This issue of the Federal Circuit Review focuses on the categories of invention that are eligible for patent protection under 35 U.S.C. § 101. In particular, we will discuss the Supreme Court’s decision in Bilski v. Kappos, which addresses the patentability of business methods and other processes, as well as Patent Office guidelines and Federal Circuit decisions applying Bilski. In addition, we will address the Federal Circuit’s pending review of Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office (the “Myriad case”), which involves claims related to isolated DNA.

The U.S. Supreme Court issued its long-awaited decision in Bilski, which addressed the patentability of a process for hedging risk in commodities markets, in June 2010. The earlier en banc Federal Circuit decision had held that Bilski’s process was unpatentable because it failed the “machine-or-transformation test”—that is, the hedging process was not tied to a particular apparatus and did not transform a particular article into a different state or thing. The Federal Circuit also held that the machine-or-transformation test was the sole test for determining the patentability of a process.

The Supreme Court unanimously agreed that Bilski’s process was not patentable. The majority opinion held that (1) the machine-or-transformation test is not the sole test for determining the patentability of a process, (2) business methods are not categorically excluded from protection under the Patent Act, and (3) Bilski’s method is an unpatentable abstract idea. In a 5-4 split, however, four of the concurring justices in Bilski would have gone further and held that methods of doing business are never patentable.

The Supreme Court also granted certiorari on two other cases that addressed § 101 issues, which the Court then remanded to the Federal Circuit to reconsider in light of Bilski. The Federal Circuit has issued a decision in one of them, Prometheus Labs., Inc. v. Mayo Collaborative Servs. (the “Prometheus case”), upholding the validity of claimed methods of determining the optimal dosage of certain drugs to treat autoimmune diseases.

1 35 U.S.C. § 101 provides that “[w]hoever 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.”

Perhaps the potentially most significant pending matter involving § 101 is the Federal Circuit’s review of the Myriad case, in which the Southern District of New York held that two genes that may signal susceptibility to breast or ovarian cancer were unpatentable products of nature. Numerous amicus briefs have been filed on both sides of the issue, including a brief by the U.S. Department of Justice that opposes the patenting of isolated genomic material. Oral argument is scheduled for April 4, 2011, and the Solicitor General of the United States is planning to argue the government’s position.

THE SUPREME COURT’S BILSKI DECISION

Bilski sought patent protection for a method that explains how buyers and sellers of commodities in the energy market can hedge against the risk of price changes. Claim 1 describes a series of steps for hedging such risk, while claim 4 sets forth the hedging concept in a mathematical formula. Bilski v. Kappos, 130 S. Ct. 3218, 3223 (2010).

Justice Kennedy authored the majority opinion, which was joined in full by Justices Roberts, Thomas, and Alito, and joined in part by Justice Scalia.

The majority explained that the term “process” should be given its ordinary, contemporary, and common meaning, which does not require a process to be tied to a machine or to transform an article. Id. at 3226. The majority further explained that the Court has placed limits on the ordinary meaning of the categories of patentable subject matter only to provide exceptions for laws of nature, physical phenomena, and abstract ideas. Id. Although the machine-or-transformation test is a “useful and important clue” for determining whether a process is eligible for protection under § 101 of the Patent Act, the Court has never dictated that it is the only test to use. Id. at 3227.

In keeping with its focus on the broad, plain meaning of the term “process,” the majority also explained that business methods should not be categorically excluded from patent protection. Id. at 3228. Bilski’s claims were unpatentable because they covered an abstract idea, not because they covered a business method. Id. at 3229-30.

The majority’s holding focused on the Court’s prior decisions in Gottschalk v. Benson, 409 U.S. 63 (1972), Parker v. Flook, 437 U.S. 584 (1978), and Diamond v. Diehr, 450 U.S. 175 (1981). Those decisions held, respectively, that (1) a patent may not wholly preempt use of a mathematical formula; (2) conventional, insignificant post-solution applications of a mathematical formula do not make it eligible for patent protection; and (3) the application of a law of nature can be patented. Id. at 3230. Bilski’s claims were unpatentable because they would preempt use of the described hedging approach in all fields and “effectively grant a monopoly over an abstract idea.” Bilski, 130 S. Ct. at 3231.

