makeup.<sup>18</sup> Sequences of DNA nucleotides contain the genetic code to create strings of amino acids from which the body builds proteins.<sup>19</sup> Not all DNA sequences code for amino acids, however. The sequences that have the information to produce amino acids are called “exons.” The sequences that do not code for amino acids are called “introns.”<sup>20</sup>

DNA produces proteins by the processes of transcription and translation. Transcription occurs when the organism is ready to produce proteins from a sequence of DNA. During this process, the DNA double helix separates into two individual strands. The strands of DNA then interact with enzymes to create complementary ribonucleic acid (“RNA”) strands.<sup>21</sup> RNA contains the same four nucleotides as DNA, except that RNA substitutes the nucleotide base uracil (U) for thymine (T).<sup>22</sup> The result of transcription is called pre-RNA. This is an inverse image of the DNA strand with which it bonded. Pre-RNA corresponds to the entire strand of DNA from which it was

<sup>14</sup> *Id.* at 1975.

<sup>15</sup> Jane B. Reece & Neil A. Campbell, *Campbell Biology* 102 (6th ed. 2011).

<sup>16</sup> *Id.* at 9.

<sup>17</sup> *Id.* at 88.

<sup>18</sup> *Id.* at 26.

<sup>19</sup> *Id.* at 335.

<sup>20</sup> *Id.* at 335.

<sup>21</sup> *Id.* at 328.

<sup>22</sup> *Id.* at 88.



created, and thus contains both exons and introns.<sup>23</sup> In the next step, the pre-RNA separates from the DNA, and the intron portions of the RNA strands are discarded, leaving only an RNA strand in which the exon portions are spliced together. The result is mRNA.<sup>24</sup> Amino acids are produced in the next part of the process, called translation. During translation, ribosomes read the mRNA strand three nucleotides at a time. These groups of three nucleotides are called “codons.” Each codon tells the corresponding ribosomes to create 1 of 20 possible amino acids or to stop production of amino acids. The resulting amino acids are then used to create proteins that are used to fulfill the specific function for which the DNA codes.<sup>25</sup>

Researchers can extract DNA from the human body and study it in the lab.<sup>26</sup> Researchers can also create cDNA in the laboratory by reverse transcription from mRNA.<sup>27</sup> Reverse transcription occurs when scientists use the enzyme known as reverse transcriptase (“RT”), which contains nucleotides, to make an inverse copy of mRNA.<sup>28</sup> Because each nucleotide base pairs only with one other base, RNA is, in effect, a mirror image of DNA, and cDNA is a mirror image of mRNA. Thus, cDNA is identical to DNA except in one significant aspect: because all introns are removed from mRNA, the cDNA that results from reverse transcription with mRNA contains only the exon-encoding sequences of the original DNA.<sup>29</sup> All intron portions are omitted. The resulting cDNA can be used to create mRNA and the resulting amino acids and proteins, but it is not chemically identical to the DNA that occurs in nature because it contains only exons.<sup>30</sup>

Research scientists find cDNA very useful.<sup>31</sup> Scientists use cDNA to create cDNA libraries of mRNA, which allows them to have libraries of the genetic sequences that code for the proteins of the cor-

<sup>23</sup> *Id.* at 329.

<sup>24</sup> *Id.* at 328.

<sup>25</sup> *Id.* at 329.

<sup>26</sup> *Id.* at 10.

<sup>27</sup> *Id.* at 401.

<sup>28</sup> *Id.*

<sup>29</sup> *Id.*

<sup>30</sup> *Id.* at 403.

<sup>31</sup> *Id.* at 401.

responding mRNA.<sup>32</sup> Reverse transcription to produce cDNA is also a common and cost-effective way to produce a significantly greater volume of the genetic material with which scientists are working.<sup>33</sup> This process is called “amplification,” and it is crucial to gene cloning and to creating gene probes to test for the presence of specific genetic material.<sup>34</sup> It is important to note that cDNA does not occur in nature, but for one exception—certain viruses create cDNA and then insert it into host cells as a way to program the cells to create proteins to replicate the virus.<sup>35</sup> This cDNA does not occur naturally in the host organism, but rather is created by the virus’s invasion of the organism and interaction with mRNA.<sup>36</sup>

Mutations in segments of DNA occur when the order of nucleotides is altered.<sup>37</sup> Mutations of even a single nucleotide can produce entirely different amino acids, or can end amino acid production.<sup>38</sup> Mutations can also occur on larger scales in which hundreds or millions of nucleotides are missing, rearranged, or repeated.<sup>39</sup> Large-scale mutations can result in the elimination of certain genes, or in their misplacement or duplication.<sup>40</sup> Some mutations have no effect. Others have debilitating consequences. Strictly speaking, there is not a single, “normal” sequence for a gene. Rather, some variation occurs across individuals. On the whole, the sequence is similar enough that the gene is the same. Common variants of DNA sequences for a gene are called “wild types” of that gene.<sup>41</sup> “Mutations” are changes in the sequence that are more significant or that cause significant effects.<sup>42</sup>

Myriad’s discovery of the location and sequence of the BRCA1 and BRCA2 genes allowed it to study and classify the various wild types

<sup>32</sup> *Id.*

<sup>33</sup> *Id.* at 409.

