## This article is featured on American Conference Instute's Blog

**Please visit http://www.americanconference.com/blog for more publications.**

***The Following article was contributed by Dr. Sarika Singh Patent Lawyer at*** McNeely & Hare LLP

# Diagnostic Method Patenting After Bilski

### What is the law on patent-eligible method after Bilski?

When the Supreme Court granted Certiorari in *In re Bilski*, much was anticipated from the decision, not just on the patent-eligibility of business methods, but also for other unconventional methods, such as, diagnostic methods, methods involving software programs, and biotech processes. The Court of Appeals for the Federal Circuit has long struggled to come up with a satisfactory objective standard for determining patent-eligibility of such methods with intermittent help from the Supreme Court. The statutory basis for determining patentable subject matter is 35 USC § 101 that allows patenting of "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof". Process is unhelpfully defined under 35 USC § 100(b) as "process, art, or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material." While both the lower court and Justice Stevens in his concurring opinion in *Bilski v. Kappos* (*Bilski*) found the definition circular and unhelpful, Justice Kennedy, writing for the Supreme Court in *Bilski* made much of the guidance provided by § 100(b).

Anyhow, the *Supreme Court* did not live up to the expectations of providing clarity in method patenting that everyone wished for. In fact, the Court provided little guidance, except for overruling Federal Circuit's latest take on patent-eligibility in *Bilski* that a "machine or transformation" test would solely govern the statutory subject matter inquiry. That test requires that the method is either (1) tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing. The Supreme Court correctly pointed out that its prior cases, *Gottschalk* v. *Benson* and *Parker v. Flook*, expressly declined to make the machine or transformation test the sole inquiry, although, the test is a useful "investigative tool" and provides an "important clue".

Further, the Court reiterated that laws of nature, physical phenomena, and abstract ideas are not patent-eligible and the Court's decisions in *Benson*, *Flook* and *Diehr* (*Diamond v. Diehr*) continue to provide the guidelines for determining what may or may not constitute patent-eligible subject matter. In a nutshell, *Benson*, *Flook* and *Diehr* provide that an algorithm, a

principle in the abstract, a motive, or an idea cannot be patented even if they are tied to a particular technological environment or are accompanied by insignificant post-solution activity. However, the application of these abstract ideas to a structure or process, even a known one, may “deserve” patent protection when such use is not an attempt to patent the idea itself. When a use of an abstract idea is a bona fide application, and not an insignificant post solution activity is anybody's guess. But, that is the what we have till such time as the Federal Circuit finds a new limiting test as suggested by the Supreme Court.

The Court also declined to endorse any interpretations of § 101, Federal Circuit may have used in the past, most likely a reference to the “‘useful, concrete, and tangible result’” test the Federal Circuit articulated in *State Street Bank & Trust Co.* v. *Signature Financial Group, Inc.*, and then overruled in all but name in *In re Bilski*. *State Street'*s broad test is blamed for encouraging the kind of software and business method patents that made many uncomfortable including some at the Supreme Court. However, the test appears to correctly articulate the only guidance the Supreme Court has provided so far. That which is not an abstract idea will likely be concrete, tangible and useful. Moreover, the State Street test also confirms to the reasoning of *Benson*, *Flook* and *Diehr*. Unfortunately, it is highly unlikely that the Federal Circuit will readopt State Street test. Will the *F*ederal Circuit formulate a new test anytime soon? Odds are, it won't. We just saw them duck the § 101 issue in *King Pharmaceuticals, Inc. v. Eon Labs, Inc*. We will likely see the court vaguely regurgitate *Benson*, *Flook* and *Diehr* criteria, and arrive at the outcomes they like.

**Does *Bilski* change the world of diagnostic patenting?**

In a word, no. But then, didn't the Supreme Court grant cert. in *Prometheus* and *Classen*, vacate the decisions below and send the cases back to the Federal Circuit for a decision in line with *Bilski*? Yes, but that could mean little change in outcome in those cases. The Court may simply be wanting the lower court to enunciate the correct test/rationale for arriving at the outcome. In fact, *Bilski* makes it a bit easier to patent diagnostic methods than before, now that the Federal Circuit need not stretch the concept of a transformative process as it did in *Prometheus* to make that diagnostic method fit into its machine or transformation test.