Justice Stevens wrote a concurring opinion joined by Justices Ginsburg, Breyer, and Sotomayor. Those justices would have held that methods of doing business are altogether unpatentable. Id. at 3232 (Stevens, J., concurring). Justice Stevens based his opinion primarily on the centuries-long history of the
Patent Act and its predecessor laws in England, throughout which patents on methods of doing business were not allowed. See id. at 3239-50 (Stevens, J., concurring). As Justice Stevens explained, “[s]ince at least the days of Assyrian merchants, people have devised better and better ways to conduct business. Yet it appears that neither the Patent Clause, nor early patent law, nor the current § 101 contemplated or was publicly understood to mean that such innovations are patentable.” Id. at 3249-50.

Justice Breyer authored a succinct concurring opinion that was joined in part by Justice Scalia. He focused on the areas of agreement among the justices, noting particularly that (1) although the text of § 101 is broad, it is not without limits; (2) the machine-or-transformation test has been described as “the clue” to patentability and has repeatedly helped to identify patentable processes; (3) the machine-or-transformation test, however, has never been the sole test; and (4) the Federal Circuit’s former “useful, concrete, and tangible result” test, which the Federal Circuit overruled in its en banc Bilski decision, is not an appropriate test. See id. at 3258-59 (Breyer, J., concurring).

In its en banc decision, the Federal Circuit posited two important unanswered questions concerning application of the machine-or-transformation test. The Supreme Court did not provide guidance on those questions: (1) whether claims reciting generic computer hardware would satisfy the “particular machine or apparatus” prong of the machine-or-transformation test; and (2) whether transformations of electronic signals or electronically manipulated data would satisfy the “transformation” prong. In re Bilski, 545 F.3d 943, 961-62 (Fed. Cir. 2008). Those questions are likely to be key issues in the future for deciding cases involving the patentability of business methods.

**Cases Referenced:**
In re Bilski, 545 F.3d 943 (Fed. Cir. 2008).
Prometheus Labs., Inc. v. Mayo Collaborative Servs., 628 F.3d 1347 (Fed. Cir. 2010).

**Patent Office Guidelines For Evaluating Process Claims in Light Of Bilski**

The U.S. Patent and Trademark Office published an Interim Guidance in July 2010 for evaluating method claims for subject-matter eligibility under § 101 in light of Bilski. Interim Guidance for Determining Subject Matter Eligibility for Process Claims in View of Bilski v. Kappos, 75 Fed. Reg. 43922 (July 27, 2010).3 The Interim Guidance provides a nonexclusive list of factors for determining “whether the claimed invention, viewed as a whole, is disqualified as being a claim to an abstract idea.” Id. at 43925. Each relevant factor is to be considered, and no single factor is determinative. Id. at 43926.

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Factors weighing toward eligibility include the following:

1. The claim recites a particular machine or a particular transformation.
2. The machine implements the steps of the method.
3. An article undergoes a change in state or becomes a different thing (e.g., it acquires an objectively different function or use).
4. The article being transformed is an object or substance.
5. If the claim is directed to applying a law of nature, that application meaningfully limits the execution of the steps.
6. The claim is more than a mere statement of a concept and either describes a particular solution to a problem or implements the concept in some tangible way.

*Id.* at 43927. Factors that weigh against eligibility include the following:

1. The claim contains no recitation, or contains an insufficient recitation, of a machine or transformation.
2. The machine or transformation is only nominally, insignificantly, or tangentially related to performance of the steps of the method.
3. The machine is recited only generically or is merely an object on which the method operates.
4. The transformation involves only a change in position or location of an article.
5. The claim would monopolize a natural force, patent a scientific fact, or effectively grant a monopoly over a concept.

