

Bilski v. Kappos: the US Supreme Court broadens patent subject-matter eligibility

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The court narrowly ruled that business methods may be patent eligible, while striking down the primacy of its main test.

With over 60 biopharmaceutical products applied for or expected to be filed at the US Food and Drug Administration this year, joining over 335 currently approved biopharmaceuticals, determining what can or cannot be patented is a threshold question protecting inventions in biotech and pharmaceutical industry¹. Up until 2008, the answer to this important question was relatively clear. However, a 2008 decision that set a new single standard for patent eligibility made addressing this inquiry fundamentally uncertain.

In a landmark decision issued 28 June, the US Supreme Court issued its holding regarding patent-eligible subject matter in *Bilski v. Kappos*. The court unanimously agreed that Bilski's claims recited no more than "abstract ideas" and were therefore not patentable under US law. Importantly, a majority of the court held that the language of the relevant law (35 USC §§100–101) broadly encompassed vast forms of subject matter as patent eligible. The court unanimously struck down the 'machine-or-transformation' test¹, a test implemented by the US Court of Appeals for the Federal Circuit in 2008 that was criticized as "unnecessary," as the sole test for determining whether a process is directed to patentable subject matter and held that the machine-or-transformation test is one test among many that can be used to determine patent eligibility. Justice Kennedy delivered the court's opinion, with Justices Roberts, Thomas and Alito joining in full and Justice Scalia joining in part. Justice Stevens filed a concurring opinion in which Justices Ginsburg, Breyer and Sotomayor joined. Justice Breyer filed a concurring opinion in which Justice Scalia joined in part.

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The facts of *Bilski v. Kappos* did not involve biotech or pharmaceutical subject matter but rather a process for hedging risk in commodity markets (that is, an invention regarding instructing buyers and sellers of commodities in the energy market to protect against the risk of price fluctuations)². For example, the application recited a series of steps instructing how to hedge risk, and in another instance the application of risk hedging was described in the form of a mathematical formula. The US Patent and Trademark Office (USPTO) denied Bilski a patent because, according to the USPTO, the patent application was directed to business methods that were patent-ineligible subject matter. The USPTO reasoned that the invention was too abstract, that it merely manipulated an idea and that it failed to practically apply concepts enough to render them patentable. The administrative appeal board affirmed, concluding that the application involved only mental steps and did not result in the transformation of physical matter.

On appeal, the Federal Circuit, sitting *en banc*, did not rely on any of the several tests used by prior courts, including the Supreme Court, but instead created and applied a new legal standard for patentability: processes are patentable only if they are tied to a particular machine or apparatus, or transform a particular article into a different state or thing—namely, the machine-or-transformation test³. The Federal Circuit reasoned that because Bilski's claims did not satisfy the new governing test, which the court made clear should be grossly applied to all areas of technology, the USPTO's decision was correct and Bilski was not entitled to a patent.

Judge Rader, now the Chief Judge of the Federal Circuit, in dissent, indicated that the language of 35 USC §101 "contains no hint of an exclusion for certain types of methods" and stated that "ironically the Patent Act itself

specifically defines 'process' without any of these judicial innovations." Rader argued that the only limits on eligibility are inventions that embrace natural laws, natural phenomena and abstract ideas. He wrote, "this court today invents several circuitous and unnecessary tests." Even so, Rader suggested that the hedging claim on appeal was abstract, and he stated, "Bilski's method for hedging risk in commodities trading is either a vague economic concept or obvious on its face." Rader pointed out that US patent law was designed to encourage ingenuity and that the law is focused not on particular subject categories but on the patentability of the specific claimed invention. He maintained that the law distinguishes eligibility from conditions of patentability and generously provides for patent eligibility. His dissent was clear: the court should not create any categorical exclusion. Rader also pointed out that in *Diehr*⁴, the Supreme Court indicated that only natural laws, natural phenomena and abstract ideas are patent ineligible. He clarified, however, that if an abstract idea is applied to a practical use, it may be patent eligible. Notably, Rader commented that the earlier Supreme Court opinion of three dissenting justices in *Lab. Corp.*⁵ misapprehended the distinction between a natural phenomenon and a patentable process, and in so doing, this opinion did not ask the fundamental question of whether the subject matter at issue is deserving of patent protection. Rader was clear that courts should not avoid this fundamental inquiry nor categorically preclude any form of invention.