<sup>34</sup> *Id.*

<sup>35</sup> *Id.* at 401.

<sup>36</sup> *Id.*

<sup>37</sup> *Id.* at 344.

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

<sup>39</sup> *Id.* at 298.

<sup>40</sup> *Id.* at 345.

<sup>41</sup> *Id.* at 288.

<sup>42</sup> *Id.*

of the genes. It also made it possible for Myriad to categorize common mutations of the genes and to study the increased risk of cancer from various mutations. Myriad used its patents to exclude others from using the BRCA1 and BRCA2 genes to test for and provide information to patients as to their risk factors for breast and ovarian cancer.<sup>43</sup> Myriad followed an enforcement practice to preserve its place as the sole test provider for BRCA1 and BRCA2 genes.<sup>44</sup> Myriad charged \$4,000 per test,<sup>45</sup> and it did not allow others to test for BRCA1 and BRCA2 mutations, even if only to provide “second opinions” as to the risk from mutation.<sup>46</sup>

The plaintiffs in the case included women who wanted their BRCA1 and BRCA2 genes tested to determine their cancer risk and Dr. Harry Osterer, a genetic researcher who sent patients’ DNA samples to a competing lab until Myriad sent letters informing the lab that testing patients’ BRCA1 and BRCA2 genes infringed its patents.<sup>47</sup> Dr. Osterer asserted that he would resume sending patients’ DNA samples to competing labs for testing if Myriad’s patents were ruled invalid. The Federal Circuit found that only Dr. Osterer had standing to bring the instant suit,<sup>48</sup> and the Supreme Court did not consider whether any other plaintiffs had standing.<sup>49</sup> Instead, the Supreme Court proceeded directly to the question of the patentability of DNA and cDNA.

The Court held that naturally occurring DNA is not patentable because it falls within the longstanding exception to patentability for natural phenomena. The Court held that cDNA is patentable, however, because it is not “naturally occurring.”<sup>50</sup>

<sup>43</sup> *Id.*

<sup>44</sup> *Id.* at 1340.

<sup>45</sup> David B. Agus, *The Outrageous Cost of a Gene Test*, N.Y. Times, May 20, 2013, at A25.

<sup>46</sup> Reece & Campbell, *supra* note 15, at 1339.

<sup>47</sup> *Id.* at 1340.

<sup>48</sup> *Id.* at 7.

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

<sup>50</sup> The Court noted that cDNA may be created in certain cases by viruses, but it held that fact to be lacking in material significance. The cDNA of genes found in the human genome generally cannot be found naturally in the body, and the Court held that the possible introduction of some cDNA by invasive viruses too rare, random, and unpredictable to disqualify cDNA from categorization as a man-made “synthetic DNA.” Myriad, 133 S. Ct. at 1350.

*Myriad* is the latest in a train of Supreme Court cases dealing with patentable subject matter. Notwithstanding very broad language in the patent statute as to what types of innovations and discoveries are patentable, the Supreme Court has—at least until recently—always understood itself to be vested with the power to determine what sorts of innovation are and are not patentable. In the early years of the Republic, the Supreme Court took on what amounted to a common-law approach to patentable subject matter.<sup>51</sup> From the outset, the Court announced three exceptions to patentable subject matter: “laws of nature, natural phenomena, and abstract ideas.”<sup>52</sup> These exceptions to what can be patented are not found in either the constitutional grant to Congress of the right to grant patents, or in the Patent Act itself. Rather, the Court has called these “important implicit exceptions” to what can be patented.<sup>53</sup> Over the years, courts have invented additional tests to exclude certain types of innovation from patentability. The Supreme Court and the Federal Circuit (or its predecessor, the Court of Claims and Patent Appeals) came up with the physical transformation test (meaning that a process had to result in a physical transformation of matter to qualify for patenting), the mathematical algorithm exception to patentability, and the mental steps doctrine (holding unpatentable processes that could also be performed as a series of mental steps). For a time, methods of doing business were also presumed to be unpatentable, but in the 1998 *State Street Bank* case, the Federal Circuit ruled that business methods are patentable, and that statements to the contrary over the years were merely dicta.<sup>54</sup>

The Court has justified its exceptions to patentable subject matter on policy grounds. First, the Court has said that laws of nature, natural phenomena, and abstract ideas “are the basic tools of scientific

<sup>51</sup> David S. Olson, Taking the Utilitarian Basis of Patent Law Seriously: The Case for Restricting Patentable Subject Matter, 82 Temp. L. Rev. 181 (2009).