*Id.* Although it is no longer the exclusive test, the machine-or-transformation test continues to play a prominent role in the analysis. According to the Interim Guidance, a method is more likely patent eligible if (1) it is tied to a specifically identified machine or apparatus that implements a step of the method and (2) the machine or apparatus is integral to the method or imposes nontrivial limits on the method. *Id.* at 43925. Additionally, a method is more likely patentable if it involves the transformation of a particular object or substance into an object or substance with a different function or use. *Id.*

**FEDERAL CIRCUIT DECISIONS AFTER BILSKI**

Since 2010, the Federal Circuit has issued two substantive decisions applying or interpreting *Bilski*.

1. **Research Corp. Techs. v. Microsoft Corp.**
   First, in December 2010, the Federal Circuit decided *Research Corp. Techs. v. Microsoft Corp.*, 627 F.3d 859 (Fed. Cir. 2010), which addressed the patentability of a method and apparatus for “halftoning” digital images. Halftoning is a way of simulating a continuous color tone in an image through the use of
dots. *Id.* at 862-63. The Federal Circuit held that the process for rendering a halftone image was not an unpatentable abstract idea because “[t]he invention presents functional and palpable applications in the field of computer technology.” *Id.* at 868.

The court explained that the claims addressed a particular need in the art for a method of utilizing a digital data processor to accomplish halftone rendering in a “simple and precise manner.” *Id.* at 868-69. The court noted that such “inventions with specific applications or improvements to technologies in the marketplace are not likely to be so abstract that they override the statutory language and framework of the Patent Act.” *Id.* at 869. Although the claimed invention utilized algorithms and formulas, the patent holder did not seek to patent a mathematical formula in the abstract, but instead a particular process for halftoning images. *Id.* Thus, the claims covered eligible subject matter under § 101. *Id.*

2. THE PROMETHEUS CASE

Also in December 2010, the Federal Circuit addressed the patentability of medical treatment claims in *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, 628 F.3d 1347 (Fed. Cir. 2010). The Federal Circuit had originally decided the *Prometheus* case in 2009, but the Supreme Court granted certiorari, vacated that decision, and remanded the case to the Federal Circuit to reconsider its original decision in light of *Bilski*. See *Mayo Collaborative Servs. v. Prometheus Labs.*, Inc., 130 S. Ct. 3543 (2010).

The *Prometheus* case involves “methods for determining the optimal dosage of thiopurine drugs used to treat gastrointestinal and non-gastrointestinal autoimmune diseases.” *Prometheus*, 628 F.3d at 1349-50. The claims generally describe “administering” a drug that provides a particular metabolite to a subject and “determining” the levels of the drug’s metabolites in the subject. *Id.* at 1350. The measured metabolites are compared to predetermined levels “wherein” the metabolite levels “indicate a need” to increase or decrease the drug administered in order to maximize treatment efficacy or to minimize toxicity. *Id.*

Prometheus marketed a thiopurine metabolites test that utilized the technology of the patents-in-suit. *Id.* at 1351. Mayo had formerly purchased and used the Prometheus test, but then announced that it intended to use its own test, which measured the same metabolites but used different levels to determine toxicity. *Id.* The district court found that Mayo infringed, but that the patents were invalid because they impermissibly claimed natural phenomena — namely the correlations between thiopurine drug metabolite levels and efficacy and toxicity — and wholly preempted the use of those correlations. *Id.* at 1351-52.

The Federal Circuit (former Chief Judge Michel, Judge Lourie, and District Judge Clark) originally held that the claims were patentable under the machine-or-transformation test because the “administering” and “determining” steps were transformative, not merely data-gathering steps, and the steps did not wholly preempt use of the correlations between metabolite levels and efficacy or toxicity. *Id.* at 1352.

After remand from the Supreme Court, the Federal Circuit again held that the Prometheus claims recite statutory subject matter under § 101. (Opinion authored by Judge Lourie and joined by Chief Judge Rader and Judge Bryson.) The initial question addressed by the court was preemption: “[1] whether
Prometheus’s asserted claims are drawn to a natural phenomenon, the patenting of which would entirely preempt its use as in Benson or Flook, or [2] whether the claims are drawn only to a particular application of that phenomenon as in Diehr.” Id. at 1354.

