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Viewpoints on Life After *Bilski v. Kappos*

Introduction

Last week, the Supreme Court announced its much-anticipated and long-awaited decision in *Bilski v. Kappos*[1], a case centered on the scope of patent-eligibility of process claims under 35 U.S.C. § 101. Not unexpectedly, the claims at issue were found by the Supreme Court to be ineligible for patent protection. And not unexpectedly, the Supreme Court held that the Federal Circuit was in error when the lower court adopted the machine-or-transformation test as the sole test for patent-eligibility of process claims under § 101.

Following our same-day and day-after coverage of the *Bilski* decision, Snippets offers this special issue to provide more on the decision itself, a reminder of how we got there, and a collection of view points from various authors, both current MBHB attorneys and one distinguished alumnus.

While reading this issue, please keep in mind that the viewpoints expressed are those of the authors themselves, and likely not their only viewpoints on *Bilski*. We hope readers appreciate these various viewpoints for their variety and for any insight they provide.

The Supreme Court's Decision

As most know by now, the Supreme Court's decision in *Bilski* came not as one opinion but as three: Justice Kennedy's (partial) majority opinion, and Justice Stevens' and Justice Breyer's respective minority concurrences (combineable, though, into what has been deemed the "Anti-State-Street Majority,"[2] seemingly ending the viability of the "useful, concrete and tangible result" test enunciated by the Federal Circuit in *State Street*[3]).

Justice Kennedy's (Partial) Majority Opinion

In the sections of his opinion having majority support[4], Justice Kennedy acknowledged the three well-known and long-accepted exclusions from patent-eligibility under § 101: laws of nature, physical phenomena, and abstract ideas.[5]

Justice Kennedy next turned to the machine-or-transformation test, and in particular to rejecting the Federal Circuit's adoption of that test as the sole test for patent-eligibility of process claims under § 101.[6] Among other statements regarding this test, Justice Kennedy made the point that the words in the Patent Act are to be given their ordinary meaning, and that the meaning of "process" as used in § 101 is not to be limited by the other statutory categories (i.e., machine, manufacture, and composition of matter).[7] Justice Kennedy concluded this section with perhaps its most important statements, that the Supreme Court's "precedents establish that the machine-or-transformation test is a useful and important clue, an investigative tool, for determining whether some claimed inventions are processes under § 101. [It] is not the sole test for deciding whether an invention is a patent-eligible 'process.'"[8]

In the next section having majority support, Justice Kennedy rejected the argument put forth by Justice Stevens in his concurrence that methods of doing business are—or at least should be—categorically ineligible for patent protection. As support for the rejection of a categorical exclusion, Justice Kennedy relied on (1) a dictionary definition of "method" (since "method" is used in 35 U.S.C. § 100(b) as a definition in the alternative of "process"), and (2) the recognition of business method patents in 35 U.S.C. § 273 (clarifying, to

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use Justice Kennedy's word "that a business method is simply one kind of 'method' that is, at least in some circumstances, eligible for patenting under § 101."[9]).

Finally, after establishing that Bilski did not necessarily lose because of a failure to satisfy the machine-or-transformation test, and that Bilski did not lose because of an attempt to patent a method of doing business, Justice Kennedy (with majority support) clarified that Bilski did lose because the claims at issue amounted to nothing more than an attempt to patent an abstract idea, specifically "hedging."[10] Justice Kennedy reviewed the Court's decisions in *Gottschalk v. Benson*[11], *Parker v. Flook*[12], and *Diamond v. Diehr*[13] in reaching this conclusion*14*, which squared with—as did the bulk of Justice Kennedy's analysis in fact—Judge Rader's prescient dissent[15] to the Federal Circuit's *en banc* decision[16] in *Bilski*.

Justice Stevens' Concurrence

In a lengthy concurrence, which was joined by Justices Ginsburg, Breyer, and Sotomayor, Justice Stevens agreed with Justice Kennedy that the claims at issue were not patent-eligible because they were directed to no more than an abstract idea[17], and further agreed that the Federal Circuit erred in adopting the machine-or-transformation test as the sole test for patent-eligibility under § 101 of process claims.[18]

Justice Stevens, however, criticized Justice Kennedy's opinion with respect to its textual arguments that no exclusion from patent-eligibility of business methods was discernible in § 101.[19] And he also criticized the majority with respect to what Justice Stevens called their "artificial limit[ation of Bilski's] claims to [the abstract idea of] hedging," opining that the "Court, in sum, never provide[d] a satisfying account of what constitutes an unpatentable abstract idea," and that they tautologically "assert[ed their own] conclusion that [Bilski's] application claims an abstract idea."[20]

In a point of further disagreement with Justice Kennedy, Justice Stevens also embarked on an extensive and detailed historical argument that methods of doing business were not and should not be—and he asserted had in fact never been—eligible for patent protection.[21] Justice Stevens started with what he deemed the "English Backdrop," and then progressed through "Early American Patent Law," "Development of American Patent Law," and "Modern American Patent Law," even stopping to address the "anything under the sun . . . made by man" statement from the legislative history of the 1952 Patent Act, perhaps most notably quoted by the Supreme Court in their decision in *Chakrabarty*.[22,23]

