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Time for Spring Cleaning

With the global economy down, now is a good time to take stock of your intellectual property portfolio and see what needs to be updated.

Check your patent portfolio, particularly patents that have been licensed in or licensed out. Recent cases from the Supreme Court and Federal Circuit potentially have impacted a number of patents—including patents in the bio/pharma fields. Likewise, check your trademark portfolio, again paying particular attention to marks that have been licensed in or licensed out. Check your assignments—as companies merge, assignments must be recorded in the full legal name of the surviving entity.

Check your license agreements: Do they allow mergers or does a change of control cause the license to terminate? Check your employee agreements regarding the protection of your inventions and trade secrets. Jobs are being lost, and key employees are here one day, but could be gone the next. Have former employees agreed to execute assignments after they leave the company? In a bad economy, things that would never otherwise happen could be happening. Diligence is needed now, more than before.

Process or Method Patents—Conduct a Bilski *Review*

Do you have any bio/pharma licenses that include method or process claims? If you answer yes, you should consider conducting a Bilski review of the method or process claims.

Last fall the Court of Appeals for the Federal Circuit, sitting en banc, issued its decision in the business method case *In re Bilski* [545 F.3d 943 (Fed. Cir. 2008)]. Here, the fundamental issue of "patentable subject matter" for patent claims directed to a process was re-evaluated under Section 101.

According to the Federal Circuit in *Bilski*, in order to be patentable subject matter under Section 101, all method or process claims (regardless of subject matter) must meet the so-called machine or transformation test:

1. The claimed process is tied to a particular machine or apparatus, or
2. The claimed process transforms a particular article into a different state or thing.

More particularly, both the use of a specific machine or the transformation of an article must impose meaningful limits on the scope of the process or method claims under review. The court further stated that the transformation of an article "must be central to the purpose of the claimed process." Finally, this warning was provided: In most cases, merely "gathering data would not constitute a transformation of any article."

The claims in *Bilski* specifically recited a method of hedging risk in the field of commodities trading. The Federal Circuit characterized the claimed subject matter as a "nontransformative process that encompasses a purely mental process of performing requisite mathematical calculations without the aid of a computer or any other device."

The Federal Circuit also held that the claim effectively would preempt any application of the fundamental concept of hedging and mathematical calculations inherent in hedging risk.

Implications for Bio/Pharma Process and Method Claims

Patent owners or licensees of method or process claims directed to biotechnology and pharmaceutical inventions cannot ignore the *Bilski* case. The case must be kept in mind during the patent drafting process; during patent prosecution; during license reviews and negotiations; and particularly prior to any patent litigation.

The Federal Circuit has adopted the "machine or transformation" test for patent eligibility under Section 101. This is a threshold question. Section 101 issues must be resolved before any other issues. If a claim fails to qualify as patentable subject matter under Section 101, the claim is invalid.

While the *Bilski* decision does not state explicitly that bio/pharma processes will be assessed according to the machine or transformation test, the Federal Circuit does not distinguish such processes

from the business methods at issue in *Bilski*.

The Federal Circuit acknowledged that the machine or transformation test (and/or its application) may need to be altered or even supplanted in certain instances by the Supreme Court, or even the Federal Circuit itself.

> Future developments in technology and the sciences may present difficult challenges to the machine or transformation test…we recognize that the Supreme Court may ultimately decide to alter or perhaps set aside this test to accommodate emerging technologies. And we certainly do not rule out the possibility that this court may, in the future, refine or augment the test or how it is applied.

Further, the Federal Circuit's footnote 26 suggests that, for example, the patentability of certain medical diagnostic process claims could be challenged under *Bilski*.

> The court notes that of course, a claimed process, wherein all of the process steps may be performed entirely in the human mind, is obviously not tied to any machine and does not transform any article into a different state.

The *Bilski* case leaves a number of unanswered questions regarding bio/pharma process and method patents, including at least the following:

- When is a bio/pharma process or method tied to a particular machine or apparatus?
- What constitutes a transformation sufficient for a bio/pharma process or method claim to qualify as patentable subject matter?
- What qualifies as a transformation that is central to the purpose of a claimed bio/pharma process or method?
- At what point does the use of a specific machine or transformation of an article impose meaningful limits on a bio/pharma process or method claim's scope so as to impart patentability under Section 101?