The Federal Circuit explained that the claims do not preempt all uses of the correlations between metabolite levels and efficacy or toxicity because “the claims recite specific treatment steps, not just the correlations themselves.” Id. at 1355. The court explained its rationale as follows:

The inventive nature of the claimed methods stems not from preemption of all use of these natural processes, but from the application of a natural phenomenon in a series of steps comprising particular methods of treatment. Other drugs might be administered to optimize the therapeutic efficacy of the claimed treatment.

Id. (emphasis added).

Next, the court explained that the claimed methods satisfied the “transformation” prong of the machine-or-transformation test because they involved transformation of the “human body and of its components following the administration of a specific class of drugs and the various chemical and physical changes of the drugs’ metabolites that enable their concentrations to be determined.” Id. at 1355-56. The court emphasized that the “administering” and “determining” steps of the claims were not just data-gathering steps, but necessarily involve physical transformations. Id. at 1356-57. The administration of a drug to treat a subject involves a transformation of the subject. Id. at 1356.

In addition, determining the metabolite levels after administration necessarily involves some manipulation or transformation to extract the metabolites from the body and determine their concentration. Id. at 1357. The determining step was a “significant part of the claimed method” because it enabled the adjustment of the dose to increase efficacy or minimize toxicity. Id. As such, the clinical tests that were used to determine the metabolite levels were not merely insignificant post-solution activity. Id.

The Federal Circuit agreed with the district court, however, that the “wherein” clauses of the claims were mental steps that were not patentable alone. Id. at 1358. Nonetheless, the addition of mental steps did not detract from the transformative nature of the previous steps nor preclude the patentability of Prometheus’s claimed methods as a whole. Id.

In the end, the Federal Circuit asked, “What did the applicant invent?” The answer was “a series of transformative steps that optimizes efficiency and reduces toxicity of a method of treatment for particular diseases using particular drugs.” Id. at 1359.

The Federal Circuit has issued one other decision addressing Bilski, in which Judge Dyk, concurring-in-part and dissenting-in-part, discussed how the rationale of Bilski might apply to patents covering isolated DNA molecules. Judge Dyk’s opinion is discussed in the next section.
Cases Referenced:
Prometheus Labs., Inc. v. Mayo Collaborative Servs., 628 F.3d 1347 (Fed. Cir. 2010).
Research Corp. Techs. v. Microsoft Corp., 627 F.3d 859 (Fed. Cir. 2010).

THE FEDERAL CIRCUIT CONSIDERS THE PATENTABILITY OF ISOLATED DNA

1. THE MYRIAD CASE

In the Myriad case a group of medical research organizations, public interest organizations, individual doctors and researchers, and women diagnosed with breast or ovarian cancer seek to invalidate 15 claims in seven patents owned by Myriad Genetics, Inc. and the University of Utah Research Foundation relating to the human Breast Cancer Susceptibility Genes 1 and 2 (“BRCA1” and “BRCA2”). See Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office, 702 F. Supp. 2d 181, 184 (S.D.N.Y. 2010).

Myriad is the current exclusive licensee of the patents-in-suit and “is the sole provider of full sequencing of BRCA1 and BRCA2 genes in the United States on a commercial basis.” Id. at 189. According to the decision, Myriad charges over $3,000 per screening test. Id. at 203. The plaintiffs include women with no insurance or whose insurance is not accepted by Myriad and who claim they cannot afford to pay for the test. Id. at 204. The plaintiffs also include women who would prefer to have a different BRCA1 or BRCA2 screening test performed by someone other than Myriad or who have been tested by Myriad but would like to seek a second confirmatory test. Id. at 206-07.

The challenged claims relate to “(1) isolated DNA containing all or portions of the BRCA1 and BRCA2 gene sequence and (2) methods for ‘comparing’ or ‘analyzing’ BRCA1 and BRCA2 gene sequences to identify the presence of mutations correlating with a predisposition to breast or ovarian cancer.” Id. at 185. After an extensive review of the scientific, legal, and policy issues addressed by the parties, Judge Sweet of the Southern District of New York concluded that the challenged claims for isolated human genes and the comparison of their sequences were not patentable under § 101. Id.

