

# Attorneys React To High Court's Gene Patent Ruling

Law360, New York (June 13, 2013, 11:04 PM ET) -- The U.S. Supreme Court ruled unanimously Thursday that human genes cannot be patented, striking down Myriad Genetics Inc.'s patents on isolated DNA associated with an increased risk of breast cancer. Here, attorneys tell Law360 why the unanimous ruling is significant.

## **Bruce Abramson, Rimon PC**

"While it does not comport to my understanding of the facts, it nevertheless represents proper judicial reasoning. I was heartened to see that the court did not delve into the public policy debates about either the exclusive ownership of therapeutic treatments or industry expectations. These are important issues, but they are not the purview of the courts. As in all such rulings, I expect this one to help patients who need genetic therapies that already exist, while slowing investment in the emergence of new genetic therapies. The proper place to debate that balance is in Congress — which can, if it wishes, override the Supreme Court on this question. In the final analysis — and in my opinion — the court got the facts wrong but the law right. Justice Thomas presented a restrained opinion that is likely to effect the future of genetic research, treatment and commercialization, but will have few ripple effects in the law."

## **Meredith Martin Addy, Steptoe & Johnson LLP**

"Not surprisingly, as often happens at the Supreme Court, the Myriad ruling strikes a balance. Myriad's [composite] DNA was held to be patentable, but its claims to isolating DNA sequences were not. At least biotechnology innovators now have some guidance about what will fly. Myriad's stock price seems to reflect shareholders' conviction that the company's BRCA analysis patents maintain significant value. And industrywide, the ruling shouldn't do too much to inhibit innovation, because smart patent attorneys already draft claims that will withstand Myriad-type scrutiny. Today, however, the court addressed outside concerns that we should not patent ourselves."

## **Cindy Ahn, Global IP Law Group**

"While the Myriad Supreme Court decision is receiving lots of attention as a landmark decision, I think that in actuality, this is a case of 'the king is dead; long live the king.' The preservation of cDNA's status as patent-eligible subject matter effectively negates the ruling on DNA. Substantively, claiming cDNA is basically the same as claiming DNA. And as cDNA is the workhorse in molecular diagnostics, biotech companies being forced to claim cDNA rather than DNA seems rather an exercise in draftsmanship and shouldn't put a noticeable ding in their ability to protect their [research and development] investments."

## **Isaac S. Ashkenazi, Paul Hastings LLP**

"The Supreme Court has reaffirmed the import of the 'law of nature' exception to patent law and found that isolated human genes are not patent eligible. But the extent to which this decision will have any practical effect on the biotechnology industry remains to be seen. This is especially true because the court also held that extraction processes, cDNA, and methods of treatment and use of DNA can be patent eligible. As a result, if the lower courts stay true to the holding of Myriad, the biotechnology industry should still be able to craft patents to protect biotechnological innovations."

**William Atkins, Pillsbury Winthrop Shaw Pittman LLP**

"No surprise in this decision, but trade secrets are even more important now. That will inhibit R&D, unfortunately. Justice [Clarence] Thomas' last section is very clear in narrowing the scope of this decision."

**Elizabeth Barnhard, Leason Ellis LLP**

"Licensors of patents claiming isolated DNA segments can expect their royalty income to rapidly disappear when their licensees terminate these licenses because of the Supreme Court's decision in Association for Molecular Pathology v. Myriad Genetics that isolated DNA segments are not patentable. For the biotechnology industry, the Supreme Court's clear limitation of its decision to isolated DNA segments and its holding that cDNAs are patent eligible means that there are still has many areas of research and development involving DNA that can lead to patentable new products and technologies."

**Michael J. Belliveau, Clark & Elbing LLP**

"The court's decision is not surprising. Most followers of this case expected a ruling in which cDNA was found patent eligible and naturally occurring DNA was not. The ruling will certainly impact a large number of issued patents. In particular, claims that encompass both cDNA and naturally occurring DNA are most vulnerable, as claims that are so broad to capture patent-ineligible subject matter are likely invalid even though they also cover patent-eligible cDNA."

**Erik Paul Belt, McCarter & English LLP**

"Today's Supreme Court decision is unfortunate in that it misunderstands the science underlying Myriad's patents. The decision also could weaken patent rights, at least in the biotech sphere, which is exactly the opposite of what this country needs to compete in the global economy. Strong patent rights correlate strongly with innovation. The court should look for ways to strengthen patents, and thus innovation, not to weaken them. The saving grace here for the biotech community is that the court held that cDNA inventions are patentable. This will help direct inventors and patent attorneys on how to patent biotech inventions in the future."

**Jeannie Boettler and Steve Kazmierski, Armstrong Teasdale LLP**

"It appears the court dictates not taking an overly broad interpretation of the exclusionary principle as such an interpretation could eviscerate patent law. It is clear that composition claims must focus on more than the genetic information encoded by the isolated DNA. Thus, the court hinted at potential ways to claim isolated DNA, such as by claiming the DNA in terms of its chemical composition — that is, by expressly relying on the chemical changes that result from the isolation of a particular section of DNA. Further, applicants appear to be able to obtain exclusive rights to methods for isolating the DNA and to new applications of knowledge gleaned from the information obtained from the genetic sequences."

