

## *Bilski* blundering biotech

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**Is the Federal Circuit's decision in *In re: Bilski* yet a further restraint on patenting biotech and pharmaceutical inventions?**

Given recent changes in the law, the state of the global economy and the recent election of a new president and executive government in the United States, there is a palpable apprehension regarding pharmaceutical and biotech intellectual property (IP), specifically in patent procurement and enforcement. Even though there are uncertainties in navigating such changes, biotech companies and universities must nonetheless pursue their fundamental goal of developing innovative new products. Navigating change is further complicated by the reality that almost every biological innovation, particularly those having significant potential to mature into drug candidates, fails at some juncture of development.

The uncertainties now confronting biotech and pharmaceutical companies and universities are accompanied by economic factors arguably unique at this point in history. Indeed, Roger Newton, Esperion Therapeutics CEO and co-inventor of the blockbuster drug Lipitor (atorvastatin) recently predicted that nearly one-third of the small US biotech companies will go out of business within a year<sup>1</sup>. Industry experts say that it is imperative that the industry address several realities that require pharma and biotech companies and universities and their licensees to “fundamentally reinvent [their] business models.” These include factors such as key patent expirations, the advancement of personalized medicine and globalization<sup>2</sup>. For example, between 2007

and 2012, more than three dozen drugs will lose patent protection, which will result in a loss of annual sales to generic competition of an estimated \$67 billion.

Given this uncertainty in the IP portfolios of companies and universities, it is more important than ever for them to exploit their existing pipelines as well as to develop new strategies for streamlining R&D to preemptively compensate for the expiration and erosion of IP rights. As biotech entities attempt to grow by advancing R&D, it is paramount that they both develop and adhere to sound strategies for protecting their inventions. But statistics suggest increasing problems in the process of procuring and enforcing biotech and pharma patents. After a spike in patenting in the 1990s, there was a slowing of patent application filing at most patent offices throughout the world in the early 2000s (ref. 3). The number of international biotech patent applications filed dropped from over 10,000 applications in 2002 to 7,200 in 2005, a 7.5% drop compared to an increase of 20.2% on average between 1995 and 2000 (ref. 3). The trend is reversed for total international patent applications filed, which continued to increase by an annual average of 4.7% from 2000. In addition, between the mid-1990s and the early 2000s in many countries, there is an observed decrease in the relative weight of biotech subject matter in all international patent application filings. “On average, biotech patents represented 5.8% of countries’ patent portfolios from 2003 to 2005, compared to 9.4% in the mid-1990s.” (ref. 3). These trends may become more pronounced as the practical impact of the World Health Organization proposals to modify IP practices and policies is felt by member states.

### The *Bilski* decision

Recent sweeping decisions in non-biotech patent cases such as *KSR International Co.*

*v. Teleflex Inc.*<sup>4</sup>, wherein the court held that a combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results; *Quanta v. LG Electronics*<sup>5</sup>, wherein the court held the authorized sale of an article that substantially embodies a patent exhausts the patent holder’s rights and prevents the patent holder from invoking patent law to control post-sale use of the article; and *In re: Seagate Technology, LLC*<sup>6</sup>, wherein the court decision makes it much more difficult for a patentee to prove a claim for willful infringement, have raised barriers to obtaining and protecting patent rights for biotech inventions. In addition to unsettling recent court precedent, Congress continues to rewrite the Patent Act and the US Patent and Trademark Office (USPTO) continues to seek implementation of proposed patent rule changes that might arguably severely affect the procurement and enforcement of biotech patents. To consider the current state of patent law in the United States as unprecedented is an understatement.

A recent change in the law, articulated in *In re: Bilski*, applies to pharma and biotech subject matter and may have a dramatic impact on the procurement and enforcement of patent rights in the US. In this en banc decision, the Federal Circuit reconsidered and significantly modified the standard for determining whether a process is statutory subject matter and therefore eligible for patenting under the Patent Act, 35 USC §101 (ref. 7). While the facts at issue involved the patentability of a method of hedging risks in commodity trading, the holding was said to be “the governing test” to be applied in determinations of process patentability, including processes encompassing biotech and pharma subject matter. Indeed, contemplating without clarifying the ramifications of the decision on biotech and pharma claims, the Court pointed out that a chemical reaction was an example of a “self-evident” physical transformation of matter.