Judge Sweet found that the composition claims, which cover isolated DNA molecules, were unpatentable because they were not “markedly different” from native DNA. Id. at 227. He explained that Supreme Court precedent establishes that “purification of a product of nature, without more, cannot transform it into patentable subject matter.” Id. at 227. Accordingly, he considered whether the isolated DNA claimed by Myriad was “markedly different” from native DNA. Id. at 227-28.

4 Plaintiffs, including the ACLU, also argued that Myriad’s patent claims violated the First Amendment of the U.S. Constitution because the patent claims “directly limit thought and knowledge, including the mental process of comparing sequences and the genetic information embodied by DNA.” See Brief for Plaintiffs [1] In Further Support of Plaintiffs’ Motion for Summary Judgment Against All Defendants and [2] In Opposition to the Myriad Defendants’ Motion for Summary Judgment and [3] In Opposition to Defendant United States Patent and Trademark Office’s Motion for Judgment on the Pleadings at 39, Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office, 702 F. Supp. 2d 181 (S.D.N.Y. 2010) [09 Civ. 4515], 2010 WL 1048410, available at http://www.aclu.org/free-speech-womens-rights/bra-memo-law-further-support-plaintiffs-msj-and-opposition-myriad-and-usp. Plaintiffs also argued that the patent claims violated Article I, Section 8, Clause 8 of the Constitution “because they impede rather than promote the progress of science.” Id. at 40-41. After finding that the plaintiffs had received adequate relief because the patents were invalid, the district court dismissed the constitutional claims against the Patent Office based on the doctrine of constitutional avoidance. Ass’n for Molecular Pathology, 702 F. Supp. 2d at 238. The constitutional claims were dismissed without prejudice and could possibly be reasserted if the patents are held valid on appeal.
Judge Sweet found that DNA has “unique qualities as a physical embodiment of information.” *Id.* at 229. The information contained in DNA is not just information about its own molecular structure, but information that is used for “directing the synthesis of other molecules in the body.” *Id.* at 228. “DNA, and in particular the ordering of its nucleotides, therefore serves as the physical embodiment of laws of nature — those that define the construction of the human body.” *Id.* Although isolated DNA can “target and interact with other DNA molecules” and thus “may be used in applications for which native DNA is unsuitable,” such as molecular diagnostic tests, the utility of isolated DNA derives from the fact that it carries the same information as native DNA (i.e., the same nucleotide sequence). *Id.* at 230-31 (internal quotation marks and citation omitted). Because both isolated and native DNA share the same “defining characteristic of DNA,” they are not markedly different and thus isolated DNA is an unpatentable product of nature. *Id.* at 229.

Next, Judge Sweet found that method claims for “analyzing” and “comparing” DNA sequences and determining whether mutations or differences exist were also invalid. *Id.* at 233. He explained that, unlike the “determining” step in the *Prometheus* case discussed above, the “analyzing” and “comparing” steps of the disputed claims were directed solely to abstract mental processes. *Id.* at 234 (discussing original Federal Circuit *Prometheus* decision).

Finally, Judge Sweet found that method claims for “‘comparing’ the growth rates of cells in the presence or absence of a potential cancer therapeutic” were invalid because they patented a basic scientific principle: “that a slower rate of cell growth in the presence of a compound indicates that the compound may be a cancer therapeutic.” *Id.* at 237. In addition, any additional transformative steps were merely “preparatory, data-gathering steps” that did not render the mental processes patentable. *Id.*

The *Myriad* case is currently on appeal to the Federal Circuit (No. 2010-1406), and oral argument is scheduled for April 4, 2011. Numerous amicus briefs have been filed, including a brief submitted by the U.S. Department of Justice that argues that (1) “engineered” DNA molecules are human-made inventions eligible for patent protection, whereas (2) isolated, unmodified DNA is not human-made and thus is not eligible for patent protection. *See* Brief for the United States as Amicus Curiae in Support of Neither Party at 14-36, *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, No. 2010-1406 (Fed. Cir. Oct. 29, 2010), 2010 WL 4853320, available at http://graphics8.nytimes.com/packages/pdf/business/genepatents-USamicusbrief.pdf. The brief did not address the “analyzing” and “comparing” claims.