Justice Stevens wrote in summation that the "limited textual, historical, and functional clues" available for analysis "all point toward the same conclusion: that [Bilski's] claim is not a 'process' within the meaning of § 101 because methods of doing business are not, in themselves, covered by [§ 101]."[24]

Justice Breyer's Concurrence

Last but certainly not least, Justice Breyer authored a concurring opinion in which only Justice Scalia joined (and only in part at that). In the section in which Justice Scalia joined (Part II), Justice Breyer identified four of what he considered to be "substantial" points of agreement among "many" of the Justices.[25]

The first such point was that, "although the text of § 101 is broad, it is not without limit," one such limit being the ineligibility for patent protection of "[p]henomena of nature . . . , mental processes, and abstract intellectual concepts."[26] The second was the important role of the machine-or-transformation test in evaluating patent-eligibility of process claims.[27] The third was that that test, while important, "has never been the 'sole test.'"[28] And fourth was what was essentially a vote of "no confidence" in the "useful, concrete, and tangible result" test enunciated by the Federal Circuit in *State Street*.[29,30] This last point, when coupled with similar statements[31] in Justice Stevens' concurrence, would seem to establish that a majority of the Supreme Court considers that test to be no longer—and perhaps to never have been—viable.

So How Did We Get Here?
(Or How Did Bilski Get There?)

Bilski's long road to the Supreme Court began on April 10, 1997, the filing date of his application.[32] Claim 1 of the application read:

> A method for managing the consumption risk costs of a commodity sold by a commodity provider at a fixed price comprising the steps of:
> (a) initiating a series of transactions between said commodity provider and consumers of said commodity wherein said consumers purchase said commodity at a fixed rate based upon historical averages, said fixed rate corresponding to a risk position of said consumer;
> (b) identifying market participants for said commodity having a counter-risk position to said consumers; and
> (c) initiating a series of transactions between said commodity provider and said market participants at a second fixed rate such that said series of market participant transactions bal-

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> ances the risk position of said series of consumer transactions.[33]

The Examiner rejected claim 1 under § 101 as being directed to non-statutory subject matter because it was "not implemented on a specific apparatus," but "merely manipulate[d an] abstract idea and solve[d] a purely mathematical problem without any limitation to a practical application."[34] Thus, according to the Examiner, the claim was "not directed to the technological arts."[35]

The Board of Patent Appeals and Interferences (BPAI) affirmed the rejection, concluding however that the Examiner had erred by requiring the method to be tied to a specific apparatus, as a method that transforms an article "from one state to another" may still be patent-eligible even if not implemented with an apparatus.[36] Applying this standard, the BPAI held that Bilski's claim 1 was not patent-eligible because it met neither prong of the machine-or-transformation test.[37]

An *en banc* panel of the Federal Circuit affirmed the BPAI, holding that a method claim is "surely" patent-eligible if it satisfies the machine-or-transformation test.[38] But in addition to holding that method claims are patent-eligible *if* they satisfy the machine-or-transformation test, the panel went further and held that such claims are patent-eligible only *if* they satisfy that test, calling it the "definitive test."[39]

The Big Three: *Benson*, *Flook*, and *Diehr*

In adopting the machine-or-transformation test as the exclusive test for patent-eligibility of method claims, the *en banc* Federal Circuit relied on the three above-referenced Supreme Court decisions: *Gottschalk v. Benson*, *Parker v. Flook*, and *Diamond v. Diehr*, noting in particular that the Court had applied this test in each of those decisions,[40] and emphasizing that the Court in *Diehr* did not reiterate the caveat in *Benson* that a process claim could be patent-eligible even if it did not satisfy the Court's prior precedents.[41] (And of course in rejecting this adoption, Justice Kennedy relied on the same three decisions.[42])

In *Benson*, the Court held that a method of converting binary-coded decimal (BCD) numerals into pure binary numerals was not patent-eligible subject matter,[43] stating that "[t]ransformation and reduction of an article 'to a different state or thing' is the clue to the patentability of a process claim that does not include particular machines."[44] The Court then offered the above-referenced caveat, affirmatively stating that they had not held that "no process patent could ever qualify if it did not meet the requirements of our prior precedents."[45]

In *Flook*, the Court held that a method of updating alarm limits in a catalytic converter was not patent-eligible subject matter,[46] stating that "[t]he only difference between the conventional methods of changing alarm limits and that described in respondent's application rests in the second step—[a] mathematical algorithm or formula."[47] The Court held that the adjustment of the alarm limit according to the formula was mere "post-solution" activity that did not transform the unpatentable algorithm into a patentable method.[48]

In *Diehr*, the Court held that a method of curing rubber using a particular equation known as the "Arrhenius Equation" was in fact patent-eligible subject matter,[49] stating that "[it could not be disputed that] respondents' claims involve the transformation of an article, in this case raw, uncured synthetic rubber, into a different state or thing . . . ."[50]

The Court in *Diehr* reasoned that, although the claimed process employed an equation that, in isolation, might be unpatentable,[51] that process only "foreclose[d] from others the use of that equation in conjunction with all of the other steps in [the] process."[52]

On to the Viewpoints . . .

