

State of flux

Following *Bilski v Kappos*, the criteria to judge patent-eligible subject matter is still uncertain. Durie Tangri's **Clement Roberts** discusses where this leaves the software and biotech industry

The US Patent Act provides that an inventor may obtain a patent for "any new and useful process, machine, manufacture, or composition of matter" provided he or she meets the other requirements of the Act¹. Although this section (§101) is written in absolute terms, it is – like many other "absolute" provisions of US law – subject to judicially created exceptions. It has long been the case, for example, that "laws of nature, natural phenomena; and abstract ideas" are not patentable even if they would otherwise qualify for protection under the literal language of the statute². In summer 2010 the US Supreme Court wrestled with the scope of these exceptions in an opinion in the case of *Bilski v Kappos*³. That decision, and its progeny, may have a profound effect both on what is patentable and how companies go about protecting their inventions.

***Bilski* and its progeny**

The patent at issue in *Bilski* dealt with a process for hedging risk by initiating a series of transactions between a single seller of commodities and multiple sets of buyers with opposite risk preferences. In an *en banc* decision, the United States Court of Appeals for the Federal Circuit (Federal Circuit) found that *Bilski* was not entitled to a patent because his invention was directed at an abstract idea. The Federal Circuit also found that the proper test for determining patent eligibility was whether the challenged invention was tied to a specific machine or involved a transformation of matter from one state to another⁴. If an invention

or transformation test is the exclusive test for determining patent eligibility, it did not give the lower courts much to point to in the way of alternatives. It is therefore, unsurprising that since the Supreme Court decided *Bilski*, a wide variety of approaches have sprung up. The administrative Board of Patent Appeals and Interferences within the US Patent and Trademark Office has, for example, taken the position that *Bilski* basically endorsed the machine or transformation test and that where an invention fails that test it is unpatentable, unless there is some compelling reason to hold otherwise⁵. The only District Court to have ruled on patent eligibility since *Bilski* also took this position⁶.

On the other hand, a decision authored by two of the Federal Circuit judges who dissented from the *en banc* decision in *Bilski* took a much more expansive approach. In *Research Corporation Technologies Inc v Microsoft*, the Federal Circuit skipped over the machine or transformation test entirely, and held that the proper analysis was to determine whether the alleged abstractness "exhibit[ed] itself so manifestly as to override the broad statutory categories of eligible subject matter"¹⁰. The court also found that there was "nothing abstract" about the claims before it (which were addressed to a method for half-toning images) and noted that "inventions with specific applications or improvements to technologies in the

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passed this "machine or transformation" test, it was directed to eligible subject matter, if it failed the test, it was not.

On appeal, the Supreme Court upheld the finding that *Bilski*'s invention was not patent eligible, but faulted the Federal Circuit for enshrining the "machine or transformation test" as an exclusive test for determining eligibility. The court did not, however, provide any alternative test and indicated that the "machine or transformation test" was still "a useful and important clue, an investigative tool" for determining eligibility⁵. The court also noted that, while it was not categorically *ruling out* business method patents, the Patent Act "does not suggest broad patentability of such claimed inventions"⁶. And the court reaffirmed earlier holdings that otherwise unpatentable subject matter cannot be rendered eligible by limiting the claim "to a particular technological environment or adding insignificant post-solution activity" such as storing the result of a mathematical operation.⁷

Thus, while the *Bilski* Court rejected the idea that the machine

marketplace are not likely to be so abstract” as to run afoul of §101.¹¹

Just nine days later, however, in *Prometheus Laboratories, Inc v Mayo Collaborative Services*¹², the Federal Circuit *did* apply the machine or transformation test, while noting “that “[t]ransformation and reduction of an article to a different state or thing’ is **the** due to the patentability of a process claim that does not include particular machines.”¹³ The court went on to find that the challenged claims were patentable precisely because they satisfied this transformational requirement.

Implications

The post-*Bilski* case law is clear on only one point: that the scope of patent-eligible subject matter is still in flux. Accordingly, the impact on industry and on practitioners will largely depend on which of the various interpretations of *Bilski* is ultimately adopted by the Federal Circuit.

