

# Medical Diagnostic Claims Are Patentable

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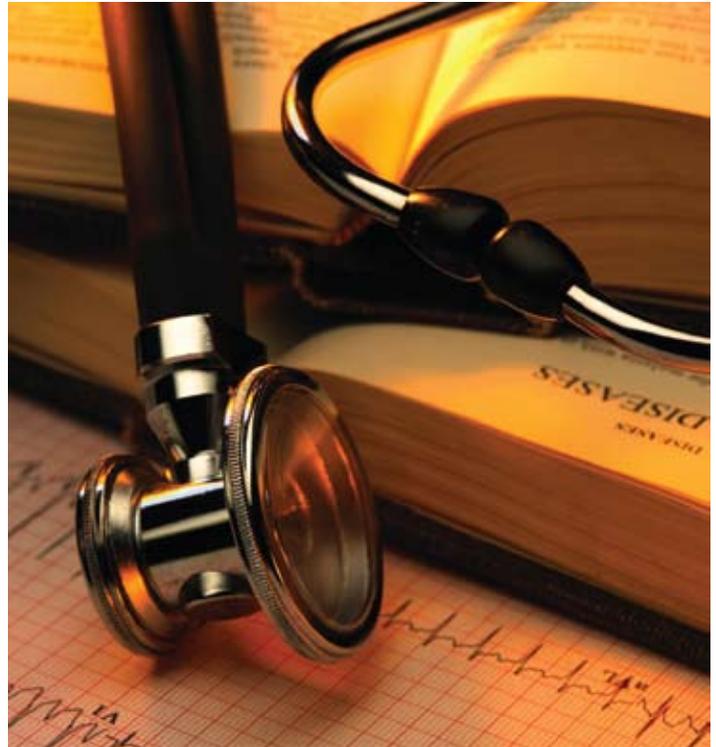
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A unanimous panel of the Federal Circuit has decided that some patent claims directed to medical treatment and diagnostic methods are patentable subject matter.<sup>1</sup> This decision was unexpected—to say the least—in light of the Federal Circuit’s 2008 decisions in *Bilski*<sup>2</sup> and its follow-up decision in *Classen Immunotherapies*.<sup>3</sup> In these opinions, the Federal Circuit narrowed the scope of patentable subject matter. In *Bilski*, the court set forth a bright-line rule requiring that a method claim be “tied to a particular machine or apparatus” or “transform a particular article into a different state or thing” to be patentable.<sup>4</sup> It then applied this rule in *Classen* in affirming the invalidity of the claims at issue.<sup>5</sup> These cases raised the question of whether methods for interpreting or manipulating information from anywhere (in these cases, financial markets and clinical results) are patentable; *Prometheus* labs says they could be. The world waits to hear what the Supreme Court has to say on this matter, as the *Bilski* case was set to be heard on November 9, 2009.

## *In re Bilski and Classen Immunotherapies*

In 1997, Bernard Bilski and Rand Warsaw filed a patent application for a method of hedging risks in commodities trading.<sup>6</sup> Their application was rejected by the United States Patent and Trademark Office (USPTO) on the grounds that “the invention is not implemented on a specific apparatus and merely manipulates [an] abstract idea and solves a purely mathematical problem without any limitation to a practical application, therefore, the invention is not directed to the technological arts.”<sup>7</sup> The applicants appealed to the Board of Patent Appeals and Interferences (BPAI), which affirmed the rejection on alternative grounds.<sup>8</sup> Although the BPAI held that the examiner erred by relying on a “technological arts” analysis that was not present in the case law and required the use of a specific piece of equipment,<sup>9</sup> it affirmed the rejection because the *Bilski* application’s claims were not directed to statutory subject matter.<sup>10</sup>

The inventors then appealed to the Federal Circuit. After an *en banc* hearing, the Federal Circuit issued its opinion on October 30, 2008,<sup>11</sup> affirming the BPAI’s ruling that the method at issue of hedging risks in commodities trading did not satisfy the patentable subject matter requirements set forth by the Supreme Court.<sup>12</sup> The court’s new standard for determining whether a process constitutes patent-eligible subject matter under § 101 is referred to as the “machine-or-transformation” test, requiring that a patentable process must either: (1) be tied to a particular machine or apparatus, or (2) transform an article into another state or thing.<sup>13</sup>



Under this new test, the two-part inquiry may be satisfied by showing that the claim is tied to a machine or that the claim transforms the article.<sup>14</sup> Since the claim at issue did not limit any process step to any specific machine or apparatus, the court did not address that portion of the analysis.<sup>15</sup> The court decided to “leave to future cases the elaboration of the precise contours of machine implementation, as well as the answers to particular questions, such as whether or when recitation of a computer suffices to tie a process claim to a particular machine.”<sup>16</sup>

