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Patents at the Supreme Court: It Could Have Been Worse

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I. Introduction

Since the formation of the U.S. Court of Appeals for the Federal Circuit in 1984, the Supreme Court has taken a mostly "hands-off" approach to patent cases. Indeed, in the first 20 years of the Federal Circuit's existence, the Supreme Court heard only 10 cases dealing with substantive patent law (and two of these cases dealt with rather esoteric issues of plant patents). Since 2004, however, the Court has shown increased interest in engaging with patent law and has granted at least 16 substantive patent cases on issues as varied as patent-eligible subject matter and the interaction of patent and FDA law. In taking these cases, the Supreme Court has been widely viewed as attempting to "rein in" the overly patent-friendly Federal Circuit. Whether or not this was the Supreme Court's goal or intent, it is undeniable that, on balance, its rulings have been far less solicitous of patentees than those emanating from the Federal Circuit.

In the last few years in particular, the Court has expanded the zone of exclusion from patent eligibility,[1] limited the availability of injunctive relief for patentees whose patents have been adjudged to be valid and infringed,[2] and broadened the scope of the patent exhaustion doctrine.[3] To be sure, not all of the Supreme Court's decisions were "anti-patent." For example, the Court chose to adhere to the rule that

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[1] Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289 (2012); Bilski v. Kappos, 130 S. Ct. 3218 (2010).

[2] eBay Inc. v. MercExchange, LLC, 547 U.S. 388 (2006).

[3] Quanta Computer, Inc. v. LG Electronics, Inc., 553 U.S. 617 (2008).

anyone seeking to challenge an issued patent's validity may do so only by the standard of "clear and convincing evidence," rather than by the lower "preponderance of the evidence" standard, as many law professors have been urging it to do.[4] Nonetheless, the overall trajectory of the Court's patent jurisprudence has been toward a narrower set of patent rights. Thus, there was significant trepidation in the patent bar and the academy when the Supreme Court decided to hear three patent cases this term: *Bowman v. Monsanto*,[5] *Association for Molecular Pathology v. Myriad Genetics*,[6] and *FTC v. Actavis*.[7] Each of the cases had the potential to rewrite decades of patent law and significantly upend major industries that have come to rely on patents. Ultimately, however, the Court adopted an incremental approach to each of the problems it addressed. And though the overall outcome in this term's patent cases leaves quite a lot to be desired, the worst fears of the patent-dependent industries did not come to pass.

II. *Bowman v. Monsanto*

Bowman turned out to be perhaps the least controversial of the intellectual property cases before the Court—though the case certainly elicited much attention because Monsanto Company was the other party to a dispute that involved genetically modified organisms (GMOs). Yet it is precisely because the issue seemed so clear-cut that the decision to hear *Bowman* raised significant worries about the direction that the Supreme Court might take.

At issue in the case was a type of soybean produced by Monsanto. By modifying the soybean's genetic makeup, the company was able to create and patent a bean that is resistant to certain pesticides—specifically to Monsanto's own Roundup. In other words, a farmer planting these particular soybeans (known as Roundup Ready) can spray his field with Roundup pesticide confident that the chemical will kill unwanted weeds but will leave the soybean cash crop unaffected. It should come as no surprise that Monsanto charges a premium for the

[4] Microsoft Corp. v. i4i Ltd. Partnership, 131 S. Ct. 2238 (2011).

[5] Bowman v. Monsanto Co., 133 S. Ct. 1761 (2013).

[6] Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107 (2013).

[7] FTC v. Actavis, Inc., 133 S. Ct. 2223 (2013). This article will not discuss *Actavis* beyond noting that in that case, as in the other two, the Court, though taking an anti-patent step, made sure that that step was rather modest.

advantage that the pesticide-resistant seed provides. A seed bought from Monsanto is thus significantly more expensive than a seed bought from a grain elevator.

