

Safe-Harbor Provision of Hatch-Waxman Act Does Not Protect Post-Approval Research Activities

October 24, 2011 by Gray Buccigross

The Federal Circuit issued its opinion in *Classen Immunotherapies, Inc. v. Biogen Idec*, 2011 U.S. App. Lexis 18126, on August 31, 2011. As part of that decision it held that the safe-harbor provision of the Hatch-Waxman Act is limited to activities reasonably related to obtaining pre-marketing FDA approval of generic counterparts, and does not protect post-approval research activities.

Two of Classen's patents are broadly directed to comparing the effectiveness of immunization schedules with regard to risk of developing chronic immune-mediated disorders (e.g., diabetes, asthma, cancer), and then immunizing according to the lower risk schedule. [1] Classen alleged Biogen and GlaxoSmithKline directly infringed by:

(1) participating in studies "to evaluate suggested associations between childhood vaccinations, particularly against hepatitis B and Haemophilus influenza ... and risk of developing type 1 diabetes; and to determine whether timing of vaccination influences risk;" and

(2) "providing instructions and/or recommendations on a proper immunization schedule for vaccines."

These research activities involved post-approval research.

The "safe harbor" provision of the Patent Act, 35 U.S.C. Section 271(e)(1), which was added by the Hatch-Waxman Act, provides:

It shall not be an act of infringement to make, use, offer to sell, or sell within the United States ... a patented invention ... solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

Judges Newman and Rader examined the Hatch-Waxman House of Representatives Report, which stated, *inter alia*, that "the only activity which will be permitted by the bill is a limited amount of testing so that generic manufacturers can establish the bioequivalency of a generic substitute." They further reasoned that "[e]very decision examining the statute has appreciated that §271(e)(1) is directed to premarketing approval of generic counterparts before patent expiration." The decision held that the safe-harbor provision "does not apply to information that may be routinely reported to the FDA, long after marketing approval has been obtained." Rather, it is limited to activities related to the "development of information for regulatory approval of generic counterparts of patented products."

Judge Moore vigorously dissented on several grounds. First, she argued that the plain text of the provision does not explicitly limit the safe harbor to pre-approval uses. Second, she argued that Supreme Court precedent (*Merck v. Integra*, which evaluated pre-approval activities) stated that the safe harbor applies to "submission of any information under the FDCA." Third, the legislative history relied on by the majority did not address whether the provision covers more than just pre-approval activity.

It remains to be seen whether the defendants will seek Supreme Court review, and, if so, whether certiorari will be granted. For the time being, companies should not rely on the Section 271(e)(1) safe harbor to shield them from activities other than those reasonably related to seeking pre-marketing FDA approval.^[2] To the extent that activities may not fall within this scope, particularly any post-approval research, it would be wise to explore in more detail: (a) whether the activities actually practice the pertinent patent claims; (b) whether they fall under the common law experimental use exemption; and (c) whether the pertinent patents are invalid.

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^[1]The opinion also addressed whether the claims recited patent-eligible subject matter under 35 U.S.C. § 101; however, that aspect is not discussed here.

^[2]Note that in *Eli Lilly v. Medtronic*, 496 U.S. 661, 671 (1990), the U.S. Supreme Court held that research activities related to obtaining approval of a medical device were protected under the safe harbor. Thus, the extent of the Safe Harbor is arguably broader than suggested by the majority opinion, which limits it to obtaining approval of generic counterparts of drugs. See also *Merck KGaA v. Integra Life Sciences I, Ltd.*, 545 U.S. 193, 207 (2005).