Classen v. Biogen Idec et al. – The Latest Installment in the Patent-Eligibility Arena

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Introduction

On August 31, 2011, the Federal Circuit issued its long-awaited decision in *Classen Immunotherapies, Inc. v. Biogen Idec et al.* The case was remanded by the Supreme Court back to the Federal Circuit with instructions to consider the Court's earlier *Bilski* decision on patent-eligibility under 35 U.S.C. § 101. At issue was the district court's application of common-law exclusions from patent eligibility, *i.e.*, "laws of nature, natural phenomena, and abstract ideas." *Diamond v. Diehr*, 450 U.S. 175, 185 (1981). The district court had granted summary judgment finding all claims ineligible because they were directed to the "abstract idea" that there is a relation between the infant immunization schedule for infectious diseases and the later occurrence of chronic immune-mediated (non-infectious) disorders. The Federal Circuit reversed its prior decision for two patents, now finding them patent eligible and affirmed its prior decision for the third patent, finding its claims patent ineligible.

Three Classen patents were at issue, No. 6,638,739 ("the '739 patent"), No. 6,420,139 ("the '139 patent") and No. 5,723,283 ("the '283 patent"), all titled "Method and Composition for an Early Vaccine to Protect Against Both Common Infectious Diseases and Chronic Immune Mediated Disorders or their Sequelae" and based on Classen's discovery that vaccines administered at an early age can substantially decrease incidence of chronic immune mediated side effects.

Claims of the '139 and '739 patents are directed to methods whereby information on immunization schedules and occurrence of chronic disease is "screened" and "compared," a lower risk schedule is "identified," and a vaccine is "administered on that schedule. They are exemplified by '739 claim 1:

1. A method of immunizing a mammalian subject which comprises:

(I) screening a plurality of immunization schedules, by

(a) identifying a first group of mammals and at least a second group of mammals, said mammals being of the same species, ..., each group of mammals having been immunized according to a different immunization schedule, and

(b) comparing the effectiveness of said first and second screened immunization schedules in protecting against or inducing a chronic immune-mediated disorder ...,

(II) immunizing said subject according to a subject immunization schedule, according to which at least one of said infectious disease-causing organism-associated immunogens of said lower risk schedule is administered in accordance with said lower risk screened immunization schedule, ...

Classen stated that the '139 and '739 patents are infringed when a health care provider reads literature and selects and uses an immunization schedule that provides lower risk for developing chronic immune-mediated disorder.

The court characterized the '283 patent claims as directed to the first step of the '739 claim, *i.e.*, as reading on reviewing and comparing published information of effects of schedule in treated and control groups with respect to the occurrence of immune-mediated disorders. This characterization was vigorously disputed by the dissent, as we summarize below. Claim 1 of the '283 patent is exemplary:

1. 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.

Classen stated that the '283 patent is infringed when a person reviews relevant information, whether the person is a producer of vaccines, a health care provider, or a concerned parent.

Defendants argued that Classen methods are directed to no more than steps of reading published information, that "determining" and "comparing" are mental steps, and that any immunizing step is simply conventional post-solution activity that cannot transform an unpatentable principle into a patentable process (citing *Parker v. Flook,* 437 U.S. 584, 590 (1978)).

Classen argued that his method is not an abstract idea, but rather a new and useful application of newly-discovered scientific fact. Classen further argued that claims of all three patents meet the machine or transformation test, citing *Prometheus Laboratories'* holding that "claims to methods of treatment … are always transformative when one of a defined group of drugs is administered to the body to ameliorate the effects of an undesired condition." 628 F.3d at 1356.

35 U.S.C. § 101 – defines the types of inventions that can be patented:

§101. Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Common law exclusions to 101's scope include "laws of nature, natural phenomena, and abstract ideas." *Diamond v. Diehr*, 450 U.S. 175, 185 (1981), although "application of a law of nature or mathematical formula to a known structure of process may well be deserving of patent protection." *Id.* at 187. "Abstract idea" has not been defined by the courts. The Federal Circuit cited to its *Research Corporation* decision (627 F.3d 859 (Fed. Cir. 2010)) for guidance on the scope of this exclusion:

This court also will not presume to define "abstract" beyond the recognition that this disqualifying characteristic should exhibit itself so manifestly as to override the broad statutory categories of eligible subject matter and the statutory context that directs primary attention on the patentability criteria of the rest of the Patent Act.

627 F.3d at 868. It also noted that commercial application of technology is relevant to deciding whether invention is so abstract as to negate §101 subject matter. *Id*. at 869.