When the farmer buys a Roundup Ready seed, he ends up growing more identical seeds, owing to the genetic features of the initial seed. That is, a farmer who planted one seed will, at the end of the season, end up with several dozen identical seeds borne by the plant that sprouted from the original. Absent unexpected (and unlikely) genetic mutations, these new seeds have the same features as the original seed—they too are Roundup-proof. Theoretically, then, a farmer wishing to grow Roundup Ready soybeans only needs to buy seeds from Monsanto once with every subsequent generation being regrown from that original purchase.

Monsanto recognized this problem and sought to address it through contractual arrangements. When selling its patented soybeans either to farmers directly or to authorized dealers, the company secures a contractual promise from buyers that they will use the purchased seeds to grow only a single generation of soybean plants and won't use the resultant seeds to plant a second generation of plants. Vernon Bowman, a commercial farmer, purchased Roundup Ready seeds from Monsanto's authorized dealer and signed the appropriate contract. He honored the terms of the contract with respect to the seeds that he purchased from Monsanto and its dealers. The seeds that Bowman grew from this original purchase were all harvested and sold to a grain elevator, with none kept for additional replanting. Bowman, however, found what he thought was an ingenious way of circumventing Monsanto's contractual restrictions. After selling his own harvest of soybeans, he purchased more soybeans, but this time not from Monsanto or any of its dealers but from a grain elevator. Though the grain elevator had a mixture of beans, it was fairly easy for Bowman to separate the progeny of the original Monsanto seeds from that of unmodified seeds. All Bowman had to do was to plant the seeds bought from the grain elevator and then spray them with Roundup. The second-generation Roundup Ready seeds would survive, whereas the second-generation unmodified seeds would not. Bowman would then be able to harvest the surviving seeds and sell the bulk of them while keeping a sufficient amount for planting the following year, when he would be able to repeat the process.

This subterfuge allowed Bowman to avoid paying Monsanto's high premium for its patented soybean and instead to pay the regular commodity price for soybeans. The grain elevator, meanwhile, couldn't charge the premium for the patented soybean as opposed to the unmodified natural one because it's not in the business of selling soybeans for future agricultural use. Indeed, federal law explicitly prohibits grain elevators from packaging or marketing their wares as agricultural products.[8] Thus, from the perspective of a grain elevator, a modified soybean is identical to an unmodified soybean, and is worth exactly the same. For that reason, all soybeans are stored together and the same commodity price is charged for all of them—regardless of whether they're descendants of the originally patented seed. Accordingly, the grain elevator (unlike Monsanto or any of its authorized dealers) could not and would not insist on a contractual promise that purchased seeds not be used for multiple generations of agricultural use.

Eventually, Monsanto discovered Bowman's operation and filed suit alleging that his activities infringed Monsanto's patents, which claimed (in one form or another) a modified gene that encoded for the herbicide resistance.[9] Monsanto argued that by growing new seeds that contain the patented gene, Bowman was infringing Monsanto's exclusive rights to "make[], use[], offer[] to sell, or sell[]" the patented invention.[10] Given that he was in fact producing seeds containing the patented gene, Bowman was forced to concede that he indeed "makes, uses, offers to sell, or sells" the patented product. The statute, however, makes an infringer only out of an individual who "makes, uses, offers to sell, or sells" the patented invention *without authority*.[11] Bowman argued that his production of new seeds was authorized by the doctrine of patent exhaustion—which holds that once the patentee has made an authorized sale of a patented invention, the purchaser can use the sold product or resell it to others as he sees fit and on whatever terms he sees fit. Bowman argued that the doctrine prevents Monsanto from objecting to downstream uses

[8] See 7 U.S.C. § 1571; Ind. Code § 15-15-1-32 (2012); Bowman, *supra* note 5, at 1765.

[9] U.S. Patent Nos. 5,352,605 (filed Oct. 28, 1993) and RE39,247 E (filed Aug. 22, 2006); Monsanto Co. v. Bowman, 657 F.3d 1341, 1344 (Fed. Cir. 2011) (describing the patented technology).

[10] 35 U.S.C. § 271(a).

