

**IP LAW ADVISORY**

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**The Federal Circuit Holds Immunization Schedules Patentable**

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*Classen Immunotherapeutics, Inc., v. Biogen Idec*, 2006-1634 -1649 (Fed. Cir. August 31, 2011)

The Federal Circuit has again considered the question of patentable subject matter and decided that "exclusions from patent-eligibility should be applied 'narrowly.'" After a remand from the Supreme Court in light of its *Bilski* decision, a divided panel of the Federal Circuit in *Classen Immunotherapeutics* held that methods of physically immunizing subjects on a schedule designed to lower the risk of chronic immune-mediated disorders constituted patentable subject matter. However, the Court held that a method of collecting and comparing known information to determine optimal immunization schedules was unpatentable. Though the mental process of collecting and comparing immunization data did not constitute patentable subject matter, when these findings were physically implemented in an immunization schedule, they were eligible for patent consideration. Slip op. at 20.

Additionally, the majority decided that the infringement safe-harbor provision of the Hatch-Waxman Act is limited to activities conducted in order to obtain pre-marketing approval for generic drugs and does not protect any post-market approval activity. *Id.* at 26-29.

**Patentable Subject Matter**

***The Majority Opinion***

The three patents at issue in *Classen* related to vaccinations to reduce the risk of chronic immune-mediated disorders. Two of the patents claimed methods for

identifying optimal schedules and administering vaccinations accordingly. *Id.* at 5-6. The third patent claimed only the method of identifying schedules with the lowest risk, which relied solely on comparing already published vaccination schedules and their disease correlations. *Id.* at 7.

Writing for the majority, Judge Newman, joined by Chief Judge Rader, held that two *Classen* patents claimed patentable subject matter because they contained a concrete, physical step of immunization. Relying on the Supreme Court's guidance in *Bilski*, the Federal Circuit concluded that the two patents "traversed the coarse eligibility filter of §101" and that "exclusions from patent-eligibility should be applied 'narrowly.'" *Id.* at 18-19. Although not an issue on appeal, the Court questioned whether *Classen's* claims were valid. *Id.* at 18.

In contrast, the Court held that *Classen's* third patent, which claimed an "idea of comparing known immunization results that are ... found in the scientific literature," not patentable. *Id.* at 20. Unlike the physical step of immunization in the other two patents, the claims of the third patent did "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."

***Additional Views by Judge Rader***

Judge Rader, joined by Judge Newman, emphasized that despite the growing number of challenges to patentable subject matter, the Federal Circuit "should decline to accept invitations to restrict

subject matter eligibility.” *Concurrence Slip Op.* at 2. He opined that “excluding categories of subject matter from the patent system achieves no substantive improvement in the patent landscape” and may cause technological research to shift to countries where protection is not as difficult or expensive to obtain. *Id.* at 3-4.

### ***The Dissent***

In dissent, Judge Moore found that Classen’s patent claims did nothing more than compare two immunized groups and determine which one was better, which constituted an unpatentable abstract intellectual concept. *Dissent Slip Op.* at 7. She further concluded that the physical step of immunizing according to these findings constituted unpatentable post-solution activity that failed to “transform the unpatentable principle ... into a patentable process.” *Id.* at 8-10. Judge Moore also strongly faulted the majority’s conclusion that two of Classen’s patents were directed to patentable subject matter without considering the inherent preemption issues in claims directed to such broad fundamental principles. *Id.* at 4.

### ***The “Safe-harbor” Provision of the Hatch-Waxman Act***

The Federal Circuit also decided that the “safe-harbor” provision of the Hatch-Waxman act only applied to the development of generic drugs. Biogen and

GlaxoSmithKline both defended Classen’s allegations of infringement on the basis that their investigation and reporting on the correlation between infant immunization and the onset of disease fell within the Hatch-Waxman exception to infringement. *Id.* at 26. The majority held that this safe-harbor provision applies only to the development of generic drugs, whereby competitors are allowed to engage in otherwise infringing activities in order to obtain FDA regulatory approval. *Id.* at 26-27. Because Biogen and GlaxoSmithKline’s reporting occurred long after marketing approval had been obtained, the Hatch-Waxman safe-harbor did not apply. *See id.* at 27.

In dissent, Judge Moore concluded that the safe-harbor provision of the Hatch Waxman Act extended to *all* uses that are reasonably related to submitting *any* information to the FDA. *Id.* at 16. Judge Moore relied on the plain language of the statutory text, which does not contain a pre-approval limitation. *Id.* at 17. She found that Biogen and GlaxoSmithKline’s participation in studies that evaluated the risks associated with different vaccination schedules was reasonably related to their requirement to review and report adverse information to the FDA, and therefore non-infringing activities under the Hatch-Waxman Act. *Id.* at 18.

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