The Editorial Board of Snippets hopes that the above background on and summary of the Supreme Court's decision in *Bilski* has been informative and helpful, and hopes that, armed with that knowledge, our readers will enjoy the following selection of viewpoints on this much-anticipated decision.

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With *Bilski* Having Come and Gone, It's Time to Get Back to Work

In my experience, when a decision from the Supreme Court or the Federal Circuit in a high-profile patent case is imminent—and indeed once such a decision has been delivered, patent practitioners (like me) nationwide ask themselves and each other questions such as: Do I need to start doing something differently? Do I need to start doing something new that I was not doing before? Do I need to stop doing something that I have been doing for years? And so on. In short, we all want to know what such decisions mean to our day-to-day existence.

My day-to-day existence has me engaged in the challenging, interesting, and rewarding task of seeking maximum patent protection for clients in technical disciplines such as computer engineering, electrical engineering, telecommunications, and so on—basically anything involving any combination of hardware, software, firmware, etc. programmed and arranged to accomplish something that the prior art could not.

On that day-to-day existence, I do not expect the Supreme Court's decision last week in *Bilski* to have much (if any) impact. To the extent that what I do involves assessing inventions that at least some would classify as business methods, such methods were patent-eligible before this decision, and they still are. To the extent that what I do involves assessing inventions that at least some would classify as no more than abstract ideas, such ideas were not patent-eligible before this decision, and they are still not. And to the extent I have been drafting or amending claims (sometimes but not always due to *Bilski*-esque § 101 rejections) to satisfy the machine-or-transformation test, this is, at least in my view, still the right and safe way to go.

Indeed, rather than rejecting the machine-or-transformation test in really any way, the Supreme Court in its various and multiple opinions gave the test high praise, stopping short only of anointing it, as the Federal Circuit had, to be the Alpha and the Omega of patent-eligibility of process (*i.e.*, method) claims. Admittedly, after mulling over the decision for the past week or so, it is still not 100% clear to me whether (1) the Supreme Court blessed the test in the sense that every claim gets a chance to satisfy it, where doing so would be sufficient (but not necessary) for patent-eligibility under § 101, or whether (2) the Court instead declared the test to be the right one for most (but not all) claims, where failing to satisfy it would be fatal with respect to § 101 for those claims for which it is the right test—and of course which claims would those be?

Either way, it seems to me to be practical, sensible, responsible, conservative, etc. to continue to do our dead-level best to draft and amend claims to satisfy the machine-or-transformation test, as a likely-to-be-effective safeguard against wandering into the territory where we must successfully argue that claims are not directed only to abstract ideas—a territory in which a predisposition on the part of a court, an examiner, the Board, etc. in favor of or against certain types of inventions could carry the day as to the level of abstractness at which the claims at issue are characterized. (For example, the Supreme Court characterized Bilski's claims as being directed to no more than the abstract idea of "hedging," where arguably many more specific and concrete (*i.e.*, less abstract) descriptions were available to the Court.)

And of course all of this makes an adequate and enabling disclosure that much more crucial (to the extent of course that there was room for the importance of this to increase), such that claims that are drafted or amended to satisfy the machine-or-transformation test do not suffer from fatal problems under § 112. Now, certainly there may be instances where drafting or amending claims in this manner would seem to be too limiting to achieve justice for our clients, but I would submit that, even then, there would typically be room for dependent claims that would satisfy this important test, this "critical clue," in the words of Justice Stevens.[1]

Time will tell of course whether I still hold this view in six months, in a year, etc., but for now, in the patriotic spirit of this past weekend, as our country's most-recent birthday has made me older and wiser (in that it was also my 34th birthday), I plan to march to the beat of the same drummer.

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Avoiding Abstract Claims by Broadly Defining the Problem

Stated narrowly, the Supreme Court's holding in *Bilski* was that the claims sought are unpatentably abstract. Moving forward, I believe that it will become increasingly important to consider how the courts and the Patent Office will delineate the boundaries of the doctrine — *i.e.*, when does a claim move into the realm of impermissible abstraction?