From this perspective, there is some reason to believe that patentable subject matter ultimately won’t matter very much. In particular, it is possible to read *RCT* and *Prometheus* as standing for the proposition that claims are patent-eligible when they pass the machine or transformation test, but that claims should not be found ineligible unless they are “manifestly abstract”. In other words, it is possible to read the Federal Circuit’s post-*Bilski* cases as standing for the proposition that the machine or transformation test is a floor, but not

unlikely that the BPAI will change its approach – at least until the Federal Circuit and (perhaps) the Supreme Court rule on some of the BPAI’s post-*Bilski* decisions.

Secondly, it seems likely that – at least in the intermediate term – patentable subject matter will *not* be a major issue for the biotechnology industry. The claims at issue in *Prometheus* were directed to a method “for optimizing efficacy and reducing toxicity of treatment regimes for gastrointestinal and non-gastrointestinal autoimmune diseases” by (1) administering a drug; (2) determining the created metabolites’ concentration levels and (3) creating a warning for a doctor to alter the dosage¹⁶. As noted above, the Federal Circuit found that this *kind* of claim resulted in a transformation of matter. In particular, the Federal Circuit found that each of the first two steps qualified, holding both that (1) “when administering a drug ... the human body necessarily undergoes a transformation” and (2) that in determining the metabolites’ levels “[s]ome form of manipulation ... is necessary to extract the metabolites from a bodily sample and determine their concentration.”¹⁷

Insofar as the logic of this decision is followed by the lower courts, the biotechnology industry is not likely to be effected by the debate over patentable subject matter because virtually all biotech patents involve therapeutics (and therefore can be drafted to include the administration of a drug) or diagnostics (and therefore can be drafted to include taking and manipulating a tissue sample)¹⁸.

It is worth noting, on the other hand, that the *Ass’n for Molecular Pathology v US Patent and Trademark Office* is still pending before the Federal Circuit. In an earlier decision in that case, a District Court in New York (in an *exceedingly* long opinion) found that Myriad Genetics’ patents on the BRCA gene sequences were not directed to patent-eligible subject matter because they did not involve a transformation, but instead merely isolated something (DNA) that already existed in human tissue. Although there are ways one could *attempt* to harmonise that decision with *Prometheus*, the two decisions are generally incompatible. Thus, the *Myriad* case presents a critical inflection point for biotech companies insofar as it will really put patentable subject matter to rest as a concern for the biotech industry if it follows *Prometheus* and will create substantial uncertainty insofar as it follows a different analysis or reaches a different conclusion.

Thirdly, it seems likely (again in the intermediate term) that the technology industry will face substantial risk with respect to the patent-eligibility of software. The BPAI has gone very far in the direction of prohibiting software patents, regularly finding that “software *per se*” (that is claims directed expressly to software) is ineligible¹⁹, and at least one case even holding a claim ineligible because it “does not **preclude** a[n] ... embodiment directed only to software and data structures *per se*.”²⁰ In support of this approach, the BPAI regularly cites to pre-*Bilski* language from the Supreme Court’s decision in *Microsoft v AT&T*²¹ holding that “[a]bstract software code is an idea without physical embodiment”.

On the other hand, it is possible to read *RCT* as standing for the proposition that software is broadly patent eligible – especially if one focuses on the court’s assertion that “inventions with specific applications or improvements to technologies in the marketplace are not likely” to fall outside the scope of §101. There are, however, problems with reading *RCT* too broadly. For example, under an expansive reading of *RCT*, the claims at issue in *Bilski* would have been patent eligible if *Bilski* had merely drafted his claims in a *Beauregard* format or otherwise specified that the claims were directed to software for more efficiently completing hedging transactions.

For this reason (ie, because *all* software cannot be patent eligible without making the exception for abstraction a dead letter) it is likely that subsequent panels of the Federal Circuit will find *some* way to limit the scope of *RCT*. It is possible, for example, to argue that the software at issue in *RCT* was directed to a

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a ceiling, when determining whether or not claims are too abstract to pass muster under 101.

