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Federal Circuit Creates "Palpable" Confusion Surrounding Patent Eligibility

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In yet another decision examining the boundaries of patent-eligible subject matter under 35 U.S.C. § 101, the Federal Circuit determined in *Classen Immunotherapies v. Biogen IDEC* that two representative claims directed to comparing immunization schedules, choosing a schedule, and immunizing a patient based on that schedule, constitute patent-eligible subject matter. Because these two claims included the step of immunization based on a selected schedule, they were directed to "a specific, tangible application." The court further held that the third representative claim, which did not include the immunization step, did not encompass patent-eligible subject matter.

BACKGROUND

The patents at issue in *Classen* cover methods for determining the effect of particular immunization schedules on the incidence or severity of chronic immune-mediated disorders. One representative claim of the Classen patents, designed to assess the relative safety of such immunization schedules, comprises administering a vaccine to specific subjects and comparing the incidence of these disorders (as well as any adverse effects) with those in a control group. The other two representative claims covered identifying two groups of mammals that had been immunized according to different schedules, comparing the effects of those schedules in order to select one, and then immunizing a subject in accordance with the selected schedule.

CASE BACKGROUND

Classen Biotechnologies sued Biogen IDEC and a number of others, alleging that the defendants infringed its patents by manufacturing vaccines that were used in assessing appropriate vaccination schedules. The defendants counterclaimed, asserting that the Classen patents are invalid as encompassing patent-ineligible subject matter under 35 U.S.C. § 101. The defendants argued that the Classen patents encompass an abstract idea – the mental process of comparing one group of patients to another – and therefore fall outside the scope of patentable subject matter. In August 2006, the District of Maryland agreed with the defendants, granting summary judgment of invalidity under § 101.

The Federal Circuit, on Classen's initial appeal, affirmed the finding of patent-ineligibility, holding that the claims at issue fail the machine-or-transformation test, which was first articulated after the oral arguments in *Classen.* In its one-paragraph, non-precedential opinion, the court stated merely that "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," and are therefore patent-ineligible subject matter under 35 U.S.C. § 101. Classen appealed to the Supreme Court, which granted certiorari, vacated the opinion, and remanded the case to the Federal Circuit for reconsideration in light of its decision in *Bilski v. Kappos*, which held that the Federal Circuit's machine-or-transformation test, while "a useful and important clue or investigative tool" for determining patent-eligibility, "is not the sole test for deciding whether an invention is a patent-eligible 'process.'"

On remand, the defendants argued that the Classen methods are directed to no more than the steps of reading published information, that the "determining" and "comparing" steps of the claims are performed in the mind, and that any immunizing step is conventional post-solution activity that cannot transform an unpatentable principle into a patentable process.

In response, the plaintiff argued that Dr. Classen had discovered a method of immunizing that lowers the risk of chronic immune-mediated disorders, and that this method is "not an abstract idea, but a new and useful application of a newly discovered scientific fact."

JUDGE NEWMAN'S MAJORITY OPINION

Writing for the majority, Judge Newman agreed with Classen in part, finding that the two representative claims that contained the step of immunization based on a selected schedule embodied patent-eligible subject matter. The majority began its analysis by noting the codified requirement for patent-eligible subject matter is derived from the statute at § 101, "substantially unchanged since the first Patent Act in 1790." The majority also noted that the application of laws of nature or formulae to a known structure can constitute patent-eligible subject matter. Striking the tone for the decision, the majority cited to *Bilski*, noting "[t]he §101 patent-eligibility inquiry is only a threshold test."

The majority next turned to the issue of mental steps, stating "precedent has recognized that the presence of a mental step is not of itself fatal to §101 eligibility, and that the 'infinite variety' of mental and physical activity negates application of a rigid rule of ineligibility." In reaching its conclusion, the court relied heavily on its decision in *Research Corporation v. Microsoft,* which described the statutory role of § 101 as a "coarse eligibility filter," and "not the final arbiter of patentability." There, the court affirmed patent-eligibility where a computer-conducted method of comparing images was "functional and palpable," and therefore not a mere abstract idea.

Turning to the individual claims, the court held that the claim involving only "comparing" two patient groups and "selecting" the appropriate immunization schedule was held non-patent-eligible, because "[t]he '283 claims do not include putting this knowledge to practical use, but are directed to the abstract principle that variation in immunization schedules may have consequences for certain diseases."