In its opinion, the Supreme Court offers a few nuggets of reasoning to explain its conclusion. In particular, the Court found that the Bilski claims were abstract because they were so broadly written so as to cover the entire concept of risk hedging:

> The concept of hedging, described in claim 1 and reduced to a mathematical formula in claim 4, is an unpatentable abstract idea, just like the algorithms at issue in *Benson* and *Flook*. Allowing petitioners to patent risk hedging would pre-empt use of this approach in all fields, and would effectively grant a monopoly over an abstract idea.[1]

The Court noted that the remaining dependent claims merely limit the hedging method to particular fields of use or add "token postsolution components."[2] As the Supreme Court held in *Flook*, these additions cannot transform an otherwise abstract claim into one that is patentable.[3]

Of course, a major difficulty with the Supreme Court's analysis is its poorly explained application of the law to the facts. Pointedly, the particular claims in question do not attempt to "patent risk-hedging" as a whole and would not have preempted the use of all or even most risk hedging methods. Rather, the claims are directed to a specific series of transactions that balance risk position in a particular way. In his concurring opinion, Justice Stevens identified this problem with the majority opinion, noting that:

> The patent now before us is not for a principle, in the abstract, or a fundamental truth. Nor does it claim the sort of phenomenon of nature or abstract idea that was embodied by the mathematical formula at issue in *Gottschalk v. Benson* and in *Flook*. . . . The Court, in sum, never provides a satisfying account of what constitutes an unpatentable abstract idea. Indeed, the Court does not even explain if it is using the machine-or-transformation criteria. The Court essentially asserts its conclusion that petitioners' application claims an abstract idea. This mode of analysis (or lack thereof) may have led to the correct outcome in this case, but it also means that the Court's musings on this issue stand for very little.[4]

Moving forward

One area ripe for skilled lawyering in future cases is in the framing of the problem solved by a claimed invention. In antitrust law, companies can avoid charges of unlawful monopolization by broadly defining their market. As an example, although a mobile-phone carrier may have a large market-share of the mobile-phone market, that same company may only be a small player (and thus not subject to certain antitrust controls) in a more broadly defined market that included all remote voice communications. Similarly, a claim that preempts the concept of hedging may not be seen as preempting the more broadly defined concept of investment strategies – especially when practical alternative solutions are identified that fall outside the scope of the claims.

Mayo Collaborative Svcs. v. Prometheus Labs. is a patentable subject matter case now pending before the Federal Circuit.[5] In that case, the challenged claims cover an iterative method of dosing 6-thioguanine (6-TG) for the treatment of an immune-mediated gastrointestinal disorder. The invention is based on a discovery that a properly treated patient should have a 6-TG body-concentration of between 283 and 493 pmol per 10,000 red blood cells, and the claims are written in a way that arguably preempts all uses of that newly-discovered natural phenomenon. In its counter, the patentee may hope to reframe the debate by focusing on the fact there are many possible ways to treat the disorder and that the claimed method is only one such mechanism.

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A Critique of *Bilski's* Textual Analysis

The majority in *Bilski* rightly decided not to categorically exclude business methods from patent-eligibility under § 101. However, in my view, the majority's "textual" analysis of § 101 is at best strains credulity, and weakens considerably the legitimacy of their strongest argument (and therefore the opinion as a whole), which is that the case should be decided based on the Court's prior decisions in *Benson*, *Flook*, and *Diehr*.

According to the majority, the "Court has more than once cautioned that courts should not read into the patent laws limitations and conditions which the legislature has not expressed."[1] However, the Court has, on more than one occasion, disregarded its own admonition. Perhaps the most egregious example of this is was in *Gandy v. Main Belting Co.*,[2] in which the Court read into the patent laws the limitation that any invalidating use or sale must be "in this country."[3] In 1892, at the time of the decision, the law allowed a patent for any invention "not in public use or on sale for more than two years prior to his application."[4] The Court conceded that "the language of this section contains no restriction as to the place or country wherein the public use is made of the invention," but nevertheless held that an invalidating use or sale must be in this country.[5]

A more recent example of the Court reading limitations into the patent laws is *Pfaff v. Wells Electronics, Inc.*,[6] in which the Court rejected the petitioner's "nontextual argument" that the on-sale bar applies only after the invention is reduced to practice, but then proceeded to provide a similarly nontextual interpretation that the on-sale bar applies as soon as the invention is "ready for patenting."[7]

In both of these cases, the Court, at least in my opinion, properly adopted "atextual" interpretations of the patent laws that furthered the policy of patent protection. In *Gandy*, the Court noted that Congress limited novelty-destroying uses and sales to those occurring "in this country," and reasoned that the same geographic limitations should apply to statutory-bar uses and sales.[8] In *Pfaff*, the Court adopted an interpretation of "sale" that allowed the inventor to "understand and control the timing" of the on-sale bar, but also to prevent the inventor from "exploit[ing] his discovery competitively after it is ready for patenting."[9] Though these interpretations of the patent laws were neither compelled nor even supported by the text of their respective statutes, these interpretations furthered sound policy determinations by the Court.

The *Bilski* majority supported its textual analysis of "process" by noting that it had similarly adopted textual analyses of "manufacture" and "composition of matter" in "accordance with dictionary definitions" and "common usage."[10] It seems unlikely, however, that the Court would follow these broad dictionary definitions and common usages to their logical extremes. For example, the Court defined a "composition of matter" as "all compositions of two or more substances and . . . all composite articles, whether they be the results of chemical union, or of mechanical mixture, or whether they be gases, fluids, powders or solids".[11] Under a textual definition of "composition of matter," an inventor could obtain a patent on a book or a sheet of music, since these are the composition of two or more substances (ink and paper fibers). Yet the Court of Customs and Patent Appeals, the predecessor to the Federal Circuit, has held that the "mere arrangement of printed matter on a sheet or sheets of paper, in book form or otherwise, does not constitute 'any new and useful art, machine, manufacture, or composition of matter.'"[12] While the Supreme Court has not directly decided the issue of whether a book can be the subject of a patent, the Court would likely hold that a book is non-statutory subject matter because the protection of such is the province of copyright law, rather than patent law. Yet the "dictionary definition" of "composition of matter" would support the patent-eligibility of such printed matter.