[11] *Id.*

of its patented seed because Monsanto exhausted its patent rights via the original sale of the modified soybean. He also argued that whatever contractual restrictions Monsanto tried to place on the use of the seed post-sale were void because they were inconsistent with the nature of the transaction between Monsanto and the dealers or farmers, thus constituting an "end run" around the patent exhaustion doctrine.

Bowman lost the infringement suit and the subsequent appeal to the Federal Circuit.[12] The Supreme Court granted Bowman's petition for the writ of certiorari to address whether the Federal Circuit erred when it created "an exception to the doctrine of patent exhaustion for self-replicating technologies."[13] Given the unanimity of the Federal Circuit panel—which included a judge generally regarded as a skeptic of broad patent law claims—the cert grant was somewhat of a surprise. As the old adage goes, the Supreme Court doesn't grant cases to affirm, and that has been especially true as of late with cases emanating from the Federal Circuit.

The question was whether the Supreme Court would take a broader view of patent exhaustion than did the lower courts, thus potentially undermining the very business model of companies making GMOs. Had the Court adopted Bowman's argument, it would necessarily follow that companies like Monsanto would be able to enjoy their exclusive rights to make and sell their technology for only a year or two (rather than the statutory 20 years of the patent term) because after the first year of sales, downstream purchasers would be able to reproduce the patented GMOs and sell them in competition with the patentee. Each subsequent year would potentially bring in more and more competitors until the price for the patented GMO soybean would be equivalent to the cost of raising *any* soybean. In other words, the patent holder would be unable to charge a premium and so would reap a much lower profit than it can now, perhaps to the point of not even being able to recoup the initial investment in creating the seed. The Supreme Court then was in a perfect position to do considerable damage to an industry that is dependent on patent protection for its business model.

[12] Monsanto Co. v. Bowman, 686 F. Supp. 2d 834 (S.D. Ind. 2009), aff'd, 657 F.3d 1341.

[13] Bowman v. Monsanto Co., 133 S. Ct. 420 (2012).

What made the grant all the more suspicious was the attack on a 1992 Federal Circuit case, *Mallinckrodt, Inc. v. Medipart, Inc.*[14] Bowman's cert petition expressly asked the Court to overrule *Mallinckrodt*. The United States, appearing as amicus curiae, though ostensibly supporting affirmance of the decision below, endorsed Bowman's argument on this point. The *Mallinckrodt* case is interesting because it stands for the proposition that the patentee can avoid triggering the patent exhaustion rights if it contractually restricts the post-sale use of the patented device. In *Mallinckrodt*, the Federal Circuit held that when the patentee sold certain medical devices imprinted with "single-use only" notice, disregarding such notice and reusing the devices constituted patent infringement. The *Mallinckrodt* decision has come under much criticism over the last 20 years, so the Supreme Court's decision to review Bowman's lawsuit was viewed as a signal that perhaps the Court not only would broaden the scope of patent exhaustion doctrine, but also would limit the licensing arrangements that have grown common between purveyors and users of various patented goods.

Ultimately, however, the Court dashed those fears—or hopes, depending on which side of the issue you happen to be on—by issuing a short and almost playful unanimous opinion that explicitly declined to address the particular problems posed by self-replicating technologies.[15] The ruling was altogether silent on the permissible scope of licensing arrangements that are meant to counterbalance the patent exhaustion doctrine. Instead, the Court merely reaffirmed the uncontroversial proposition that the patent exhaustion doctrine "restricts a patentee's rights only as to the 'particular article' sold, it leaves untouched the patentee's ability to prevent a buyer from making new copies of the patented item."[16] This proposition was so uncontroversial that Bowman readily conceded it in his brief and at oral argument. This concession proved fatal to Bowman's case.[17] Simply put, the Court concluded that by growing successive generations of Roundup Ready soybean seeds, Bowman was making new, additional patented soybeans—an activity beyond the scope of the

[14] Mallinckrodt, Inc. v. Medipart, Inc., 976 F.2d 700 (Fed. Cir. 1992).

[15] Bowman, *supra* note 5, at 1769.

[16] *Id.* at 1766.