In response to the Federal Circuit's decision, Bilski petitioned for and obtained Supreme Court review. The *Bilski* decision garnered the attention of many, prompting an unprecedented number of submissions of unsolicited briefs expressing the views of nonparties. Among the 66 briefs, 13 were submitted by or on behalf of life science organizations, including biotech and

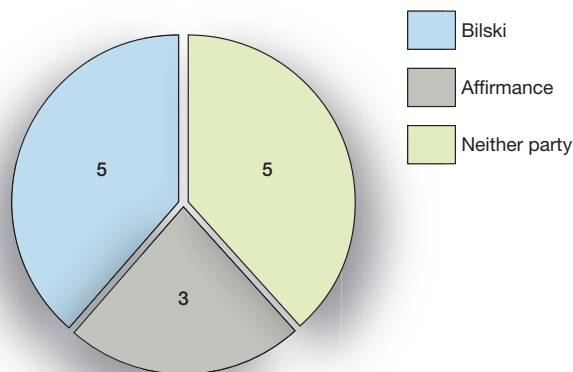


Figure 1 Number of amicus briefs from biotech and pharma sector vis-à-vis *Bilski v. Kappos*. Chart compares numbers of briefs arguing for a decision in favor of Bilski, for affirmance of the court’s decision against Bilski or for neither party.

pharmaceutical interests (**Fig. 1** and **Table 1**). Interestingly, there are differing opinions on the desired outcome of the case within the industry, including support for affirmance of the decision. However, among the 13 briefs submitted, only one brief appeared to support the machine-or-transformation test (with the caveat that the test be applied correctly; **Figs. 1** and **2**, and **Table 1**).

During the oral arguments heard at the Supreme Court in November 2009, several justices expressed their concerns that in the absence of unambiguous limitations regarding patent eligibility, the public could be harmed by the grant of patents to inventions directed to unworthy subject matter or commercially useful subject matter that might stifle business or innovation if granted a monopoly. The chief justice and several other justices appeared dissatisfied with the Federal Circuit’s machine-or-transformation test as the sole test for patent eligibility but seemed to be concerned to avoid expanding the scope of patent-eligible subject matter beyond that limited by the court’s precedent⁵. In defense of its decision, the USPTO argued that the *Bilski* process did not comply with the machine-or-transformation test, that the claimed process was a method of conducting business that was *per se* unpatentable and that the claimed process was no more than an abstract idea and therefore unworthy of a patent. The USPTO was clear about the devastating effects of banning entire categories of inventions from patenting and further asserted, “to say that business methods are categorically ineligible for patent protection would eliminate new machines, including programmed computers, that are useful because of their contributions to the operation of business.”

The Supreme Court’s decision was supported by all justices but the Court divided 5–4 in holding that under some undefined circumstances, at least some business methods may be patented. The Court did not clarify under which circumstance one could distinguish a patent-eligible business method from an unpatentable “abstract idea,” leaving this issue for the Federal Circuit to decide.

In reaching its decision, the court looked to the language of the law that describes four categories of patentable subject matter: processes, manufactures, machines and compositions of matter. A problem, however, arises in that the law sets forth a circular definition of ‘process’, making it difficult, at times, to determine whether a process meets the requirements of the statute. According to the court, the machine-or-transformation test, when applied as the sole test of determining a statutory process, violates proper statutory interpretation because “[t]he term ‘process’ means process, art or method, machine, manufacture, composition of matter or material” and the ordinary definition of process does not require that it be tied to a machine or transform an article.⁵ Joined by three other justices, Justice Kennedy explained that “[s]ection 101 is a dynamic provision designed to encompass new and unforeseen inventions” and that as new technologies evolve, the statute allows for the development and application of additional tests to assist in determining which processes are patent eligible.

Regarding the contention that business methods are *per se* unpatentable, the court rejected this argument. However, the court reasoned that, in view of specific on-point legislation—namely, 35 USC §273—which creates a defense to alleged infringement of a business method

claim, the legislature intended that claims directed to business methods can be patentable subject matter. Justice Kennedy reiterated that abstract ideas (which he did not define) are not patentable and that the court’s decisions regarding the unpatentability of abstract ideas were useful in determining which business methods may be protected under the patent law. The court held that *Bilski*’s claims were unpatentable because they were directed to “abstract ideas.” According to the court, *Bilski* sought a patent on “the use of the abstract idea of hedging risk in the energy market,” which was too abstract to be patent eligible. Even though the court rejected application of an exclusive machine-or-transformation test, the court was careful to point out that inventions should be considered as a whole, not analyzed by dissecting the claims into old and new elements. Although it rejected the machine-or-transformation sole standard, the court provided the Federal Circuit with great flexibility in developing and applying “other limiting criteria” useful for determining patent eligibility. This guidance by the court is important and when properly implemented will fundamentally impact method patenting in every act.

