



# Biotechnology and Pharmaceutical Litigation

Ernest V. Linek

## *Bilski* Highlights

On June 28, 2010, the Supreme Court handed down its decision in *Bilski v. Kappos*, affirming the Federal Circuit's decision rejecting the claims of the patent application, but doing so on different grounds.

All nine justices agreed on the outcome stating that the patent claims defined an "abstract idea." However, there was a sharp 5 to 4 split among the justices regarding whether so-called business methods should be eligible for patent protection.

The majority of the Court said that business methods should be eligible for patent protection as long as they do not constitute an "abstract idea" or fall within one of the other previously recognized exceptions to patentability. Unfortunately, nothing in the majority opinion gives practitioners or inventors meaningful guidance regarding the definition of an "abstract idea."

Justice Stevens, in his final opinion, and writing for the minority wanted to "restore patent law to its historical and constitutional moorings." According to Justice Stevens:

1. The majority's approach to interpreting Section 101 according to "ordinary, contemporary, common meaning" was flawed;
2. A method of doing business is not a "process" under Section 101,
3. "Useful arts" in early American patent law did not include business methods,
4. The phrase "anything under the sun" in the legislative history of

the Patent Act has been quoted out of context,

5. The majority argument based on Section 273 is flawed, and
6. "Patents on business methods may prohibit a wide swath of legitimate competition and innovation."

Clearly Justice Steven's last opinion for the Court sends a not so subtle message to Congress that he and like-minded justices believe that "business methods" should **not** be eligible for patent protection.

## ***The Federal Circuit Test—Rejected as the Sole Test***

Confirming what many practitioners predicted before the ruling, the Court held that the machine-or-transformation test is *not* the sole test for patent eligibility under Section 101.

The Court further stated, that, the Federal Circuit, in holding to the contrary, violated two principles of statutory interpretation: (1) courts "should not read into the patent laws limitations and conditions which the legislature has not expressed" [*Diamond v. Diehr*, 450 U.S. 175, 182], and (2) "unless otherwise defined, 'words will be interpreted as taking their ordinary, contemporary, common meaning,'" [*id.*]

## ***Some Business Methods Can Be Patented***

The Court further stated that Section 101 precludes a reading of the term "process" that would categorically exclude business methods.

The term "method" within Section 100(b)'s "process" definition, at least

as a textual matter and before other consulting other Patent Act limitations and this Court's precedents, may include at least some methods of doing business.

The categorical exclusion argument is further undermined by the fact that federal law explicitly contemplates the existence of at least some business method patents:

Under § 273(b)(1), if a patent-holder claims infringement based on "a method in [a] patent," the alleged infringer can assert a defense of prior use. By allowing this defense, the statute itself acknowledges that there may be business method patents. Section 273 thus clarifies the understanding that a business method is simply one kind of "method" that is, at least in some circumstances, eligible for patenting under § 101.

Justice Stevens found the Court's reliance on Section 273 a "red herring." He said that "the wiser course would have been to hold that petitioner's method is not a 'process' because it describes only a general method of engaging in business transactions—and business methods are not patentable" and that "more precisely, although a process is not patent-ineligible simply because it is useful for conducting business, a claim that merely describes a method of doing business does not qualify as a process under Section 101."

The majority dismissed this argument, stating that a contrary conclusion would violate the canon against interpreting any statutory provision in a manner that would render another provision superfluous. [See *Corley v. United States*, 556 U.S. \_\_\_ (2009).]

Thus, while the majority recognized that the subject matter of "business methods" could meet the Section 101 requirement, they also recognized that such inventions might not qualify for "broad patentability." For example, some business method patents raise

special problems in terms of vagueness and suspect validity.

Thus, said the majority, if a high enough bar is not set when considering patent applications of this sort, patent examiners and courts could be flooded with claims that would put a chill on creative endeavor and dynamic change.

### **Abstract Ideas Are Not Patentable**

The majority further provided that in searching for a limiting principle, the Supreme Court's precedents on the unpatentability of "abstract ideas" provide useful tools. Here the Court cited as "unpatentable" examples, the inventions discussed in the cases *Gottschalk v. Benson* [409 U.S. 63 (1972)] and *Parker v. Flook* [437 U.S. 584 (1978)]. Compare these cases to *Diamond v. Diehr*, [450 U.S. 175 (1981)] which set forth a patentable process.

More importantly, the Court suggested that if the Federal Circuit was to succeed in defining a narrower category or class of patent applications that claim to instruct how business should be conducted, and then rule that the category is unpatentable because, for instance, it represents **an attempt to patent abstract ideas**, this conclusion might well be in accord with controlling precedent.

The Court further stated that beyond this or some other limitation consistent with the statutory text, the Patent Act leaves open the possibility that there are at least some processes that can be fairly described as "business methods" that are within patentable subject matter under Section 101.

The Court noted that, even if a particular business method fits into the statutory definition of a "process," that does not mean that the application claiming that method should be granted. In order to receive patent protection, any claimed invention must be novel, Section 102, nonobvious, Section 103, and fully and particularly described, Section 112.

[NOTE: From these comments, practitioners and litigators can expect to see more business method patents challenged under Section 101, based on a contention that the claims are simply directed to an "abstract idea" and thus, they are not eligible for patent protection.]

Patent prosecutors may want to review pending business method claims to check for *Bilski* issues. Patent owners should review their patent claims to see if they should be reissued to avoid a *Bilski* challenge. Litigators should review patent claims for possible *Bilski* issues.