The court characterized §101 as a "coarse eligibility filter" rather than the final arbiter of patentability. Accordingly, when claims are within the general classes of §101 subject matter and not manifestly abstract, it is preferred to apply the substantive conditions and requirements of patentability. It cited to the Supreme Court which, in its *Bilski* decision, disfavored "categorical rules that might have wide-ranging and unforeseen impacts," and suggested narrowly-applied patent-eligibility exclusions. 130 S. Ct. 15 3229.

Applying this analysis, the court concluded that because claims of the '139 and '739 patents include the physical step of immunizing on the determined schedule, they are directed to a specific, tangible application and thus "traverse[] the coarse eligibility filter of §101." *Classen* slip opinion at 18-19. As to defendants' arguments related to "mental steps," the Federal Circuit pointed out "precedent establishing that the presence of a mental step is not of itself fatal to §101 eligibility, and that 'infinite variety' of mental and physical activity negates application of rigid rule of ineligibility" *Classen* slip opinion at 15, internal citations omitted.

In contrast, the court held that claim 1 of the '238 patent, which does not require using the information about immunization schedules for immunization purposes, was not patentable stating, "methods that simply collect and compare data, without applying the data in a step of the overall method, may fail to traverse the §101 filter." *Classen* slip opinion at 19-20 (internal citations omitted). It distinguished "immunizing" in '238 patent as referring to gathering of published data from "immunizing" recited in the '139 and '739 where it was a concrete, physical step of these process claims.

Judges Rader and Newman wrote separately to provide additional views. In advancing reasons for declining to restrict subject matter eligibility further, they pointed out several instances in which "judge-created standards" limiting patent eligibility were met with new claim forms (*e.g.*, "Beauregard" claims in the U.S. and "Swiss-style" claims in Europe). They suggested that some restrictions end up driving research funding to more hospitable locations. Supporting their arguments were examples of decisions from the U.S. and abroad that favored the early development of the U.S. biotechnology industry. "Thus, with some considerable blame on its eligibility doctrines, Europe lost innovation investment to the United States. Our country became the world leader in biotechnology innovation. Nevertheless, the tide can turn against us, too. The effect of eligibility restrictions can send innovation investment elsewhere." *Classen* additional views at 5.

Judge Moore's dissent criticized the majority's analysis and characterized the claims as directed to "a fundamental scientific principle so basic and abstract as to be unpatentable subject matter …. Classen claimed a monopoly over the scientific method itself." *Classen* dissent at 2. She criticized the majority for not considering "the extent of preemption by these staggeringly broad and abstract claims." *Classen* dissent at 3. Unlike the claims in *Prometheus*, which were drawn to administration of a specific drug for treatment of a specific disease, and measurement of a specific metabolite, Classen's claims are not directed to any specific treatment steps or any specific chronic immune disorder. She saw no difference between the claims of the '139 patent and '739 patent on the one hand (both of which the majority found patent eligible) and those of the '238 patent. The '238 claims, she argued, require two steps: "(1) immunizing a group of mammals according to a schedule and then (2) comparing the incidence of chronic immune mediated disorder in the group to a control group." *Id*. at 4. She was "perplexed by the majority's suggestion that the claim 'is directed to the single step of reviewing the effects of known immunization schedules,' as the claim clearly requires *immunizing mammals* and then comparing the results to the known group." *Id*., internal citations omitted.

As for all three patents, Moore felt each fell quite far on the wrong side of the patent-eligibility line. She explained that for the '283 patent, Classen's claims were directed to the scientific method as applied to the field of immunization. She pointed to the absence of limitations with respect to the immunogen, the schedule, the type of chronic immune disorder, and the nature of the control group. She noted similar absences in representative claims from the '139 and '739 patents, and concluded that "Classen cannot escape the fundamental abstractness of his claims by limiting them to a single field of use – immunization – since 'the prohibition against patenting abstract ideas cannot be circumvented by attempting to limit the use … to a particular technological environment. *Id*. at 7, internal citations omitted. Her analysis characterized the immunizing step of the '238 patent as "data gathering" and that for the '139 and '739 patents as "post-solution activity," neither one of which, she argued, could transform an unpatentable principle into a patentable process." *Id.* at 9-10.

Moore's dissent focuses on preemption analysis and points out logical inconsistencies in the majority's analysis based on both claim language, and the court's precedents for § 101. The policy considerations raised by Judges Rader and Newman might hold the key to how the majority "split the baby" in finding claims of the '238 patent and those of the '139 and '739 patents on opposite sides of § 101's patent eligibility line. The preemption issue is now front and center in the *Prometheus* Supreme Court case. Hopefully the Court will provide better guidance on this issue than it did years ago in setting out the test for obscenity – we'll know it when we see it.

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