<sup>52</sup> See *Diamond v. Diehr*, 450 U.S. 175, 185 (1981); *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980); *Le Roy v. Tatham*, 55 U.S. 156, 175 (1852); *O’Reilly v. Morse*, 56 U.S. 62, 112–20 (1853).

<sup>53</sup> *Mayo Collaborative Servs. v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289, 1293 (2012).

<sup>54</sup> *State St. Bank & Trust Co. v. Signature Fin. Group, Inc.*, 149 F.3d 1368 (Fed. Cir. 1998).

and technological work.”<sup>55</sup> Second, and more practically, the Court has claimed that to allow patents in these areas would “tie up” these basic building blocks of science and research, and therefore “inhibit future innovation premised upon them.”<sup>56</sup> Indeed, if one examines the case law carefully, one sees that for the majority of U.S. history, the Supreme Court decided what sorts of innovation should be patentable and what should not. These determinations were based on a rough, implicit calculus as to whether patentability for a certain type of innovation would likely benefit society with enough increased invention to outweigh the costs of granting patents—in terms of both higher prices to consumers and possible holdups to research from the difficulties in licensing all of the necessary patents.<sup>57</sup>

Historically, the Court’s approach to patentable subject matter was very much like its approach to making antitrust law—the Court seemed to view the broad patentable subject matter section of the Patent Act as an invitation for judicial lawmaking. While this view was never explicitly endorsed by an act of Congress, it was never rejected by Congress either. In fact, Congress has never substantially changed the patentable subject-matter section of the Patent Act. Instead, Congress has seemed content to let the courts hash out what types of innovation should and should not be patentable.

The historic approach to judges shaping the law of patentable subject matter faded in recent decades until, in *Bilski v. Kappos*,<sup>58</sup> the Court explicitly rejected any substantial role in developing the law

<sup>55</sup> *Mayo*, 132 S. Ct. at 1293.

<sup>56</sup> *Id.* at 1301. The Supreme Court’s concern that patents in these areas would deter science and innovation rests upon two implicit assumptions. First, the Court assumes that an adequate level of research and innovation in these areas is possible without the incentive effects of patent grants. Second, the Court assumes that the transaction costs of clearing rights to successive and overlapping patents would be great enough to deter a significant amount of socially beneficial research that would occur but for these patent rights. Basically, the Court assumes that patents are not needed for adequate innovation in these areas and/or that, to the extent that patents might spur more innovation in these areas, the subsequent costs of licensing the patent rights to allow further research would be great enough to deter more scientific advancement than they encourage. Although these assumptions seem reasonable and even intuitive, there is little and conflicting empirical support for them.

<sup>57</sup> See Olson, Taking the Utilitarian Basis of Patent Law Seriously, *supra* note 51. But note that either a low-transaction-cost licensing environment or widespread unpunished infringement can overcome problems of patent thickets.

<sup>58</sup> *Bilski v. Kappos*, 130 S. Ct. 3218, 3221 (2010).

of patentable subject matter.<sup>59</sup> Instead, the Court in *Bilski* announced that it was going to interpret the Patent Act according to the ordinary meaning of the text of the act.<sup>60</sup> Moreover, the Court has “more than once cautioned that courts ‘should not read into the patent laws limitations and conditions which the legislature has not expressed.’”<sup>61</sup> The Court made its textual approach to Section 101 even more clear in *Bilski* when it said, “In patent law, as in all statutory construction, ‘[u]nless otherwise defined “words will be interpreted as taking their ordinary, contemporary, common meaning.””<sup>62</sup>

There are two problems with the Court’s hard turn to textualism in the Patent Act. First, while there is great merit to textualism—in that it allows Courts to enforce the law rather than say what the law is—a sudden swerve to textualism in patentable subject-matter determinations is problematic if Congress has basically concluded that it has delegated patentable subject-matter determinations to the Court. Second, and more fundamentally, the plain text of the Patent Act reads to make everything patentable.