The court’s reasoning was grounded on precedent, such as that articulated in *Benson*⁷, *Flook*⁸ and *Diehr*⁵. The court held that the claims at issue were unpatentable because allowing *Bilski* “to patent risk hedging would pre-empt use of this approach in all fields, and would effectively grant a monopoly over an abstract idea.” The court did not formulate a new test but instead held “precedents establish that the machine-or-transformation test is a useful and important clue, an investigative tool” and nothing more. It is therefore clear that the machine-or-transformation test is a nonexclusive option for lower courts, in addition to the tests set forth in the court’s earlier decisions.

The guidance set forth in *Benson*, *Flook* and *Diehr* should therefore be carefully considered and revisited. Briefly, in *Benson*, the patent sought related to an algorithm that converts numbers from binary-coded decimal form into pure binary form, which arguably could be applied to specific computer applications. The Supreme Court held that the recited algorithms were not patentable because they were drawn to abstract ideas, were not tied to a particular machine or apparatus and did not change articles or materials to a “different state or thing.” The court found it important to determine whether, assuming the algorithm to be patentable, patenting of the invention would pre-empt use of the mathematical formula. In *Flook*, the Supreme Court held that a method for updating alarm limits in catalytic conversion processes, which recited a mathematical

Table 1 Amicus summary (selected) in *Bilski v. Kappos*

| Amicus | Industry or group represented | Summary |
|--|--|---|
| Novartis Corp. ¹⁵ | Health care solutions; pharmaceutical | Machine-or-transformation test unduly narrows the scope of diagnostic process claims. If upheld, the court should clarify that the test is not the dispositive standard. |
| Caris Diagnostics, Inc. ¹⁶ | Personalized medicine; tailoring therapeutics for individual patients using biomarkers | Machine-or-transformation test is not the exclusive test for patent eligibility of processes. Many diagnostic tests do not involve a machine or transformation. |
| Georgia Biomedical Partnership, Inc. ¹⁷ | Life sciences | Machine-or-transformation test is too rigid. Precedent is flexible and permissive. |
| University of South Florida ¹⁸ | University; research facility | Only presents arguments for the first question presented. Machine-or-transformation test excludes from patent eligibility certain processes that Congress intended to be patent eligible. |
| Ananda Chakrabarty ¹⁹ | University medical research | Machine-or-transformation test finds no support in the statute and is bad policy. |
| Prometheus Laboratories ²⁰ | Manufacturer of pharmaceutical, medical treatment and diagnostic processes | Court's interpretation of section 101 may have significant ramifications beyond business methods and may adversely affect the field of medical diagnostic and treatment processes. |
| Monogram Biosciences, Inc. <i>et al.</i> ²¹ | Emerging field of personalized medicine, using molecular diagnostic tests to correlate genetic and molecular biomarkers with clinically useful disease characteristics | Federal Circuit erred in holding that a process must be tied to a particular machine or transformation. This should not be the sole test. Nonphysical processes should not be excluded. |
| Medtronic, Inc. ²² | R&D of medical technology | Machine-or-transformation test would adversely affect medical technology innovation. Such a test would render significant medical advances patent ineligible. |
| Pharmaceutical Research and Manufacturers of America ²³ | Pharmaceutical and biotechnology industry | Court should not adopt a new test for the boundaries of section 101. Medical processes have long been protected. |
| Biotechnology Industry Organization <i>et al.</i> ¹¹ | Biotech and medical technology industries | Bilski test is not appropriate for determining patent eligibility of biotechnology and medical technology under section 101. |
| Knowledge Ecology International ²⁴ | Advocate of new incentive and financing models for biomedical information | It is not necessary to fashion an overly broad definition of patentable subject matter merely to save medical innovations from an imagined and speculative danger. |
| Adamas Pharmaceuticals <i>et al.</i> ²⁵ | Biomarkers and pharmaceuticals | Problematic business method patents should be eliminated. Machine-or-transformation test violates NAFTA and the 1994 TRIPS Agreement. This test directly over-rules Congress's choice (35 USC section 287(c)) to maintain broad subject-matter coverage for health care-related technology. |
| American Medical Association <i>et al.</i> ²⁶ | Medical profession; physicians and geneticists | Bilski's claims are not directed to technology. Machine-or-transformation test must remain secondary and cannot supplant this court's requirement that claims address a technology or the court's pre-emption standard. Machine-or-transformation test must be allowed to vary with each particular case. |