Frankly, the Court's textual analysis of § 101 troubles me. At best, the Court merely overlooks those cases where it has not followed its own advice that it should not read limitations into the patent laws that Congress has not expressed, and is not mindful of the ramifications of the broad interpretations given to "process," "manufacture" and "composition of matter." At worst, the Court is cognizant of these issues, but selectively cites those cases that support its position (and ignores those that don't). Either way, in my opinion, the Court's textual analysis unfortunately (and unnecessarily) undermines the cogency of its holding: that *Benson*, *Flook*, and *Diehr* prohibit the patenting of abstract ideas.

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Questions Surrounding a Shift to an "Abstract Idea" Test

After the Supreme Court's recent decision in *Bilski,* there are yet more questions about what constitutes patent-eligible subject matter under § 101, as the focus of the analysis appears to be shifting from the machine-or-transformation test to the amorphous question of whether a claimed method is an attempt to patent an abstract idea.

In *Bilski,* the Supreme Court struck down the Federal Circuit's ruling that a method claim *must* satisfy the machine-or-transformation test in order to be patentable under § 101. Instead, the Court advised that while the machine-or-transformation test "is a useful and important clue, an investigative tool, for determining whether some claimed inventions are processes under § 101," the "machine-or-transformation test is not the sole test for deciding whether an invention is a patent-eligible 'process.'"[1] The Court stressed that its existing precedents establish "broad patent-eligibility principles" with the only exceptions being "laws of nature, physical phenomena, and abstract ideas."[2]

Within this framework, Justice Kennedy, joined by Chief Justice Roberts and Justice Thomas, made clear that "the Patent Act leaves open the possibility that there are at least some . . . business methods that are within patentable subject matter under § 101."[3] However, the Court unanimously agreed that Bilski's claims to be outside the scope of § 101, with a majority finding that the "claims attempt to patent the use of the abstract idea of hedging risk."[4]

Thus, the ultimate question for patentability of method claims now appears to be whether the method is an abstract idea. A post-*Bilski* USPTO memorandum to Examiners follows this in principle, providing that:

> Examiners should continue to examine patent applications for compliance with section 101 using the existing guidance concerning the machine-or-transformation test as a tool for determining whether the claimed invention is a process under section 101. If a claimed method meets the machine-or-transformation test, the method is likely patent-eligible under section 101 unless there is a clear indication that the method is directed to an abstract idea. If a claimed method does not meet the machine-or-transformation test, the examiner should reject the claim under section 101 unless there is a clear indication that the method is not directed to an abstract idea. If a claim is rejected under section 101 on the basis that it is drawn to an abstract idea, the applicant then has the opportunity to explain why the claimed method is not drawn to an abstract idea.[5]

Interestingly, not only does the ultimate question now appear to be whether a method is drawn to no more than an abstract idea, but the burden appears to ultimately be placed on the applicant to show that a method *is not* just an abstract idea, rather than on the examiner to positively explain why a method *is* an abstract idea. There is certainly a question as to whether this procedure, which burdens claims that do not pass the machine-or-transformation test with a difficult-to-meet escape from being labeled as abstract ideas, is really what the Supreme Court had in mind.

The bigger question, however, is: what exactly is an abstract idea? The *Bilski* opinion offers some guidance, but in doing so, also creates more questions. The Court indicated that "an *application* of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection."[6] The Court reiterated "the need to consider the invention as a whole, rather than 'dissect[ing] the claims into old and new elements and then … ignor[ing] the presence of the old elements in the analysis.'"[7]

However, in finding Bilski's claims to be directed to an abstract idea, the Court reasoned that "limiting an abstract idea to one field of use or adding token post-solution components did not make the concept patentable."[8] In other words, the Court condones the practice of identifying certain claim elements as post-solution components and ignoring them, and analyzing patent-eligibility based solely on the remaining components. This seems to be in direct opposition to the proposition that claims should not be dissected into new elements (*i.e.*, elements that are the solution) and old elements. This begs the question as to where the line is drawn between (i) not dissecting the claims and therefore considering the invention as a whole, and (ii) ignoring post-solution components for the purposes of a § 101 analysis. Moreover, it introduces the additional question of what exactly a post-solution component is. It will be interesting to see how this plays out in practice, as the Patent Office and courts apply *Bilski*.