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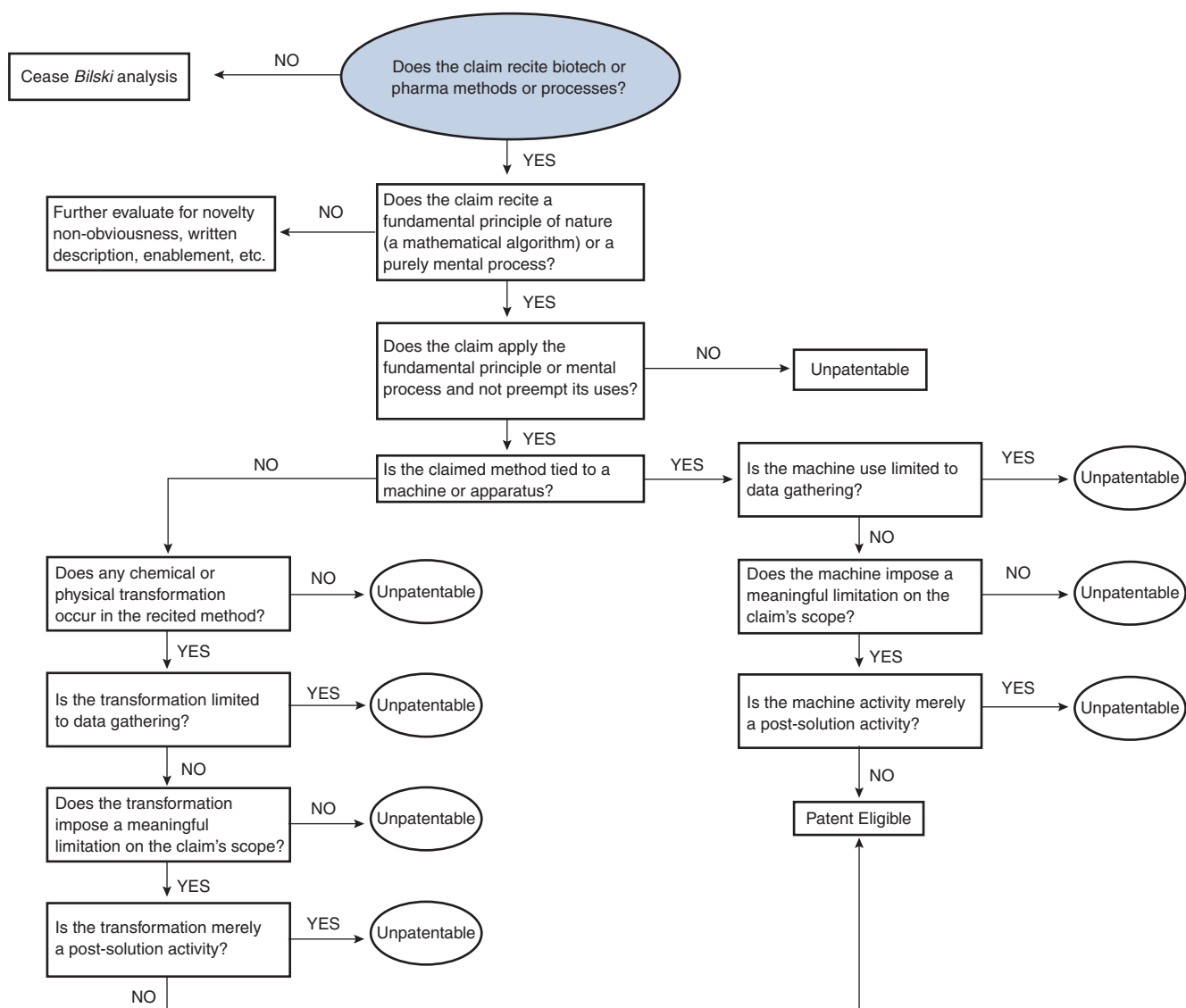


Figure 1 A flow chart for putting claims to the *Bilski* test.

The *Bilski* test is therefore critical to understand and apply because it requires a tie to a particular machine or apparatus or transformation of a particular article into a different state or thing.