Section 101 of the Patent Act lays out the requirements for patentable subject matter.<sup>63</sup> The statute says: “Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.”<sup>64</sup> This statutory text is very broad. The plain text of those words makes everything patentable. Every physical item in the world is a composition of matter.<sup>65</sup> And just about everything that is

<sup>59</sup> *Id.*

<sup>60</sup> *Id.* at 3225.

<sup>61</sup> *Id.* at 3221 (quoting *Diamond v. Diehr*, 450 U.S. at 182).

<sup>62</sup> *Bilski*, 130 S. Ct. at 3226 (2010) (quoting *Perrin v. United States*, 444 U.S. 37, 42 (1979)).

<sup>63</sup> 35 U.S.C. § 101.

<sup>64</sup> *Id.*

<sup>65</sup> The *American Heritage Dictionary* defines “matter” as: “1.a. Something that occupies space and can be perceived by one or more senses; a physical body, a physical substance, or the universe as a whole.” It defines “composition” as: “The combining of distinct parts or elements to form a whole.” When you put these definitions together, you get that anything that has physical matter, or can be described as a process, is patentable.

not a composition of matter can be called a process. Thus, when you put these terms together, everything is patentable.<sup>66</sup>

Moreover, a textual definition of Section 101 should make even naturally occurring matter patentable, because Section 101 says that inventions and discoveries are patentable so long as they are newly “discovered.”<sup>67</sup> Indeed, the Court in *Bilski* recognized that the plain text of Section 101 did not support and require the three exceptions to patentability. The Court instead said that they were “consistent” with the statute: “[w]hile these exceptions are not required by the statutory text, they are consistent with the notion that a patentable process must be ‘new and useful.’”<sup>68</sup> But consistency is not enough; under a textual approach to patentable subject matter, the text of the statute must prohibit patentability for something to be unpatentable. The Court in *Bilski* recognized that Section 101 does not do that. Instead, the Court relied on the fact that the judicial exceptions to patentable subject matter go back 150 years.<sup>69</sup> The Court thus said that it was granting the exceptions “statutory *stare decisis*.”<sup>70</sup>

The problem with a plain-text approach to patentable subject matter, or any other approach that does not balance the costs of patents for certain types of innovation against their benefits, is that such approaches result in bad patent policy and indeterminacy. At the end of the day, we should only grant patents for areas of innovation in which the availability of patents gives us enough additional innovation to outweigh the inherent costs of patents in terms of higher prices on patented goods and potential patent thickets that clog research and development.

The Court should resurrect its historic approach to patentable subject matter. Instead of trying to decide patentability for cDNA

<sup>66</sup> Michael Risch, *Everything Is Patentable*, 75 *Tenn. L. Rev.* 591 (2008).

<sup>67</sup> Some argue that naturally occurring substances are foreclosed by the text of Section 101, because the text grants patents only to “new and useful” processes, compositions of matter, etc. Thus, according to this argument, previously existing matter cannot be patentable. *Id.* This argument ignores, however, that Section 101 also says “invents or discovers.” The plainest reading of the text is that someone may invent something new, or discover something previously unknown by others, and that either of these is patentable.

<sup>68</sup> *Bilski*, 130 S. Ct. at 3225 (2010).

<sup>69</sup> *Id.*

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

based on whether cDNA is man-made even though it is sometimes naturally created by viruses, the Court should ask the simple and central question: Will society on net benefit from patents on DNA and cDNA? The answer to this question should determine patentability of genetic material, not nuanced discussions of what constitutes “natural phenomena.”

The *Myriad* case touches upon two important areas of genetic research and innovation. First, it is very beneficial to society for scientists to determine the location and sequence of genes, and mutations thereto, that have significant health effects. Second, genetic therapies aimed at repairing mutated genes have great potential to improve health and save lives. The fundamental question to be asked about these two areas of genetic research is whether allowing them to be patented will benefit society more in terms of increased innovation than it costs society in terms of increased consumer prices and decreased research due to excessive patents in a field. In other words, do we need patents on genes, or are they a drag on research and innovation?

Under current law, gene therapies that involve synthesized, non-naturally occurring genetic sequences are patentable subject matter as man-made products. Likewise, discovering a process to administer genetic therapy using existing genetic material is also patentable in that it qualifies as a new use of a known product. Under *Myriad*, however, discovering a new gene, including its location, sequence, function, and dangerous mutations, is not patentable.