**Courtenay Brinckerhoff, Foley & Lardner LLP**

"The decision is likely to have the greatest impact on diagnostic/genetic screening patents similar to those at issue in Myriad, but the ruling will impact the patent-eligibility of other newly discovered compounds that are 'isolated' from nature, such as medicinal compounds isolated from plants, beneficial proteins isolated from human or animal sources, and beneficial microorganisms isolated from soil or the deep sea. Further, while the Supreme Court leaves open the possibility of obtaining patents directed to 'new applications' of 'discoveries' like the BRCA1 and BRCA2 mutations, the patent-eligibility of diagnostic methods is limited by its decision in Mayo v. Prometheus."

**Jennifer Camacho, Greenberg Traurig LLP**

"The court has drawn the line between discovery and invention when it comes to the patenting of genes, and effectively raised the bar for genetic inventions. A newly discovered gene is simply not an invention that is eligible for patenting. However, the knowledge gained by the new discovery may give rise to novel methods or compositions of matter that are eligible for patenting. Put otherwise, it is not the gene itself, but what you do with the gene that matters in the patent world."

**Robin A. Chadwick, Schwegman Lundberg & Woessner**

"The problem is with the scope of the Supreme Court decision: If DNA is ineligible for patenting because it is a 'product of nature,' what other natural products will also be ineligible? Certain products like penicillin, vaccines, antibodies and proteins like erythropoietin are all products of natural processes that are currently patented and marketed as highly useful therapeutic products. Who will pay the billion-dollar costs of proving the efficacy and safety of these products if there is no way to recoup on these expenses? If no one will do so, we are left with only unnatural products as therapeutics — is this good social policy?"

**Randolph V. Clower, Phillips Lytle LLP**

"Of biotechnologies most likely to enjoy market success, a large percentage disproportionately emanate from university research and their cognate spinoffs. The monetary fragility of these embryonic-stage companies imparts the categorical need for patent protection, i.e., to attract investors. As such, the holding in Myriad, however narrow, will indeed impact the biotech industry if for no other reason than the inevitability of waning investor confidence. Going forward, moreover, biotechnologies relating to stem cells, gene therapy and personalized medicine will be confronted with uncertainties ascribed to the ensuing litigation over 'intragenic cDNA' — a non sequitur in the scientific community."

**Gary D. Colby, Shawn Li and Philip Foret, Dilworth Paxson LLP**

"The courts unwisely focused on patent eligibility. Here, the Supreme Court held that 'a naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated.' It thus appears that every U.S. patent for a chemical or composition that occurs anywhere in nature is invalid, even if (like Myriad's DNA) it existed only a subpart of a larger chemical or a complex mixture, regardless of whether its existence was known or its production or isolation possible. Focusing instead on whether Myriad adequately described the claimed DNA would have more specifically limited Myriad to its actual invention."

**Kendrew H. Colton, Fitch Even Tabin & Flannery LLP**

"The Supreme Court's twin rulings were pretty much expected based on what the current administration proposed in its amicus brief. Meanwhile, the court noted Myriad's patent claims to methods for applying the isolated DNA were left unchallenged. How much modification to DNA beyond isolating will be required? Since the devil is in the details, those seeking patent protection to modified DNA may encounter fresh disputes over written description. It remains to be seen whether the court's reasoning about 'isolated' DNA being patent ineligible will affect patentability for non-DNA products, intermediates in a synthesis, antigens or vaccines."

**John W. Cox, Alston & Bird LLP**

"Justice Scalia admits an inability to understand the technical details at issue. The patent bar and the general public should be alarmed by the fact that the judiciary is admittedly poorly versed in these arts. Because they impact what medical treatments are available and will become available, the judiciary must understand them before it decides whether particular claims satisfy [Section] 101. Litigants must continue to educate the courts on

these arts. But as Justice Scalia admitted, he could not affirm the details of the molecular biology at issue despite studying the opinions below and expert briefs presented. Sound the alarm."

**John DiMatteo, Willkie Farr & Gallagher LLP**

"The decision by the Supreme Court, which 'splits the baby,' is great news for the general public and good news for the biotechnology industry. For the public, DNA testing will become more widely available at a lower cost along with related technology involving basic DNA sequences. For the biotech industry, they now have clear guidance on the patentability of cDNA and related technology. True innovation will be rewarded and the industry will thrive with decent patent protection for the future."

**Matthew J. Dowd, Wiley Rein LLP**

"The court's decision today presents a clear affirmation of Dr. [James] Watson's long-held view that human genes should not be patented. As the former head of the Human Genome Project, Dr. Watson argued that human genes should not be patented. He spoke out against the patenting of human genes over 20 years ago. Now, 60 years after the discovery of the double helix and 10 years after completion of the Human Genome Project, it is wonderful to see the Supreme Court confirm that human genes belong in the public domain."

