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# CERTAIN POST-APPROVAL ACTIVITIES TO SUPPORT SUBMISSIONS TO THE FDA ARE NOW SUBJECT TO CLAIMS OF PATENT INFRINGEMENT

On August 31, the Federal Circuit significantly restricted the scope of the "safe harbor" provision of 35 U.S.C. § 271(e)(1), which immunizes the use of patented inventions in connection with regulatory submissions to the Food and Drug Administration ("FDA"). *Classen Immunotherapies, Inc. v. Biogen Idec*, – F.3d – (Case No. 2006-1634, -1649) (August 31, 2011).

Under the FDA safe harbor clause:

> It shall not be an act of infringement to make, use, … or sell … 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.

The Supreme Court has twice interpreted this clause expansively, in *Merck KGaA v. Integra Lifesciences I, Ltd.* and *Eli Lilly & Co. v. Medtronic, Inc.*, holding that it protects the activities of device manufacturers, and that it applies to preclinical experiments where there is a reasonable basis for believing that the research, if successful, would be appropriate to include in a submission to the FDA.

The safe harbor provision was enacted as part of the 1984 Hatch-Waxman Act. It responded to caselaw holding that the manufacture and use of a patented invention constituted an act of infringement, "even if it was for the sole purpose of conducting tests and developing information necessary to apply for regulatory approval." *Eli Lilly*. "The basic idea behind this provision was to allow competitors to begin the regulatory approval process while the patent was still in force, followed by market entry immediately upon patent expiration." *Proveris Scientific Corp. v. Innova Systems, Inc.*

Of course, obtaining approval is hardly the end of a regulated manufacturer's interactions with the FDA. Drug manufacturers, for example, must file submissions to the FDA regarding changes or deviations from the approved manufacturing process, labeling

changes, adverse events, and investigations of adverse events. Manufacturers sometimes must also perform and report upon post-approval studies and clinical trials, or submit a risk evaluation and mitigation strategy. A manufacturer may also want to supplement an NDA to obtain approval for additional indications. The regulations regarding biological products (which are at issue in *Classen*) and medical devices are similar.

In *Classen*, the plaintiff held patents describing a method for analyzing the effect that the scheduling of immunizations has on the later development of various chronic illnesses. The patent holder sued vaccine manufacturers for infringement. The allegedly infringing activity included work done in connection with the manufacturers' obligations under 21 C.F.R. § 600.80(b), (c) to review and report on "adverse experience information." The district court held that such activity was protected by the safe harbor provision.

The Federal Circuit reversed in a 2–1 decision. Judge Newman wrote the majority opinion, joined by Chief Judge Rader. Judge Moore dissented.

The *Classen* court wrote that the purpose of the safe harbor provision was "to expedite development of information for regulatory approval of generic counterparts of patented products." The court therefore 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," and does not apply to the challenged conduct, which was "not related to producing information for an IND or NDA, and [not otherwise related] to marketing approval."

The dissenting opinion views this holding as contrary to the Supreme Court's statement that "§271(e)(1)'s exemption from infringement extends to all uses of patented inventions that are reasonably related to the development and submission of any information under the [Food, Drug, and Cosmetic Act]." *Classen* Dissent, *quoting Merck*. The *Classen* majority, however, while not specifically discussing this language, viewed *Merck* as applicable only to the sort of preapproval activity that was at issue in *Merck*.

*Classen* also does not fit comfortably with an earlier decision of the Federal Circuit, *Amgen, Inc. v. International Trade Comm.* In *Amgen*, the Federal Circuit held that post-approval activity could be protected by the safe harbor provision if "supplemental to the [approval] and intended for submission to the FDA." *Amgen* is not cited in any of the opinions in *Classen*.

*Classen* is not the first Federal Circuit decision to interpret § 271(e)(1) narrowly. The Federal Circuit indicated in *Proveris* that the safe harbor provision applies only where the infringed patent covers a product that is subject to FDA premarket approval. Together with *Proveris*, *Classen* paves the way for a new class of patent infringement disputes. It could also put companies in patent litigation if full compliance with post-approval obligations happens to require the use of a patented product or method. Regulated companies should assess their procedures to determine whether they are at risk from a *Classen*-type infringement suit. They may also want to assess whether their patent portfolios cover procedures that others may be using without a license.

(Most of the discussion in *Classen* is devoted to the question of whether the subject patents were "patent eligible" under 35 U.S.C. § 101, as interpreted by *Bilski v. Kappos*. While this is also an important issue, it is beyond the scope of this *Commentary*.)

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