In deciding *Bilski*, the court ultimately affirmed the decision of the USPTO Board, finding that the method claims at issue in *Bilski* and *Warsaw's* patent application were not directed to patentable subject matter and that *Bilski* and *Warsaw* were not entitled to a patent for the claims. The court applied a newly announced test, which the court referred to as the “machine-or-transformation” test, for determining patent eligibility under the governing statute. The court indicated that the machine-or-transformation should be used to determine whether any process claims are patentable in the United

States. In its most reduced form, the test aims to determine if a claimed process is tied to a particular machine or apparatus, or transforms a particular article into a different state or thing. If either prong of the test is met, the subject matter claimed is deemed eligible for continued analysis for patentability (e.g., novelty, nonobviousness, etc.).

The *Bilski* patent application did not include claims directed to biotech processes. However, the court pointed out that the articulated machine-or-transformation test governs regardless of the nature of the technology. *Bilski's* claims related to methods for hedging risk in commodities trading, the claims at issue in the case. The USPTO rejected the claims, arguing that the process claims were not patentable because the method described by the claims did

not involve the “technological arts.” The USPTO also argued that the method claims were not patentable because the claims were not limited by a specific apparatus (e.g., a digital computer).

In an administrative appeal, the USPTO Board of Appeals held that the office personnel were incorrect in relying on the “technological arts” test. Interestingly, the Board also held that the office was incorrect in requiring a specific machine in the claim language. Even though the Board admitted that the office applied the wrong tests, the Board’s ultimate conclusion was that *Bilski's* hedging risk claims were unpatentable because the claims were to nonpatentable subject matter. The rationale for the Board’s conclusion was that *Bilski's* claims were to an abstract idea, and that abstract ideas were

ineligible for patent protection. *Bilski* appealed the Board's decision to a higher court, the Federal Circuit.

Without request by *Bilski*, the Federal Circuit ordered an en banc review of the issues, meaning that the case was heard and decided before all judges of the court, a procedure sometimes used if a case is of unusual significance. In resolving the issues, the court analyzed the language of the relevant statute and noted that four categories of patent-eligible subject matter are recited explicitly, including processes, machines, manufactures and compositions of matter. The court pointed out that the simple dictionary definition of "process" is not the meaning accorded to the process described in the governing law because the Supreme Court has held that the meaning of "process" as used in 35 USC §101 is narrower than its ordinary meaning, excluding, for example, a process that embodies a "fundamental principle," such as a law of nature, natural phenomenon or abstract idea. The court held that a process claim that includes a fundamental principle is patentable only if the claim recites a particular application of the fundamental principle (Fig. 1). The court indicated that under a proper application of the machine-or-transformation test, "[a] claimed process is surely patent-eligible under §101 if: (i) it is tied to a particular machine or apparatus, or (ii) it transforms a particular article into a different state or thing."

The *Bilski* court included limited guidance on the machine-or-transformation test in determining whether claims include patent-eligible subject matter. The court indicated that one could demonstrate that patentable subject matter is in the language of the claim by demonstrating that the process is tied to a particular machine. Alternatively, an applicant can demonstrate patentable subject matter by demonstrating that the process includes transforming an article. But the court warned that mere mention of a machine or transformation was not enough—the use of a "specific machine or transformation of an article must impose meaningful limits on the claim's scope to impart patent-eligibility." (Fig. 1) The court also indicated "the involvement of the machine or transformation in the claimed process must not merely be insignificant extra-solution activity." Regarding the transformation aspect of the test, the court held that a claimed process must transform an article into a different state or thing to be patent eligible and that the transformation must be central to the purpose of the claimed process. The court warned that "the

raw materials of many information-age processes...are electronic signals and electronically manipulated data" and may involve the "manipulation of even more abstract constructs such as legal obligations, organizational relationships, and business risks."

In deciding *Bilski*, the court warned the public, however, that other courts may need to modify the machine-or-transformation test because "future developments in technology and the sciences may present difficult challenges to the test," drawing into question the general applicability and the longevity of the holding.