**John Dragseth, Fish & Richardson PC**

"What we learned today is that gDNA is not patent eligible, cDNA is and other forms of altered DNA probably are. In short, 'slice' is not patentable, but 'slice and dice' is. Beyond that, we have to go back to the decisions in Mayo and CLS Bank to figure out what to do next — though companies with DNA patents should probably at least study narrowing reissue as an option for some of their cases. We are seeing here the very edge of the judiciary's ability to handle issues that are enormously complex legally and technologically — and Justice Scalia thinks dicta from the majority went over that edge."

**Robert Fischer, Fitzpatrick Cella Harper & Scinto**

"The Supreme Court's decision, holding that naturally occurring DNA segment is not patent eligible, but that cDNA may be patent eligible, largely was no surprise in view of the questioning during oral argument. It is interesting to note that the court did not accord deference to the [U.S. Patent and Trade Office's] past practice of awarding patent protection to isolated DNA, finding no congressional endorsement of the practice and noting that concerns about reliance interests of patent holders are better directed to Congress, not the courts."

**Grant Foster, Holland & Hart LLP**

"The court drew a bright line and declared that isolated DNA is not patentable subject matter. The court focused on information provided by isolated DNA, finding that it should be available for all to use. It specifically stated, however, that methods of isolating DNA, new applications of isolated DNA and changes made to isolated DNA remain patentable subject matter. Thus, Myriad can continue to innovate for the benefit of human kind. At the same time, this is a victory for cancer patients and other biotechnology companies who can also innovate based on the isolated DNA."

**Jennifer Fox, Brinks Hofer Gilson & Lione**

"The true effects of the decision are yet to be seen. SCOTUS had to oversimplify the science to arrive at its bright line between patent-ineligible 'natural' DNA and patent-eligible 'synthetic' DNA. As a former scientist, I believe this oversimplification could cast a broader net on nature than intended. As science advances, it is increasingly difficult to determine where natural existence ends and synthetic life begins."

**Bill Gaede, McDermott Will & Emery LLP**

"To some extent, while the issue is of great concern to those involved, these types of isolated DNA sequence patent claims are increasingly difficult to obtain. The Myriad patents stem from work performed in the early 1990s and would have expired in 2015. Today, such techniques are standard and the publication of information from the innumerable human genome sequencing projects have placed much of this information in the prior art. In our practice, we do not see today parties attempting to patent isolated DNA sequences given the large body of prior art. Many of these patents that claim isolated DNA are old and have either expired or would expire shortly. So, from this perspective, the decision's impact is somewhat muted."

**Cathleen Garrigan, Farella Braun & Martel LLP**

"Though patent claims to cDNA sequences may be secure from a [Section] 101 challenge under Myriad, it is unclear what practical impact this will achieve as competitors can develop methods and tests that do not use a cDNA intermediate. The key to patent protection may lie, as the court suggests, in what the opinion does not address: manipulation of genes and applications of knowledge about genes."

**Richard Gilly, Akerman Senterfitt LLP**

"The Supreme Court's decision in Myriad is likely to lower some medical research costs for life science companies, while still affording such companies patent protection needed to justify investments in such research. As such, many medical professionals and researchers view the court's ruling that isolated genes are unpatentable as positive. They can now generally isolate genes, study their effects and detect harmful genes in the human body without the same concerns over infringing patents as before. On the other hand, various claims of the Myriad patents at issue, including certain method claims related to the breast cancer genes, remain patentable despite the court's decision, as were cDNA compositions necessary to create tests and therapies that fight a gene's harmful effects. Thus, the court's ruling lowers research costs while preserving incentives for investment into research for gene therapy."

**Jorge A. Goldstein, Sterne Kessler Goldstein & Fox**

"The interesting question is how [this will] affect ancillary industries, such as those in natural antibiotics or nanotech, both of which rely on patenting natural products. These products are isolated from nature, and their eligibility is now in question. The court said nothing about precedents such as Parke Davis that upheld, 100 years ago, the eligibility of purified adrenaline as a composition of matter. The Myriad case today did not deal with 'purified' genes, only 'isolated' genes. This is critical in that the parties stipulated that isolated did not mean purified. So, there is still hope that if interpreted properly, today's decision will not preclude the eligibility of purified natural materials, such as purified antibiotics or purified nanotubes. [It] remains to be seen and I think that after today it will be an uphill struggle."

**Michael A. Gollin, Venable LLP**

"Patentability of natural products has waxed and waned over the decades, and biotechnology patent attorneys learn to be adept at adapting to changing standards. Patent owners should now re-evaluate their portfolios, looking for chemical and biological distinctions from native DNA. Licensees may consider whether to continue licensing patent claims that are now invalid in view of the Myriad decision. Competitors may enter markets where patent protection has been lost. It will be harder to attract investors to support genomic research."

