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Fed. Cir. Confirms § 271(e)(1) Safe Harbor Applies to Post-Approval Development of Clinical Data for Citizen Petition and Supplemental New Drug Application

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On appeal from the District of Maryland, the Federal Circuit held in *Classen Immunotherapies, Inc. v. Elan Pharmaceuticals, Inc.*, that the § 271(e)(1) safe harbor applied to Elan's post-approval development of clinical data on its approved drug Skelaxin, and submitting that information to the Food and Drug Administration (FDA) in a citizen petition and a supplemental new drug application (sNDA).

Years after initial approval of a New Drug Application (NDA) for Skelaxin, Elan learned of another companies' bioequivalence fasting studies and *in vitro* dissolution tests of a generic version of Skelaxin, prompting Elan to initiate its own clinical studies on Skelaxin administered with and without food in humans, where it observed a significant effect of food on the drug's bioavailability.

Elan thereafter submitted a citizen petition to the FDA, requesting the FDA require bioavailability data from an applicant of any Abbreviated New Drug Application (ANDA) for a generic version of Skelaxin, and also a sNDA to revise the Skelaxin label. Elan included its clinical study report with its citizen petition and sNDA, which the FDA granted and approved. Elan also subsequently filed two patent applications with the United States Patent and Trademark Office derived from its clinical bioavailability data.

Based on these activities, Classen asserted that Elan infringed claims directed to a method for accessing and analyzing data on a commercially-available drug to identify a new use of that drug, and then commercializing that new use.

The district court found that Elan's activities were protected by the safe harbor of § 271(e)(1), which provides in relevant part that: "It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into 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." Specifically, the district court reasoned that Elan's submission to the FDA were necessary to update the Skelaxin product label and to change the FDA approval process for generic versions of Skelaxin.

On Appeal, the Federal Circuit affirmed, focusing on the language of § 271(e)(1). The Court explained that 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 it limit the safe harbor to those activities necessary for seeking approval of a generic version of a brand-name drug product. While the Court noted that it may be less straightforward to determine in the post-approval context whether an accused infringer's use of a patented invention was "solely for uses reasonably related to the development and submission of information," as required by § 271(e)(1), it

concluded that the submission of post-approval studies with a sNDA is no different than submission of pre-approval studies with a NDA or ANDA, where applicants submit relevant data to the FDA to support their applications. Thus, the Court concluded that the activities associated with submission of a sNDA are an integral part of the regulatory approval process exempt from infringement liability under § 271(e)(1).

The district court did not address and the Federal Circuit declined to decide Classen's additional argument that after Elan generated and submitted the clinical data to the FDA, its subsequent actions of reanalyzing the clinical data to identify patentable information and filing patent applications are commercial activities outside the scope of the § 271(e)(1) safe harbor. Nonetheless, the Court observed that post-submission disclosure or use of information obtained from an exempt clinical study, even for purposes other than regulatory approval, does not repeal that exemption of the clinical study, provided the subsequent use is itself not an act of infringement. The Court further observed that filing a patent application is not commercializing an invention, which requires introducing an invention into commerce, or making preparations to do so, an act not satisfied by Elan's actions here.

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