This is pretty clearly the view of Chief Judge Randall Rader who authored the decisions in *RCT* and concurred in *Prometheus* and who, in his dissent from the Federal Circuit’s *en banc* decision in *Bilski* argued that there was nothing wrong with patenting even natural phenomena so long as the claims “achieve a useful, tangible and concrete result” and don’t attempt to merely claim the natural phenomena itself¹⁴. On the other hand, the fact that the *RCT* decision was authored by Rader and supported by Newman (who also dissented in *Bilski*)¹⁵ suggests that it may have trouble getting traction. Indeed, the Federal Circuit’s *en banc* decision in *Bilski* strongly suggests that Rader and Newman are out of step with most other members of the Federal Circuit on this issue.

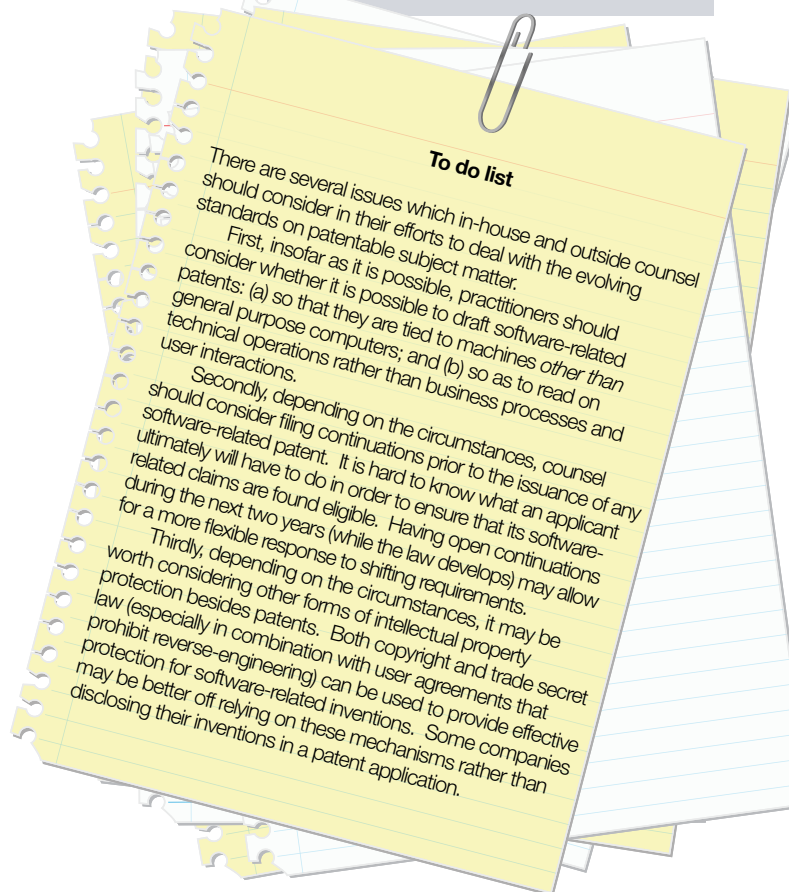
In light of this dynamic, it is still far too early to predict which approach ultimately will be adopted by a majority of Federal Circuit panels, and thus difficult to make accurate predictions about the implications. But several things seem likely.

First, it seems likely that – at least in the intermediate term – the Board of Patent Appeals and Interferences (BPAI) will continue to invalidate claims that do not pass the machine or transformation test. While it is *possible* that the BPAI (which is required to follow Federal Circuit precedent) will revise its approach in light of *RCT*, the BPAI has a long history of being aggressive in order to force the higher courts to flesh out the law. Indeed, that is how *Bilski* got brought to the Federal Circuit in the first place. It therefore seems

specific computational and technical process (namely rendering half-tone images) and that this distinguishes it from software claims directed, more generally, to solving *business* problems. Thus, even if *RCT* is followed by other Federal Circuit panels, it may be limited to its facts or to software directed to highly technical processes. That of course, would create an enormous open question, namely what factors will be considered in deciding whether a piece of software is directed to business or technical process. No matter how that line is drawn, a lot of software will fall in the grey area.