***Classen Immunotherapies, Inc. v. Biogen Idec***

One of the claims found to not confirm to “machine or transformation” test in *Classen* recited:

> A method of 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, which comprises:
>
> immunizing mammals in the treatment group of mammals with one or more doses of one or more immunogens, according to said immunization schedule, and
>
> comparing the incidence, prevalence, frequency or severity of said chronic immune-mediated disorder or the level of a marker of such a disorder, in the treatment group, with that in the control group.

Is it likely that on remand the Federal Circuit will find the claim to cover statutory subject matter? If I was a betting person, I will be betting against Classen. The court will probably find the claim to cover an abstract idea, where the immunizing step is a data gathering step, incidental to the main invention which is embodied in the comparison step, a mental step akin to an algorithm, á la In re Grams. Thus, Classen would easily fail to meet the *Benson*, *Flook* and *Diehr* standard. After all, the claim seeks to cover all methods to determine the efficacy of an immunization schedule, and hence the concept of scheduled immunization as such. The fundamental problem with the claim formulation is the use of broad generic terms and the scope of the claim that renders it susceptible to characterization as an abstract idea, the same problem that *Bilski* faced.

### *Prometheus Laboratories, Inc. v. Mayo Collaborative Svcs*

How would *Prometheus* fare post *Bilski*? An example of the claims at issue reads:

> 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 8×108 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 8×108 red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.

Those claims appear sufficiently specific and the Federal Circuit liked it enough to creatively

characterize the administration step of the drug and resulting therapeutic effect on the body as a transformative process. The court also found the changes in the blood sample during diagnostic testing , although, not recited in the claim, to be transformative. Again, the invention here lies in the interpretation of the test results, a mental step, not the well known steps of administration, or the unremarkable step of detecting 6-thioguanine level, both being data gathering steps incidental to the diagnosis. Now that the Court need not fit the claim into the machine or transformation straight-jacket, it can convincingly decide that the invention is not an abstract idea, because the claim, when seen as whole and not as fragmented steps divorced from their correlation, do cover a specific application of the mental step, a diagnostic method which optimizes dosage of a 6-thioguanine providing drug. Moreover, the mental step of interpreting the test results includes very specific results for 6-thioguanine levels, such that they do not appear, at least on its face, to monopolize all methods of optimizing dosage of 6-thioguanine providing drugs. My guess is, one way or the other, the Federal Circuit will find *Prometheus* patent-eligible.

***Association for Molecular Pathology v. USPTO* (Myriad)**

How about the method claims in Myriad that Judge Sweet invalidated as patent-ineligible? I have to confess that this one is a tough call. A representative claim reads:

> A method for detecting a germline alteration in a BRCA1 gene, said alteration selected from the group consisting of the alterations set forth in Tables 12A, 14, 18 or 19 in a human which comprises analyzing a sequence of a BRCA1 gene or BRCA1 RNA from a human sample or analyzing a sequence of BRCA1 cDNA made from mRNA from said human sample with the proviso that said germline alteration is not a deletion of 4 nucleotides corresponding to base numbers 4184-4187 of SEQ ID NO:1.

While the claims may appears specific and detailed rather than an abstract idea, Judge Sweet characterized the claim as a process of analyzing a BRCA1 sequence and noting whether or not the specified naturally occurring mutation exists. Judge Sweet's formulation does make the claim appear rather broad and an attempt to cover all gene testing involving BRCA1 to detect mutations. On the other hand, the details in the claim do indicate that specific mutation testing in a specific gene are sought to be covered and the claim seen as a whole does cover a useful discrete diagnostic genetic test, not an amorphous concept.

