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The Safe Harbor Provision in §271(e)(1) Protects Acts of Infringement Connected to Submissions of Data to Federal Agencies

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A split Federal Circuit panel recently held that the safe harbor provision of 35 U.S.C. §271(e)(1) providing a defense to infringement applies if the allegedly infringing activity is "reasonably related to submitting information" to the US Food and Drug Administration ("FDA"). *Edwards Lifesciences Corp. v. Meril Life Sciences Ltd.* (Fed. Cir. March 25, 2024). But as noted by the strongly worded dissent, §271(e)(1) requires that the provision applies "solely for uses reasonably related to the development and submission of information under a federal law" that regulates sales of drugs or medical devices. The conflicting opinions raise an issue that could be reviewed en banc by the Federal Circuit.

In *Edwards*, Meril imported two transcatheter heart valves into the US for a medical conference. But the two heart-valve systems were not presented at the conference—they remained in a bag until its handlers took the devices to a conference in Europe. However, Meril presented information at that conference on its heart valve products. Edwards, a prominent supplier of artificial heart-valve systems filed a patent infringement suit against Meril based on Meril's importation of those devices. Meril defended on grounds that its actions fall under the safe harbor provisions of §271(e)(1) because it must submit data to the FDA to receive pre-market approval for its products. The district court agreed and granted summary judgment in favor of Meril.

On appeal, the Federal Circuit's majority opinion presented the question as whether the safe harbor provision applies if the infringing activity "was reasonably related to recruiting investigators for a clinical trial to support FDA approval." Notably, the question did not consider the statute's use of the word "solely." Specifically, while it noted that the safe harbor provision applies to acts "that bear a reasonable relation" to the development and submission of data to the FDA, the acts need not be *only* reasonably related to the development and submission of information to the FDA. On those grounds, the majority affirmed the district court's decision because Meril's importation was "reasonably related to submitting information" to the FDA.

The dissent seized on both the majority's and the district court's omission of the word "solely" from their analyses, and the strained interpretations that effectively eliminated the term from their

application of the statute. The dissent argues that "solely" means the safe harbor applies *only* for acts for supplying information to the FDA and not for other commercial acts. Commentary at the time of enactment of §271(e)(1) supports the dissent as it states that infringing activity beyond development and submission of information under a federal law "would not be exempt," such as marketing a patented drug instead of merely testing the drug for purposes of submitting data to the FDA.

The crux of the dispute is whether commercial activity, which may cross over or occur simultaneously with uses reasonably related to the development and submission of information, still triggers the §271(e)(1) safe harbor provision and provides a defense to an infringement allegation if the infringer's acts are also "reasonably related" to the submission of data to the FDA. As a result, commercial activity that would be infringing is excused if the activity is also reasonably related to submitting data to a government agency.

If this issue is not addressed by a higher court, then it may open the door for entities to partake in more aggressive commercial activity while at the same time gathering data for submission to a governing agency. Those commercial activities would be protected from infringement allegations by the §271(e)(1) safe harbor under the *Edwards* decision.

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