If you own a patent with a possible *Bilski* issue, you may want to file a reissue application to make an appropriate correction. If you are the licensee of a patent with a possible *Bilski* issue, you have several options: (1) do nothing; (2) ask the patent owner to fix it; or (3) seek to invalidate the patent under the Supreme Court's 2007 *Medimmune* case. This last option assumes that your license agreement does not terminate if a court case is filed.

Advice to Avoid Bilski *Issues*

One possible way around the *Bilski* issue is to use kit claims. Kit claims recite actual objects used to perform the method. Another way around *Bilski* would be to tie the claim to a device. For example, claim a device that includes "an automated machine" that performs the recited method.

Recent Bio/Pharma Bilski *Cases*

In December 2008, in a non-precedential opinion, the Federal Circuit affirmed a lower court's decision in *Classen v. Biogen IDEC* to invalidate process claims as encompassing non-patentable subject matter citing *Bilski*.

Classen's claims were directed to methods for determining an optimal immunization schedule based on comparing the observed incidence of immune-mediated disorders in treatment groups subjected to different vaccination schedules.

Claim 1 of Patent No. 5,723,283 reads 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 following is the Federal Circuit's entire opinion in this case:

> In light of our decision in *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008) (en banc), we affirm the district court's grant of summary judgment that these claims are invalid under 35 U.S.C. § 101. Dr. Classen's claims are neither "tied to a particular machine or apparatus" nor do they 'transform a particular article into a different state or thing.' *Bilski*, 545 F.3d at 954. Therefore we affirm.

In January 2009, the Eastern District Court in New York, in the case *King Pharmaceuticals, Inc. v. Eon Labs, Inc.*, granted the defendant's motion for summary judgment invalidating two Patents (6,407,128 and 6,683,102) each relating to SKELAXIN® (metaxalone) based on *Bilski*.

Claim 21 of the '128 patent reads as follows:

> 21. The method of claim 1,
>
> [1. A method of increasing the oral bioavailability of metaxalone to a patient receiving metaxalone therapy comprising administering to the patient a therapeutically effective amount of metaxalone in a pharmaceutical composition with food]
>
> further comprising informing the patient that the administration of a therapeutically effective amount of metaxalone in a pharmaceutical composition with food results in an increase in the maximal plasma concentration (Cmax) and extent of absorption (AUC(last)) of metaxalone compared to administration without food.

Claim 6 of the '102 patent reads as follows:

> 6. A method of using metaxalone in the treatment of musculoskeletal conditions comprising: informing a patient with musculoskeletal conditions that the administration of a therapeutically effective amount of metaxalone with food results in an increase in at least one of C(max) and AUC(last) of metaxalone compared to administration without food.

The District Court judge criticized these two claims because they each do away with all physical steps and attempt to claim a monopoly on information.

Bilski *at the Supreme Court*

On January 28, 2009, attorneys for Bilski filed a petition for writ of certiorari, requesting Supreme Court review of the Federal Circuit's *Bilski* decision. The questions presented in the petition are:

1. Whether the Federal Circuit erred by holding that a "process" must be tied to a particular machine or apparatus, or transform a particular article into a different state or thing ("machine-or-transformation" test), to be eligible for patenting under 35 U.S.C. § 101, despite this Court's precedent declining to limit the broad statutory grant of patent eligibility for "any" new and useful process beyond excluding patents for "laws of nature, physical phenomena, and abstract ideas."
2. Whether the Federal Circuit's "machine-or-transformation" test for patent eligibility, which effectively forecloses meaningful patent protection to many business methods, contradicts the clear Congressional intent that patents protect "method[s] of doing or conducting business." 35 U.S.C. § 273.

On May 4, 2009, the US Solicitor General Elena Kagan filed the federal government's brief in opposition to the petition for a writ of certiorari in the case, questioning the petitioners' claim that the Federal Circuit's 9–3 ruling was "fractured."

According to the Solicitor General, the *In re Bilski* machine-or-transformation test for patentable subject matter is "drawn directly from" the US Supreme Court's decisions on the issue. Saying that further review of the case is not warranted, the brief also noted with approval that the US Court of Appeals for the Federal Circuit repudiated its "useful, concrete, and tangible" test for patentable processes.

Further, in countering both the petition and the dissenting opinions in the *Bilski* case, the government's brief contended that the patent application in the instant case does not provide an opportunity to confront the issue of whether the machine-or-transformation test forecloses patentability on "frontier technologies."

A decision from the Supreme Court to grant or deny certiorari is expected soon.

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