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Bilski v. Kappos: Effects on Biotechnology Patents

Although long-anticipated, the Supreme Court's opinion in *Bilski* did not provide much in terms of "pellucid" teachings regarding the metes and bounds of patent-eligible subject matter. Against this backdrop, the Court decided last Tuesday to grant *certiorari,* vacate the Federal Circuit's decision below and remand to the appellate court two cases related to medical diagnostic claims: *Prometheus Laboratories, Inc. v. Mayo Collaborative Services* and *Classen Immunotherapies, Inc. v. Biogen Idec*.[1] On earlier appeal, the Federal Circuit decided that the claims in *Prometheus* were patent-eligible under the "machine-or-transformation" test,[2] and that the claims in *Classen* were not.[3] How the Federal Circuit decides these cases on remand, and whether its decision(s) change, will provide the first inklings of how the court will implement whatever insights the *Bilski* decision may provide.

The types of claims in these cases and the grounds for the Federal Circuit's disparate decisions may be informative. In *Prometheus*, the claims recited methods for determining whether treatment for immune-related gastrointestinal disorders needed adjustment, *i.e.* whether the amount of a drug administered to treat the disorder should be changed.[4] The asserted claims of the patents-in-suit specifically relate to methods for identifying the administered drug, thiopurine, or metabolites thereof, in red blood cells of a patient.[5] Claim 1 of one of the two patents-in-suit was cited in the Federal Circuit opinion as being representative:

> A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising: (a) administering a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and (b) determining the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder, wherein the level of 6-thioguanine less than about 230 pmol per $8x10^8$ red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and wherein the level of 6-thioguanine greater than about 400 pmol per $8x10^8$ red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.[6]

The Federal Circuit reversed a finding by the district court on summary judgment that the claims were not patent-eligible.[7] The panel held that the administering and determining steps, dismissed by the district court as constituting mere "necessary data-gathering steps," were instead transformative and thus satisfied the transformation prong of the *Bilski* machine-or-transformation test.[8] The Federal Circuit opined that "[t]he transformation is of the human body following administration of a drug and the various chemical and physical changes of the drug's metabolites that enable their concentrations to be determined."[9] The panel found that these steps were essentially "method of treatment" steps, "which are *always transformative* when a defined group of drugs is administered to a body to ameliorate the effects of an undesired condition."[10] A human body to which drugs such as thiopurines are administered "necessarily undergoes a transformation," since "[t]he drugs do not pass through the body untouched without affecting it," which the Federal Circuit characterized as "the entire purpose of administering these drugs."[11] The panel rejected Mayo's contention that the transformations are the result of "natural processes" because "quite literally every transformation of physical matter can be described as occurring according to natural processes and natural law."[12] But the transformation encompassed by the administering step of the asserted claims are not "natural processes" according to the panel: "[i]t is virtually self-evident that a process for a chemical or physical transformation of physical objects or substances is patent-eligible subject matter."[13] Finally, the Federal Circuit opined that the district court erred in deciding that Prometheus' asserted claims "wholly preempt[ed]" the use of correlations between metabolites of thiopurine drugs and their toxicity and efficacy.[14] Rather, according to the Federal Circuit, the claims utilize, not preempt, the correlations of natural processes "in a series of specific steps" that are patent-eligible subject matter according to the statute, citing *Diamond v. Diehr*[15] and its analogous use of the Arrhenius equation for curing rubber (a transformative step). "Regardless" of this issue, the Federal Circuit held, satisfaction of the machine-or-transformation test renders the claims patent-eligible and thus "they do not preempt a fundamental principle."[16]

In *Classen*, on the other hand, the Federal Circuit summarily rejected the claims based on failure to satisfy the *Bilski* machine-or-transformation test (in a 69-word opinion that was shorter than the claims at issue).[17] The claims at issue in *Classen* were directed to methods for determining whether an immunization schedule affects the incidence or severity of a chronic immune-mediated disorder in a treatment group of mammals, relative to a control group of mammals.[18] Although the *Classen* claims recited "immunizing" steps that could be analogous to the "administering" steps in the *Prometheus* claims, they also recited a step of "comparing" the "incidence, prevalence, frequency or severity" of the immune-mediated disorder between the experimental and control groups,[19] making it easier to characterize

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continued from p. 8

the immunization step as a mere "data-gathering" step.

The use of the "comparing" language was also reminiscent of the claims in the *Laboratory Corp. v. Metabolite Labs., Inc.* case ("*LabCorp*"), which was criticized by Justice Breyer in his dissent from the Court's decision not to decide the patent-eligibility of claims for determining whether a patient had a vitamin deficiency.[20] Those claims were directed to a method for detecting a deficiency of cobalamin (B12) or folate having the steps of assaying a body fluid for an elevated level of total homocysteine and correlating an elevated level of total homocysteine in said body fluid with a deficiency of cobalamin or folate.[21] There are clear parallels between the structure of the *Metabolite* claim and the *Classen* claim. Each recites a preamble directed to identifying a biological phenomenon (a vitamin deficiency in *LabCorp*, a chronic immune-related disorder related to a acute immunization schedule in *Classen*), comprising an unambiguous diagnostic/tangible step (assaying a bodily fluid to detect elevated homocysteine levels in *LabCorp*, immunizing mammals with one or more doses of one or more immunogens, according to an immunization schedule in *Classen*), followed by an interpreting step (correlating elevated homocysteine with the vitamin deficiency in *LabCorp*, comparing the incidence, prevalence, frequency or severity of chronic immune-mediated disorders in mammals immunized according to the immunization schedule in *Classen*).