**Jennifer Gordon, Baker Botts LLP**

"For intellectual property cases in general, the Myriad case reinforces the reality that 35 U.S.C. 101 has become a potent weapon with which to challenge patents. For the biotechnology industry, the impact of the case might be quite significant, but we won't know how significant for some time. At a minimum, the industry faces some immediate losses of patent rights. Beyond that, the industry faces the uncertainty of how far the reasoning in this decision will be extended, what the combined effects of Myriad and Mayo may be, and, consequently, what other biologically based inventions are now potentially at risk."

**Lisa A. Haile, DLA Piper**

"The decision did not come as a surprise. The Supreme Court both took away and left certain subject matter intact. Full genes, including coding and noncoding regions as they occur naturally, are no longer patentable merely by snipping them from the genome. However, manipulating the gene in the lab (e.g., cDNA less introns) is patentable. Most patentees with gene patents have claims that include cDNA, so those patent claims remain valid. Science has come a long way and we know most diseases and therefore therapies are based on much more than just gene sequences, so while the decision will impact certain gene-based diagnostics directly, the biotech industry will not likely be significantly altered. Synthetic DNA (e.g., Craig Venter) and our understanding of genetic disease have come a long way since the BRCA genes were patented."

**Brenda Herschbach Jarrell, Choate Hall & Stewart LLP**

"In Myriad, the Supreme Court attempted to answer the important question of what scope of patent protection for nucleic acids would provide the right incentive level to encourage investment in diagnostic tests without allowing companies to control a swath of biology. Unfortunately, the court's decision to draw a line between what it calls 'isolated' DNA versus 'synthetic' DNA doesn't make technological sense. This just increases uncertainty and reduces the probability of achieving the right balance of incentives. Moreover, the decision leaves open critical related questions about patentability of other naturally occurring agents, including proteins and even small-molecule drugs."

**Bryan Jones, Baker Donelson Bearman Caldwell & Berkowitz PC**

"Given the new [America Invents Act] patent law that just went into effect and now with this decision, it will make for an interesting landscape in the next few years in this arena as stakeholders maneuver through the recent developments."

**Jeremy Kapteyn, Snell & Wilmer LLP**

"The Supreme Court's decision in Myriad demonstrates the court's continued willingness to shape patent law — notwithstanding well-established Federal Circuit and Patent Office principles — here finding isolated genes unpatentable. As also evidenced in the Prometheus decision, the court clearly wants to prevent patents from extending rights too far beyond the invention that gave rise to the patent, and this decision, to some extent, accomplishes that. The impact of the decision will remain to be seen: Will it adversely affect the bio industry? Or will it provide certainty necessary to foster growth and competition in genetic testing and personalized medicine? Time will tell."

**Theresa Kavanaugh, Goodwin Procter LLP**

"The court's ruling today indicated that, while isolated DNA alone is a 'product of nature' and not patentable, nonnaturally occurring cDNA remains patentable subject matter. While this holding will affect the many issued patents with claims to isolated DNA, this decision will likely have minimal impact for companies developing new chemical therapeutics or chemically modified biologics. However, the ruling highlights the importance of pursuing method-of-use claims. Companies developing diagnostics or therapeutics based on purified

natural materials such as purified proteins may well need to consider including method-of-use claims as part of their patent portfolio strategy."

**Eric King, Miles & Stockbridge PC**

"The court's decision is a step forward in the difficult task of delineating meaningful boundaries of Section 101. However, its applicability to process-related conundrums of Section 101 is limited, because, and as the court noted, this case does not involve method claims. Notwithstanding, it is notable that much of the court's opinion is devoted to an analysis of the informational aspects of Myriad's claims. In particular, the court appears to have grounded its determination of patentability on whether or not the claims encompassed information that exists in a state of nature, on one hand (in the case of isolated DNA), versus synthetic cDNA, which involved some human transformation of otherwise naturally occurring information."

**Chad Landmon, Axinn Veltrop & Harkrider LLP**

"It's a very interesting decision in both what it says and what it doesn't say. The decision will have an immediate impact on the biotechnology industry, both impacting patents that are already out there and pending patent applications. The opinion also leaves unresolved the question of whether short strands of cDNA are patentable, given that a short strand of cDNA could potentially be indistinguishable from naturally occurring DNA."

**Joe Liebeschuetz, Alston & Bird LLP**

"Despite the invalidation of analogous claims in [3,000] patents implied by the decision, the positive reaction of the stock market shows relief that the decision did not go even further in reshaping the contours of patentable subject matter. Isolated DNA now lies outside the bounds of patentable subject matter in the United States, but cDNA and presumably other manipulated forms of DNA or other biomolecules can still be patented by appropriately drafted claims going forward."