The Department of Justice’s brief acknowledges that its position on the patent eligibility of isolated DNA “is contrary to the longstanding practice of the Patent and Trademark Office, as well as the practice of the National Institutes of Health and other government agencies that have in the past sought and obtained patents for isolated genomic DNA.” *Id.* at 18. According to correspondence sent to the Federal Circuit clerk on February 10, 2011, the U.S. Solicitor General is planning to present the government’s position at oral argument.5

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2. **Intervet Inc. v. Merial Ltd.**

In August 2010, the Federal Circuit addressed another case involving isolated DNA, *Intervet Inc. v. Merial Ltd.*, 617 F.3d 1282 (Fed. Cir. 2010). That case prefaces the types of patentability analysis that may be made in the appeal of the *Myriad* case.

The patent in *Intervet* relates to a disease that affects livestock pigs and has claims directed to DNA molecules that were isolated from pig kidney cells. *Intervet*, 617 F.3d at 1284-85, 1286. The panel decision by Judge Prost, joined by Judge Bryson, disagreed with the district court’s interpretation of certain claim terms and its application of the doctrine of prosecution history estoppel and remanded the case to the district court for an infringement analysis consistent with this opinion. *Id.* at 1292. It did not address validity under § 101.

Judge Dyk filed a concurring opinion, which clarified that the panel decision had not addressed whether the claims were directed to patentable subject matter. *Id.* (Dyk, J., concurring-in-part and dissenting-in-part). According to Judge Dyk, at least one of the claims “raises substantial issues of patentable subject matter,” because it was “not limited to the use of a particular isolated DNA molecule in a vaccine or other application” but rather was directed to an “isolated DNA molecule.” *Id.* (emphasis in original) (citation omitted).

Providing a glimpse of the issues that may arise in the *Myriad* case, Judge Dyk explained that gene patents raise serious questions of patentability, particularly in light of the Supreme Court’s *Bilski* decision, because they may “preempt the use by others of substances that should be freely available to the public.” *Id.* at 1294. Judge Dyk, relying on some of the same cases previously noted by the district court in the *Myriad* case, explained that for a product of nature to be patentable it must be “qualitatively different from the product occurring in nature, with markedly different characteristics from any found in nature.” *Id.* at 1294-95 (citation and internal quotation marks omitted).

Judge Dyk explained that the mere fact that DNA does not occur in isolated form in nature does not resolve the patentability issue, noting that “[i]t would be difficult to argue for instance, that one could patent the leaves of a plant merely because the leaves do not occur in nature in their isolated form.” *Id.* at 1295.

* * *

The *Myriad* case has the potential to be one of the most significant cases that addresses § 101 in the upcoming year, as it may affect a wide variety of private and public interests in the patent system.

Plaintiffs argued that gene patents have a “chilling effect . . . on the advancement of both genetic research and clinical testing.” *Ass’n for Molecular Pathology*, 702 F. Supp. 2d at 208. For example, two of the plaintiffs, Drs. Kazazian and Ganguly, designed BRCA1 and BRCA2 screening tests and “provided screening to approximately 500 women per year starting in 1996” but then stopped because of the *Myriad* patents. *Id.* at 187.
On the other hand, “Myriad and many of the amici suggest that the invalidation of the patents-in-suit will result in the decimation of the biotechnology industry.” Id. at 228 n.51. Various amici for defendants assert that “patent exclusivity is required for the development of personalized medicine.” Id. at 192. A survey of biotechnology companies in the therapeutic and diagnostic healthcare industry reported that 77% of respondents “expect to spend 5-15 years and over $100 million developing a commercial product.” Id. at 211. In addition, the case involves significant revenue for Myriad because, as the district court found, “[i]n 2008, the total cost to Myriad of providing these tests was $32 million with resulting revenues of $222 million.” Id. at 203.

Cases Referenced:
Intervet Inc. v. Merial Ltd., 617 F.3d 1282 (Fed. Cir. 2010).
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