Bilski provides no clear instruction for resolving the different results in the *Prometheus* and *Classen* cases; indeed, the Court (for the first time since the *Hilton Davis* case[22]) appears content to let the Federal Circuit develop its case law on the extent to which tests other than the machine-or-transformation test are used to determine patent-eligibility. For biotechnology, it remains the case that including active, technology-dependent steps in method claims is prudent, and to draft claims that minimize the likelihood that the invention can be characterized as merely an "abstract idea." In this regard, dicta from the *Bilski* opinion provides a certain level of comfort that the Court (or at least some members of the Court) understand the proper protocol for performing claim analysis. For example, the opinion noted that the judiciary does not have "*carte blanche* to impose other limitations that are inconsistent with the text and the statute's purpose and design."[23] And in a portion of the "majority" opinion joined by Justice Scalia, Justice Kennedy reminds us that a court "need[s] to consider the invention as a whole, rather than 'dissect[ing] the claims into old and new elements and then . . . ignor[ing] the presence of the old elements in the analysis,'"[24] citing *Diamond v. Diehr*.[25] However, this is arguably just the analytic mistake Justice Breyer made in his *LabCorp* dissent, where he argued that

> here, aside from *the unpatented test*, [the claims] embody only the correlation between homocysteine and vitamin deficiency that the researchers uncovered. In my view, that correlation is *an unpatentable* "*natural phenomenon*," and I can find nothing in claim 13 that adds anything more of significance.[26]

On the other hand, the four "concurring" Justices clearly believe that the scope of patent eligibility is (and must be) limited by the proscription that a patent "Promote the Progress of . . . the Useful Arts," and that Justice Breyer's antipathy to medical diagnostic patents retains some currency on the Court:

> For even when patents encourage innovation and disclosure, "*too much* patent protection can impede rather than 'promote the Progress of . . . useful Arts.'" *Laboratory Corp. of America Holdings* v. *Metabolite Laboratories, Inc.*, 548 U.S. 124, 126–127 (2006) (BREYER, J., dissenting from dismissal of certiorari). Patents "can discourage research by impeding the free exchange of information," for example, by forcing people to "avoid the use of potentially patented ideas, by leading them to conduct costly and time-consuming searches of existing or pending patents, by requiring complex licensing arrangements, and by raising the costs of using the patented" methods. *Id.*, at 127.[27]

Thus, even as the Federal Circuit develops additional tests in this area, it is incumbent on patent applicants and their lawyers to recognize these tensions in the High Court's attitudes about patenting and to ensure that their claims are clearly directed to patent-eligible subject matter.

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Endnotes

Viewpoints on Life After *Bilski v. Kappos*
Endnotes

[1] *Bernard L. Bilski and Rand A. Warsaw v. David J. Kappos, Undersecretary of Commerce for Intellectual Property and Director, Patent and Trademark Office*, U.S. Supreme Court Slip Opinion No. 08–964 (June 28, 2010), 561 U.S. ____ (2010).
[2] *See* Dennis Crouch's "Patently-O" patent law blog, "Bilski v. Kappos and the Anti-State-Street-Majority," posted June 28, 2010 at http://www.patentlyo.com/patent/2010/06/bilski-v-kappos-and-the-anti-state-street-majority.html.
[3] *State Street Bank & Trust Co. v. Signature Financial Group*, 149 F.3d 1368 (Fed. Cir. 1998).
[4] Justice Kennedy delivered the opinion of the Court, which was joined in full by Chief Justice Roberts and by Justices Thomas and Alito. Justice Scalia joined in all sections except II-B-2 and II-C-2.
[5] *Bilski* Slip Opinion, Kennedy at 5.
[6] *Id.* at 6-8 (Section II-B-1).
[7] *Id.*
[8] *Id.* at 8.
[9] *Id.* at 11.
[10] *Id.* at 13 (Section III).
[11] 409 U.S. 63 (1972).
[12] 437 U.S. 584 (1978).
[13] 450 U.S. 175 (1981).
[14] *Bilski* Slip Opinion, Kennedy at 13-16 (Section III).
[15] *In re Bilski*, 545 F. 3d 943, 1011 (Fed. Cir. 2008) (en banc).
[16] *Id.* at 943.
[17] *Bilski* Slip Opinion, Stevens at 8.
[18] *Id.* at 1.
[19] *Id.* at 7, 12-14, and 34-38.
[20] *Id.* at 8-9.
[21] *Id.* at 15-34 (Section IV).
[22] *Diamond v. Chakrabarty*, 447 U. S. 303 (1980).
[23] *Bilski* Slip Opinion, Stevens at 15-34 (Section IV).
[24] *Id.* at 47.
[25] *Bilski* Slip Opinion, Breyer at 1-4 (Section II).
[26] *Id.* at 2.
[27] *Id.*
[28] *Id.* at 3.
[29] *State Street*, 149 F.3d at 1373.
[30] *Bilski* Slip Opinion, Breyer at 3-4.
[31] *Id.*, Stevens at 2, n. 1.
[32] *In re Bilski*, 545 F. 3d at 949.
[33] *Id.*
[34] *Id.* at 950.
[35] *Id.*
[36] *Id.*
[37] *Id.*
[38] *Id.* at 949, 954, and 963-966.
[39] *Id.* at 954.
[40] *Id.* at 955-56.
[41] *Id.* at 956.
[42] *Bilski* Slip Opinion, Kennedy at 6-8 (Section II-B-1).
[43] 409 U.S. at 68, 71-72.
[44] *Id.* at 70.
[45] *Id.* at 71.
[46] 437 U.S. at 590-92.
[47] *Id.* at 585-86.
[48] *Id.* at 590.
[49] 450 U.S. at 184.
[50] *Id.*
[51] *Id.* at 188.
[52] *Id.* at 187.