The question as a matter of policy is whether this distinction makes sense. Without the reward of patentability, will enough scientists engage in enough research to discover relevant genes, their health effects, and effects of mutations thereto? Will keeping naturally occurring genes free of patents make it easier for researchers to make discoveries unencumbered by potential patent infringement?<sup>71</sup> These are ultimately empirical questions to which we can never know the answers to a certainty. Nevertheless, it would be worthwhile for the Court to make its best attempt at determining the answers to the empirical questions and decide patentability from those

<sup>71</sup> But note that it is uncommon for patent holders to sue researchers, especially if the research would make the patent more valuable. *Myriad* itself only sued rival testing providers, not scientists studying BRCA1 and BRCA2 mutations.



answers. If an adequate amount of research into the correlations between specific genes and disease will not be done but for the patent grant, then society is better off with patents on even naturally occurring genetic material. If such patents hurt more than they help, then non-patentability is in order.

The Court seemed to recognize this balancing act in *Myriad*,<sup>72</sup> but did not embrace it as the best test for patentable subject matter. Rather, the Court mentioned the balance and then inquired as to whether DNA and cDNA are naturally occurring. The Court could simply adopt this test and uphold patents on naturally occurring genetic material if it thinks doing so will be beneficial. After all, nothing in the plain text of the Patent Act disallows patentability for natural phenomena. That exception to patentability is merely judicially created and can be eliminated in the same way.

Although the Court in *Myriad* did not adopt the most straightforward and efficient way of determining patentable subject matter, its parsing of patentability for DNA and cDNA may have served the function of granting enough patent rights to incentivize research, but not so many patents as to cause very high consumer costs and research blockages. By preserving naturally occurring DNA in the public domain, the Court made sure this material is free of patents and available to all. By allowing cDNA to be patented, the Court ensured that some incentives flow to genetic researchers for their discoveries of important gene-disease correlations. At least until a DNA-based test is perfected, *Myriad* seems to have a patent on the most effective way of conducting BRCA1 and BRCA2 tests.<sup>73</sup> Indeed, since the Supreme Court's decision, *Myriad* has already filed suit against two competing lab companies that are seeking to offer BRCA1 and BRCA2 testing. The company has asserted some of the claims that

<sup>72</sup> *Myriad*, 133 S. Ct. at 2116 ("As we have recognized before, patent protection strikes a delicate balance between creating incentives that lead to creation, invention, and discovery and impeding the flow of information that might permit, indeed spur, invention.") (internal quotation omitted).

<sup>73</sup> See John Timmer, Supreme Court Blocks Patenting of Genomic DNA, *Ars Technica*, Jun. 13, 2013, <http://arstechnica.com/tech-policy/2013/06/supreme-court-blocks-patenting-of-genomic-dna>; Megan Krench, New Supreme Court Decision Rules That cDNA Is Patentable—What It Means for Research and Genetic Testing, *Scientific American Blogs*, Jul. 9, 2013, <http://blogs.scientificamerican.com/guest-blog/2013/07/09/new-supreme-court-decision-rules-that-cdna-is-patentable-what-it-means-for-research-and-genetic-testing>.

the Supreme Court upheld and has also asserted method-of-testing claims from some of the 24 other patents it owns related to BRCA1 and BRCA2 genes. In its filings, Myriad claims that the competing testing companies cannot test for BRCA1 and BRCA2 genes without creating the cDNA to which Myriad has exclusive right.<sup>74</sup>

### Conclusion

The Supreme Court this term maintained protections for genetic patents in terms of both genetically modified seeds and synthetic versions of genes. As a practical matter, these decisions uphold patent rights and incentives of genetic scientists to both create new GMOs and to continue to research gene-disease correlations. As to the development of patent law, in *Bowman* the Court left us without significant answers to persistent questions about the boundaries of the patent exhaustion doctrine. The Court unanimously rejected the argument that patent exhaustion should govern new plants containing patented genetic material, but did not venture further than that on the questions of contract versus exhaustion doctrine. As to patentable subject matter, in *Myriad* the Court declined the opportunity to set forth a comprehensive cost-benefit approach to what sorts of things should be patentable. Instead, the Court's decision extended the uncertainty in patentable subject matter that has been in existence for some time, and that *Bilski's* textualist approach exacerbated. Nevertheless, the Court's decision allowing patents on man-made cDNA but not on naturally occurring DNA probably threads nicely the needle of encouraging investment in studying genetic disease while leaving open to others the use of DNA. In all, the Court's decisions this term should maintain conditions for the encouragement of important genetic science.

<sup>74</sup> See, e.g., Motion for Prelim. Injunctive Relief, University of Utah Research Foundation v. Ambry Genetics Corp., No. 2:13-cv-00640-RJS (D. Utah filed Jul. 9, 2013).