With respect to the transformation requirement, the court made clear that one physical substance being turned into a second physical substance constitutes transformation and is patent eligible.<sup>17</sup> More non-traditional processes are not as clearly defined. The court cited cases where graphically displaying variances of data was unpatentable, but when X-ray data was produced in a two-dimensional field by a scanner, the “transformation of that raw data into a particular visual depiction of a physical object on a display was sufficient to render that more narrowly-claimed process patent eligible.”<sup>18</sup>

In analyzing the *Bilski* claims, the court found that the commodities-hedging process as claimed does not transform any item to a different state or thing. The process was unpatentable because “transformations or manipulations simply of public or private legal obligations or relationships, business risks, or other such abstractions cannot meet the test because they are not physical objects or substances, and they are not representative of physical objects or substances.”<sup>19</sup> The transformation of the relationships between the commodity broker, consumer, and the market was insufficient to be patentable. However, as Judge Randall Rader notes in his dissent, this decision still leaves many questions regarding the limits of what constitutes “transformation” to make a process patent-eligible.<sup>20</sup>

## USPTO Guidelines

Acknowledging that the state of the law with respect to subject matter eligibility under 35 U.S.C. § 101 is in flux, this past August the USPTO published new Interim Instructions for Evaluating Subject Matter Eligibility Under § 101.<sup>21</sup> The Instructions provide a two-step analysis for determining subject matter eligibility.

The first step asks if the claim is directed to one of the four patent-eligible subject matter categories (process, machine, manufacture, composition of matter). If it is not, the claim is not eligible for patent protection and should be rejected under § 101. Likewise, a claim that covers both statutory and non-statutory embodiments fails the first step and should be rejected.

Step two of the analysis asks if the claim “wholly embrace[s] a judicially recognized exception, which includes abstract ideas, mental processes or substantially all practical uses (pre-emption) of a law of nature or a natural phenomenon, or is it a particular practical application of a judicial exception.” If the claim is wholly directed to a judicially recognized exception, it is not eligible for patent protection and should be rejected under § 101. However if the claim is limited to a particular application of a judicially recognized exception, it is eligible for patent protection.

For machines, manufactures, and compositions of matter where a judicial exception is recited in the claim, the Instructions require that the claimed product have a practical application. To qualify as a practical application of the judicial exception, the claim must recite a structural limitation. A man-made, tangible embodiment with a real-world use is evidence of a practical application. If the claim recites a tangible embodiment, the next step is to confirm that the claim does not cover substantially all practical uses of the judicial exception. When the claim is limited to a particular practical application and does not cover substantially all practical uses of the judicial exception, the claim is directed to statutory subject matter and eligible under § 101.

For a process claim, *Bilski*'s machine-or-transformation test is employed to ensure that the process is limited to a practical application.<sup>22</sup> Thus, a machine or transformation must be identified either explicitly or inherently in the claim. However, the mere presence of a machine or transformation is insufficient because the claimed process must be tied to a *particular* machine or must *particularly* transform a *particular* article to a different state or thing.<sup>23</sup> If the machine or article transformed covers all machines or transformations of all articles and/or it cannot be specifically identified, it is not “particular.” Additionally, the particular machine or transformation must impose a meaningful limitation on the claim's scope by, for example, being present in more than a mere field-of-use limitation, and its use must involve more than insignificant extra-solution activity.

Only if all conditions are met does the claim qualify as eligible subject matter under § 101.

## Prometheus

The most recent case in which the Federal Circuit was called upon to interpret *Bilski* specifically for medical diagnostic claims

was in mid September. The Federal Circuit issued an opinion in a case called *Prometheus v. Mayo*, where it was called upon to answer the question of what constitutes patentable subject matter under § 101, as interpreted in *Bilski*.

The case commenced on June 15, 2004, when Prometheus sued Mayo Collaborative Services for the infringement of patents that generally claim methods for calibrating the proper dosage of thiopurine drugs, which are used for treating gastrointestinal and non-gastrointestinal autoimmune diseases.<sup>24</sup> On March 28, 2008, the district court granted Mayo's motion for summary judgment based on invalidity under § 101. The district court reasoned that the asserted claims have three steps: (1) administer the drug to a subject; (2) determine metabolite levels; and (3) be warned that a dosage adjustment may be required.<sup>25</sup>

The district court then based its decision on three findings. First, the trial court concluded that the first two method steps were merely non-patentable data-gathering steps, while the third was a non-patentable mental step that did not require any change in the dosage but merely warned the doctor.<sup>26</sup> Second, the trial court found that the correlations were “natural phenomena and not patentable inventions because the correlations resulted from a natural body process.”<sup>27</sup> Third, the trial court determined that because the claims cover the correlations themselves, the claims wholly preempt the correlations—which is a fundamental principle—and therefore the claims are not patentable.<sup>28</sup>