algorithm for computing an updated alarm limit from measured present values of variables, was not patent eligible. The court held that the identification of a limited category of useful post-solution applications of a formula does not make an otherwise unpatentable formula patentable because a process itself, not merely the mathematical algorithm, must be new and useful in order to meet the requirements for patentability. In *Diehr*, the court addressed a process for molding uncured synthetic rubber into a cured product. The claims were directed to a method that constantly measured the actual temperature inside a mold. The court held that the process constituted patentable subject matter under 35 USC §101 because the transformation and reduction of an article “to a different state or thing” is one clue to the patentability of a process claim that does not include a specific machine. In this instance, the court determined that the invention manifested the transformation of an article, uncured synthetic rubber, into a different state or thing. Although the invention used a well-known mathematical equation, the court remarked that the applicants did not seek to pre-empt the use of the equation.

Impact on life science technologies

In *Bilski*, four Supreme Court justices unequivocally indicated that nascent technologies, such as biotech and pharmaceutical processes, are patent eligible. This plurality expressed appreciation for technological progress and acknowledged that “unforeseen innovations such as computer programs” are patent eligible⁹. Justice Kennedy reasoned that the machine-or-transformation test may be an appropriate test for evaluating the patent eligibility of processes of the Industrial Age but should not be the sole test for newer types of inventions, such as medical diagnostic techniques. Interestingly, Justice Kennedy was careful to point out that he was “not commenting on the patentability of any particular invention, let alone holding that any of the above-mentioned technologies from the Information Age should or should not receive patent protection.” Regarding limiting interference with the development of nascent technologies, such as biotechnology and biopharmaceuticals, the court indicated that some types of inventions “raise special problems in terms of vagueness and suspect validity” and could “put a chill on creative endeavor and dynamic change.”

In dramatic contrast, however, Justice Stevens' concurrence (joined by Justices Breyer, Ginsburg and Sotomayor), in a separate 47-page opinion, “strongly disagree[d] with the court's disposition of this case.” Justice Stevens expressed great concern that the court “never provides a satisfying account of what constitutes an unpatentable abstract idea” and indicated that business method patents are *per se* unpatentable even though Bilski's claims and application materials presented concrete parameters that may have amounted to more than an abstract idea or generalized concept. Justice Stevens cited English and early American patent jurisprudence and legislation as supportive of the opinion, concluding that the scope of patent-eligible subject matter is “broad” but not limitless because, according to history, neither the patent statute nor patent law was intended to include business methods. Interestingly, biotech or pharmaceutical processes were not differentiated from business methods in the opinion, and it remains unclear to what extent such inventions could be distinguished, sufficient to survive Stevens' *per se* ban.

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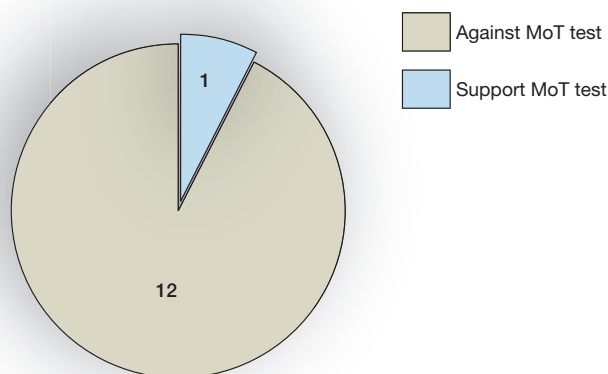


Figure 2 Amicus briefs from biotech and pharma sector supporting or against Bilski machine-or-transformation test. MoT, machine-or-transformation.