[17] *Id.*

patent exhaustion doctrine. And though the Court agreed that seeds are generally meant to be planted and thus Monsanto would likely be unable to restrict the planting (or other use) of the very seeds purchased from itself or an authorized dealer had it attempted to do so, the *re*planting of new seeds and growing additional generations of the patented product were outside the safe harbor provisions of the exhaustion doctrine.

The Court unquestionably got the answer right. As Justice Elena Kagan recognized in her unanimous opinion, under a contrary holding:

> Monsanto's patent would provide scant benefit. After inventing the Roundup Ready trait, Monsanto would, to be sure, "receiv[e] [its] reward" for the first seeds it sells. But in short order, other seed companies could reproduce the product and market it to growers, thus depriving Monsanto of its monopoly. And farmers themselves need only buy the seed once, whether from Monsanto, a competitor, or (as here) a grain elevator. The grower could multiply his initial purchase, and then multiply that new creation, *ad infinitum*—each time profiting from the patented seed without compensating its inventor.[18]

The trouble, though, is that the question the Court answered was not of particular importance to anyone. Both Bowman and Monsanto agreed "that the exhaustion doctrine does not extend to the right to 'make' a new product."[19] The answer to that question in no way depends on various contractual arrangements that Monsanto and its dealers entered into with farmers like Bowman. Bowman would have been adjudged an infringer even absent the restrictive covenants in the sale, because what he violated was not a contractual clause—after all, he bought his seeds from a grain elevator and not from Monsanto—but Monsanto's exclusive right to make new, additional copies of the patented product.

Two far more interesting questions remained unanswered after *Bowman*. First, can a patentee sidestep the exhaustion doctrine via restrictive contractual covenants attendant to the sale of a patented device? Second, in the case of self-replicating technologies, can a party whose wares, through no fault of his own, were contaminated by a

[18] *Id.* at 1767 (citations omitted).

[19] *Id.* at 1766 (citations omitted).

patented product be an "infringer" within the meaning of 35 U.S.C. § 271? In other words, had Monsanto's soybeans been blown over onto Bowman's field and cross-pollinated his plants—causing some of Bowman's seeds to contain the patented gene—would Bowman still be liable for infringement? The Court chose not to answer either of these questions in its opinion, perhaps because this case was a poor vehicle to address those issues. After all, Bowman was not an innocent party whose fields were simply contaminated by Monsanto's product. Nor did he plant his seeds in violation of a contractual obligation with the patent holder. Thus, there was no need to delve into these matters.

But that does not mean that these issues simply disappear. Instead, they have been deferred. When they come up—and they will—the Court will need to consider seriously how to reconcile the strict liability nature of infringement with the unavoidable infringement resulting from actions of the *patentee* (and forces of nature) alone. It's quite possible that the doctrine of patent exhaustion at issue in *Bowman* isn't the best tool to resolve this problem, and therefore this question was best left unaddressed in the present case. However, companies like Monsanto may need to develop legal arguments in anticipation of future cases. Similarly, the patent world is now on notice that the federal government views *Mallinckrodt* as incorrectly decided and should expect that argument to be made in due course to the Supreme Court. Patent-reliant companies should be prepared to adjust their business models accordingly. For now, though, industries that rely heavily on patented technology can breathe a little more easily knowing that the Court didn't expand the doctrine of patent exhaustion to the point at which it would undermine the de facto term of the patent and therefore the economic incentives to innovate.

III. *Association for Molecular Pathology v. Myriad Genetics*

Whereas *Bowman* ultimately broke no new ground by relying exclusively on well-established and agreed-upon precedent and deferring the hard questions for later, *Myriad* did none of those things, instead plunging head-on into scientific issues that the Court, judging from oral arguments, clearly did not understand. The result was an incoherent opinion instead of a clear exposition of patent law. That said, the ultimate outcome in *Myriad* is not as bad or as radical as claimed by the petitioners and by a large segment of legal academia.