**John D. Lopinski, Hodgson Russ LLP**

"The decision includes an astonishingly incorrect interpretation of patent law. It says, 'Myriad's patents would, if valid, give it the exclusive right to isolate an individual's BRCA1 and BRCA2 genes.'" However, even the most junior patent attorneys know that a patent does not give its owner any affirmative right, other than those specified in 35 U.S.C. Section 154, which is the right to exclude others, not the right to do it yourself. I suggest not asking any of the justices for a freedom-to-operate opinion related to the invention covered by a patent you own, unless it is for a patent with claims only to isolated, naturally occurring DNA segments, in which case you can now predict the answer."

**Ralph Loren, Edwards Wildman Palmer LLP**

"The decision in the Myriad case dashed the hopes of some of the biotech industry, although it was not a complete loss for Myriad. The court gave short shrift to the argument that the U.S. Patent Office has been granting patents on isolated DNA for a long time and this should be given deference, holding that it is up to Congress to change the law. All those who obtained patents for isolated DNA should review their portfolios in light of this decision to determine how it affects them."

**Alice O. Martin, Barnes & Thornburg LLP**

"The Myriad decision was based on the court's interpretation that isolated DNA is a 'product of nature.' The Supremes carved out some wiggle room for patent eligibility: cDNA, methods of use of DNA, DNA in which the coding sequence is altered by man. Researchers and practitioners will have to examine their inventions to see at what stage they might be patentable, and how they should be claimed."

**Susan McBee, Baker Donelson Bearman Caldwell & Berkowitz PC**

"The decision will be considered as a blow to smaller startup companies in which the identification of genes, albeit in isolated form and not existing as in nature, was their primary business plan. Small companies will need to find a way to work around the decision to keep their doors open. The next recourse for these companies may be to go to Congress."

**Matthew McFarlane, Robins Kaplan Miller & Ciresi LLP**

"The court's categorical exclusion of naturally occurring DNA sequences from patent-eligible subject matter raises key questions about which applications will add enough to those natural products to justify patent protection. The court has once before limited suitable applications in *Mayo v. Prometheus*, holding that natural correlations relating to function are insufficient. Further activity in the lower courts will clarify the potential breadth of *Mayo* and now *Myriad*. But certainly moving forward, claims covering an invention involving a particular DNA sequence are of questionable validity if that sequence might be found in any organism."

**Thomas C. Meyers, Brown Rudnick LLP**

"The *Myriad* decision appears to be consistent with prior decisions regarding patent-eligible subject matter. The court's decision will free many molecular diagnostics innovators from concern over infringing 'isolated gene' patents. As a result, the window for diagnostic arrays and similar technologies that make use of genetic mutations is open a little wider, and we should expect to see more robust product offerings in the tools and diagnostic methods spaces. As I mentioned last year, the focus has been, and still is, on quality patent claim drafting. The *Myriad* decision highlights the importance of good claim drafting and the distinction between claiming 'a technology' and using patent claims to create commercial barriers to entry."

**Charles E. Miller, Sills Cummis & Gross PC**

"The decision will have wide repercussions in the law of patents on chemical compositions, most notably those involving polymers in general (of which DNA and cDNA are but examples in the life sciences area), purified natural products, and small-molecule pharmaceutical compositions featuring optical isomers as isolated components of racemic mixtures. As such, the decision is a 'black swan,' i.e., a startling event, of major unforeseen consequences, and which commentators will seek to rationalize in hindsight. The court's refusal to characterize DNA segments obtained by the cleaving of chemical bonds to release these moieties as new chemical entities not found in the native state seems counterintuitive."

**Matt Moore, Latham & Watkins LLP**

"Based on its recent experiences with 101 cases, the court recognizes that there are many nuances with regard to defining patentable subject matter, and took the middle road. It held that certain naturally occurring DNA segments are not patent eligible, while others that have been altered are patent eligible. It was a pretty straightforward ruling, without much of the sweeping rhetoric that the court sometimes employs."

**Barbara Mullin, Akin Gump Strauss Hauer & Feld LLP**

"As the *Myriad* challengers advocated, this decision may ultimately reduce the cost of genetic testing available to determine if a patient is at heightened risk for certain devastating medical conditions. But, on the flip side, companies may be less willing to invest in the expensive research necessary to understand genetic information — research that might be used to develop important diagnostics and therapeutics — if the opportunity to



even recoup the prohibitive costs required for these is limited. Hopefully, the decision that cDNA is still patent eligible will be the balance that allows patient care to be advanced without thwarting research efforts."

**Dr. William D. Noonan, Klarquist Sparkman LLP**

"The Myriad decision moves United States patent protection for biological inventions more toward developing-world levels of patent eligibility. When combined with the Supreme Court's 2012 Prometheus decision about patent ineligibility of medical diagnostic claims, damage has been done to the American biotechnology industry and its competitiveness in world markets. Myriad's potential damage extends beyond DNA inventions to all types of medical breakthroughs based on products derived from nature. The Supreme Court has returned to the dark days of the 1960s, when the patent system was undermined by technophobic decisions that eventually led to the establishment of the Federal Circuit."