The dissenting justices agreed with the majority that the machine-or-transformation test was not the exclusive test for method claim patentability, but they went further, indicating that business methods are categorically excluded from patentable subject matter. Justice Stevens indicated that the court should have held “that Petitioners’ claim is not a ‘process’ within the meaning of Section 101 because methods of doing business are not, in themselves, covered by the statute.” Regarding the majority opinion’s holding that the patentability of business methods was clear from a reading of the statute, Stevens asserted that Congress did not explicitly state that it was amending and expanding the patent statute to include business methods; thus, he wrote, it was improper for the court to make such a presumption. Justice Stevens did not indicate how business method patents are categorically distinct from other forms of patent protection (for example, life science processes or therapeutic processes) but rather expressed “serious doubts” about whether business method patents are needed to encourage business innovation. It is unclear to what extent a safe harbor defense to those alleged of infringement of a business method claim applies to biotech or pharmaceutical businesses. The dissent therefore encompasses life science methods and Stevens’ logic applies equally well to biotech and pharmaceutical method patents vis-à-vis therapeutic innovations, making it critical for the industry to consider how each of their process inventions encourage medical innovations.

Justice Breyer filed a separate concurring opinion, joined by Justice Scalia, indicating that agreement was reached by all of the

justices on at least four points: (i) the statute is broad but has some narrow limits; (ii) the machine-or-transformation is a useful test; (iii) the machine-or-transformation test is not to be misunderstood as the governing test; and (iv) by no means is everything that produces a “useful, concrete and tangible result” a patent-eligible process.

Regarding the breadth of patent-eligible subject matter, Justice Breyer considered the issue at oral argument wherein he indicated, “...every successful businessman typically has something. His firm wouldn’t be successful if he didn’t have anything others didn’t have...—and it’s new, too, and it’s useful, made him a fortune—anything that helps any businessman succeed is patentable because we reduce it to a number of steps, explain it in general terms, file our application, granted...” to which the attorney answered yes, what was described by Justice Breyer is *potentially* patentable. The Justice was also concerned that by simply assigning a set of instructions to a computer, and including the computer in the patent, an otherwise unpatentable process would be rendered patentable, asking, “how you are going to later, down the road, deal with the situation of all you do is get somebody who knows computers, and you turn every business patent into a setting of switches on the machine because there are no businesses that don’t use those machines.” This concern was directly addressed by Judge Rader, in the *Bilski* dissent at the Federal Circuit, wherein he focused the court not on patent ineligibility but rather on the fundamental inquiry of determining if an invention was worthy of patent protection (e.g., if an invention is novel and not obvious).

Important pending life sciences cases

Following the Federal Circuit’s decision in *Bilski*, several cases were decided based solely on the machine or transformation test. Parties whose patent claims were held to be invalid under *Bilski* will take advantage of the change in law and seek reversal of these decisions. One such case is *Association for Molecular Pathology v. USPTO* (hereinafter, *AMP*), wherein the patent claims at issue are related to isolated DNA containing all or portions of the *BRCA1* and *BRCA2* gene sequence and methods for comparing or analyzing *BRCA1* and *BRCA2* gene sequences to identify the presence of mutations correlating with a predisposition to breast or ovarian cancer¹⁰. In a decision that radically changed the law, the court held that the step of isolating or purifying DNA does not sufficiently change the genetic sequence found in nature to make a claim to the gene *per se* patent eligible and that comparisons of DNA sequences are abstract mental processes, and thus not patent eligible. The court discussed abstract ideas, referring to the Federal Circuit’s opinion in *Bilski*, and applied the machine-or-transformation test to invalidate the process claims. In deciding *AMP*, the court discussed and distinguished another critical case, *Prometheus Laboratories v. Mayo*¹¹.

Prometheus Laboratories owns patents covering a method to optimize dosage of two drugs useful for autoimmune diseases, which involves administering a drug at certain dosage, detecting the concentration of certain metabolites and then comparing the value to a preset threshold value and subsequently increasing or decreasing the drug dosage accordingly. The Federal Circuit considered that this diagnostic process based on a correlation between drug metabolites level and drug efficacy and toxicity was patent eligible because, consistent with *In re Bilski*, a claimed process is patent-eligible if the claimed process is transformative (e.g., citing the administering step and various chemical and physical changes of the drug’s metabolites that enable their concentrations to be determined). The court reasoned that determining the levels of drug metabolites was *per se* transformative because drug metabolite levels cannot be determined by mere inspection. And because these transformations were central to the invention, according to the court, the process was found to be patent eligible and the patent was held valid. The court provided no guidance as to when the interaction of a drug metabolite with the human body is a natural phenomenon.