### **PTO Response to Bilski**

On June 28th the US Patent and Trademark Office (PTO) issued a memo to the examiners on applying the US Supreme Court's *Bilski* opinion. The memo states, ". . . If a claimed method does not meet the machine-or-transformation test, the examiner should reject the claim under section 101 unless there is a clear indication that the method is not directed to an abstract idea. If a claim is rejected under section 101 on the basis that it is drawn to an abstract idea, the applicant then has the opportunity to explain why the claimed method is not drawn to an abstract idea."

### **Future of Patentable Inventions**

According to the majority, the *Bilski* decision was not commenting on the patentability of any particular invention, let alone holding that any of the above-mentioned technologies from the Information Age should or should not receive patent protection. This Information Age puts the possibility of innovation in the hands of more people and raises new difficulties for the patent law. According to the majority, nothing in this opinion should be read to take a position on where that balance ought to be struck.

### **Further Case Law on Processes**

The Court further stated that because petitioners' patent application can be rejected under the Court's precedents on the unpatentability of abstract ideas, the Court need not define further what constitutes a patentable "process," beyond pointing to the definition of that term provided in Section 100(b) and looking to the guideposts in *Benson*, *Flook*, and *Diehr*.

### **Two Bio/Pharma Process Cases Remanded**

The Supreme Court next remanded two cases on June 29, 2010, dealing with patents for "medical processes" in light of its *Bilski* decision that the machine-or-transformation test is not the only measure for deciding patentability.

The court vacated the decisions in *Classen Immunotherapies Inc. v. Biogen Idec* and *Mayo Collaborative Services v. Prometheus Laboratories Inc.*, sending them both back to the Federal Circuit. In *Prometheus*, the Federal Circuit will reconsider its September 2009 decision upholding the validity of two patents covering a process for correlating the level of certain chemicals in a patient's blood with his health. In *Classen*, the Federal Circuit affirmed a district court ruling invalidating a patent for a method of determining whether or not an immunization schedule is effective in treating a chronic immune-related disorder.

### **Update on Inequitable Conduct**

On June 3, 2010, the Court of Appeals for the Federal Circuit issued a scheduling order regarding the en banc review of the panel decision in *Therasense v. Becton Dickinson & Co.* [Appeal No. 2008-1511. This case was discussed in detail in my last column, *IP Litigator*, July/August 2010]. Oral arguments en banc are scheduled for November 9, 2010. Counsel for

each side will be allowed 30 minutes for argument. By August 16, 2010, counsel for each party will notify the court the name of the attorney who will argue for that party.

## Split Federal Circuit Overturns Summary Judgment of Inequitable Conduct and Remands for Evidentiary Hearing

On May 28, 2010, in *Leviton Mfg. Co. v. Universal Security Instruments, Inc.* [(No. 2009-1421)], the Federal Circuit [Chief Judge Michel (21 pages) with a dissent by Judge Prost (26 pages)], vacated a \$1 million award of attorney fees and costs based on a summary judgment of inequitable conduct and vexatious litigation.

## Patent Claims Mean What They Say

On June 2, 2010, the Federal Circuit Court of Appeals vacated a \$15.7 million judgment in favor of Haemonetics Corp. in its suit against rival blood processing technology company Fenwal Inc., finding a lower court erred in construing a claim in a patent for a centrifuge blood separation device.

The Federal Circuit found that Claim 16, the sole patent claim at issue in the dispute, only has one clear construction, even if it's not the one the lower court reached, and even if it renders the claim inoperable or invalid. The Federal Circuit noted that *"An 'error' may have occurred in drafting claim 16, but it is what the patentee claimed and what the public is entitled to rely on."*

## False Marking Update

The Federal Circuit issued its decision in the *Pequignot v. Solo Cup Co.* case on June 10, 2010. The Federal Circuit held that an article covered by a now-expired patent is "unpatented" as it is now in the public domain. Thus, *articles marked with expired patent numbers are falsely marked* and the first requirement of 35 U.S.C. § 292(a) has been satisfied.

The second statutory requirement is that the marker acted "for the purpose of deceiving the public." Prior case law has found that the combination of a false statement with knowledge that the statement was false creates a rebuttable presumption of intent to deceive the public. More importantly, *this presumption cannot be rebutted by "the mere assertion by a party that it did not intend to deceive."*

While a *qui tam* action is civil in form, it is criminal in nature—as the penalty is a statutory fine; one half paid to the plaintiff and the other half paid to the Federal Government. Thus, the bar for proving deceptive intent is particularly high. The statute requires that the false marker acted "for the purpose of deceiving the public," a purpose of deceit, rather than knowledge that a statement is false.

Thus, merely knowing that a patent marking is false is insufficient to prove intent if the marker can prove that it did not consciously desire the result that the public be deceived. Solo's proof of lack of deceptive intent included reliance on the advice of counsel. Solo further acted in good faith by removing expired patent numbers from product molds cavities when the expensive molds were replaced due to wear or damage.

Tip: Check your products and advertisements for listing of expired patents!

---

*Ernie Linek is a principal shareholder of Banner & Witcoff, Ltd. This article is for educational and informational purposes only and should not be construed in any way as legal advice. This column reflects the opinion of the author and should not be attributed to the firm Banner & Witcoff, Ltd. or to any of its clients.*

Reprinted from *IP Litigator* September/October 2010, Volume 16, Number 5, pages 51-53, with permission from Aspen Publishers, Inc., Wolters Kluwer Law & Business, New York, NY, 1-800-638-8437, [www.aspenpublishers.com](http://www.aspenpublishers.com)