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A legal update from Dechert's Intellectual Property Group

Federal Circuit Court Hears Oral Argument in *In re Bilski*: Implications for Life Sciences Patents

*In a packed courtroom in Washington, D.C., the U.S. Court of Appeals for the Federal Circuit engaged in a spirited dialogue and heard a wide range of views on May 8 regarding the types of business methods and other processes that should—or should not—be eligible for patent protection. The case (*In re Bilski*, Appeal No. 2007-1130) specifically concerns a rejected application to patent a method for hedging fixed price commodities, but the court's decision can impact patentability of a broader range of subjects, including medical diagnostics and procedures. A decision likely will be handed down by the second half of 2008; in the interim, the May 8 hearing sheds light on what factors might be key to the court's ruling. From the tenor of the discussion at the oral argument, it seems likely that the Federal Circuit will articulate new or modified tests, particularly for methods comprising solely human actions or mental processes and are not machine implemented.*

State of the Law on Patentability of Business Methods Prior to *Bilski*

Section 101 of the Patent Law sets out the categories of “patentable subject matter,” meaning those inventions that are eligible for patentability: “any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof.” 35 U.S.C. § 101. In addition, in a series of decisions interpreting this statute, the U.S. Supreme Court established three categories of inventions that are excluded from patentability: laws of nature, natural phenomena, and abstract ideas. See, e.g., *Diamond v. Diehr*, 450 U.S. 175 (1981).

The current debate in the Federal Circuit centers on the appropriate scope and interpretation of the term “any new and useful process.” Nearly ten years ago, in its 1998 *State Street* decision, the Federal Circuit rejected the widely-held belief that a method of doing business should always be viewed as abstract and therefore not eligible for patenting. *State St. Bank & Trust Co. v. Signature Fin. Group, Inc.*, 149 F.3d 1368 (Fed. Cir. 1998). The *State Street* case involved a hub-and-spoke investment method that was implemented by a computer. The Federal Circuit concluded that a method of doing business should not be viewed as abstract *per se*; rather the patentability of the method or process would depend on whether it produces a “useful, concrete and tangible result.” *Id.* See also *AT&T Corp. v. Excel Commc'nns, Inc.*, 172 F.3d 1352 (Fed. Cir. 1999).

Following *State Street*, the number of business method patents applied for and issued, particularly in the financial services industry, increased exponentially. Meanwhile, the U.S. Patent & Trademark Office, the agency responsible for examining patent applications, faced the challenge of applying the new standard for patent eligibility articulated in *State Street*. In general, the test could be readily applied where an invention involved data that were transformed by a machine. In such circumstances, applying the *State Street* test, a method would be found patentable where it “constituted a practical application of an abstract idea (a mathematical algorithm, formula, or calculation) because it produced ‘a useful, concrete and tangible result.’” *In re Alappat*, 33 F.3d 1526 (Fed. Cir. 1994). On the other hand, applying the *State Street* test to

inventions having claims that could be performed entirely by mental process or human action, without the use of any machine or technology, or without a transformation step, proved relatively more difficult.

At the same time, there are indications that at least some justices on the U.S. Supreme Court viewed the *State Street* test as overbroad or possibly even wrong. In 2006, in a closely watched case that involved a medical diagnostic method, *Lab. Corp. of Am. Holdings v. Metabolite Lab., Inc.*, 548 U.S. 124 (2006), the Supreme Court came close to addressing the patentability of methods that encompass mental steps. The claim at issue in *Lab. Corp.* entailed “[a] method for detecting a deficiency of cobalamin or folate in warm-blooded animals” comprising 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.” Although methods of assaying a body fluid for homocysteine were known in the prior art, the correlating step, which consists “simply of a physician’s recognizing that a test that shows an elevated homocysteine level—by that very fact—shows the patient likely has a cobalamin or folate deficiency” was said to impart patentability on the claim. The Court never reached the merits of the appeal, however, dismissing *certiorari* as improvidently granted. But in his dissent from the dismissal of *certiorari*, Justice Breyer appeared to question the validity of the *State Street* test, noting that *State Street*’s “useful, concrete and tangible result” test had never been uttered or embraced by the Supreme Court, and expressing concern that the application of this tests would have resulted in finding patentability in situations that Justice Breyer deemed undeserving, such as the patenting of natural phenomena, whereby a medical practitioner would infringe the claim “merely by thinking about the relationship after looking at a test result.” Notably, Justices Stevens and Souter joined in the dissent, with Chief Justice Roberts taking no part in the opinion.