**Gerard P. Norton, Fox Rothschild LLP**

"The decision was a split-the-baby approach, so there was something for everyone. Although the Supreme Court held claims to naturally occurring DNA sequence patent ineligible subject matter, it noted that the decision does not involve method claims, patents on new applications of knowledge about BRCA1 and BRCA2 genes, or the patentability of DNA in which the order of the naturally occurring nucleotides has been altered. With this decision the biotech industry and patent practitioners now have a rule book in which to stake claims in patent-eligible subject matter. The word on Wall Street is that the Myriad case is viewed favorably by investors and, as Mark Twain once said, 'The reports of my death are greatly exaggerated.'"

**Kevin O'Connor, Neal Gerber & Eisenberg LLP**

"While this has been referred to as a gene patent case, the question involved isn't about genes inside any particular human being, but rather about synthetic molecules made in the laboratory for diagnostic purposes. The implications span the fields of pharmaceuticals, biotechnology, agriculture and others, and could have a wide-reaching impact on innovation. Also, concerns surround the impact on further development of diagnostics in the area of personalized medicine. These tests can help determine which drugs are right for a patient based on genetic makeup or because of response level or susceptibility to side effects. In the long run, this type of innovation produces a tremendous cost savings — not to mention a boost for patient safety — if we can identify which therapies will and won't work for a particular patient before beginning what may be an expensive — or even dangerous — therapy for that patient."

**Rahul Pathak, Squire Sanders**

"Today the U.S. Supreme Court corrected a long-standing oddity in patent law. The oddity can be traced back to Judge Learned Hand's opinion in the 1911 Parke-Davis adrenaline case, holding that an isolated product of nature was somehow different from the same product in its natural environment. Under today's Supreme Court holding, simply separating a natural product — such as a gene — from its surrounding natural environment does not create patentable subject matter. This provides some certainty to the life and health sciences industries. At the same time, the court's unanimous decision indicates that the incentive of patent protection remains available for new substances made by man, including those based on natural substances, as well as inventive methods of isolating and methods of using natural substances."

**Patrick L. Patras, Hinshaw & Culbertson LLP**

"The court's decision harkens back to Feist, where it similarly held that lots of hard work that generates a beneficial result to society does not necessarily justify intellectual property

protection. The court emphasizes that even 'groundbreaking' or 'brilliant' discovery is not sufficient alone to justify patent eligibility. If the biotechnology industry needs incentive to undertake such work, it will have to come from the patent reward available to those who find new applications of knowledge about the genes that they discover. This is consistent with the court's other recent Section 101 jurisprudence in that the court is pushing inventors to apply their discoveries rather than allowing them to preempt entire fields."

**T. Gregory Peterson and Nicholas J. Landau, Bradley Arant Boult Cummings LLP**

"The Supreme Court's Myriad decision invalidates thousands of patent claims to DNA isolated from natural organisms, when the DNA sequence occurs in nature. However, the court affirmed patentability of nucleic acid molecules, such as cDNA, if they contain nonnaturally occurring nucleic acid sequences. The opinion throws into doubt long-standing law regarding the patentability of other substances that are purified from natural sources. While Myriad will impact the biotechnology sector, especially in the area of genetic testing, the industry has decreased its reliance on pure gene patents over the last five to 10 years, lessening the impact across the industry as a whole."

**Edward Reines, Weil Gotshal & Manges LLP**

"The Supreme Court has finally found a claim to cover patentable subject matter — now that's newsworthy! This decision in Myriad was expected, and ruled that isolated natural DNA is not patentable subject matter, but cDNA is. The Myriad investors appear to believe that patent coverage of synthetic DNA is adequate to protect the franchise. However, with the question of software patentability still open, the court is not likely finished with its run of decisions in this important area."

**Charles Rothfeld, Mayer Brown LLP**

"Today's Myriad decision strongly reaffirmed the rule that naturally occurring substances and phenomena cannot be patented, holding that a company that identified and isolated specific genes — here, genes closely associated with breast and ovarian cancer — does not have the right to patent those genes. The immediate result is that testing for these genes (the test recently publicized by Angelina Jolie) will become much cheaper and more readily available; the broader result is that it will become much difficult for individual companies to claim a monopoly on biological and biotechnical products."

**Barbara R. Rudolph, Finnegan Henderson Farabow Garrett & Dunner LLP**

"Today, the Supreme Court held that claims to naturally occurring BRCA gene sequences are products of nature and therefore are not eligible for patent protection. The decision could have an immediate effect on existing patent portfolios of some biotech companies, particularly those in the fields of diagnostics and personalized medicine. It may cause biotech companies to re-evaluate their existing patent portfolios, and may presage a shift toward more reliance on trade secret protection for DNA-based inventions. The decision's long-term effect on biotech and medical research remains to be seen."