Myriad Genetics is a company located in Salt Lake City. In the late 1980s, scientists worldwide, realizing that certain forms of breast and ovarian cancer have a genetic component, began searching for genes that increase the likelihood of developing these maladies. Among the hundreds of scientists searching for the answer, Myriad was first to find the location of the gene and first to decode its chemical structure or, in the words of molecular genetics, its "sequence." Myriad managed to separate the cancer-causing gene from the thousands of other genes located on the same chromosome and to develop a test capable of confirming the presence or absence of mutations in that gene. Between 1997 and 2000, Myriad obtained a number of patents on the method of testing for breast cancer and on the isolated gene itself. Because the company had these patents, it possessed exclusive rights to conduct genetic testing for the particular genes known as BRCA1 and BRCA2 (pronounced "brack-uh one" and "brack-uh two"). Myriad did license a number of laboratories to conduct the same tests, but it was under no legal obligation to do so and extracted a price for its license. Unsurprisingly, Myriad charged a higher price than it would have been able to if it had multiple competitors providing the same testing service.

Unhappy with this state of affairs, a collection of doctors, patients, and medical organizations sued Myriad and sought to declare these patents invalid. Throughout the litigation, the challengers essentially argued that genetic materials are not human "inventions," but rather "products of nature" and thus beyond the scope of patent protection. This argument was accepted wholesale by the district court, but rejected, in a split decision, by the Federal Circuit, which held that isolated DNA isn't a product of nature and is therefore eligible for patent protection.[20] In 2012, the Supreme Court vacated that decision and remanded the case to the Federal Circuit in light of a case it had just decided, *Mayo Collaborative Servs. v. Prometheus Labs.*, which limited the scope of patent-eligible subject matter.[21] On remand, the Federal Circuit reissued its original decision with only minor changes.[22] The Supreme Court again granted cert.

[20] Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 702 F. Supp. 2d 181 (S.D.N.Y. 2010), aff'd in part & rev'd in part, 653 F.3d 1329 (Fed. Cir. 2011).

[21] Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 132 S. Ct. 1794 (2012).

[22] Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 689 F.3d 1303 (Fed. Cir. 2012).

To understand the nature of the legal dispute in *Myriad*, it is necessary to understand the basic science underlying the case. Bear with me through this section, because grasping it is key to understanding what's going on here and evaluating the Supreme Court's ruling.[23]

A DNA molecule consists of two strands of a repetitive sugar-phosphate chain called deoxyribose. Each strand is a long molecule (called a polymer) composed of four types of subunits molecular bases known as adenine, cytosine, guanine, and thymine—("A," "C," "G," and "T," respectively, if you recall your high school biology)—leading to a structure resembling four kinds of beads strung on a necklace. Each adenine base on one strand is paired with a thymine base on the other, and each cytosine base is paired with a guanine base, generating strands that are complementary, not identical. The DNA molecule can be visualized as a zipper with each strand serving as tape and the A, C, T, G base pairs forming the teeth. Unlike a regular zipper, a molecule of DNA is neither straight nor flat. Instead, in its "native" state—the state it assumes naturally inside a living organism—the DNA molecule is twisted into a spiral ladder shape, giving rise to the famous "double helix" model. The chemical and physical properties of native DNA emerge from this combination of factors: the entire sequence of base pairs (rather than a particular isolated fragment); the chemical modification of its nucleotides; the association with proteins such as "histones"; and the overall packaging into superstructures such as chromosomes. Each of these factors plays a role in defining and controlling native DNA's molecular weight, chemical charge, three-dimensional structure, responsiveness to particular chemicals and enzymes, availability of electrons for other chemical reactions, and every other property.

The function of DNA is to provide a set of genetic instructions for the production of other critical molecules: proteins. Amino acids are the building blocks of proteins, and DNA codes for amino acids. This coding operates by grouping nucleotides together in groups of three. Mathematically, each triad drawn from the set of four nucleotides defines a potentially distinct code, yielding 64 distinct possible values, or "codons."[24] For reasons not wholly understood, genes

[23] For a more detailed exposition see Gregory Dolin, Exclusivity Without Patents: The New Frontier of FDA Regulation for Genetic Materials, 98 Iowa L. R. 1399, 1407–17 (2013).