Against this background, the BPAI in late 2006 considered the *Bilski* invention, which involves a method for controlling risks in connection with commodity contracts.¹ In affirming the Patent Office examiner’s rejec-

tion of the *Bilski* claims as not directed to patentable subject matter under Section 101, the BPAI observed that, although the *State Street* test was not limited to machine-implemented methods, that case did involve a computer-implemented method. The BPAI concluded that (1) the *State Street* decision did not provide guidance whether the “useful, concrete and tangible” test applied to a process practiced entirely by human action and without any machine or technology and, (2) if the test were relevant to such inventions, the Federal Circuit had provided no guidance how it should be applied. See *Ex parte Bilski*, Appeal No. 2002-2257, 2006 WL 4080055 (B.P.A.I. September 26, 2006) (holding that “a ‘process’ under § 101 requires a transformation of physical subject matter to a different state or thing.”). In affirming the rejection of *Bilski*’s claims, the Board expressed hope that the Federal Circuit would take up the matter and clarify the tests—which is precisely what occurred upon *Bilski* appealing the Board’s decision to the Federal Circuit in early 2007.

The *Bilski* Briefing and Oral Argument

The *Bilski* appeal was fully briefed, including an *amicus* brief from the American Intellectual Property Law Association that generally supported *Bilski*’s position, and was argued before a three-judge panel in October 2007. The issue of patentable subject matter under Section 101 already was receiving considerable attention as just days earlier, the Federal Circuit had handed down decisions in two other cases in which patentability was not found under Section 101: *Comiskey* (*In re Comiskey*, 499 F.3d 1365 (Fed. Cir. 2007)) and *Nuijten* (*In re Nuijten*, 500 F.3d 1346 (Fed. Cir. 2007)). The claimed invention in *Comiskey* was an improved method of arbitration that was performed entirely by human action and mental processes, without the use of any particular technology.

¹ Independent claim 1 of the *Bilski* application sets forth the method as:

1. 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 balances the risk position of said series of consumer transactions.

In its September 2007 decision, the *Comiskey* panel held that where a process is comprised solely of mental processes, the process is abstract and unpatentable unless it embodies, operates on, transforms, or otherwise involves the other two categories of statutory subject matter—namely, the use of a machine or the transformation of matter. *Comiskey*, 499 F.3d at 1376. The court noted that the transformation of data entirely by human action or mental processes, as in the *Comiskey* invention, does not qualify as transformation of matter and, therefore, is not patentable.

Rather than deciding the *Bilski* appeal at that time, the court *sua sponte* took the unusual step of ordering the case to be reheard *en banc* by the full 12-judge panel. The court sought further briefing on a variety of issues, including whether it should overrule its prior decisions in *State Street* and *AT&T*.