**Bhanu K. Sadasivan, McDermott Will & Emery LLP**

"[The] decision was not a surprise. But the court provided directions on subject matter that may be patentable. While isolated DNA (complete gene or gene portions found in primers and probes) may not be patentable, applications of the knowledge, such as its relevance in gene mutations (of use in diagnostic tests or personalized medicine), may be patentable subject matter."

**Ken Schuler, Latham & Watkins LLP**

"The court was careful to note what it was not deciding — method claims. While the ruling reinforces the law of nature restriction on patentability, it leaves open various pathways for

biotech companies, both in terms of methods of use and cDNA and, perhaps more generally, in applying the knowledge gained as a result of isolating particular genes."

**Stephanie Seidman and Karen Potter, McKenna Long & Aldridge LLP**

"The decision, while not unexpected, is disappointing in undermining years of precedent and patents upon which the biotechnology industry developed. Nevertheless, the decision appears to be somewhat limited in its holding in that cDNA remains patentable. It is clear from the decision that technology in this area remains patent eligible. The limited holding, however, may lead to uncertainties regarding the nature of patent-eligible subject matter in the biotechnology area."

**Matthew Siegal, Stroock & Stroock & Lavan LLP**

"The Supreme Court's forays into Section 101 are setting dangerous precedent with unintended consequences. How long before every defendant challenges every chemical/drug patent as a natural phenomenon? Atoms exist in nature. For example, iron is the isolation of elemental iron that exists in nature as iron ore. Drugs and chemicals are the rearrangement of pre-existing atoms found in nature before they were isolated and recombined. Even the cDNA upheld by the court existed in nature, but was first isolated from the DNA by the removal of the introns. Isolated genes are new, tremendously useful and if they truly existed in nature, it would not take millions of dollars of funding and the work of brilliant scientists to isolate them."

**Robin Silva, Morgan Lewis & Bockius LLP**

"The question before the court was 'is human DNA patentable?' The decision reads on all DNA, including plants, bacteria, viruses, etc. This means that there can be no protection for isolated genes from any organism. For example, HCV screening of blood is done in this country based on the rather phenomenal work of sequencing the entire HCV genome and then claiming portions of it to screen blood. Many of those patents are now gone."

**Stephen E. Stein, Thompson & Knight LLP**

"The case provides guidance as to what is likely to be patentable going forward. Hereafter the incentive to isolate a particular gene, on a stand-alone basis, may not make economic sense. But the creation of cDNA is endorsed as patentable generally and the decision intentionally sidesteps method claims or new applications of knowledge about specific genes, which by implication endorses their patentability as well. The likely result is that the [US]PTO will be seeing an increase in applications from biotech companies focused on methods, new applications and cDNA in connection with the isolation of specific genes."

**Jonathan Steinsapir, Kinsella Weitzman Iser Kump & Aldisert LLP**

"The most interesting thing about this decision is the brief concurrence of Justice [Antonin] Scalia. He states that he cannot join portions of the opinion discussing relatively basic principles of biology because they are beyond his 'knowledge or ... belief.' District judges deal with more complicated technology than what was involved here every day (without the benefit of amicus briefs from the finest lawyers and scholars in the world, moreover). What message does this send to district judges regarding the effort they should put into such cases? What message does this send to the public regarding the legitimacy of patent verdicts based on lay juries' decisions concerning such technology?"

**Tate Tischner and Edwin Merkel, LeClairRyan**

"One immediate and significant impact of the Myriad decision will be its effect on licensors of gene patents. Licensees of such patents may choose to avoid payment of royalties based on the invalidity of certain claims pursuant to Myriad. In these situations, patent holders should review affected patents in their portfolios to determine if corrections can and should

be made to bolster the patent-eligible subject matter of their claims. These corrections may be effected through the use of continuation and/or reissue applications."

**Estelle J. Tsevdos, Gibbons PC**

"A unanimous Supreme Court today held that claims to isolated DNA were unpatentable. The court did indicate that synthetic cDNA did constitute patentable subject matter. The practical ramifications of this decision are not yet clear. About 40,000 US patents claiming isolated DNA have been issued. Although the court limited its decision to the Myriad case, patents not only with isolated DNA claims, but also isolated proteins, may be attacked. The ramifications will become more evident in the coming years. The Chakrabarty decision 33 years ago encouraged investment in the nascent biotechnology industry. Now will the Myriad decision serve to discourage future investment?"

**Dr. Michael S. Tuscan, Cooley LLP**

"It's interesting how the court did this, as it's a fairly straightforward and purposefully narrow decision directed to the patentability of naturally occurring isolated and purified genomic DNA. While a fair number of existing patent claims are now likely invalid, many of these patents are at or near the end of their term. The decision is actually not too disruptive for the industry, as it leaves open many ways for companies to build patent exclusivity around manipulated nucleic acids, methods of using even naturally occurring nucleic acids, etc. Much of what this decision pertains to is research and discoveries that took place more than 10 years ago, not what is generally new to the life sciences industry in this day and age."