### Possible ramifications

On January 28, 2009, *Bilski* filed a petition for certiorari with the US Supreme Court. *Bilski* challenged the requirement that a patent-eligible process must be tied to a particular machine or apparatus, or transform a particular article into a different state or thing. *Bilski* argued that the lower court's test was incongruent with the Supreme Court's prior determination to not limit the broad statutory grant of patent eligibility for any new and useful process. *Bilski* also requested that the court determine whether the Federal Circuit's machine-or-transformation test for patent eligibility contradicts the broadly articulated intent of Congress that patents protect "method[s] of doing or conducting business"<sup>8</sup>. In the request for Supreme Court review, *Bilski* argues that the machine-or-transformation test is inconsistent with Supreme Court precedent and the intent of Congress and is contrary to the court's rejection of the test in two prior precedential cases. *Bilski*'s petition also asserts that method patents must include emerging technologies (that is, biotech).

The potentially devastating extension of *Bilski* from business methods to biotech is illustrated by two recent district court cases using the test to invalidate pharmaceutical claims. In *King Pharmaceuticals v. EON Labs*,<sup>9</sup> King Pharmaceuticals sued Eon Labs, and Eon argued that King claimed non-patentable subject matter under the *Bilski* rule. The subject matter involved a method of increasing the oral bioavailability of Skelaxin (metaxalone) to a patient receiving Skelaxin therapy, comprising administering to the patient a therapeutically effective amount of Skelaxin in a pharmaceutical composition with food. The court held that because increased oral bioavailability was an inherent property of the prior art, informing a patient of that inherent property does not constitute patentable subject matter (that is, informing a person of the phenomenon does not transform the Skelaxin into a different state or thing). Thus, the test articulated in *Bilski* was, according to the court, not satisfied

and the claims were directed to subject matter that was not patentable.

A second case is *Prometheus Labs v. Mayo Collaborative*. In the case, a lower court determined that the patent at issue was invalid under §101 for claiming unpatentable subject matter (that is, natural phenomena). The patent at issue contains claims that describe the process of testing levels of certain metabolites in the blood of patients taking thiopurine drugs, which permits doctors to monitor a patient's metabolite level and thereby adjust medication levels to reach certain therapeutic goals. The court characterized the correlations between thiopurine drug metabolite levels and toxicity as natural phenomena. The court based its decision, at least in part, on the steps in the process directed to "administering" the medication and "determining" metabolite levels, indicating that determining the correlation was not patentable subject matter. Several briefs have been filed in *Prometheus*, including those submitted by Novartis Pharmaceuticals, the Biotechnology Industry Organization and the American Intellectual Property Law Association. The case is now pending before the Court of Appeals for the Federal Circuit. On January 9, 2009, *Prometheus Labs* filed its arguments for appeal, stating in terms found in the court's holding in *Bilski*, "the whole point of these processes is to transform the patient's body...the patient's body is transformed by administration of a synthetic thiopurine drug...[and] a sample of bodily fluid or tissue is transformed [using] sophisticated laboratory machines... and the resulting data is transformed into a warning..." *Prometheus Labs* asserts that the lower court's finding would "threaten to invalidate the entire field of medical treatment and diagnostic patents on which the innovative and lifesaving biotech industry is built."

Another important case before the court is *Ariad Pharmaceuticals Inc. v. Eli Lilly & Co.*<sup>10</sup> The biotech process claim language at issue in this case describes a method for modifying effects of external influences on a eukaryotic cell, which external influences induce NF- $\kappa$ B-mediated intracellular signaling, the method comprising altering NF- $\kappa$ B activity in the cells such that NF- $\kappa$ B-mediated effects of external influences are modified, wherein NF- $\kappa$ B activity in the cell is reduced, and wherein reducing NF- $\kappa$ B activity comprises reducing binding of NF- $\kappa$ B to NF- $\kappa$ B recognition sites on genes which are transcriptionally regulated by NF- $\kappa$ B. Recently, *Ariad* and *Eli Lilly* argued before the Federal Circuit, wherein *Lilly* asserted that NF- $\kappa$ B inhibition to reduce the expression of genes was not patent eligible subject matter because it was no more than a "fundamental principle of nature. ... They may have

discovered something about that, but it's always been there and that's always the way it's been." Ariad rebutted this assertion, arguing that "the reduction of NF- $\kappa$ B ... is very much a transformation," sufficient to meet the standard set for under the "machine-or-transformation" test the Federal Circuit recently announced as law in *In re: Bilski*. Ariad argued that the subject matter of the claims at issue is "a method for transforming the state of living cells, which are compositions of matter, which is a traditional transformative process. ... It does not appropriate anything that exists in nature." He elaborated that the transformation was "changing the way a cell responds to its environment." In response, Lilly asserted, "it's not a particular transformation of a particular article" because "restricting the use to reducing NF- $\kappa$ B to reduce gene expression" fails to limit the invention so as to preempt all uses of a principle of nature.<sup>11</sup>