In addition to receiving the requested supplemental briefs from the parties, the court received over 30 *amicus curiae* briefs. These “friend of court” briefs came from a wide range of companies in the financial services, electronics (hardware and software), and pharmaceutical industries, as well as from various patent law associations and academia. The level of interest was indeed high, with many diverse positions being taken on the questions the court had set forth. An *amicus* brief on behalf of the Biotechnology Industry Organization cautioned of the potentially far reaching consequences of the questions posed in the Federal Circuit’s decision to hear *Bilski en banc*, and argued that the court should not create a new test for patent eligible subject matter, as such a test would likely violate the Supreme Court’s interpretation of Section 101 and may also result in frustrating progress in the biotechnological arts. A diametrically opposite position was adopted by an *amicus* brief jointly filed by parties with a different perspective in the life sciences arena, Eli Lilly And Company (“Lilly”) and the Association of American Medical Colleges (“AAMC”). Lilly and AAMC sought affirmation of the BPAI’s rejection of *Bilski*’s patent application, arguing that, pursuant to the 1952 Patent Act, a process is patent-eligible only if it contain one or more discrete steps, each step of which must be limited to an act that is physically transformative, i.e., operates on something.

Under the standard enunciated by Lilly and AAMC, the claim at issue in *Lab. Corp.* would be invalid, because the correlating step does not entail any physical transformations and may occur in the mind of physicians. The Federal Circuit did not have an opportunity to address whether the correlating claim in *Lab. Corp.* was defective under 35 U.S.C. § 101, because the issue was

not raised on appeal. However, a recent decision handed down by Judge Houston in the Southern District of California, in which the court struck down on summary judgment patent claims similar to the claim at issue in the *Lab. Corp.* decision as invalid under 35 U.S.C. § 101, may shed some light on how the Federal Circuit may address a claim directed to a diagnostic correlation. Applying a test articulated by the Supreme Court in *Gottschalk v. Benson*, 409 U.S. 63 (1972), the district court found that patent claims directed to a correlation between thiopurine drug metabolite levels and therapeutic efficacy for Crohn’s disease and/or toxicity recite a natural phenomenon and “wholly pre-empt” use of the correlation such that the practical effect is a patent on the phenomenon itself. Furthermore, the patentee’s argument that *Comiskey* demonstrates that the inclusion of patentable subject matter (i.e., machines) in the claim makes the claims patentable under section 101 is unavailing because, even if *Comiskey* were applicable, any recitation of a machine in the claims is merely incidental and thus insufficient to “save” the claims from their Section 101 defects. *Prometheus Laboratories, Inc. v. Mayo Collaborative Services*, Civil No. 04cv1200 JAH (RBB) (S.D. Cal., March 28, 2008).

Ultimately, two of the *amici*, representing financial industry clients, were also invited to participate in the oral argument.

Insights Provided by the May 8 Hearing

While one cannot necessarily predict the court’s ruling based solely on questions raised in oral argument, the arguments made at the May 8 hearing, including the nature of the questions and comments from the judges, suggest that the court is dissatisfied with the current enunciations of patentability standards and is grappling with what fixes can and should be implemented.

Chief Judge Michel, in particular, expressed frustration with the *State Street* test, under which patentability of a process involving a “transformation” resides in its achieving a “useful, concrete, and tangible” result, terming these criteria simply “adjectives” that, in turn, needed further explanation and did little to inform the correct result. Questions were posed about the various terms making up the tests: What does “transformation” mean? Is “concrete” different from “tangible”? Is “useful” to be understood as simply the antithesis of the prohibited “abstract concept”? Unfortunately, the answers were few and often more confusing than the questions.

Similarly, in response to questions to counsel for guidance on the proper test to apply, no unified positions were forthcoming from those arguing before the court. Judge Newman sought views about the “space of uncertainty” which appeared to exist between the clearly patentable categories (e.g., tangible and concrete subject matter) and the clearly non-patentable categories (e.g., abstract concepts). Judge Michel, when told by counsel that no “bright line” test was possible, asked whether at least a “dim line” test could be fashioned. But counsel mostly avoided taking firm lines as to what test was appropriate, with one *amicus* simply urging that “caution” be applied by the court and that any type of *per se* rule would be improper.