**Shashank Upadhye, Seyfarth Shaw LLP**

"Today's decision is a victory for both parties. Myriad, having lost its isolated DNA patents, maintained its patents on the cDNA. As cDNA is mostly used in the experimentation and testing, Myriad still has protection to cDNA. Myriad also has enforceable patents on its methods of screening for DNA, as the lower court upheld those patents, which [American Civil Liberties Union] did not appeal. In general now, it means isolated DNA is free to use and build upon, thereby allowing companies to make investments in other tests or diagnostics that avoid Myriad's screening patents, but allow others to compete."

**Mark E. Waddell, Loeb & Loeb LLP**

"The Supreme Court's decision in Myriad coincides with the USPTO's first decision resulting from a post-grant review under the America Invents Act. Both decisions are grounded in patent ineligibility under Section 101 of the U.S. Patent Statute. It appears likely that the Myriad decision, coupled with the [US]PTO's decision in the SAPmatter, will encourage the filing of post-grant proceedings on patents with claims directed to isolated naturally occurring DNA."

**William L. Warren, Sutherland Asbill & Brennan LLP**

"This decision most directly affects the burgeoning field of individualized health care. In the short term, the cost for determining the presence of the BRCA1/BRCA2 genetic mutation and other genetic diagnostic tests will be reduced as a result of increased competition. In the longer term, however, the Supreme Court's decision in Myriad has removed a significant incentive to identify and commercialize other diagnostic genetic markers, thereby impeding the development of individualized medicine, which could otherwise more dramatically reduce overall health care costs."

**Vernon Winters, Sidley Austin LLP**

"It's an important decision; that said, it's also important not to overlook its limits. The court went out of its way to emphasize that it was not offering opinions on whether method

claims for manipulating genes or DNA satisfy Section 101 or whether claims for new and specific applications for DNA sequences (as opposed to the isolated sequences themselves) satisfy Section 101. The latter exclusion is particularly important, because the work that biotechnology companies perform — and the patents that they try to obtain — is often directed to a specific application for the gene or DNA sequence in question.”

**Tim Worrall, Dorsey & Whitney LLP**

“The Supreme Court unanimously ruled today that isolated but otherwise unaltered DNA segments taken from the human genome are not eligible for patent protection (widely characterized as 'gene patents'). The decision is regarded as a victory for those who argued that such patents interfere with the practice of medicine and scientific research. The Supreme Court also ruled that cDNA, or DNA altered to include only those portions of DNA encoding a protein, is patent eligible. The decision could have long-term consequences on incentives for creating new medical diagnostics and personalized medicine.”

**Daniel W. Young, Wolf Greenfield & Sacks PC**

“The decision was significant, but it’s not a funeral for the entire diagnostics industry. There are many gene-related patents falling in a middle ground that wasn’t explicitly addressed by the decision, and the court left intact many of Myriad’s claims. The ruling may embolden companies to offer further genome sequencing or diagnostic tests because they may perceive a reduced risk of patent infringement. But the bottom line is [that] there likely will be more litigation to address unresolved issues, including those relating to other commercially relevant synthetic nucleic acids. Some companies may have patents reissued with narrower claims and some patents will be challenged through re-examination at the [US]PTO.”

**George Yu, Schiff Hardin LLP**

“Despite the relatively limited commercial impact of this decision, it is still an important decision philosophically as to the patentability of naturally occurring molecules. It is interesting to see how the court views this issue, specifically how it draws the line between cDNA and isolated DNA. The practical results of the decision are that (1) companies like Myriad marketing genetic diagnostics will seek other approaches to maintain exclusivity of their diagnostics and (2) the \$3,000 BRCA (a test for genetic susceptibility for breast cancer) test will likely be much less expensive.”

**Maria Laccotripe Zacharakis, McCarter & English LLP**

“I am optimistic that the biotechnology industry will continue to develop its life-saving diagnostic technology irrespective of this decision. The positive news is that the Supreme Court did not include in the ‘patent ineligible’ category the complementary DNA ... claims or claims directed to new methods applying the knowledge about the genes. This leaves the door open for diagnostics companies to pursue and successfully obtain patents covering their life-saving diagnostics technologies. How broad the scope of protection will be that is afforded by that ‘open door’ remains to be seen. The trick for patent practitioners is to draft diagnostic claims with language that satisfies both the requirements of the Prometheus decision and those of the USPTO’s guidelines published last summer. The remaining biotechnology industry (nondiagnostic industry) won’t be affected much by this decision.”

**Ari Zytcer, Vorys Sater Seymour and Pease LLP**

“The decision in Myriad reinforces the importance of a diversified, comprehensive approach to patent protection. The law is fluid; a narrowly focused approach to claiming inventive subject matter is insufficient. Applicants must draft patent applications with multiple claim types, such that written description is provided for all possible permutations of the inventive subject matter described therein.”

--Editing by Elizabeth Bowen