"In contrast," the court explained, "the claims of the '139 and '739 patents require the further act of immunization in accordance with a lower-risk schedule, thus moving from abstract scientific principle to specific application." The court found that these two claims "are directed to a specific, tangible application, as in *Research Corporation*, and in accordance with the guidance of *Bilski v. Kappos* that '[r]ather than adopting categorical rules that might have wide-ranging and unforeseen impacts,' exclusions from patent-eligibility should be applied 'narrowly,'" it concluded that "the subject matter of these two patents traverses the coarse eligibility filter of §101."

The court went on to describe the many ways in which claims like the ones at issue, although they contained eligible subject matter, may nonetheless be invalid as indefinite, obvious, or on any number of other grounds. But the court left those issues for the future, explaining that "patentability of subject matter that is facially within the classes set forth in §101 is most reliably resolved in accordance with the conditions of §§102, 103, and 112[,]" none of which were raised on appeal.

In its only reference to *Prometheus Labs v. Mayo*, which is currently on appeal to the Supreme Court, the court explained that "[t]he principles applied in *Prometheus* support the patent eligibility of the Classen claims that include such

transformative steps[.]" Notably, however, the court did not directly apply the machine-or-transformation test used in *Prometheus* to reach its conclusion of patent-eligibility.

OTHER ISSUES

The court affirmed summary judgment of non-infringement in favor of Merck. It explained that there was no dispute that Merck did not participate in the only allegedly infringing study cited by Classen, and Classen had failed to provide any other evidence of Merck's infringement.

As to Biogen and Glaxosmithkline, the court ruled that their activities did not fall within the "safe harbor" protection of 271(e), because they were not directed at pre-market development of a generic counterpart to an existing drug. The court urged that the protection of the statute "does not apply to information that may be routinely reported to the FDA, long after marketing approval has been obtained."

Finally, the court refused to address Merck's public use argument, because the court's denial of summary judgment as to invalidity on that basis was not immediately appealable.

JUDGE RADER'S ADDITIONAL VIEWS

Judge Rader, joined by Judge Newman, offered some additional views to highlight the policy reasons for placing "few, if any, limits on subject matter eligibility[.]" He opined that creating new eligibility restrictions results in prosecutors carefully crafting claims that avoid those restrictions, imposing high costs on patent prosecution and litigation. This cost and complexity, he goes on, "can cheat naïve inventors out of their inventions due to poor claim drafting." The combination, he concluded, results in "our national innovation policy tak[ing] on characteristics of rewarding gamesmanship."

DISSENT

Judge Moore wrote an emphatic dissent, arguing that the claims covered such fundamental principles that they "claimed a monopoly over the scientific method itself." If these claims are held patent-eligible, she urged, "nobody else can search for new immunogens, for use of new immunizations, to treat either existing or currently unknown chronic immune-mediated disorders without infringing."

As to the two claims ruled patent-eligible by the majority, Moore argued that the "immunizing" step was simply post-solution activity that "does not transform the unpatentable principle – that a correlation exists between vaccination schedules and incidence of chronic immune disease – into a patentable process." She also criticized the majority's conclusion that, because the specified method was "functional and palpable," the claims are drawn to statutory subject matter. In Judge Moore's view, this analysis was tantamount to a return to the "useful, concrete, and tangible" test that was rejected by the court in *Bilski.*

Moore also leveled criticism at Rader and Newman's additional views, arguing that encouraging drafting of "careful, concrete, specific claims over abstract, conceptual claims" was not a negative outcome, and that issues of "national innovation policy" should be left to Congress, and not the courts, which must take the statutes as they find them.

Finally, Moore would have reached Merck's public use argument, because while denials of summary judgment are typically not immediately appealable, this issue had been fully briefed and was an appropriate alternative ground on which to decide invalidity. She also disagreed with the majority's interpretation of the safe harbor statute as covering only pre-approval activities. As such, she would have vacated summary judgment of non-infringement as to Glaxosmithkline and

Biogen and remanded for further proceedings, because some (but not all) of their activities were "reasonably related to their requirement to review and report adverse information to the FDA."

CONCLUSION

The *Classen* decision is proof that the Federal Circuit continues to grapple with the task of articulating objective standards for determining the scope of patent-eligible subject matter under §101. However, the decision did provide some helpful guidance for method claims that include mental steps of gathering, reviewing, or comparing information. Based on the court's reasoning, if a claim were to include an active step applying the information gathered, in this case, actually immunizing a patient on the chosen schedule, the claims would likely be patent-eligible. Claims without such practical applications, on the other hand, will remain vulnerable to a 35 USC §101 attack, but what kinds of steps will fall into the definition of a practical application remains to be seen. As a result, we are likely to see more activity in this area as the courts make further attempts to articulate a workable test for patent-eligibility.

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