In addition to deciding what test might be appropriate under Section 101, the court focused on how a test should interoperate with the other parts of the Patent Statute. Judge Rader, for example, pointed out that some of the explanations offered by counsel seemed merely redundant of terms already expressed in the patent statute. Judge Linn and others asked counsel about the interaction between Section 101 and the conditions for patentability set forth in Sections 102 (anticipation), 103 (obviousness), and 112 (lack of written description, lack of enablement, and indefiniteness). In this regard, Mr. Hansen, representing Mr. Bilski, noted that the broader a claim, the more likely it was going to encompass abstract ideas and thus the more likely it was to suffer from lack of enablement. Professor Duffy, making *amicus* arguments in support of Bilski, suggested that to the extent a method encompasses “post solution,” i.e., post mental step, activity, that post mental step activity cannot be obvious over the art. In other words, the mental step cannot impart novelty or nonobviousness on a claim.

The court also expressed concern over the potential impact of a test for patentable subject matter on areas beyond just financial services. One counsel was questioned because the position being urged seemed to invalidate software patents, while another was asked whether the position he was urging might invalidate patents in biologic areas. Other examples of the court’s concerns over the impact of any test arose in the context of hypotheticals that were used to isolate and simplify the issues at hand: a method for throwing curve balls and whether it effected any “transformation” of the ball or its flight path, as well as chiropractic methods to align spines and whether such changes constituted “transformation”.

Except for one of the *amicis*—who represented the above-described financial services industry consortium—

counsel generally did not press for reversal of either the *State Street* or *AT&T* decision. The reasons given for not doing so ranged from embracing the tests those cases already provided, to keeping the court’s ruling focused on only the subject matter claimed in by Bilski rather than digging back into the facts of either *State Street* or *AT&T*. Nonetheless, both the Patent Office and the financial services consortium took the position that a machine could not be merely ancillary to a method claim for the method claim to be patentable.

While the court’s dissatisfaction with the current tests was apparent, it did little to signal in what direction a solution might proceed. In part, this was due to the broad range of approaches and criticisms the large panel voiced: no one direction was apparent. Overall, it appeared that the court is looking for a test that can be uniformly understood and applied, while avoiding one that might have a disastrous impact on patents already issued. The court also expressed concerns about providing a test that did not cause problems with the Patent Office’s examination process, either by causing the rejection of claims that were proper or by causing the examiner’s to undertake substantive (e.g., prior art) review of claims that were clearly unpatentable.

The court also raised questions concerning what role it can and should have in this process. For example, is it within the power of the Federal Circuit to create another (fourth) category of subject matter excluded from patentability, or was that solely within the province of the Supreme Court or even Congress? Still other questions signaled concern over whether the court could deduce additional categories of non-patentable subject matter or whether it was restricted only to construe current categories.

Observations

The May 8 hearing revealed the predicament that is facing the court: how to fix a patentability standard that doesn’t seem to be working satisfactorily. The essentially philosophical discussions that occurred at the hearing evidenced the court’s appreciation for the possibility any ruling will have impact well beyond the financial methods that are the subject of the Bilski application. It does seem likely that later this year the court will issue a new test, or at least improvements to the current tests. It remains to be seen, however, whether it will provide the absolute clarity that the participants on both sides of the issue are seeking. At the same time, the court’s questions and comments did little to signal a plan to reverse either *State Street* or *AT&T*.

Even after the Federal Circuit hands down its ruling, the prospect remains that the Supreme Court may take up the issue in turn. The dissent in *Lab. Corp.* indicated that at least some justices have concerns about the present tests and believe that the Supreme Court should be the source of the standard to be used. The Supreme Court has an opportunity to address this issue sooner rather than later. On May 9, 2008, Mr. Nuijten (real party in interest: U.S. Philips Corporation) filed a petition for writ of certiorari to the Supreme Court, asking the Court to address whether the Federal Circuit erred in its *In re*

Nuijten decision by adding new requirements to 35 U.S.C. § 101. Stay tuned for further developments on this issue.



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