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Application of *Bilski* Decision Raises Questions about Enforceability of Biotechnology Business Method Patents

On October 30, 2008, the Federal Circuit issued an opinion that many believe will significantly alter the issuance and enforceability of business method patents in the United States. In that decision, *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008), the Federal Circuit established a new test for the patentability of business methods, holding that the method must be “tied to a particular machine or apparatus” or must “transform[] a particular article into a different state or thing.” Shortly thereafter, hearing an appeal of *Classen Immunotherapies, Inc. v. Biogen IDEC*, slip. Op. (Fed. Cir. 2008), the Federal Circuit applied *Bilski*’s “machine or transformation” test to invalidate a business method patent within the biotechnology arena.

The *Bilski* court explicitly stated that its “machine or transformation” test replaced the previous requirement, first articulated in *State Street Bank and Trust Co. v. Signature Financial Group Inc.*, 149 F.3d 1368 (Fed. Cir. 1998), that a business method must produce “a useful, concrete, and tangible result.” As such, it appears that the *Bilski* test will govern the patentability of many, if not all, business methods.

The appeal to the Federal Circuit in *Classen*, first heard by the U.S. District Court for the District of Maryland in 2006, was still pending when *Bilski* was decided. Initially ruled unenforceable by the District Court, the *Classen* patents concerned the effects of immunization schedules on the incidence and severity of immune disorders. Each patent described a method for recording and comparing different groups’ incidence of immune disorders and using the resulting data to determine low-risk immunization schedules. Although the patents were drafted as descriptive of a process, the District Court said, they simply described a general inquiry into the existence of a correlation between immunization schedules and the incidence of chronic disorders. As such, the patents were simply an indirect attempt to patent an unpatentable natural phenomenon.

In reviewing *Classen* on appeal, the Federal Circuit did not address the district court’s finding that the patents merely described a natural phenomenon. Instead, in a non-precedential 69-word decision, the court applied *Bilski* to affirm the patents’ invalidity,

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stating only: "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.'"

What *Bilski* and *Classen* mean for biotechnology businesses

Although the extent of its impact remains to be seen, the *Classen* decision's application of *Bilski* creates a great deal of uncertainty about the enforceability of biotech business method patents. Because the applicants in *Bilski* conceded that their claim did not satisfy the "machine" prong of the court's test, the court's opinion explicated only the "transformation" prong. The crux of the determination as made in *Bilski* rests not on the transformation itself but on the "particular article" that is transformed. When the article at issue is considered to be data, as it was in *Bilski* and presumably was in *Classen*, the inquiry concerns what that data represents: on one hand, data may represent physical objects or substances; and on the other, data may represent intangibles. Business methods that transform data of the first type are generally patentable, but transformations of the second type of data are not.

This second class of data may be divided into two further subsets. First is data that is equivalent to a variable in an equation or algorithm—data with no specific content. Second, and more importantly in this context, is data with specific content that itself represents an intangible. Applying these distinctions to the patent at issue in *Classen*, it seems that the court most likely considered the incidence of immunological disorders and the immunization schedules to be intangibles and thus determined the transformation of that data to be ineligible for a patent. The actual, physical acts of immunizing patients and collecting the data would be considered "insignificant extra-solution activities" and therefore insufficient to lend tangibility to the data's content.

Prior to the decision in *Classen*, Prof. Christopher M. Holman noted that "*Bilski* acknowledges that the machine-transformation test is really just a proxy for weeding out patent claims that preempt 'fundamental principles,'" and further stated that "[t]his might make sense in the context of so-called business method patents, where the fundamental principle implicated is typically

characterized as an abstract idea or mental process. But it is unclear to what extent this test will prove applicable to patent claims arising out of the life sciences, where [challenges to] patentable subject matter...more often allege preemption of a natural phenomena or law of nature, rather than an abstract idea or mental process." *Classen* established that business method patents in the biotech sector may indeed fall under *Bilski*'s ambit, but the court's laconic opinion explained nothing of its reasoning.

At least two other similar patent cases are now pending before the Federal Circuit, so it is hoped that more guidance will be forthcoming. What *is* clear, however, is that the Federal Circuit is serious about applying the new "machine or transformation test" to business method patents. Although *Bilski* is widely expected to be appealed to the U.S. Supreme Court, businesses need to consider the implications of the case and should review their patent portfolios in search of patents which may be rendered invalid by the new test. To the extent possible, businesses should consider filing reissue applications to add details that strengthen patents that may not comply.