Thus, the software industry faces a good deal more risk with respect to patent eligibility than the biotech industry. In biotech, the vast majority of patents are filed to protect processes for the treatment or diagnosis of disease – both of which generally involve the transformation of some biological material (either a person or a tissue sample). Software and business method patents, on the other hand, are much more likely to fail the machine or transformation test. Thus, until there is more clarity about whether and how such cases will be decided, a great deal of risk remains.

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Footnotes

1. 35 USC 101
2. *Diamond v Diehr*, 450 U.S. 175, 185 (1981); see also *Gottschalk v Benson*, 409 U.S. 63, 67 (1972) (“Phenomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work.”).
3. *Bilski v Kappos*, 51 U.S. ____ (2010)
4. See *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008)
5. *Bilski v Kappos*, 51 U.S. ____ (2010) at 8
6. *Id* at 11
7. *Id* at 14.
8. See, eg, *Ex Parte Jorge Heuer, Andreas Hutter and Ulrich Niedermeier* (BPAI, August 4 2010) (invalidating claims directed to a method for decoding a binary representation of an XML based document using this approach); *Ex Parte Frank S. Caccavale, Sridhar C. Villapakkam and Skye W. Spear* (BPAI July 23 2010) (invalidating claims directed to analyzing the performance of a computer system by computing metric entropy using this approach); *Ex Parte Brian S. Christian, Russell M. Eames, Thomas Fakes and Bhavesh R Thaker* (BPAI August 23, 2010) (invalidating claims directed to web-based security screening using this approach).
9. See *Ultramerical LLC v Hulu* (C.D. Cal, Aug 13, 2010) (finding that “even after the Supreme Court’s decision in *Bilski*, the machine or transformation test appears to have a major screening function ... even though [it] is no longer the litmus test for patentability, the Court will use it here as a key indicator of patentability.” *Id.* at 3.
10. No. 2010-1037 (Fed Cir. Dec. 8, 2010) at 14.
11. *Id* at 15.
12. No 2008-1403 (Fed Cir. Dec. 17, 2010)
13. *Id* at 14-15 (emphasis added).
14. 545 F.3d 943, 1014 (Fed. Cir. Oct. 2008)
15. In his *Bilski* dissent, Newman went so far as to argue that *Bilski* should be entitled to a patent on his claimed method for hedging risk – a position with which none of the Supreme Court justices agreed. *Id* at 997.

16. *Prometheus* at 5-6.
17. *Id* at 17-18.
18. It is worth noting that Judge Rader advocated exactly this analysis in his dissent in *In re Bilski* 545 F.3d 943, 1014 (Fed. Cir. Oct. 2008) (arguing that the relationship between homocysteine and folate deficiencies was not patentable in itself, but would be if part of a process for diagnosing a disease). Thus, even if Rader’s view of the patentability of software does not prevail, his views in the biotech area seem likely to get traction.
19. See eg, *Ex Parte Brian S Christian, et al.* (BPAI August 23, 2010) (concluding that claims were not eligible because the “claimed invention is directed to software per se ... including various data structure and named entities, such as a declarative module and various sections thereof.”); *Ex Parte Gopalan Ramanujam* (BPAI August 12, 2010) (finding that the challenged “claims are therefore directed to software per se, which falls outside the scope of patentable subject matter.”); *Ex Parte Craig William Fellenstein et al.* (BPAI July 27, 2010) (rejecting claims on the ground that they were “directed to software per se, abstract ideas ... and the like including various data structures, software, software applications and abstract processes associated with them.”).
20. *Ex Parte Tse-Huong Choo, Scott A. Keerssen and Jobbert Berger* (BPAI July 28 2010) (emphasis added).
21. 550 U.S. 437, 449 (2007)

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