[24] Because there are only 20 amino acids, several codons may code for the same amino acid.

have noncoding regions (known as "introns") that are interspersed among coding regions (known as "exons"). Indeed, the majority of genetic material consists of noncoding regions. Mutations in a codon sequence—which may occur, for example, by adding or deleting a nucleotide or by changing one nucleotide into another—often result in coding for an incorrect amino acid, leading to a defective or completely nonfunctional protein. Thus, when diagnosing genetic disorders, it is important to compare the subject sequence with both the normal sequence and all known mutations. Furthermore, though DNA is composed of two strands, only one strand codes for proteins, while the other simply binds the coding strand. Which strand is coding and which is merely binding can change from one gene to another, however, and even occasionally within a single gene.

DNA doesn't directly code for proteins. Instead, an intermediary molecule known as RNA is used. Thus, the process of "decrypting" the DNA's code begins when the DNA region containing the relevant active gene is "transcribed" into a corresponding RNA molecule. RNA is composed of nucleotides attached to a single strand of a sugar molecule called ribose (as opposed to the dual strands of deoxyribose in DNA). In a similar vein, single-stranded RNA transcribes only the coding strand, never the binding strand. RNA and DNA differ in several other significant ways as well. Unlike the native DNA strand that contains multiple genes, only some of which are active, an RNA molecule contains only a single active gene. Also unlike DNA, RNA lacks the bound histones that fold DNA into the complex chromosomal structures. RNA strands also possess several chemical modifications that native DNA lacks.

Finally, before protein production can begin, a further preprocessing step, known as "RNA splicing," removes noncoding introns from the RNA and splices the remaining exons together in an uninterrupted string known as "messenger RNA," or mRNA. That sets the stage for the "translation" step, where cellular mechanisms read the mRNA, one codon at a time, to produce the final protein structure.

Myriad's patents claimed two types of DNA structures. First, they claimed an isolated gene coding for BRCA1 and BRCA2.[25] In other words, the claim covered a gene excised from the chromosome, separated from various associated proteins and neighboring genes, and

[25] See, e.g., claim 1 of U.S. Patent No. 5,747,282 (filed on May 5, 1998).

otherwise purified.[26] It's important to understand that contrary to various press accounts, Myriad did not attempt to patent genes that are carried by individuals as part of their genetic makeup. Instead, Myriad created and patented a small molecule that, standing alone, isn't carried by any individual. The second set of claims was directed to a yet further-refined molecule: Myriad constructed a DNA molecule that was complementary to the sequence of mRNA. In other words, like mRNA (and unlike the native-state DNA) this molecule no longer had any noncoding introns. Instead, it had only the coding exon regions. In all other respects, it had features of DNA rather than RNA. This molecule, because it is *complementary* to the RNA molecule, is known as cDNA.[27]

The petitioners in *Myriad* argued that neither isolated DNA nor cDNA are patent-eligible because both are products of nature. Under longstanding patent principles, only inventions created by human ingenuity are eligible for a patent, while naturally occurring products—for example, gold, trees, and so forth—are not patent-eligible.[28] The petitioners' argument rested on the premise that, isolated or not, these pieces of DNA ultimately perform the same function as naturally occurring DNA: they code for proteins. In other words, native DNA, isolated DNA, and cDNA all carry the same information. In the petitioners' view, DNA's information-carrying capacity rendered *all* DNA molecules carrying that information patent-ineligible subject matter.

Myriad, on the other hand, pointed out that these precise molecules (whether isolated DNA or cDNA) never existed in nature until isolated from larger structures. The company argued, and the Federal Circuit agreed, that the molecules described in the patents have vastly different chemical properties—such as molecular weight, ionic charge, and ability to react with other reagents—than naturally

[26] Technically, the claim went to a wholly synthetic DNA molecule that merely had the same nucleotide sequence that an excised piece of a chromosome would have had. This fact alone should have sufficed to settle the patent-eligibility question. The Court chose to read the claim more broadly, however, so that it would cover not just synthetic constructs but also genetic material excised from the chromosome. I engage the Court's reasoning on its own terms.