Prometheus appealed to the Federal Circuit arguing that the claimed processes satisfy the machine-or-transformation test articulated in *Bilski*. The Federal Circuit agreed with Prometheus and reversed the district court's grant of summary judgment, concluding that the “methods of treatment claimed in the patents in suit” satisfied the transformation prong of the machine-or-transformation test. The court found that the district court erred in concluding that the disputed claims merely claim natural correlations and data-gathering steps.<sup>29</sup>

The court's first point was that the initial administering step is transformative: “the 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.”<sup>30</sup> The fact that the change of the drug into metabolites is a natural process does not disqualify the administering step from the realm of patentability.<sup>31</sup>

Next, the court explained that the determining step is also transformative and “central to the claimed methods.”<sup>32</sup> The level of the drugs in each subject cannot be determined by mere inspection. Some manipulation is involved in the process. Indeed, the court cited testimony from a Prometheus expert that at the “end of the process, the human blood sample is no longer human blood; human tissue is no longer human tissue,” and stated that this “is clearly a transformation.”<sup>33</sup>

Third, with regard to the final warning step, the Federal Circuit agreed with the district court that this was a mental step, but concluded that this fact alone does not negate the transformative nature of the administering and determining steps.<sup>34</sup> A subsequent

mental step does not negate the whole, and when “viewing the treatment as a whole, Prometheus has claimed therapeutic methods that determine the optimal dosage level for a course of treatment.”<sup>35</sup>

In conclusion, the Federal Circuit found that the claimed methods of Prometheus satisfy all the requirements under *Bilski*'s transformation prong for patent-eligible subject matter under § 101 because they transformed the human body by the administration of a drug and further transformed the drug itself during analytical tests used to determine the drug's concentration in the body, and these transformations were central to the claimed method's purpose.

## Conclusion

The Federal Circuit's decisions in *Bilski* and its progeny have called into question what constitutes patentable subject matter under 35 U.S.C. § 101. The USPTO intervened and provided practitioners some guidance by publishing new Interim Instructions regarding subject matter eligibility. The Federal Circuit attempted to do the same in its opinions in *Classen Immunotherapies* and *Prometheus Labs*. Ultimately, though, both practitioners and patentees alike anxiously await the Supreme Court's *Bilski* decision, with the hope that with the decision comes some much needed clarity.

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1 *Prometheus Laboratories, Inc. v. Mayo Collaborative Services*, 2009 WL 2950232 (Fed. Cir. Sep. 16, 2009).

2 *In re Bilski* 545 F.3d 943 (Fed. Cir. 2008).

3 *Classen Immunotherapies, Inc. v. Biogen Idec, et. al.*, Appeal No. 2006-1634 (Fed. Cir. 2007). Although *Classen Immunotherapies* is not precedential, it had a warning effect to patentees.

4 *Bilski*, 545 F.3d at 954.

5 The claim at issue stated as follows: “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.” The court found this claim invalid in light of *Bilski*, finding that the claim is neither “tied to a particular machine or apparatus” nor does it “transform a particular article into a different state or thing.”

6 This claim was a business method claim. *State Street Bank & Trust Co. v. Signature Financial Group, Inc.*, 149 F.3d 1368 (Fed. Cir. 1998) (“Whether the claims are directed to subject matter within §101 should not turn on whether the claimed subject matter does “business” instead of something else.”).

7 *Bilski*, 545 F.3d at 954.

8 *Ex parte Bilski*, 2006 WL 5738364 at \*41-42, Appeal No. 2002-2257 (Bd. Pat. App. & Interf. Sept. 26, 2006).

9 *Id.* at \*42.

10 *Id.* at \*46-49.

11 *In re Bilski* 545 F.3d 943 (Fed. Cir. 2008).

12 *Id.* at 949.

13 *Id.* at 961.

14 *Id.*

15 *Id.* at 962.

16 *Id.*

17 *Id.*

18 *Id.* at 963.

19 *Id.*

20 *Id.* at 1015.

21 United States Patent and Trademark Office, *Interim Examination Instructions For Evaluating Subject Matter Eligibility Under 35 USC 101*: [www.uspto.gov/web/offices/pac/dapp/opla/2009-08-25\\_interim\\_101\\_instructions.pdf](http://www.uspto.gov/web/offices/pac/dapp/opla/2009-08-25_interim_101_instructions.pdf).

22 The two-step analysis is based on the rule set forth by *Bilski*.

23 *Id.*

24 *Prometheus Laboratories, Inc.*, 2009 WL 2950232 at \*1.

25 *Id.* at \*3.

26 *Id.*

27 *Id.*

28 *Id.*

29 *Id.* at \*11-12.

30 *Id.* at \*8.

31 *Id.*

32 *Id.* at \*16.

33 *Id.* at \*17.

34 *Id.* at \*10.

35 *Id.* at \*20.

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