With *Bilski* Having Come and Gone, It's Time to Get Back to Work
Endnotes

[14] *Bilski* Slip Opinion, Kennedy at 13-16 (Section III).

Avoiding Abstract Claims by Broadly Defining the Problem
Endnotes

[1] *Bilski* Slip Opinion, Kennedy at 15 (majority opinion)
[2] *Id.*
[3] *Id.* at 15-16.
[4] *Bilski* Slip Opinion, Stevens at 8-9 (internal quotations and citations omitted).
[5] App. No. 08-1403.

A Critique of *Bilski*'s Textual Analysis
Endnotes

[1] *Bilski* Slip Opinion, Kennedy at 6 (majority opinion) (quotations omitted).
[2] 143 U.S. 587 (1892).
[3] *Id.* at 593.
[4] *Id.* at 592.
[5] *Id.* at 592-93.
[6] 525 U.S. 55 (1998).
[7] *Id.* at 63, 67-68.
[8] *Gandy*, 143 U.S. at 592-93.
[9] *Pfaff*, 525 U.S. at 67-68.
[10] *Bilski* Slip Opinion, Kennedy at 6 (majority opinion).
[11] *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980).
[12] *In re Russell*, 48 F.2d 668 (C.C.P.A. 1931).

Questions Surrounding a Shift to an "Abstract Idea" Test
Endnotes

[1] *Bilski* Slip Opinion, Kennedy at 8 (majority opinion).
[2] *Id.* at 5 (internal quotations and citations omitted).
[3] *Id.* at 12.
[4] *Id.* at 15 (majority opinion); *See also Bilski* Slip Opinion, Stevens at 47, and *Bilski* Slip Opinion, Breyer at 1.
[5] Bahr, Robert W., Memorandum to Patent Examining Corps at 2 (June 28, 2010), available at http://www.ipwatchdog.com/2010/06/28/uspto-memo-to-examiners/id=11439/.
[6] *Bilski* Slip Opinion, Kennedy at 14 (majority opinion); *quoting Diamond v. Diehr*, 450 U.S. 175, 187 (1981).
[7] *Id.* at 15 (majority opinion); *quoting Diehr*, 450 U.S. at 188.
[8] *Id.*; *citing Parker v. Flook*, 437 U.S. 584 (1978).

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Endnotes

[1] 561 U.S. ___, June 29, 2010 Order List, available at http://www.supremecourt.gov/orders/courtorders/062910zr.pdf.
[2] 581 F.3d 1336, 1345-46, 1350 (Fed. Cir. 2009).
[3] 2008 U.S. App. LEXIS 25661 (Fed. Cir. 2008).
[4] 581 F.3d at 1339.
[5] *Id.*
[6] *Id.* at 1340.
[7] *Id.* at 1350.
[8] *Id.* at 1346-47.
[9] *Id.* at 1346.
[10] *Id.* (emphasis added).
[11] *Id.*
[12] *Id.*
[13] *Id.* (emphasis in original text; internal quotations omitted).
[14] *Id.* at 1349.
[15] 450 U.S. 175 (1981).
[16] 581 F.3d at 1349.
[17] 2008 U.S. App. LEXIS 25661 (Fed. Cir. 2008).
[18] *See Classen Immunotherapies, Inc. v. Biogen Idec*, 2006 U.S. Dist. LEXIS 98106, at *10 (D. M.D. 2006).
[19] U.S. Patent No. 5,723,283.
[20] 548 U.S. 124, 125 (2006).
[21] *See id.*
[22] 520 U.S. 17 (1997).
[23] *Bilski* Slip Opinion, Kennedy at 6 (majority opinion).
[24] *Id.* at 15.
[25] 450 U.S. at 188.
[26] 548 U.S. at 137-38 (emphasis added).
[27] *Bilski* Slip Opinion, Stevens at 43 (emphasis in original).

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