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Federal Circuit Patent Bulletin: *Classen Immunotherapies, Inc. v. Elan Pharms., Inc.*

May 15, 2015

"Information obtained from exempt activities [under the safe harbor provision of 35 U.S.C. § 271(e)(1)] does not cease to be exempt once the [FDA regulatory application] is approved."

On May 13, 2015, in *Classen Immunotherapies, Inc. v. Elan Pharms., Inc.*, the U.S. Court of Appeals for the Federal Circuit (Prost, Lourie,* Gilstrap) vacated and remanded the district court's summary judgment that Elan did not infringe U.S. Patent No. 6,584,472, which related to accessing and analyzing data on a commercially available drug to identify a new use of that drug, and then commercializing that new use. The Federal Circuit stated:

Under § 271(e)(1), the exemption from infringement "extends to all uses of patented inventions that are reasonably related to the development and submission of any information under the [(Federal Food, Drug, and Cosmetic Act)] FDCA." The statute does not exclude "certain information from the exemption on the basis of the phase of research in which it is developed or the particular submission in which it could be included." Nor does the statute limit the safe harbor only to those activities necessary for seeking approval of a generic version of a brand-name drug product. Although in the post-approval context it may be less straightforward to determine whether an accused infringer's use of a patented invention was "solely for uses reasonably related to the development and submission of information" under the FDCA, the statutory language does not categorically exclude post-approval activities from the ambit of the safe harbor. Indeed, under the FDCA, drug manufacturers may voluntarily, or sometimes may be required to, conduct post-approval

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studies on their products for purposes of developing and submitting information to the FDA.

In some circumstances, drug manufacturers voluntarily conduct post-approval scientific studies and clinical trials to support "supplemental" new drug applications, seeking the FDA's approval to revise the label of their products. Just like NDA or ANDA applicants, [(supplemental new drug application)] sNDA applicants must submit relevant data to the FDA to support their applications. Thus, after the initial approval of a drug, its manufacturer may perform additional research to further characterize the drug and submit that information to the FDA for a labeling change. Such post-approval studies serve similar purposes as pre-approval studies in ensuring the safety and efficacy of approved drugs. As an integral part of the regulatory approval process, those activities are "reasonably related to the development and submission of information" under the FDCA and are therefore exempt from infringement liability.

Here, Elan's clinical study and its FDA submissions clearly fall within the scope of the safe harbor. After learning that the FDA proposed to change the designation of metaxalone tablets, Elan initiated its own clinical trial to characterize the effect of food on the absorption of Skelaxin and observed a significant increase in bioavailability when Skelaxin was administered with food. Elan submitted that information to the FDA to revise the Skelaxin product label and to propose changes to the approval requirements for generic versions of Skelaxin. Those activities were anything but "routine" post-approval reporting; rather, they were "necessary" to the approval of both the brand-name and generic versions of Skelaxin. The district court therefore did not err in holding that Elan's clinical activities and FDA submissions are exempt from infringement under the safe harbor provision. . . .

Classen asserts that Elan's filing of patent applications based on the clinical data infringed the method claims and that Elan's sale of Skelaxin with the revised label containing information derived from the clinical trial infringed the kit claims. As indicated, when granting summary judgment of noninfringement, the district court did not determine whether those post-submission activities constituted infringement of the '472 patent or whether they were exempt under the safe harbor. Rather than deciding those issues in the first instance on appeal, we vacate the judgment of noninfringement and remand the case to the district court for further proceedings on the parties' pending claims and counterclaims, including issues of validity, enforceability, and infringement of the asserted patent.

To assist the district court in its analysis of infringement, if the court reaches that issue on remand, we make the following observations of the record. Filing a patent application is generally not an infringement of a patent. It is not the making, using, offering to sell, selling, or importing of an invention. It is the act of

approaching an agency of the government in order to obtain a limited privilege and to fulfill a public goal of making knowledge of an invention available to the public. It is not commercializing an invention, which requires introducing an invention into commerce, or making preparations to do so. Moreover, infringing a multi-step method claim requires carrying out all the steps of the claim. As filing a patent application is not commercializing an invention, a method claim requiring commercialization, as claim 36 does, is likely not infringed by Elan's actions here.

In addition, placing the information submitted to the FDA on the product label after sNDA approval generally cannot be an infringement. Information obtained from exempt activities does not cease to be exempt once the sNDA is approved. It is a requirement of law that a drug product contains the labeling approved by the FDA. This is not to say that a pharmaceutical patent claiming a method of treatment, a method of preparation, or a composition of matter cannot be infringed by the subsequent actions of making, using, offering to sell, selling, or importing of a drug covered by that patent based on information derived from exempt activities. But that is not the case here. Having stated the above, we leave it to the district court to deal with any infringement or other issues as it deems appropriate.