

***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 8x10⁸ 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 8x10⁸ 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 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* case²²) 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

¹561 U.S. ___, June 29, 2010 Order List, available at <http://www.supremecourt.gov/orders/courtorders/062910zr.pdf>.

²581 F.3d 1336, 1345-46, 1350 (Fed. Cir. 2009).

³2008 U.S. App. LEXIS 25661 (Fed. Cir. 2008).

⁴581 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)**.