### Going forward

Without doubt, the decision in *Bilski* significantly affects patent eligibility in the biotech arts. With respect to strategies for obtaining patents under the new law, *Bilski* indicates that claims must be considered as a whole, not analyzed as individual steps. In preparing a patent application, one should consider explicit reference to articles undergoing a transformative process. Such transformations can be explicitly included in the written application or by way of reference, for example, by incorporating the contents of a paper describing the transformation or by way of reference to what is already known in the state of the art. *Bilski* suggests that tying a claim to a machine (e.g., a computer) is not in and of itself sufficient to make allegedly nonstatutory subject matter patent eligible. The case also indicates that insignificant data gathering (that is, accumulating scientific data without specifying how it affords meaning to claim language) and post-solution or other extra-solution activity is insufficient to meet the threshold requirements for patentability. Rather, the implementation of a machine or the transformation of an article must impress meaningful limits on the claim's scope before the subject matter is patent eligible. The mere recitation of physical steps in a claim is insufficient to render the process patentable if the claim is not tied to a particular

machine and does not result in a transformation. Thus, it may be advantageous to add claims that integrate steps and machines in the language of the claims.

Additional strategies to minimize risks associated with noneligible subject matter issues in patent procurement include preparing a description of the invention that adequately emphasizes various technical aspects of the biotech invention. There is an advantage in implementing this strategy in both the written description of the invention and the drawings depicting the invention as both serve to describe the invention. It is best to include various embodiments of the invention and to assess, before attempting to obtain a patent, secondary positions in the event that a *Bilski* issue arises. Additional strategies include providing descriptions, in biotech and pharma applications, of generic computer or machine processes, as well as very specific examples of machine implementation in the claimed processes. In doing so, it might be advantageous to have multiple recitations of the machine-implemented process, so that it can be argued that the machine or apparatus plays a fundamental role in the overall claimed process. Be aware that extra-solution activity is not enough to confer patent eligibility. If possible, prepare examples and information that defines transformed data as physical phenomena (that is, the visual depiction is not simply the manifestation of a single algorithm). The *Bilski* court observed that "transformation of that raw data into a particular visual depiction of a physical object on a display" may constitute a sufficient transformation to confer patent eligibility.

Regarding the protection of vital claims in patents that have already issued but arguably may not meet the test set forth in *Bilski*, it is possible to request a reissue under 35 USC §251. In this process, a patent is re-considered by the USPTO even though it was previously determined that the claims are patent eligible based on the patentee's assertion that there is an error in the claims or specification. To be eligible for this process, the "error" (that is, failure to comply with the test set forth in *Bilski*) must have been made without any deceptive intent. During this process, once claims are amended to comport with the machine-or-transformation test and subsequently allowed, the patentee must surrender the patent at issue to obtain a new patent. However, if this strategy is undertaken, it is

important to remember that compliance with other provisions in the patent statute (such as novelty, nonobviousness and enablement) must also be determined and that there is no guarantee that the reissue process will proceed expeditiously.

Regarding addressing *Bilski* issues during litigation of an issued patent, in prelitigation negotiations or settlement talks, it is of value to fully understand the potential for compliance with the machine-or-transformation test of every process claim central to the dispute because each potentially susceptible claim may provide a new ground for an adversary to launch an invalidity attack. It is also important to consider whether or not a jury would be more or less sympathetic to and understanding of the science of biotech, as a *Bilski* issue is a legal issue, not an issue of fact for a jury to decide.

### Conclusions

It is clear that as a result of the fundamental change in patent law and enforcement of the test articulated in *Bilski*, further limiting patent subject matter eligibility, the preexisting legal challenges facing biotech companies will only increase. This is particularly true for those companies seeking procurement or enforcement of IP involving medical diagnostics, therapeutic methods and personalized medicine. As companies and universities await potential modification of the *Bilski* test by the Supreme Court, they must act to ensure the future of their biotech R&D.

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