However, the question is bigger and more significant, socially and politically, in *Myriad* than in *Prometheus*. Diagnostic gene testing holds a promising breakthrough for hitherto difficult to

tackle disease, and recognizing unhindered patent monopoly to such testing will possibly shut the doors not only on affordable testing, but also on collaboration and data sharing among the academia and industry that has been a key to much progress in the field of gene characterization and therapy. At least, that is the rather convincing argument that probably won the day for Association for Molecular Pathology. On the other side is the commercial biotech industry that warns that without patents, it will be hard to get the much needed private financing that fuels the genetic research. Who will win the battle in the gene patenting battle is hard to predict and I can only foresee both the Federal Circuit and the Supreme Court struggling to strike the right balance. We have already seen the dissenters in a cert. denial in *Laboratory Corp. of America Holdings v. Metabolite Laboratories Inc.* viewed the diagnostic claims there as 1) obtaining test results and (2) thinking about them, and characterized the correlation to a natural phenomenon. One of the claims in question reads:

> 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.

The claims appear similar to that in Prometheus, albeit, not restricted by any specified levels of concentration. Even if that case did not relate to genes and that view is apparently a minority view, that dissent together with the fragmented decision in *Bilski*, with two concurring (partly dissenting) opinions gives a good indication of the difficulties the Supreme Court faces in coming out decisively on either side of a diagnostic method patent, more so when that method involves genetic testing. For now, my best guess is that the Federal Circuit is more likely than not to come down on the side of *Myriad* and the Supreme Court will deny cert unless the Federal Circuit does a really bad job of explaining its standard, or the Supreme Court feels compelled to take up the separate but linked issue of patent-eligibility of isolated genes as such (the bigger issue presented in *Myriad* that I will spare for another day). In case the Supremes do take up genetic diagnostic method patent-eligibility, I again hazard a guess that will rule affirm an outcome in favor of *Myriad.*

**Conclusion**

With a bench composition at the Federal Circuit that has increasingly shown a pro-patent inclination, especially in the pharmaceutical/Biotech field, and a conservative pro-business

majority at the Supreme Court that has refrained from its alleged anti-patent inclination at least when it comes to pharmaceutical/Biotech field, it is safe to say that a well crafted diagnostic method patent that does not attempt to cover the sun, the moon and the stars has a good chance of surviving the vagaries of any newly crafted patent-eligibility tests. But, when the claims do get as ambitious as in *Classen*, defending them will likely be a loosing battle. For the somewhere in the middle variety, and those pesky gene method patents, my guess is they will survive and flourish till we see a radical change in the composition of the two courts or some sweeping legislative changes to patent law by the congress.

So, is all lost for those who are waging the war against diagnostic patents, including the life saving gene diagnostics if the courts come down in favor of the patentees in *Myriad* and *Prometheus*. Not really. There is enough ammunition for the opponents of such patents in *Bilski*. If a claim can be effectively characterized as an attempt to cover an abstract idea, motive or law of nature and the accompanying limitations painted as trivial pre/post solution activity, there is some hope that the patent could be invalidated. Those who do not like diagnostic method patents are probably better off augmenting their arsenals by mounting a § 112 ¶ 1 or 2, or § 103 challenge, arguing the inventor's lack of possession of the invention across its breadth, failure to point out and distinctly claim the subject matter that was invented, or obviousness of the test and the interpretation of the test result. Indeed, in case of gene based diagnostic method such as those in *Myriad*, once the gene is isolated and characterized and mutations identified, and that information is in public domain, there may be nothing non-obvious about the testing method when claimed in broad terms.



Sarika Singh is a Patent Attorney at McNeely & Hare LLP whose practice includes all aspects of intellectual property law, especially in the chemical, pharmaceutical and biotech fields. Having worked for nine years in the patent department at Ranbaxy, and three years as a chemist in process development and up-scaling of active pharmaceutical ingredients, Dr. Singh brings real world scientific and business perspective to her practice. Her experience of more than five years in managing and supporting patent litigation worldwide gives her extensive knowledge of diverse patent practices not only in the United States but also throughout Europe, South Africa, Russia, CEE, and Canada. She has a Ph.D. in Synthetic Organic Chemistry from University of Delhi and a J.D. from Rutgers School of Law-Newark.

Dr. Sarika Singh's full biography at

http://www.patentek.com/CM/FirmOverview/FirmOverview267.asp

Contact Dr. Sarika Singh on linkedin at

http://www.linkedin.com/pub/sarika-singh-ph-d-esq/10/114/8a0/