[27] See, e.g., claim 2 of U.S. Patent No. 5,747,282 (filed on May 5, 1998).

[28] See, e.g., Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980).

occurring molecules. In short, the dispute centered on whether DNA should be judged on its chemical or biological functions.

The solicitor general, arguing the case as amicus curiae, took a "split the baby" approach. With respect to native DNA, he argued that isolated DNA is too similar to what occurs in nature to qualify for patent protection. With respect to cDNA, however, he argued that human intervention was of sufficient magnitude to make the resultant product patent-eligible.

The Court's opinion ultimately adopted the solicitor general's position and held isolated DNA to be patent-ineligible but cDNA to be patent-eligible. Surprisingly, this split decision prompted news media worldwide to announce that the Court "invalidated gene patents."[29] That isn't what the Court did, although the media's confusion is understandable given the incoherent nature of the opinion. In concluding that isolated DNA is *not* patent-eligible subject matter, the Court, per Justice Clarence Thomas, concluded that

> Myriad's claims [are not] saved by the fact that isolating DNA from the human genome severs chemical bonds and thereby creates a nonnaturally occurring molecule. Myriad's claims are simply not expressed in terms of chemical composition, nor do they rely in any way on the chemical changes that result from the isolation of a particular section of DNA. Instead, the claims understandably focus on the genetic information . . . . [I]ts claim is concerned primarily with the information contained in the genetic *sequence*, not with the specific chemical composition of a particular molecule.[30]

The Court apparently agreed with the petitioners' argument that DNA is primarily an information-carrying molecule, not subject to the same rules as other chemical molecules. But a mere page later, in a single, cursory paragraph, Justice Thomas wrote that the "creation of a cDNA sequence from mRNA results in an exons-only molecule that is not naturally occurring," making "cDNA . . . distinct from the DNA from which it was derived. As a result, cDNA is not a 'product

[29] See, e.g., David G. Savage, Supreme Court Rejects Gene Patents, L.A. Times, Jun. 14, 2013, at 1.

[30] Myriad, *supra* note 6, at 2118 (emphasis in original).

of nature' and is patent eligible."[31] There is no mention of cDNA's information-carrying capacity.

The legal analysis leading to the conclusion of patent ineligibility for isolated DNA is thus irreconcilable with the legal analysis leading to the conclusion of patent eligibility for cDNA. Whereas the former looks to the information encoded in the DNA molecule, the latter looks at its chemical structure. No explanation is given as to why such different approaches are appropriate.

The concluding section of the opinion makes the matter even more opaque. There, Justice Thomas states that the methods used by Myriad to find and isolate BRCA1 and BRCA2 genes "were well understood, widely used, and fairly uniform insofar as any scientist engaged in the search for a gene would likely have utilized a similar approach."[32] But it's unclear why this is legally significant. Methods for creating cDNA are also "well understood, widely used, and fairly uniform." But it has long been the law that the method of arriving at an invention isn't relevant to the inquiry of whether the invention is novel or patent-eligible. The inclusion of this phrase only adds confusion to the requirements for patent eligibility going forward. Will the courts below now be required not only to identify the amount of difference between a lab-created product and naturally occurring substances, but also to determine whether "enough effort" went into creating these differences? If so, how much effort will be "enough"? It remains to be seen how the Federal Circuit and district courts apply this decision to new facts, but the creation of these problems was entirely unnecessary.

The reason for this confusion is the Court's accepting the erroneous argument that DNA is somehow unique with respect to its information-carrying function and capacity. In fact, there's nothing particularly unique about DNA. It's true that DNA carries information that the cellular mechanisms then use to make RNA and proteins. But the same can be said about a number of other molecules. For example, a number of molecules work by binding to cellular proteins on the outside of the cell, which results in a chain reaction inside the cell leading to very particular outcomes. Such molecules could be easily described as "information-carrying" because they carry instructions for the cell to act a certain way at a certain time. Other proteins bind

[31] *Id.* at 2119.