In *Bilski*, Justice Kennedy discusses the technological aspects of the Industrial Age and the Information Age, suggesting that the differences between the two periods provides insight

into how inventions are reduced to “physical or tangible form¹².” Justice Kennedy seemed to be concerned that adoption of a single test—the machine-or-transformation test—could retard innovation by “creating uncertainty as to the patentability of ... advanced diagnostic medicine techniques...” This issue is addressed again later, where Justice Kennedy refers to “the tension, ever present in patent law, between stimulating innovation by protecting investors and impeding progress by granting patents when not justified by the statutory design¹³.” This tension is most evident in the field of biotechnology and biopharmaceuticals.

In deciding *AMP*, the district court looked to *Prometheus Labs*¹⁰ in determining what constitutes a ‘transformation’ in the biotechnological arts; for example, if an alleged transformation is mere preparatory “data gathering,” it falls outside the “central” focus of the recited method. Myriad’s patents were directed to methods of “analyzing” or “comparing” isolated or purified DNA, not host DNA. Although the district court recognized the great difficulty in isolating the subject DNAs, the court characterized this technical accomplishment as a mere “data-gathering step,” thus invalidating the claimed methods as being directed to patent-ineligible subject matter. The district court’s new patent eligibility test is that to be patent eligible, isolated material must be “markedly different” from its naturally occurring counterpart. The court referred to the Supreme Court landmark decision in *Diamond v. Chakrabarty*¹⁴ as precedent but did not define a “markedly different” invention. However, the district court went further and applied a “fundamental qualities” test to invalidate Myriad’s isolated DNA composition claims, indicating that a naturally occurring DNA’s “fundamental quality” is to contain “the physical embodiment of biological information,” which is the same “fundamental quality” as isolated DNA. The court appeared to reason that because both forms of DNA shared this quality, the isolated DNA was not sufficiently different from the naturally occurring DNA to render it patent eligible—a sweeping conclusion that draws into question the validity of thousands of patents susceptible to the application of similar logic.

It is also important to remember the questions raised by the court in *Lab Corp. v. Metabolite*⁵ in attempting to differentiate patent eligible subject matter from ineligible biotech inventions. In this case, the Supreme Court declined to explicitly consider the issue of the patent eli-

gibility of claims to a method for detecting the deficiency of cobalamin or folate by measuring the level of homocysteine in body fluids. The Federal Circuit held that the claims were valid but did not address the issue of patent eligibility under 35 USC §101. The Supreme Court then declined to review the decision, with Justices Stevens, Breyer and Souter dissenting. The dissenting opinion maintained that the claims were invalid because they recited only natural phenomena, which are not patent eligible. The dissent was compelled by public policy considerations and indicated that if the correlations between metabolite levels and disease were patent eligible, physicians may not be able to exercise their best judgment or might waste time, and the cost of healthcare would increase a result that would outweigh the value of protecting the invention at issue.

Conclusion

In *Bilski*, the Supreme Court expanded the forms of biotech and pharmaceutical inventions that are patent eligible in the US, holding that the machine-or-transformation test is not the sole test for patent eligibility in the US and the types of patent-eligible subject matter are vast. But the Court narrowly avoided a catastrophe for the biotech and pharmaceutical industry. A majority of the court declined to adopt the view that “new technologies may call for new inquiries” directed to patent eligibility, which would adapt patent law to inventions of the Information Age. While the court unanimously held that *Bilski*’s process claims were not patent eligible, it indicated that the machine-or-transformation test may be useful for determining whether a method claim meets the threshold requirements of eligibility. Thus, universities and companies should consider providing sufficient evidence to satisfy the machine-or-transformation test when seeking to obtain patents.

Although a 5–4 majority held that business methods are not categorically unpatentable, the court was a single vote away from denying business methods patent protection. This is chilling in view of the implications of such a ruling for other areas of technology, such as biotech and pharmaceutical method patenting. The court refrained from articulating a generic test that would distinguish a patentable method from an abstract idea. It remains to be seen how the USPTO, district courts and the Federal Circuit will proceed to define a new standard of patent eligibility designed to accommodate future

innovations such as those emerging in the life sciences. The courts must provide guidance to the biotech industry as to what is patentable. What is clear, however, is that based on the court’s determination that *Bilski*’s claims were unpatentable because they were directed to abstract ideas, it is essential for the pharmaceutical and biotech industry to pursue and obtain method claims of varying scope and pre-emptively evaluate any available evidence to address future attacks on their intellectual property based on *Bilski*, at least until a medically important “abstract idea,” which could include an otherwise patentable invention under US law, is distinguished by the courts or the legislature.

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COMPETING FINANCIAL INTERESTS

The author declares no competing financial interests.

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