[32] *Id.* at 2120.

to DNA itself in order to activate or deactivate certain genes. This process too could be described as "information-carrying" because only as a result of such binding do cellular mechanisms know when to express a particular gene and when to leave it quiescent.

Much medical research is centered on intervening in these processes to modify the expression of certain deleterious genes or to enhance the expression of beneficial genes. Laboratory-designed molecules must have the same "informational" capacity as naturally occurring molecules to work. Consider laboratory-made insulin. Most of it is either identical or nearly identical to naturally occurring insulin,[33] and for good reason. If the laboratory-designed molecule were different, it wouldn't be insulin at all, and could not treat diabetes. This similarity to the naturally occurring product is to be celebrated and rewarded rather than held as the basis for patent ineligibility. If the identity of informational function were to serve as a bar to patent eligibility, such research will grind to a halt.

The Supreme Court should instead have focused on the fact that isolated DNA and cDNA are merely research, diagnostic, and treatment tools in much the same way as various dyes that are used to stain biopsies or centrifuges that are used to separate blood products. There is little doubt that dyes, centrifuges, pipettes, and the like are all patent-eligible subject matter. The fact that new tools are biological rather than mechanical should not change the analysis. Yet this fact was lost on the Supreme Court, the petitioners, the solicitor general, and even, in some respects, on Myriad itself. This misconception led to the illogical and disjointed opinion.

The Court's opinion, though problematic and at war with itself, was not a total loss. The Court did reject the more extreme version of the argument pressed by the petitioners and a number of amici, which urged the Court to declare all DNA to be patent-ineligible on the theory that the functionality of the invented product should decide its eligibility for a patent. Had the Court adopted that argument, it would have created significant problems for the biotechnology industry by essentially declaring that medical innovations that rely on biologic solutions (rather than traditional chemical pills) are beyond the reach of the Patent Act. The perverse result of such a decision

[33] See FDA, NovoLog Insulin Aspart Label (2013), available at http://www.accessdata.fda.gov/drugsatfda_docs/label/2005/020986s033lbl.pdf.

would have been to incentivize less desirable forms of medical treatments while disincentivizing the more desirable kind. Luckily, the Court did not go that far, leaving plenty of room for innovation and patent protection in biotechnology and biopharmaceuticals.

But the Court's opinion does sow confusion where none was necessary, especially in light of the previous term's extraordinarily broad anti-patent opinion in *Mayo*. But given the choice between confusion remediable in lower courts by careful application of *Myriad* to new facts and complete prohibition on patenting the fruits of genetic research, the former is clearly better.

IV. Conclusion

This past term, the Supreme Court faced a number of complicated patent questions. Given the Court's recent performance on patent law, the industry had much to be concerned about. The Court seemed poised to: (1) expand the patent exhaustion doctrine significantly, giving a new and broad shield to infringers; (2) limit the scope of patent eligibility, potentially taking an entire industry outside the ambit of patent protection; and (3) restrict the ability of patentees to enforce their patents not only through litigation, but also through settlement.[34] At the end of the term, however, each industry could breathe a little easier. Though the Court did manage to make the law a little less patentee-friendly, and did create confusion where none was necessary, the outcome was far from the worst-case scenario. That's not to say that patentees can fully relax because it remains to be seen how lower courts and eventually the Supreme Court answer the questions left open and resolve the confusion stemming from this term's decisions. But at least patentees will live to fight another day—an outcome that was not a given when these cases were set for argument. In short, for patentees, the Supreme Court's October Term 2012 can best be characterized by an old Jewish saying: "It could've been worse."

[34] See Actavis, *supra* note 7. In that case, the Supreme Court did not adopt a bright line, per se rule that under antitrust laws, patentees cannot enter certain types of settlement agreements with patent challengers. Instead, the Court settled on a "rule of reason" analysis that, though more restrictive than the current practice, continues to allow the patentees to protect their patents through settlement agreements. Nonetheless, the Court's decision sowed much confusion about how to actually apply this new rule. In that sense, *Actavis*'s incremental approach is similar to the one taken in *Bowman* and *Myriad*.